GEORGIA DEPARTMENT OF PUBLIC HEALTH

STANDARD NURSE PROTOCOLS FOR REGISTERED PROFESSIONAL NURSES IN PUBLIC HEALTH 2023

Office of Nursing

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STANDARD NURSE PROTOCOL GUIDANCE AND REQUIREMENTS

INTRODUCTION

The nurse protocol legislation (O. C. G. A. § 43-34-23) enacted in 1989, authorizes Registered Professional Nurses (RNs) and Advanced Practice Registered Nurses (APRNs) who are agents or employees of a county board of health or the Georgia Department of Public Health (DPH) and who are adequately prepared, to perform certain delegated medical acts under the authority of nurse protocol. Since the passage of this important legislation, DPH has provided direction and guidance relative to public health nursing practice under nurse protocol.

The purpose of this nurse protocol manual is to provide guidelines and standards for public health nursing practice under nurse protocol. **Each year**, DPH Office of Nursing coordinates the ongoing process of reviewing, revising and updating the nurse protocols to be consistent with best practice, current technology and research; throughout **the year**, revisions and updates to the nurse protocols and nurse protocol manual are made and distributed as needed. The districts must review the nurse protocols used by RNs and APRNs at least once annually and make certain that the nurse protocols are signed and dated annually by the RNs, APRNs and delegating physicians. The term “annually” is at least once within a twelve-month period. Thus, protocols used by RNs and APRNs can be dated and signed within twelve (12) months from the previous date but must not exceed twelve (12) months.

Nurse protocols become effective in districts when signed each year by the delegating physician(s). Each district must maintain a copy of the nurse protocol manual and all signed nurse protocols for five (5) years. The manuals can be maintained electronically or in hard copy.

The nurse protocol manual is posted on the **Public Health Information Library (PHIL) 2.0.**

New updates and wording changes in the manual are highlighted in bold print.

PROCESS FOR PROTOCOL DEVELOPMENT

Nurse protocols are standardized and consistent across programs, consistent with current statutes, rules and regulations and based on the latest technology, current practice standards and cost-effective measures. The process continues at the district level where the nurse protocols are adopted for local use and signed and dated at least once annually. Although minor changes may need to be made at the district level (e.g., due to district medication availability), it is recommended that the nurse protocols be adopted without modification.

MECHANISM FOR NURSE PROTOCOL DEVELOPMENT, REVIEW AND REVISION

1. The Office of Nursing:
   a. Convenes meetings of the Nurse Protocol Committee **annually**.

b. Oversees the **annual** process of reviewing, revising and updating all nurse protocols and the nurse protocol manual.
c. Manages revisions to nurse protocols in collaboration with the appropriate state office program nurses, state office of pharmacy, office of legal services, physicians and other staff as needed.
d. Assures that the Department of Public Health Legal Services Office reviews and approves the final draft of each nurse protocol manual and nurse protocol that is reviewed, revised and updated.
e. Assures that final signatures are obtained from the State Medical Officer and physician who serves as the Medical Consultant for each respective nurse protocol before distributing the revised nurse protocol or the updated nurse protocol manual.
f. Conducts Nurse Protocol Orientation and Credentialing Program for State Office Nurses at least **annually**.

2. Each Nurse Protocol Committee:
   a. Includes at least one Medical Consultant who is a physician in clinical practice, DPH Nurse Consultants, nurses from districts and counties, DPH Pharmacy representative, and as needed laboratory, and nutrition offices.
   b. Reviews all proposed new nurse protocols to assure that they meet established criteria for format and content.
   c. Reviews any significant/extensive revisions to existing nurse protocols to assure that they continue to meet established criteria for format and content.
   d. Reviews and approves recommended nurse protocols for inclusion in the nurse protocol manual during the biannual process of reviewing, revising, and updating of the manual.

3. State Office Nurses (SONs):
   Attend Nurse Protocol Orientation and Credentialing Program offered by the Office of Nursing at least **annually**. This credentialing program for SONs provides a formal orientation to cover the nurse protocol statute, frequently asked questions, the role of the nurse consultant and the interface between **the Office of Nursing,** nurse protocol practice, **and the Policy and Procedure Manual for Public Health Nurse Training**. The goal is to assure the integrity of the nurse protocol process and the quality of technical assistance and consultation provided regarding statutory requirements related to public health nursing practice.

   This is required for designated SONs who have responsibility for the lead role in nurse protocol development, review, revision and updating, who provide consultation and technical assistance to districts and who chair the clinical teams for their program areas, as well as any designated back-up SONs who work in those program areas and are expected to provide consultation and technical assistance. It is recommended that all other SONs and others who provide critical input into nurse protocols (e.g., members of the Nurse

Protocol Committee representing Pharmacy, Nutrition, Immunizations, Epidemiology and Laboratory) also complete the program.

a. Assure that each program for which there is a nurse protocol has a designated and qualified Medical Consultant to provide and/or assist with clinical consultation and development, revision, updating and utilization of nurse protocols.
b. Assure that the clinical team reviews the nurse protocols for their respective program and assists in drafting revisions and/or new nurse protocols **annually.** (Each clinical team comprises, at a minimum, the state office nurse, state pharmacy director/designee, physician/medical specialist, and nurses in clinical practice. Nutrition, immunization, laboratory, and epidemiology representatives are included as needed.)
c. Assure that nurse protocols are developed or revised **annually**.
d. Finalize revisions and new nurse protocols after considering all comments, questions and recommendations from the clinical team and Nurse Protocol Committee reviewers.
e. Obtain signed approval form from the clinical team Medical Consultant to accompany the updated program section or any revisions.

4. Steps for Adoption of Nurse Protocols for District Use:
   a. The newest version of the protocols should replace existing versions in electronic and hard copy form.
   b. New Nurse Protocol Agreement pages for RNs and delegating physicians are required annually and any time protocols are updated. See Signing Nurse Protocol Agreement section that follows.
   c. If Districts remove any of the protocols or make other modifications, the nurse protocol header should be changed from DPH to the appropriate district information before uploading to the electronic health system, printing a hard copy of the manual, or issuing the protocols to nurses.
   d. Provide annual nurse protocol update for all nurses practicing under protocol that covers changes and new information.

5. Steps for District Development or Modification of Nurse Protocols:
   a. Develop the protocol in collaboration with the delegating physician.
   b. Submit the protocol, along with a list of the district clinical review team and justification statement for the request to modify or develop a new nurse protocol, to the Office of Nursing to request Chief Medical Officer or Commissioner approval.

GUIDELINES FOR NURSE PROTOCOLS

DEFINITIONS

1. Nurse Protocol:

   Nurse Protocol means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which the physician delegates to that nurse the authority to perform certain medical acts pursuant to subsection (b) of O.C.G.A. § 43-34-23. These acts shall include, without being limited to, the administering and ordering of any drug. O.C.G.A. § 43-34-23(a)(7).

   Each registered professional nurse (RN) must have access to the current standard nurse protocol(s), under which the RN is practicing at the practice site. Each RN may have his/her individual set of standard nurse protocols which are signed by the nurse and the delegating physician(s) or there may be one set of standard nurse protocols which each RN and the delegating physician(s) sign. Protocols may be in electronic or hard copy form.

2. Order:

   Order means to select a drug, medical treatment or diagnostic study through physician delegation in accordance with a nurse protocol or a physician assistant's job description. Ordering under such delegation shall not be construed to be prescribing, which act can only be performed by the physician, nor shall ordering of a drug be construed to authorize the issuance of a written prescription. O.C.G.A. § 43-34-23(a)(8).

   The RN shall write the drug order in accordance with the nurse protocol and based on a patient assessment each time the drug is ordered. If the patient continues the drug on subsequent visits, the nurse must reorder the drug based on the nurse protocol. Documentation of the written drug order by the RN shall include the following components:

   a. Date ordered
   b. Generic name or actual brand name of drug
   c. Strength of drug
   d. Dose
   e. Dosage form
   f. Route of administration
   g. Frequency
   h. Duration of therapy
   i. Quantity dispensed/provided
   j. Signature of RN or APRN who ordered the drug

3. Delegating Physician:

Delegating Physician means the physician(s) who has/have mutually agreed to and signed the nurse protocol. The District Health Director may be the delegating physician or one of the delegating physicians. The Department of Public Health recommends that each delegating physician be engaged in current clinical practice on a full-time or part-time basis.

4. Dispensing Physician:

Dispensing Physician is a physician that dispenses[1] medications from their own prescription. They cannot act as a pharmacist and fill other provider's prescriptions. State law allows physicians to dispense pharmaceuticals from their office once processes are completed to become compliant with state law regulations regarding dispensing pharmaceuticals. More information can be found at https://medicalboard.georgia.gov/become-dispensing-physician

5. Legal Signature:

Entries into the patient's medical record must be dated and signed by the person responsible, using full name and letters that denote professional title (e.g., Suzie A. Jones, R.N. or Suzie A. Jones, A.P.R.N.).

6. Dispensing Procedure:

Dispensing procedure means a written document signed by a licensed pharmacist and a licensed physician, which establishes the appropriate manner under which drugs may be dispensed pursuant to this Code Section.[2] A nurse operating in accordance with O.C.G.A. § 43-34-23 may not dispense without a signed dispensing procedure.

7. Record Review:

Specify that record reviews of nursing practice under nurse protocol (of RNs and APRNs) by the delegating physician will be completed at least once annually. Ideally, it is preferred that record reviews be completed on a quarterly basis throughout each year to identify strengths and opportunities for improvement in a timely manner.

DRUGS TO BE COVERED BY NURSE PROTOCOL

Any drugs which the RN orders and dispenses must be covered by nurse protocol. The following drugs are to be covered by nurse protocols: Dangerous Drugs means any dangerous drug as defined in O.C.G.A. § 16-13-71 but does not include any controlled substance or Schedule I controlled

1 Dispense means to issue one or more doses of any drug in a suitable container with appropriate labeling for subsequent administration to, or use by, a patient. O. C.G.A. § 43-34-23 (a) (3.1)
2 O. C.G.A. § 43-34-23

substance. Dangerous drugs are required to bear upon the package the words "Caution Federal Law Prohibits Dispensing Without Prescription," "Rx Only" or words of like import. These drugs may also be referred to as "Legend" drugs.

Dangerous drugs are not to be stored in the nurse's home, car, or other prohibited location.

DRUGS COVERED BY NURSE PROTOCOL OR OTHER POLICY OR PROCEDURE

1. Immunizations/Vaccines: All public health locations that provide vaccine services will utilize the current edition of the Georgia Department of Public Health Immunization Program (GIP) Manual, which is developed based on the Advisory Committee on Immunization Practices Recommendations and the Centers for Disease Control and Prevention's (CDC) Epidemiology and Prevention of Vaccine Preventable Diseases' (Pink Book) for administering vaccines to children and adults located at: https://dph.georgia.gov/immunization-publications
    a. RNs and APRNs administer vaccines under a nurse protocol based on Code Sections 43-34-23 and 43-34-25 in accordance with the Immunization Program Manual.
    b. LPNs do not practice under nurse protocol. LPNs administer vaccines (they do not order or dispense drugs) under the supervision of an RN, APRN or Physician in accordance with the Georgia Licensed Practical Nurse Practice Act [O.C.G.A. § 43-26-32(7)].
    c. For Off-site Settings**:** vaccine services will be provided under the same immunization nurse protocol in off-site settings (e.g., school flu clinics) as described above. A copy of the immunization nurse protocol document should be taken to each off**-**site clinic location. The GIP Manual can be accessed off-site via the web link above.

2. Over the Counter (OTC)/Nonprescription Drugs are given to patients or called in to a pharmacy. These drugs include vitamins, oral iron preparations, acetaminophen, etc., which do not bear upon the package the words "Caution Federal Law Prohibits Dispensing Without Prescription," or "Rx Only."
    a. Nurse Protocol must be in place for the following situations:
        1) If the OTC drug is repackaged (i.e., taken out of the manufacturer's original container, such as a bottle of 100 tablets) and/or labeled in any manner or with any information different from the manufacturer's label, the drug must be provided in accordance with nurse protocol.
        2) If the OTC drug is called in to a licensed pharmacist who will provide the drug to the patient (e.g., NIX Creme Rinse for a Medicaid eligible patient), the drug must be provided in accordance with nurse protocol.
    b. District/County Policy & Procedure or Nurse Protocol. If the OTC drugs are in the original manufacturer's container and no changes are made in the directions on the manufacturer's label (i.e., given to the patient just as it comes from the manufacturer), this may be covered by either

district/county policy and procedure or nurse protocol.

c. No Policy and Procedure or Nurse Protocol Needed. If an OTC drug is recommended to the patient by the RN but not given to the patient nor called in to the pharmacy, it does not need to be covered by a policy, procedure, or nurse protocol. Such recommendations should be documented in the patient's medical record.

3. Professional Medical Device and Drug Samples: The use of professional Medical Device and Drug Samples must adhere to the Department's policy "**Professional Medical Device and Drug Sample Policy for Public Health Clinics**"and complete the mandatory Medication and Device Sample Quarterly Report and provide it to the Office of Pharmacy.

4. Dangerous drugs: Drugs whose packaging includes the words "Caution Federal Law Prohibits Dispensing Without Prescription," or "Rx Only." RNs must follow nursing protocol to dispense or call in to pharmacy. Refer to Dispensing Dangerous Drugs and the Drug Dispensing Procedure.

5. During times of emergency, an emergency nurse protocol agreement should be developed to establish an agreement between a delegating physician and RNs and/or APRNs to authorize them to administer, order and dispense specific dangerous drugs. See the Emergency Nurse Protocol **Vaccine** Agreement sample that follows **(appendix B).**

REQUIREMENTS FOR A REGISTERED PROFESSIONAL NURSE WHO USES A NURSE PROTOCOL

A Registered Professional Nurse who uses a nurse protocol must:

1. Hold a current license to practice as a registered professional nurse (RN) in Georgia,

2. Document preparation and performance specific to each medical act authorized by a nurse protocol, including ordering dangerous drugs, medical treatments, or diagnostic studies. Prior to the RN functioning under a nurse protocol, there should be written documentation that the RN has training, preparation and/or orientation relative to each medical act authorized by the specific nurse protocol and can perform such acts. Documentation may include supervisory notes, orientation plans, direct observation of clinical performance, skills checklist(s) and/or performance appraisal(s), and

3. Adhere to the written nurse protocol.

LICENSED PRACTICAL NURSES

LPNs in public health administer drugs as assigned under the supervision of

either an RN, APRN or physician and in accordance with the Georgia Licensed Practical Nurse Practice Act [O.C.G.A. § 43-26-32(7)].

REQUIREMENTS FOR NURSE PROTOCOLS

A nurse protocol must meet all the following requirements:

1. Be reviewed, revised, or updated annually. Per DPH legal services, the term "annually" is interpreted to mean twelve (12) months. However, nurse protocols can be dated and signed within twelve (12) months of the previous date but must not exceed twelve (12) months. This means that if a nurse protocol was signed on January 15, 2021, that same nurse protocol must be signed on or by January 15, 2022, continue to practice under the respective nurse protocol. The nurse protocol must bear the review date and signatures of the delegating physician(s) and RN(s). There is no authority to perform acts using a nurse protocol which has expired without annual review, revisions, and updates.

2. Specify that record reviews of nursing practice under nurse protocol (of RNs and APRNs) by the delegating physician will be completed at least once annually. Ideally, it is preferred that record reviews be completed on a quarterly basis throughout each year to identify strengths and opportunities for improvement in a timely manner.

3. Be available and accessible in each of the specific settings where RNs function under nurse protocols and be available upon request.

4. Include the specific terms/conditions under which delegated medical acts may be performed.

5. Include the condition(s) for immediate consultation with a delegating physician or a physician designated in his or her absence.

6. Include a statement that the RN has read and understands all statutes, rules and regulations pertaining to nursing practice under nurse protocol and has read and understands the drug dispensing procedure.

DELEGATED AUTHORITY FOR ORDERING DANGEROUS DRUGS

RNs who are delegated the authority to order dangerous drugs must do so in accordance with written nurse protocols. The nurse protocol must outline the parameters that must be followed pursuant to ordering the drug and must also specify the drug and the specific conditions under which it may be ordered.

DISPENSING DANGEROUS DRUGS

NOTE: Georgia Board of Pharmacy Rules 480-30-.02- General Requirements, "Any person who dispenses drugs in accordance with a dispensing procedure and under the authority of a job description or standard nurse protocol shall comply with all record keeping, labeling, packaging and storage requirements imposed upon pharmacists and pharmacies with regard to such drugs pursuant to O.C.C.A. § 26-4 and 16-13, and those regulations contained in this chapter."

RNs are authorized to dispense dangerous drugs only under the following conditions:

1. The dispensing is in accordance with a written drug dispensing procedure[3] signed by a licensed physician and a licensed pharmacist that has been reviewed by the Georgia Board of Pharmacy and under the authority of an order issued in conformity with a nurse protocol.

2. There must be documented preparation and performance (i.e., ability to perform) specific to dispensing dangerous drugs based on a written dispensing procedure. Documentation should include that each RN has read and understands the drug dispensing procedure.

3. A copy of the drug dispensing procedure must be accessible in each of the specific sites where the RN is practicing under nurse protocols and be available upon request. The procedure must be signed by the pharmacist and physician who have established it.

4. The RN shall exercise diligence in protecting drugs and records from loss or theft, in accordance with the rules of the Georgia Board of Pharmacy.

5. The RN is not authorized to dispense a drug:
   a. Based on a prescription written by either a public health or private physician,
   b. Based on an order received from the District Health Director or delegating physician if the drug is not listed in the appropriate nurse protocol,
   c. Pursuant to an order written on a patient's chart by a physician, an advanced practice registered nurse, physician's assistant or another RN,
   d. Based on a written or verbal recommendation from a communicable disease specialist (CDS); or
   e. Based on a drug order received over the phone.
   f. When any of the above situations occur, the RN functioning under nurse protocols:
      1) Adds the written information or documents the oral information received (e.g., medical diagnosis, physician's prescription) to the patient's chart,

2) Reviews any written information in the chart and,
3) Based on his/her review of the information and clinical assessment of the patient, decides whether to order any of the drugs listed in the appropriate nurse protocol, to seek medical consultation or to refer the patient.

g. When a nurse orders a drug listed in the nurse protocol, they assume responsibility for ordering the drug in accordance with the nurse protocol and dispensing the drug in accordance with a written drug dispensing procedure.
h. If a nurse seeks medical consultation, the results of the consultation are documented in the patient's record. Based on the medical consultation and clinical assessment of the patient, the nurse decides whether to order any of the drugs in the nurse protocol, to seek further medical consultation or to refer the patient. This includes when the medical consultation results in a dosage, drug or any medical act which is not covered by the current nurse protocol.
i. When nurses decides to refer a patient, the referral must be documented in the patient's record. The documentation should include where and to who the patient was referred, what medical information was sent with the patient or authorized to be released, and any assistance and/or instructions provided to the patient. Results of the referral and any changes in the patient's plan of care should subsequently be documented.

ACCOUNTABILITY

The District Health Director is accountable for ensuring that the appropriate nurse protocols are in place in **their** district. The District Health Director and the District Nursing and Clinical Director should collaborate in the monitoring and updating of nurse protocols, assuring compliance with all statutes, rules and regulations pertaining to practice under nurse protocol.

RETENTION OF NURSE PROTOCOLS

1. The district shall retain one copy of each nurse protocol for at least five years, either electronically or in hard copy form.

2. The Department of Public Health shall maintain copies of the Nurse Protocol Manual produced by the Department for at least five years.

SIGNING NURSE PROTOCOL AGREEMENTS

1. Signature Requirements
   a. Items to include on the signature page to document compliance with specific rules and regulations of the Georgia Board of Nursing (GBON) and the Board of Pharmacy:
      1) That each RN is adequately trained and prepared to perform the

delegated medical acts (document the specific training in the nurse's personnel or supervisory file).

2) That the RN has read and understands all statutes, rules, and regulations pertaining to nursing and nursing practice under nurse protocol and have read and understand the drug dispensing procedure and protocols they will be practicing under.
3) That record reviews of nursing practice under nurse protocol (of RNs and APRNs) by the delegating physician will be completed at least annually. Ideally, it is preferred that the record reviews be completed on a quarterly basis throughout each year to identify strengths and opportunities for improvement in a timely manner.

b. The signature page represents an agreement between the delegating physician(s) and the RN(s).
c. Each person should use his/her legal signature as it appears in patient records (i.e., full name/letters denoting the professional title - MD, DO, RN).
d. Nurse protocols must be revised or updated annually, and annual review of protocol changes must be completed. The nurse protocol signature page must be dated within 12 months of the previous date signed. This means that if a nurse protocol was signed on January 15, 2022, that same nurse protocol must be signed on or by January 15, 2023 to continue to practice under the respective nurse protocol.
    i. The nurse protocol agreement is a legal document used by the Registered Professional Nurse (RN) and each RN and delegating physician(s) should assure the nurse protocol signature page is signed within 12 months of the previous date.
e. A single signature page may cover a single nurse protocol, a set of nurse protocols or multiple nurse protocols if revisions are signed and dated by all parties (refer to the example on the following page).
f. If the delegating physician changes within the 12-month period, a new protocol agreement must be signed by the new delegating physician and each nurse.

2. Review/Revision Requirements

All nurse protocols must be reviewed at least annually. Changes in drug treatment and health care technology should be incorporated into revised nurse protocols in a timely manner. Annual reviews and revisions which involve ordering drugs, diagnostic studies and/ or treatments should be signed and dated by the delegating physician(s) and the nurse(s). Supervisors should assure that nurses have been taught about each nurse protocol and any revisions before they sign the nurse protocol agreement.

APPENDIX A

EXAMPLE NURSE PROTOCOL SIGNATURE PAGE

NURSE PROTOCOL SIGNATURE PAGE

The signatures below indicate an agreement between the delegating physician(s) and the registered professional nurse(s) (RNs) or **advanced practiced registered nurse (APRN)** who are authorized to perform the delegated medical acts contained in the nurse protocols for [insert name of designated nurse protocols (e.g., Women's Health) and date on nurse protocols (e.g., 1/10/23)].

All RNs and APRNs whose signatures appear on this page:

1. Have been adequately trained and are prepared to perform the delegated medical acts contained in the designated nurse protocols; such training is documented in the nurses' personnel/supervisory files.

2. Have read and understand all statutes, rules and regulations pertaining to nursing practice under nurse protocol and have read and understand the drug dispensing procedure.

3. Have been given an opportunity to have questions answered.

Record reviews by the delegating physician(s) will be completed at least once annually. It is preferred that record reviews be completed on a quarterly basis throughout each year when possible to identify strengths and opportunities for improvement in a timely manner.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN/**APRN** Date

APPENDIX B

STANDARD NURSE PROTOCOL FOR IMMUNIZATIONS DURING PUBLIC HEALTH EMERGENCIES

All staff that provide vaccine services as part of a Public Health clinic, campaign, or mass vaccination event will adhere to the requirements of the **Georgia Immunization Program (GIP) Manual** that provides Public Health personnel with up-to-date information and guidance. The GIP Manual is based primarily on the Recommendations of the Advisory Committee on Immunizaiton Practices (ACIP). The ACIP Recommendations are located at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

The GIP Manual and ACIP recommendations are the official Department of Public Health (DPH) policies, procedures, and standards for administering vaccines, providing and documenting immunization services, and assuring and evaluating quality vaccine services provided in Public Health Districts.

The signatures below indicate an agreement between the delegating physician(s) and the registered professional nurse(s) RN(s) or **advanced practiced registered nurse (APRN)** who are authorized to administer the vaccines included in the Nurse Protocol Agreement for Administering Vaccines during Public Health Emergencies.

The RNs or APRNs whose signature appears below on this signature page:

1. Has successfully completed all required training on the provision of vaccines in accordance with the requirements of the GIP Manual and for the vaccines included in the Nurse Protocol Agreement for Administering Vaccines during Public Health Emergencies.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN/APRN Date

APPENDIX C:

EXAMPLE:

NURSE PROTOCOL AGREEMENT
FOR ADMINISTERING VACCINES DURING PUBLIC HEALTH EMERGENCIES

The signatures below indicate an agreement authorized through O.C.G.A. § 43-34-23 between the delegating physician(s) and the registered professional nurse(s) (RNs) and/or advanced practice registered nurses (APRNs) that the undersigned individuals are authorized to administer, order and dispense the specific vaccines listed below in accordance with the requirements of the Nurse Protocol for Administering Vaccines During Public Health Emergencies.

Vaccine Administration:

Vaccines can be administered for the following populations (all ages or specific age groups):

1. _____

The following vaccines can be administered:

1. Example: COVID-19 Vaccines under EUA
2. _____
3. _____
4. _____

The signatures below indicate an agreement between the delegating physician(s) and the RN(s) and/or APRN(s) who are authorized to administer the vaccines listed in this agreement.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN or APRN Date

APPENDIX D

EXAMPLE:

STANDARD NURSE PROTOCOL FOR ADMINISTERING VACCINES SIGNATURE PAGE

NOTE: This type of signature page would be used by RN or APRNs when the vaccine must be transported to non-county Health Department sites such as school-based clinics.

The signatures below indicate an agreement between the delegating physician(s) and the registered professional nurse(s) RN(s) who are authorized to administer the following vaccines:

- Seasonal Influenza Vaccine
- Meningococcal Vaccine
- Pneumococcal Vaccine
- Tetanus-containing Vaccine

All RNs and APRNs whose signatures appear on this signature page:

1. Have been adequately trained and are prepared to perform the delegated medical acts contained in the designated nurse protocols; such training is documented in the nurses' personnel/supervisory files.

2. Have read and understand all statutes, rules and regulations pertaining to nursing practice under nurse protocol and have read and understand the drug dispensing procedure.

3. Have been given an opportunity to have questions answered.

Record reviews by the delegating physician(s) will be completed at least once annually. Ideally, it is preferred that record reviews be completed on a quarterly basis throughout each year to identify strengths and opportunities for improvement in a timely manner.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN/**APRN** Date

ORIENTATION, TRAINING, AND QUALITY ASSURANCE FOR NURSE PROTOCOLS

A. INITIAL ORIENTATION AND TRAINING

A comprehensive orientation and training program ensure that registered professional nurses are effectively integrated into the Public Health system, are prepared to practice under the authority of nurse protocols, are introduced to the concepts of population health-based nursing practice and contribute to quality assurance and quality improvement (QA/QI) for public health nursing practice.

Orientation and training of Public Health Nurses includes both the general orientation given to all new public health employees and more specific clinical orientation and training necessary to function under standards and nurse protocols for one or more specific programs. The Office of Nursing in collaboration with DPH Nurse Consultants, Medical Consultants, DPH Office of Pharmacy, and DPH Program Managers has the responsibility to set training and practice standards that are in accordance with the most current research, evidence-based practice, and standard of care. **The Policy and Procedure Manual for Public Health Nurse Training** provides standards and training requirements improving the quality of public health nursing practice in Georgia. Initial and annual training requirements are delineated **within the manual**. This provides a standard for nurses to assure their preparation and competency in practicing under nurse protocol. **The Policy and Procedure Manual for Public Health Nurse Training** is posted on the **Public Health Information Library (PHIL) 2.0.**

Although orientation and training should be individualized as much as possible per the expertise the nurse brings to the job, and to meet the needs of the particular public health setting, individual RNs practicing under nurse protocol must complete all listed initial required trainings prior to practicing under a specific nurse protocol.

The clinical orientation may be concurrent with the general orientation. By observing other nurses and beginning to perform some tasks under supervision, the nurse should gain understanding of the role of the Public Health Nurse and the use of nurse protocols in the delivery of health services.

District/county orientation, training, and QA/QI plans should be consistent with nursing practice standards and Department of Public Health guidelines found in **The Policy and Procedure Manual for Public Health Nurse Training** and Nurse Protocol Manual.

B. ONGOING TRAINING

Every Public Health Nurse should have the opportunity for continuing education and training in accordance with changes in technology**,** job responsibilities, and professional growth. Training programs are an appropriate way to educate nurses about any changes to nurse protocols after the annual review.

C. DOCUMENTATION OF TRAINING

Each RN and APRN is responsible for documenting examples of their professional growth and development at least once annually (e.g., workshops, seminars, community/professional meetings).

RNs and APRNs must document all required training to demonstrate that they are prepared and competent to practice under standards and nurse protocols for one or more specific programs. These records must be maintained by the individual nurse and on file at either the district **office or by the County Nurse Manager or supervisor.** Training files must be made available for review during QA/QI reviews **or as indicated**.

DRUG DISPENSING PROCEDURE

DRUG DISPENSING PROCEDURE

The Drug Dispensing procedure is for the proper procurement, storage, record keeping, labeling, and handling of drugs and/or devices by authorized agents or employees of the Georgia Department of Public Health and the County Boards of Health. The procedure is required to be signed annually by a pharmacist and physician licensed to practice in Georgia (Appendix A, District Drug Dispensing Agreement).

All **RNs**, **APRNs,** or physician's assistants who dispense dangerous drugs and/or devices under the authority of an order issued in conformity with a nurse protocol or job description and as an agent or employee of the Department of Public Health or any county board of health, shall meet the same standards and comply with all record-keeping, labeling, packaging, storage and all other requirements for the dispensing of drugs imposed upon pharmacists and pharmacies with regard to such drugs and/or devices, as outlined by the following dispensing procedure. This procedure applies to all drugs and devices within the district, whether purchased through state or local funds. The Pharmacy Director for the Department of Public Health, or a qualified designee, may make periodic on-site visits to health districts and/or local health departments to provide technical assistance and review drug utilization, dispensing, storage and handling.

DEFINITIONS

For this dispensing procedure, the following definitions apply:

1. Administer or Administration means to give a unit dose of any drug or to perform any medical treatment or diagnostic study. O.C.G.A. § 43-34**-**23(a) (1).

2. Dangerous Drug means any dangerous drug as defined in O.C.G.A. § 16-13-71 but does not include any controlled substance or Schedule I controlled substance. See also O.C.G.A. § 43-34-23(a) (3). Dangerous drugs are required to bear upon the package, the words "Caution Federal Law Prohibits Dispensing Without Prescription", "Rx only," or words of like import. These drugs may also be referred to as "Legend" drugs.

3. Device means an instrument, apparatus, contrivance or other similar or related article, including any component part or accessory, which is required under federal law to bear the label, "Caution: federal or state law requires dispensing by or on the order of a physician". O.C.G.A. § 26-4-5(9).

4. Dispense means to issue one or more doses of any drug in a suitable container with appropriate labeling for subsequent administration to, or use by, a patient. O.C.G.A. § 43-34-23 (a) (3.1)

5. Dispensing Procedure means a written document signed by a licensed pharmacist and a licensed physician that establishes the appropriate manner under which drugs may be dispensed pursuant to O.C.G.A. § 43-34-23(a) (4).

6. Distribute means the delivery of a drug or device other than by administering or dispensing. O.C.G.A. § 26-4-5(11).

7. Job description" means a document, signed by the primary supervising physician and the physician assistant, in which the primary supervising physician delegates to that physician assistant authority to perform certain medical acts and which describes the professional background and specialty of the primary supervising physician and the qualifications including related experience of the physician assistant; and includes a general description of how the physician assistant will be utilized in the practice. A job description shall not be required to contain every activity the physician deems the physician assistant qualified to perform but shall confine the activities of the physician assistant to those in the scope of practice of the primary supervising physician. O.C.G.A. § 43-34-102(4).

8. Nurse means a person who is a registered professional nurse licensed as such under Article 1 of Chapter 26 of Title 43. O.C.G.A. § 43-34-23(a) (6).

9. Nurse Protocol means a written document mutually agreed upon and signed by a nurse and a licensed physician, by which document, the physician delegates to that nurse the authority to perform certain medical acts pursuant to subsection (b) of O.C.G.A. § 43-34-23. These acts shall include, without being limited to, the administering and ordering of any drug. O.C.G.A. § 43-34-23(a) (7).

10. Order means to select a drug, medical treatment or diagnostic study through physician delegation in accordance with a nurse protocol or a physician's assistant's job description. Ordering under such delegation shall not be construed to be prescribing nor shall ordering of a drug be construed to authorize the issuance of a written prescription. O.C.G.A. § 43-34-23(a) (8).

11. Practitioner or Practitioner of the Healing Arts means a physician, dentist, podiatrist or veterinarian, and shall include any other person licensed under the laws of Georgia to use, mix, prepare, dispense, prescribe and administer drugs in connection with medical treatment to the extent provided by the laws of Georgia. O.C.G.A. § 26-4-5(33).

12. Prescription Drug Order means a lawful order of a practitioner for a drug or device for a specific patient; such order includes an electronic visual image prescription drug order and an electronic data prescription drug order. O.C.G.A. § 26-4-5(36).

GENERAL REQUIREMENTS

1. The Department of Public Health and the county boards of health may also stock drugs and related supplies which are not considered dangerous drugs (e.g., ferrous sulfate tablets, reagent strips), but the storage, record keeping, and inventory control requirements shall apply to all drugs, biologicals (vaccines and diluents), and related items. Furthermore, all biologicals (vaccines and diluents)

must be handled and stored according to any specifics related to the individual vaccine listed in the storage and handling guidelines located in the Georgia Immunization Program Manual. The manual may be accessed at https://dph.georgia.gov/immunization-publications.

2. All districts/counties must comply with the Pharmacy Distribution Tracking Policy. The policy provides supervision and oversight responsibilities of the procurement, distribution and tracking of drugs within the Georgia Department of Public Health. Responsibilities include proper storage, distribution, labeling, documentation, maintenance, and recording. The policy is assessable on DPH's **Public Health Information Library (PHIL) 2.0.**

3. The District Health Director or licensed physician signing this agreement shall designate a secure lockable area, room(s), which shall be known as the medication room(s) which is devoted to business related to pharmaceuticals and medical devices. Also, they shall designate a person in charge of the medication room(s). The District Health Director shall keep this information current and on file, available upon request. All drugs should be kept out of reach of unauthorized staff and patients.

4. A hard copy and/or electronic access to current medication reference materials must be available in all health departments and/or health centers (at a minimum, a hard copy or electronic version of Drug Facts and Comparisons [eFacts and Comparisons], American Hospital Formulary Service or Lexi-Comp Drug Information Handbook [Lexi-Comp Online]).

5. All drugs or devices which bear, or are required to bear, upon the package, the words "Caution, Federal Law Prohibits Dispensing Without Prescription", "Rx only" or words of like import, shall be issued pursuant to one of the following:
   a. A prescription from a licensed practitioner authorized to prescribe.
   b. An order issued in conformity with a nurse protocol or job description.

6. A registered professional nurse is only authorized to dispense in accordance with a nurse protocol, not a prescription or an order written on a chart or phoned in by a physician.

7. The telephone number of a poison center shall be conspicuously posted in the medication room and pharmacy areas (e.g., Georgia Poison Center 1-800-222-1222).

DRUG STORAGE AND RECORD KEEPING

1. All drugs shall be stored in designated areas known as the medication room, within the facility that are sufficient to insure the proper sanitation, temperature, light, ventilation, moisture control, segregation and security. Drugs cannot be stored on the floor. These conditions must also be considered when drugs are being distributed/transported from one area/facility to another area/facility.

There must be a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated.

a. All pharmaceuticals are to be stored and maintained at the correct temperature according to the individual product package insert for 24 hours a day, seven days a week.

b. All drugs requiring refrigeration must be stored in a refrigerator designated for drug use. The refrigerator and/or freezer must have either a thermometer or an electronic temperature monitoring device (TMD) that monitors the unit's internal temperature. The temperature must be recorded by a clinic employee.

   If the facility TMD provides minimum/maximum temperatures, the following must be recorded by clinic staff at the beginning of each workday: the minimum/maximum temperature, date, time, and name of the person documenting the temperature. If the TMD does not record minimum/maximum temperatures, temperatures must be documented at the beginning and end of the workday at a minimum. If initials are used when documenting temperatures, the document must include printed name and identifying initials.

   Certain types of TMDs have significant limitations and should not be used to measure temperatures in a pharmaceutical/vaccine storage unit (see list below). A Digital Data Logger (DDL) is recommended as this device provides accurate, consistent documentation of all temperatures at scheduled intervals. DDLs also detail how long a unit has been operating outside the recommended temperature range, referred to as a temperature excursion.

   CDC does not recommend the following TMDs:
   - Alcohol or mercury thermometers, even if placed in a fluid-filled, biosafe, liquid vial
   - Bimetal stem TMDs
   - TMDs used for food
   - Chart recorders
   - Infrared TMDs
   - TMDs without a current and valid Certificate of Calibration Testing

NOTE: Refrigerators/freezers can be monitored with an external electronic temperature monitoring device which electronically monitors internal temperatures with a temperature probe (e.g., Sensaphone).

c. Pharmaceuticals stored at room temperature must be monitored by either a thermometer or an electronic temperature monitoring device that monitors the storage area. The temperature must be recorded by a clinic employee. Documentation shall be made once daily by initialing a temperature log during clinic hours to insure the proper temperature range. Extreme changes in temperature have the potential to change the effectiveness and/or stability of

the drug. All pharmaceuticals that are improperly stored must be immediately segregated from stock and labeled unusable. See section Outdated, Deteriorated, Returned and Recalled Drugs**.**

d. Temperature logs must be kept on file for three years.
e. Store drugs for external use apart from drugs for internal use or injection (segregate at least by using different shelving or bins).

2. All drugs shall be stored in a secured area (room, cabinet) under lock and key when not in actual use. All entry points providing access to each individual medication storage areas must be always locked prohibiting outside entry. Security of the medication storage area(s) must be maintained 24 hours a day. Authorization to access the medication room(s) must be reserved to those employees performing functions requiring access such as dispensing and inventory management and control.

   Whenever more than one authorized person has access to drugs from a common inventory, one person shall be designated "in charge" of said inventory. The person designated "in charge" of said inventory shall ensure that a complete and accurate record of all drugs on hand, received, dispensed, issued, removed or otherwise disposed of, has been kept in accordance with the record-keeping requirements of the Board of Pharmacy. The district must keep a current list of those employees authorized to have access to the medication room(s). This list must be kept on file and signed annually by the District Health Director and the person “in charge” of said inventory.

   The medication room(s) should be sufficiently secure to deny access to unauthorized persons. When the security of the medication room is breached, a police report should be filed, and an actual count of the inventory should be conducted and documented.

3. Upon receipt of pharmaceuticals and/or medical devices, invoices must be signed and dated. Any discrepancies must be clearly noted on the invoice and reported within one business day to the distributor. Resolution must be noted on the invoice. All invoices must be maintained on file for five years. For purchases made by the State Office of Pharmacy, signed and dated invoices must be submitted to the State Office of Pharmacy within 72 hours of receiving the product.

4. Records of dispensing are to be made and kept by the dispensing facility for two (2) years (Georgia Board of Pharmacy Rule 480-27-.03) in a secure location and retrievable upon request. Dispensing records may be a manual hard copy on a *Drug Dispensing Sign-out Sheet* or a retrievable electronic version.

   Required documentation for dispensing records when a drug or device is dispensed pursuant to an order issued in conformity with a nurse protocol includes:

   a. Patient’s name and address,

b. Name, strength, and dosage form of drug dispensed with the National Drug Code (NDC) number,
c. Quantity dispensed,
d. Date dispensed,
e. Name of the nurse ordering and dispensing,
f. Name of practitioner (delegating physician),
g. Lot number and expiration date, per legal requirements, and
h. Identifying serial number (prescription number).

If using an electronic dispensing record in place of the manual *Drug Dispensing Sign-out Sheet*, the electronic dispensing record should clearly identify who is ordering the pharmaceutical or medical device and ideally the computer entry person, if other than the person ordering. The electronic dispensing records must be printed in hard copy every twenty-four (24) hours and filed in a secure location. The electronic dispensing print-out record must be readable without the aid of a special device. The dispenser(s) is/are responsible for verifying completeness and accuracy of the entries to the system**,** including any voided transactions, and must provide documentation that medication order information entered into the computer is correct, by dating and signing the print-out in the same manner as signing a check or legal document (e.g., Mary A. Smith or M. A. Smith).

5. A running inventory of drugs received, dispensed, and removed from designated storage areas must be verified by actual count at least monthly. Discrepancies in inventory should be researched and findings should be clearly noted. Reconciliation should occur immediately if variances are found. If a manual and an electronic inventory are kept simultaneously, then both inventories must be the same.

6. The District/County must ensure no drug diversion and no violations of federal or state laws or regulations.

7. All records pertaining to drug accountability (from ordering and receipt of drug to actual patient administration) must be kept on file. The Georgia Drugs and Narcotics Agency and the Department of Public Health and its inspectors shall have the authority to conduct inspections or audits on all drugs received and/or disposed of by an agent or employee of the Department of Public Health or any County Board of Health. Prescriptions and/or orders shall be kept on file for a minimum period of two (2) years from the date they are filled. **Refer to the Public Health Record Retention Policy for specific program requirements that may be more stringent.**

8. No health center in which drugs are handled shall operate in any manner or dispense any drugs under unclean, unsanitary, overcrowded, unhealthy conditions or under any condition that endangers the health, safety or welfare of the public. All drugs shall be kept beyond the normal reach of small children.

9. The use of professional Medical Device and Drug Samples must adhere to the

Department's policy "**Professional Medical Device and Drug Sample Policy for Public Health Clinics**" and complete the mandatory Medication and Device Sample Quarterly Report and provide it to the Office of Pharmacy.

OUTDATED, DETERIORATED, RETURNED AND RECALLED DRUGS

1. Examine drug stock at least monthly and remove from stock all outdated, improperly stored, and deteriorated drugs. Stock must be rotated so the shortest dated stock will be used first. No outdated or deteriorated drug may be kept in stock for patient use. Under no circumstance shall any drug be dispensed or administered that bears a date of expiration that has been reached or that is in a deteriorated condition.

2. Remove all outdated, improperly stored, deteriorated, unused or overstocked drugs from inventory and label unusable. For vaccines, contact the Immunization Program for guidance. The District Pharmacist or District/County Drug Coordinator will be responsible for compiling and sending the required documentation to the drug manufacturer, drug wholesaler or the reverse drug distributor (i.e., INMAR) for handling the drugs appropriately. For any drug purchased through the State Office of Pharmacy, prior notification and a copy of the prepared documentation is required to be sent to the State Office of Pharmacy to ensure that credit is applied to the appropriate state account. For any drugs purchased by the county or district, documentation must be retrievable and available upon request. The proper documentation should be kept on file for a minimum of two (2) years. Information on drugs purchased or supplied with state or federal funds must be submitted upon request. Documentation should include the following:

   a. Name and strength of the drug, expiration date, lot number, unit or size and quantity of drug returned.
   b. The name and street address of the clinic/county/district returning drugs.
   c. The date of the return.
   d. The reason the drug is being returned (e.g., out-of-date, improperly stored, deteriorated, discontinued, unused, overstocked).

   Depending on the drug and/or the contract, an exchange for fresh stock, a return for credit or a return for "destruction only" may occur.

3. Drug Recalls. If a drug recall for pharmaceutical supplies purchased by the Office of Pharmacy is issued by a manufacturer or other authorized agency, the District Pharmacist or Drug Coordinator will be notified of the procedure to follow to ensure that all recalled public health issued drugs are removed from stock at the state, district and county level.

   For pharmaceutical supplies purchased by the district or county, the district pharmacist or drug coordinator would work with the drug manufacturer or wholesaler and pull any recalled drugs. Documentation must be submitted to the State Office of Pharmacy upon request.

4. See the Georgia Immunization Program Manual, Storage and Handling Guidelines, regarding the disposition of outdated, expired or wasted vaccines. The manual is located at https://dph.georgia.gov/immunization-publications.

   For compliance with the Drug Quality and Security Act, please utilize forms provided in the Pharmacy Distribution Drug Tracking Policy located on the Department of Public Health, Office of Pharmacy webpage https://dph.georgia.gov/health-topics/office-pharmacy

INVENTORY

1. Annual Inventory is an inventory of all drugs and/or devices in each health district, including all clinics/medication rooms. Annual inventory must be conducted, documented, and signed at the end of each fiscal year. This inventory must include all drugs for use in public health whether these drugs are located in the district or the county health department. The completed annual inventory must be maintained on file at the district level for a period of two (2) years and a copy must be submitted annually by the 15th of July to the State Office of Pharmacy on an annual basis. Inventory information on drugs purchased or supplied with state or federal funds must be submitted upon request.

2. Each health district should maintain a supply of drugs on hand within the district, adequate to supply the needs of the district, but not to exceed a three (3) month supply. Inventory levels for each drug should be established, and then reviewed and adjusted on a routine basis to maintain proper inventory control.

3. Vaccine inventory must be documented and managed in the Georgia Registry of Immunization Transactions and Services (GRITS). O.C.G.A. § 31-12-3.1

LABELING AND APPROPRIATE CONTAINERS

1. All drugs and/or devices for use in the health department shall be in appropriate containers (manufacturer's original package or prescription vial), including the use of:
   a. Child-proof containers.
   b. Light-resistant and moisture-proof containers.
   c. Adequately labeled containers to identify, at a minimum, the brand name or generic name, strength, lot number and expiration date.

2. Any drug and/or device issued or dispensed to the patient for self-administration shall be in appropriate containers (manufacturer's original package or light resistant prescription vial, both with child-proof caps, unless a waiver is on file for non-safety caps) and labeled with the following information:
   a. Name, address and telephone number of the health district, health department or health center.
   b. Date and identifying serial number (at minimum, the three (3) digit county code and any other necessary identifying numbers).

c. Full name of the patient.
d. Name of the drug and strength.
e. Name of drug manufacturer (optional).
f. Directions for use to the patient.
g. Name of delegating physician.
h. The expiration date of the drug.
i. Such other accessory cautionary information as may be required or desirable for proper use and safety to the patient.
j. FDA labeling requirement. For drug products dispensed in health departments, it is a requirement to provide the FDA Side Effect Statement, "Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088." Each authorized dispenser or pharmacy must distribute the side effects statement with each prescription drug product dispensed. One or more of the following options to distribute the side effects statement must be selected:
   1) Distribute the side effects statement on a sticker attached to the unit package, vial, or container of the drug product,
   2) Distribute the side effects statement on a preprinted pharmacy prescription vial cap,
   3) Distribute the side effects statement on a separate sheet of paper,
   4) Distribute the side effects statement in consumer medication information, or
   5) Distribute the appropriate FDA-approved Medication Guide that contains the side effects statement.

3. All drugs must be identified up to the point of administration to, or use by, the patient. **Prior to dispensing or administering, all nurses must read labels three times.**
   a. When the drug is selected from the storage area.
   b. When preparing, labeling, and dispensing or administering the product.
   c. When returning the original container or package to the storage area or discarding it.

4. The contents and the label of every drug must be verified by the licensed individual authorized to dispense, issue, or administer drugs before each drug is given to the patient.

5. When **the** dispensing nurse uses any person to assist in the measuring of quantities of medication and the typing of labels, excluding the dispensing of drugs, the dispensing nurse must be physically present in the dispensing area and observing the actions of such person in doing such measuring and typing, and the dispensing nurse must be the verifier of the contents and the label.

PATIENT COUNSELING COMPONENTS

The following patient counseling components are a requirement of the Omnibus Budget Reconciliation Act of 1990, and the Georgia State Board of Pharmacy Rules and Regulations. The purpose, in part, is to enhance the public health and welfare

by requiring that consultation be offered to patients regarding their medications and various conditions that could affect or be affected by the use of those medications.

1. Patient Records
   a. A patient record system shall be maintained for patients for whom **drugs are dispensed** under the authority of a nurse protocol. The patient record system shall provide for the immediate retrieval of information necessary for the **RN or APRN** to identify previously dispensed drugs. Such patient's record shall contain, at a minimum:
      1) Full name of the patient for whom the drug is intended,
      2) Date of birth,
      3) Patient's gender, and
      4) Address of the patient (and telephone number if available).

   b. Unless the patient or the patient's agent refuses such information, the **RN or APRN** dispensing under the authority of a nurse protocol shall make a reasonable effort to obtain from the patient or patient's agent and record:
      1) Any known allergies, drug reactions or idiosyncrasies,
      2) Chronic conditions or disease states of the patient, and
      3) The identity of any other drugs, including over-the-counter drugs, or medical devices currently used by the patient.

      If the patient or the patient's agent refuses to provide such information as listed above, it should be documented with the patient's or patient's agent's signature.

   c. The **RN or APRN** dispensing under the authority of a nurse protocol shall make a reasonable effort to obtain, record and maintain a list or record of all drug orders obtained by the patient at the site where the drug was dispensed within the preceding two (2) years, showing the following information:
      1) Name and strength of the drug,
      2) Quantity and date dispensed,
      3) Name of the nurse ordering and dispensing the drug, and
      4) Comments from the nurse relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

   d. A patient's record shall be maintained for a period of not less than two (2) years from the date of the last entry in the profile record. **Refer to the Public Health Record Retention Policy for specific program requirements that may be more stringent.**

2. Prospective Drug Review

   For the purpose of promoting therapeutic appropriateness, before ordering a drug(s) from a nurse protocol and before dispensing any such drug(s), the **RN or APRN must** review the patient's records and each drug(s) ordered to identify:

   a. Drug over-utilization or under-utilization.

b. Therapeutic duplications.
c. Drug-disease contraindications.
d. Drug-drug interactions.
e. Incorrect dosage, dosage form or duration of therapy.
f. Drug-allergy interaction(s).
g. Clinical abuse or misuse.

Upon recognizing any of the above, the **RN or APRN** ordering the drug shall take appropriate steps to avoid or resolve the problem including, if necessary, consultation with the delegating physician.

3. Patient Counseling
   a. Before dispensing a drug and/or device which has been ordered under the authority of a nurse protocol, and following a review of the patient's record, the **RN or APRN** shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient, or caregiver of such patient. Such discussion shall include appropriate elements of patient counseling, based on the professional judgment of the nurse. Such elements may include but are not limited to the following:
      1) The name, strength and description of the drug.
      2) The dosage form, dose, route of administration and duration of drug therapy.
      3) Intended use of the drug and expected action or result.
      4) Any special directions and precautions for preparation, administration and use by the patient.
      5) Common, severe side effects, adverse effects or interactions, and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.
      6) Techniques for self-monitoring drug therapy.
      7) The proper storage of the drug.
      8) Follow-up information regarding the need for continued drug therapy, if applicable.
      9) Action to be taken in the event of a missed dose.
      10) Comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

   b. Additional forms of patient information may be used to supplement verbal patient counseling when appropriate or available.

   c. Documentation of drug and/or device counseling must be clearly noted in the patient’s chart.

DRUG PROGRAMS/CONTRACTS

1. 340B Drug Pricing Program

   The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the

Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified disproportionate share hospitals.
Source: U.S. Department of Health and Human Services, Health Resources and Service Administration, Office of Pharmacy Affairs. More information is located at http://www.hrsa.gov/opa/

Eligible programs (covered entity) within Georgia Public Health:

a. An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA) (relating to categorical grants for outpatient early intervention services for HIV disease) - Early HIV Intervention Services Categorical Grants (Title III of the RWCA).
b. A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA.
c. An entity receiving funds under section 318 (42 USCS §247c) (relating to treatment of sexually transmitted diseases) or section 317(j) (2) (42 USCS§247b (j) (2)) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary.

2. 340B Prime Vendor Program (PVP):
The program is free and voluntary to facilities that are already 340B eligible. The 340B PVP provides additional savings to 340B participants registered with the Prime Vendor. The program provides access to 340B sub-ceiling prices for drug products, favorable rates to access multiple wholesale distributors, and access to other related value-added products. The PVP is free to all 340B covered entities, but the covered entity must enroll in the PVP. More information is located at https://www.340bpvp.com/

3. MMCAP Infuse
MMCAP Infuse is a voluntary group purchasing organization operated and managed by the State of Minnesota serving government-authorized healthcare facilities. The state of Georgia is a MMCAP Infuse participant. The Department of Administrative Service (DOAS) is the administrator for Georgia. The goal of MMCAP Infuse is to provide member organizations the combined purchasing power to receive the best prices available for pharmaceuticals, hospital supplies, and related products. More information is located at http://www.mmd.admin.state.mn.us/mmcap/

DISPENSING/ADMINISTERING OF 340B AND 340B PVP PRODUCTS

1. 340B and 340B PVP purchased products may only be administered/dispensed to a patient of the covered entity. The Office of Pharmacy Affairs has published final notice of guidelines on definition of a patient to allow a clearer understanding of which individuals may receive prescribed medications purchased at the legislatively mandated discount of Section 602of the Veterans Healthcare Act of 1992.

In summary, an individual is a “patient” of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

a. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care, and
b. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
c. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally Qualified Health Center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a State operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.
For more information, please refer to the October 1996 Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility.

2. 340B PVP may contract to allow use of pharmaceutical products to patients that do not meet the patient definition. The 340B PVP will provide notification on each product in this category to the participating 340B PVP entities.

3. Products purchased through MMCAP may only be distributed to public health clients.

ADDITIONAL INFORMATION

1. The Prescription Drug Marketing Act (PDMA) of 1987 establishes legal safeguards for prescription drug distribution to ensure safe and effective pharmaceuticals. It was passed in response to the development of a wholesale sub-market (known as the "diversion market") for prescription drugs. More information is located at https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/prescription-drug-marketing-act-1987

2. The Robinson-Patman Act (15 U.S.C. 13 (a)-(f)) specifically makes it unlawful for “one engaged in commerce to discriminate in price between different purchasers of commodities of like quality and grade where the effect may be substantially to lessen competition.”

3. The Food and Drug Administration:

   The Code of Federal Regulations (CFR) is a codification of the general and permanent rules published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 21 of the CFR is reserved for rules of the Food and Drug Administration. Each title (or volume) of the CFR is revised once each calendar year. A revised Title 21 is issued on approximately April 1st of each year. CFR 21 is downloaded from the files of the Government Printing Office (GPO) and contains the most recent revision. The CFR at GPO, both current and historical, can also be searched directly here.

   a. To report non-emergencies about medical products: medicines, medical devices, blood products, biologics, and special nutritional products:
      - The FDA's MedWatch program allows healthcare professionals and consumers to voluntarily report a serious adverse event, product quality problem or product use error suspected to be associated with the drugs, biologicals, medical devices, and dietary supplements they prescribe, dispense or use.
      - These problems include serious adverse reactions and events, product quality problems and product use errors. Reporting can be done online, by phone, or the MedWatch 3500 form by mail or fax. Visit the MedWatch site, https://www.fda.gov/Safety/MedWatch/default.htm, for more details.

   b. Non-emergencies, adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is maintained by FDA and the Centers for Disease Control and Prevention. The vaccine reporting form may be found at http://vaers.hhs.gov. A copy of the form may also be obtained by calling 1-800-822-7967 or at the FDA website, http://www.fda.gov/.

4. Report accidental poisonings to Georgia Poison Center. 80 Jesse Hill Drive, SE
   P.O. Box 26066. Atlanta, GA. 30335-3801
   Emergency Phone: 1-800-222-1222
   TTY/TDD: (404) 616-9287
   Administrative Phone: (404) 616-9237
   Website: www.georgiapoisoncenter.org

APPENDIX A

District Drug Dispensing Agreement

In the _____ District, all registered professional nurses, **advanced practice registered nurses**, or physician's assistants who dispense dangerous drugs and/or devices under the authority of an order issued in conformity with a nurse protocol or job description and as an employee of the Georgia Department of Public Health or a County Board of Health, shall meet the same standards and comply with all record-keeping, labeling, packaging, storage and all other requirements for the dispensing of drugs imposed upon pharmacists and pharmacies with regard to such drugs and/or devices, as outlined by the following dispensing procedure. This procedure applies to all drugs and devices within the district, whether purchased through state or local funds.

Licensed Pharmacist:

Print name _____

Signature _____ _____
Date

Licensed Physician:

Print name _____

Signature_____ _____
Date

STANDARD NURSE PROTOCOL FOR ALLERGIC REACTION AND ACUTE ANAPHYLAXIS AND EMERGENCY PROCEDURES

2023 STANDARD NURSE PROTOCOL FOR ALLERGIC REACTION AND ACUTE ANAPHYLAXIS CLINICAL REVIEW TEAM

Alexander (Alex) Millman, MD **Chief Medical Officer** **Department of Public Health**	**Ashlie Pullen** **Deputy Chief Nurse, EP** **Office of Nursing** **Department of Public Health**
Tracy Dabbs, PharmD **EP Pharmacist** **Office of Pharmacy** **Department of Public Health**	

2022 STANDARD NURSE PROTOCOL FOR ALLERGIC REACTION AND ACUTE ANAPHYLAXIS CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR ALLERGIC REACTION AND ACUTE ANAPHYLAXIS

DEFINITION

Allergic reactions are potentially life-threatening (anaphylactic) reactions, that occur after exposure to an antigen which has been injected, ingested, or inhaled. Reactions range from mild, self-limited symptoms to rapid death:

1. Mild to moderate allergic reactions involve signs and symptoms of the gastrointestinal tract and skin. Observing the patient for rapid increase in severity of signs and symptoms is important, as the sequence of itching, cough, dyspnea, and cardiopulmonary arrest can lead quickly to death.

2. Severe/anaphylactic reactions involve signs and symptoms of the respiratory and/or cardiovascular systems. These may initially appear minor (i.e., coughing**,** hoarseness, dizziness, mild wheeze) but any involvement of the respiratory tract or circulatory system has the potential to rapidly become severe. Death can occur within minutes without treatment. Therefore, prompt, and effective treatment is mandatory if the patient's life is to be saved.

ETIOLOGY

Agents commonly associated with allergic reactions/anaphylaxis, include:

1. Medications:
   a. Over the counter, especially non-steroidal anti-inflammatory drugs.
   b. Prescribed medication, especially antibiotics; may occur with vaccines.
   c. Injectable medications.
   d. Herbal or home remedies.

2. Food:
   a. Especially tree nuts, peanuts, shellfish, and eggs.

3. Environmental:
   a. Stings (e.g., bee, wasp, yellow jacket, hornet, fire ants).
   b. Pollens, grass, molds, smoke, animal dander.
   c. Iodinated contrast media.

SUBJECTIVE

Allergic reactions may affect one or more organ systems:

1. Skin (itching, hives, welts, flushing or skin edema, tingling)
2. Gastrointestinal (abdominal pain, nausea, diarrhea)

3. Cardiac (dizziness, fainting, palpitations, chest pain)
4. Respiratory (difficulty breathing, upper airway swelling, including lips and tongue)

OBJECTIVE

Allergic reactions may affect one or more organ systems and range from mild to severe:

1. Skin (hives, welts, flushing, skin edema)
2. Gastrointestinal (vomiting, diarrhea)
3. Cardiac (hypotension)
4. Respiratory (wheezing, angioedema)

ASSESSMENT

The most common signs and symptoms are cutaneous (e.g., sudden onset of generalized urticaria, angioedema, flushing, pruritus). However, 10**%** to 20% of patients have no skin findings.

DANGER Signs: Rapid progression of symptoms, evidence of respiratory distress (e.g., stridor, wheezing, dyspnea, increased work of breathing, retractions, persistent coughing, cyanosis), signs of poor perfusion, abdominal pain, vomiting, dysrhythmia, hypotension, collapse.

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Mild Allergic Reaction Without Anaphylaxis:

    a. Uticaria and itching only:
        1) Adults:
            a. Diphenhydramine 25 mg p.o. every 4-6 hours **as needed** or 50 mg every 6-8 hours as needed (maximum dose 200 mg in 24 hours).
            b. Diphenhydramine 1 mg/kg up to 50 mg IM every 6 to 8 hours as needed (maximum dose 200 mg in 24 hours). Refer to Diphenhydramine dosing chart. Diphinhydramine Hydrochloride injection is indicated when the oral form is not appropriate (e.g., patient can't swallow).
        2) Children 2 years and over follow dosing chart guidance below.
        3) Children younger than 2 years should receive diphenhydramine only after consulting with a physician.
    b. Observe patients with mild allergic reactions without anaphylaxis for 60 minutes before releasing from the health department. Patients that receive

Diphenhydramine IM Dosing The standard dose is 1 mg/kg body weight, maximum dose: **50 mg per dose**. May repeat dose every 6 to 8 hours **as needed**. The max dose for infants, children and adults is **200** mg in 24 hours.	
Weight Lbs. (kg)	Diphenhydramine Dose (Injection: 50 mg/mL)
24-37 (11-17)	15 mg / 0.3 mL
37-51 (17-23)	20 mg / 0.4 mL
51-77 (23-35)	30 mg / 0.6 mL
77-99 (35-45)	40 mg / 0.8 mL
99+ (45kg+)	50 mg / 1 mL

diphenhydramine should be advised to have someone drive them home.

Diphenhydramine PO Dosing The standard dose is 1 mg/kg body weight, maximum dose: **50** mg **per dose.** May repeat dose every 6 to 8 hours **as needed**. The max dose for infants, children and adults is **200 mg** in 24 hours.	
Weight Lbs. (kg)	Diphenhydramine Dose (Suspension: 12.5mg/5mL)
22-26 (10-12 kg)	5 ML
27-32 (12-14 kg)	6.25 ML
33-37 (14-16 kg)	7.5 ML
38-43 (17-19 kg)	8.75 ML
44-54 (20-24 kg)	10 ML
55-65 (25-29 kg)	12.5 ML
66-76 (30-34 kg)	15 ML
77-87 (35-40 kg)	17.5 ML
88 and > (40 kg and >)	20 ML

2. Acute Anaphylaxis:

NOTE: The first and most important treatment in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis. **Antihistamines and/or glucocorticoids are not reliable interventions to prevent anaphylaxis and are considered second-line since they have a slow onset of action. They are effective for treating pruritis, flushing, and urticaria associated with anaphylaxis but are not effective in treating cardiovascular and respiratory symptoms**.

a. Call for someone, preferably two people to help (do not leave patient).
   1) Support staff should immediately call #911 and notify delegating physician.
   2) Assign one person to be timekeeper and record events in anaphylaxis record (Appendix A).
b. Promptly and simultaneously give:
   1) IM epinephrine (1mg/ml preparation): Give epinephrine 0.3 to 0.5 mg intramuscularly, preferably in the mid-outer thigh. Can repeat every 5 to 15 minutes (or more frequently), as needed. If epinephrine is injected promptly IM, most patients respond to one, two, or at most three doses. IM Epinephrine Dosage Chart follows

below.
2) Place patient in recumbent position, if tolerated, and elevate lower extremities.
3) Administer oxygen at 8 to 10 L/minute via nasal cannula or up to 100% oxygen as needed.

NOTE: EMS must be called for transport of any patient who has received epinephrine. Patients who refuse transport should be advised to have someone drive them home and to see their private provider or call emergency services if their condition worsens.

c. If condition deteriorates prior to EMS arrival:
   1) If patient becomes unresponsive and no pulse is detected, assure an open airway and begin CPR.
   2) A copy of the anaphylaxis record (Appendix A) must be provided to EMS to go with the patient.

Weight-based intramuscular epinephrine dosing and administration for anaphylaxis in health care settings (Table recreated from UpToDate):

In patients with severe symptoms or who are rapidly deteriorating, use an autoinjector if drawing up the dose will cause a significant delay. There are three available autoinjector strengths: 0.1 mg (Auvi-q), 0.15 mg (EpiPen Jr, others), 0.3 mg (EpiPen, others)		
Weight	**Preferred**	**Alternative**
<10 kg (infants)	Draw up 0.01 mg/kg (0.01 mL/kg of epinephrine 1 mg/mL)	0.1 mg autoinjector If not available, 0.15 mg autoinjector may be given OR draw up 0.1 mg (0.1 mL of epinephrine 1 mg/mL)
10 to 25 kg (infants and children)	0.15 mg autoinjector	Draw up 0.15 mg (0.15 mL of epinephrine 1 mg/mL)
>25 to 50 kg	0.3 mg autoinjector	Draw up 0.3 mg (0.3 mL of epinephrine 1 mg/mL)
>50 kg	Draw up 0.5 mg (0.5 mL of epinephrine 1 mg/mL)	0.3 mg autoinjector

- If the dose is to be drawn up, confirm that the 1 mg/mL epinephrine solution is being used. Draw up into a 1 mL syringe. The intramuscular injection is given into the mid-outer thigh.
- If using an autoinjector, it should be held in place for three seconds after the injection, which is sufficient to deliver the dose.
- Most patients respond to a single dose of intramuscular epinephrine. However, if there is no response or an inadequate response, then intramuscular epinephrine may be repeated at 5-to-15-minute intervals or sooner, if clinically indicated.

PATIENT EDUCATION/COUNSELING

1. For cutaneous symptoms, after release from the health department:
   a. Follow diphenhydramine over the counter product dosing instructions if symptoms persist.
   b. Advise to call #911 if it becomes difficult to breathe or they experience chest pain.
   c. Provide guidance about the importance of following up with their primary care provider about the reaction including symptoms, treatment required and any information that is known about the potential causative agent (e.g., medication, vaccine, food, etc.).

CONSULTATION/REFERRAL

1. Consult with delegating physician for alternative treatment options when allergen is medication that was ordered/dispensed under nurse protocol.
2. Immediately refer patients with wheezing, laryngeal edema, hypotension, shock, or cardiovascular collapse to ER via EMS.
3. Refer to primary care provider for further evaluation**.**

FOLLOW-UP

1. Place an allergy label on the front of patient's medical record and/or enter the allergy into the electronic medical record as appropriate.
2. If the allergic reaction is immunization-induced, complete a vaccine adverse event record (VAERS).

REFERENCES

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5. UpToDate. Emergency treatment of anaphylaxis. Accessed September 21, 2021. https://www.uptodate.com/contents/anaphylaxis-emergency-treatment?search=self%20treatment%20of%20anaphylaxis&source=search_result&selectedTitle=2~150&usage_type=default&display_rank=2

Appendix A: ALLERGIC REACTION/ANAPHYLAXIS RECORD

District/Clinic Site _____ Date _____

Patient Demographic Information:

Name: _____

DOB _____/_____/_____ AGE _____ months / years

Estimated/Actual Weight (*please circle one)* Infant / Child / Adult _____lbs/kg

Event which precipitated reaction:

_____ Immunization
_____ Medication administered
_____ Biologicals administered
_____ Food ingested
_____ Exposure to Environmental Hazard(s)
_____ Other: (please explain) _____

TIME OF REACTION: _____ TIME EMS CALLED: _____

Signs and Symptoms: (please check)

_____ Apprehension
_____ Flushing and/or skin edema
_____ Palpitations
_____ Numbness and tingling
_____ Itching
_____ Localized or generalized urticaria (rash, welts)
_____ Seizure Activity
_____ Choking sensation
_____ Coughing/hoarseness/wheezing
_____ Difficulty breathing
_____ Nausea and vomiting
_____ Severe hypotension
_____ Vasomotor collapse
_____ Loss of consciousness

Other (e.g., dizziness): _____

OTHER OBSERVATIONS/COMMENTS: _____
_____
_____
SIGNATURE OF RN/APRN: _____

DISPOSITION: _____

REVIEWER: _____

NOTE: Send copies of both pages of this record with patient when transported to hospital/ER or referred to a physician's office or hospital.

1. Call for HELP
2. Assign timekeeper/recorder
3. Assure AIRWAY
4. Check VITAL SIGNS every 5 minutes
5. CPR if necessary
6. Call EMS if indicated

For cutaneous symptoms with or without anaphylaxis:

Diphenhydramine IM Dosing The standard dose is 1 mg/kg body weight, maximum dose: **50 mg** per dose. May repeat dose every 6-8 hours **as needed**. The max dose for infants, children and adults is **200** mg in 24 hours.	
Weight lbs (kg)	Diphenhydramine Dose (Injection: 50 mg/mL)
24-37lb (11-17kg)	15 mg / 0.3 mL
37-51lb (17-23kg)	20 mg / 0.4 mL
51-77lb (23-35kg)	30 mg / 0.6 mL
77-99lb (35-45kg)	40 mg / 0.8 mL
99lb+ (45kg+)	50 mg / 1 mL
*Note: Children younger than 2 years of age should receive diphenhydramine only after consulting with a physician.	
Diphenhydramine PO Dosing The standard dose is 1 mg/kg body weight, maximum dose: 50 mg per dose. May repeat dose every 6 – 8 hours as needed. The max dose for infants, children and adults is 200 mg in 24 hours.	
Weight lb(kg)	Diphenhydramine Dose (Suspension: 12.5/5mL)
22 – 26lb (10-12kg)	5mL
27 – 32lb (12-14kg)	6.25mL
33-37lb (14-16kg)	7.5mL
38-43lb (17-19kg)	8.75mL
44-54lb (20-24kg)	10mL
55-65lb (25-29kg)	12.5mL
66-76lb (30-34kg)	15mL
77-87lb (35-40kg)	17.5mL
88lb and greater (40kg and greater)	20mL
*Note: Children younger than 2 years of age should receive diphenhydramine only after consulting with a physician.	

For severe reactions (anaphylaxis) involving more than one organ system or causing difficulty breathing or hypotension/shock:

Epinephrine IM Dosing

Weight-based intramuscular epinephrine dosing and administration for anaphylaxis in health care settings		
In patients with severe symptoms or who are rapidly deteriorating, use an autoinjector to avoid delays with drawing up. 3 available autoinjector strengths: 0.1 mg (Auvi-q), 0.15 mg (EpiPen Jr, others), 0.3 mg (EpiPen, others)		
Weight	Preferred	Alternative
< 10 kg (infants)	Draw up 0.01 mg/kg (0.01 ml/kg of epinephrine 1 mg/ml)	0.1 mg auto injector If not available, 0.15 mg autoinjector may be given OR draw up 0.1 mg (0.1 ml of epinephrine 1 mg/ml)
10 to 25 kg (infants and children)	0.15 mg autoinjector	Draw up 0.15 mg (0.15 ml of epinephrine 1 mg/ml
>25 kg to 50 kg	0.3 mg autoinjector	Draw up 0.3 mg (0.3 ml of epinephrine 1 mg/ml)
>50 kg	Draw up 0.5 mg (0.5 ml of epinephrine 1 mg/ml)	0.3 mg autoinjector

PATIENT NAME: _____
PATIENT WEIGHT: _____
PATIENT DOB/AGE: _____
TIME EMS CALLED: _____
TIME EMS ARRIVED: _____

VITAL SIGNS (monitor every 5 minutes)

Time	B/P	Pulse	Resp
_____	___/___	____	___
_____	___/___	____	___
_____	___/___	____	___
_____	___/___	____	___
_____	___/___	____	___
_____	___/___	____	___
_____	___/___	____	___

CPR Indicated: _____YES _____NO
TIME CPR started: _____AM / PM
TIME CPR ended: _____AM / PM

Oxygen started: _____YES _____NO

TIME	DOSE	ROUTE
____	_____	_____

Epinephrine 1mg/1mL ampule

TIME	DOSE	ROUTE	SITE
_____	_____	IM	____
_____	_____	IM	____
_____	_____	IM	____

Epinephrine Auto-Injector

TIME	DOSE/TYPE	ROUTE	SITE
____	_____	IM	____
___	_____	IM	____
____	_____	IM	____

IM Diphenhydramine 50 mg/mL vial

TIME	DOSE	ROUTE	SITE
_____	_____	IM	____

Oral Diphenhydramine 12.5 mg/5mL (Elixir/Solution) OR 25mg, 50 mg (Capsules)

TIME	DOSE	ROUTE
_____	_____	PO

EMS DEPARTED TO HOSPITAL: _____

HOSPITAL NAME: _____

Patient's status when transported to hospital: _____

If not transported, patient's status when leaving clinic: _____
_____

PROCEDURE FOR EMERGENCY KITS/CARTS IN PUBLIC HEALTH CLINIC SITES

A. GENERAL

Local factors such as anticipated Emergency Medical System (EMS) response time, the availability of a physician and the ability of trained personnel to initiate an emergency procedure in the event of vasovagal syncope, and/or an acute anaphylaxis/allergic reaction will determine the need for medications and supplies beyond the minimum as identified in these guidelines. Emergency plans and procedures should be coordinated with a local EMS agency.

All emergency drugs and supplies should be kept together in a secured kit or cart that is easily moveable and readily accessible/visible during clinic service hours. Inventory should be checked monthly with careful attention to medication expiration dates and the working condition of equipment.

Emergency drills must be conducted at least once annually at each clinic site and documented to ensure staffs familiarity with the cart and emergency procedures.

EMERGENCY KIT/CART

Emergency kits/carts are those drugs and supplies which may be required to meet the immediate therapeutic needs of patients, and which are not available from other authorized sources in sufficient time to prevent risk or harm to patients. Medications may be provided for use by authorized health care personnel in emergency kits/carts, provided such kits/carts meet the following requirements:

1. Storage:
   Emergency kits/carts shall be stored in limited-access areas and sealed with a disposable plastic lock to prevent unauthorized access and to insure a proper environment for preservation of the medications in them.

2. Labeling:
   - Exterior:
     The exterior of emergency kits/carts shall be labeled to indicate it clearly and unmistakably is an emergency drug kit/cart and is for use in emergencies only.
   - Interior:
     All medications contained in emergency kits/carts shall be labeled in accordance with the name of the medication, strength, quantity, lot number and expiration date.

3. Removal of Medications:
   Medications shall be removed from emergency kits/carts only pursuant to nurse protocol/procedure, by authorized clinic personnel, a physician or pharmacist.

4. Inspections of emergency kits and supplies:
   - Each emergency kit/cart should be opened and inspected once a month by one of the following: LPN, RN, APRN, Pharmacist or MD.
   - Document the monthly inspection of the emergency kit/cart on the Emergency Check-Off Log sheet (Appendix B) that includes:
     a. List of emergency supplies and equipment
     b. The name of medication(s) included, strength, quantity, lot number and expiration date. Documentation that the disposable lock was found intact. If the lock contained an identification number/marking, document that it was correct.
     c. Name of staff who performed the inspection and date.
     d. After monthly inspection, the emergency kit/cart should be locked with the appropriate disposable lock. If locks that contain and identification number/marking, it should be recorded.
   - Oxygen canisters should be inspected every 6 months.
   - AEDs should be visually inspected once a month and batteries and electrode pads replaced as needed. The TEST feature should also be completed monthly if AEDS is equipped with that feature.

5. Minimum Medication(s) included in the emergency kit/cart:
   - Epinephrine vials 1mg/mL AND/OR Epinephrine auto-injectors.
     a. The cart should contain 1mg/ml vials of epinephrine OR the cart must have 3 doses each of both 0.3mg and 0.15mg auto-injectors of epinephrine.
     b. 0.1mg auto-injector is recommended to be included when available on the market.
   - Diphenhydramine 50mg/mL (2 vials)
   - Diphenhydramine elixir/solution 12.5mg/5mL (1 bottle with dosing apparatus).
   - Diphenhydramine HCl 25mg capsules or tablets (#10, may be blister packs).
   - Portable oxygen (by nasal cannula at 5L/ min for children and adults unless patient has history of emphysema or chronic lung disease then it should be administered at 2L/min). Document oxygen tank capacity as F, ¾, ½, ¼, or E along with expiration date.

6. Minimum Supplies:
   - Blood pressure cuffs (adult and child): check function
   - Stethoscope
   - Flashlight/extra batteries
   - Copy of emergency protocols/procedures
   - Allergic Reaction/Acute Anaphylaxis Record
   - Bag-valve-mask (AMBU) for resuscitation (Infant/Child/Adult)
   - Automated external defibrillator (AED)
   - Pulse-oximeter: check batteries
   - Copy of current Monthly Checklist of Drugs and Supplies document with appropriate signatures/initials

- Nasal cannula for oxygen administration
- Needles and syringes for IM injection

7. Recommended Additional Supplies and Medications:
   - Stop the Bleed Kit
   - Glucometer kit and **single use lancets**
   - Glucose tab
   - Bulb syringes

APPENDIX B: Emergency Cart Checklist _____**County Health Department** **Year**

Instructions: This checklist is intended to assist with Emergency Cart quality assurance. Please fill in the lot number, expiration date, and quantity for all medications and supplies in the emergency cart.

MEDICATIONS																					
Medication Name/Strength	**Unit**	**Amount Required**	**Mfg.**	**Lot #**	**Expiration Date**	**Amount on Hand**	**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**July**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
Epinephrine 1mg/1 ml OR	Vial	3																
Epinephrine Auto-Injector 0.3 mg AND	auto-injector	3 doses																
Epinephrine Auto-Injector 0.15 mg		3 doses																
Epinephrine Auto injector 0.1 mg		3 doses																
Diphenhydramine 50 mg/1 ml	Vial	2																
Diphenhydramine elixir 12.5 mg/5 ml	Elixir/solution	1 bottle																
Diphenhydramine HCl 25 mg (may be blister packs)	Capsules/ Tablets	10																
SUPPLIES																		
Portable Oxygen																		
Oxygen Tubing																		
Oral Dosage Syringe																		
Nasal Bulb Syringe Aspirator																		
Adult and Child Nasal Cannulas																		
Adult, Child, and Infant Ambu Bags																		
Adult and Pediatric Blood Pressure Cuffs																		
Stethoscope																		
Flashlight w/extra batteries																		
Needles and Syringes for IM Injection (filter needles if ampules are used)																		
Copy of Emergency Protocols/ Procedures																		
Allergic Reactions/Acute Anaphylaxis Record																		
Copy of Current Monthly Checklist with Appropriate Signatures/Initials																		
Pulse-oximeter with extra batteries																		
Automated External Defibrillator (AED)																		
Stop the Bleed Kit (optional)																		
Glucometer Kits (optional)																		
Glucose tablets (optional)																		
Date:																		
Initials																		

PROCEDURE FOR REVIEWING EMERGENCY PROTOCOLS AND PROCEDURES IN ALL PUBLIC HEALTH CLINIC SITES

A review of emergency protocol and procedures shall be completed at least once annually at each clinic site. A designated Nursing Supervisor will be responsible for coordination and implementation of an annual review and assure the Emergency Checklist for Public Health Clinic Sites (Appendix C) and the Evaluation Tool for Practice Drills (Appendix D) are completed.

Staff member(s) listed below participated in training updates for all age ranges and performed in a mock emergency drill on _____.
(Date)

Name(s) of Staff Member(s)

_____ _____

_____ _____

_____ _____

_____ _____

_____ _____

Nursing Supervisor or County Nurse Manager:

_____ _____
Signature Date

District Nursing & Clinical Director:

_____ _____
Signature Date

APPENDIX C: EMERGENCY CHECKLIST FOR PUBLIC HEALTH CLINIC SITES

The Nursing Supervisor/County Nurse Manager and District Nursing & Clinical Director will assure that this checklist is completed annually for each site and that follow-up occurs for any inadequacies/incomplete areas.

#	EMERGENCY ITEM	Complete/ Adequate	Incomplete/ Inadequate	Comments
1.	Emergency numbers posted on each phone.			
2.	Exits clear.			
3.	Hallways clear.			
4.	Staff able to describe action to take in case of emergency.			
5.	Staff demonstrates use of emergency supplies and equipment.			
6.	Emergency kit/cart stored in secured area except during clinic hours.			
7.	AED in visible and accessible location.			
8.	Emergency kit/cart stocked according to Emergency Protocol for Anaphylaxis and has been checked monthly **for expiration**, as required.			
9.	All staff trained in emergency procedures and certified in CPR (every 2 years).			
10.	Evacuation/Exit maps posted			
11.	Emergency drill(s) conducted and documented at least annually for infants, children, and adults.			

Clinic Site and County: _____

Date of Review: _____ Date Corrective Actions Completed: _____

Nursing Supervisor or County Nurse Manager: _____
Signature

District Nursing & Clinical Director: _____
Signature

APPENDIX D: EVALUATION TOOL FOR PRACTICE DRILL

		Yes	No
A.	Response Team		
1.	Team effort utilized and well-coordinated.	_____	_____
2.	Response team timely.	_____	_____
3.	Patient assessment complete.	_____	_____
4.	*Agency specific code called.	_____	_____
5.	Emergency Medical Services/ Physician/APRN/Nurse Manager notified.	_____	_____
6.	Emotional support provided to significant others, if applicable.	_____	_____
B.	Patient Outcome		
1.	Level of consciousness assessed.	_____	_____
2.	Vital signs monitored.	_____	_____
3.	Appropriate drugs given.	_____	_____
4.	CPR instituted, if applicable.	_____	_____
5.	EMS/physician/APRN/Nurse Manager responded.	_____	_____
6.	Documentation complete.	_____	_____

C. Recommendations/Comments:

_____
_____
_____
_____
_____
_____

Site_____ Date_____

Evaluator Printed Name_____

Evaluator Signature _____

**Agency specific codes should be used to signal an emergency*

SUSPECTED OPIOID OVERDOSE

2023 STANDARD NURSE PROTOCOL FOR SUSPECTED OPIOID OVERDOSE CLINICAL REVIEW TEAM

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Ricky Schutter **CBRNE Planning & Operations Coordinator** **Health Protection/Emergency Preparedness/PHEP Georgia Department of Public Health**	**Tracy Dabbs, PharmD** **EP Pharmacist** **Office of Pharmacy** **Department of Public Health**
Kimberley Hazelwood, PharmD **Pharmacy Director** **Department of Public Health**	

2022 STANDARD NURSE PROTOCOL FOR SUSPECTED OPIOID OVERDOSE CLINICAL REVIEW TEAM

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Angela Griffin, RN, BSN County Nurse Manager Appling County Health Department District 9-2	Rebecca Y Kershner, MSN, WHNP-BC Women's Health and STD Coordinator Richmond County Health Department District 6
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STANDARD NURSE PROTOCOL FOR SUSPECTED OPIOID OVERDOSE

*DO NOT USE IN PERSONS WITH KNOWN NALOXONE HYDROCHLORIDE HYPERSENSITIVITY

DEFINITION

Overdose is defined as the accidental or intentional ingestion of a drug at a quantity substantially greater than normally used or recommended resulting in serious harmful symptoms or death. An overdose is a medical emergency in which response time is of the essence to save the person who is usually unconscious, hypoxic, and in the more severe cases, apneic. Initiating treatment for an opioid overdose as early as possible is medically imperative and a critical determinant of outcome in opioid overdose.

ETIOLOGY

Heroin and prescription opioids (e.g., oxycodone, hydrocodone, codeine, fentanyl, and morphine) are opioid receptor agonists. With larger doses, respiratory depression can occur, limiting adequate oxygenation of blood, which reduces oxygen availability to the brain and heart, leading to unresponsiveness, anoxia, cyanosis, and death. Respiratory depression, which is reversible until death occurs, can be sudden or take 1 to 3 hours and can be reversed with the pharmacological antidote naloxone, which displaces opioids from the opioid receptor and blocks the binding of additional opioids for 20 to 90 minutes.

Note: Please note that fentanyl-based substances should be treated as significant contamination and all related protocols should be enacted (e.g., contamination avoidance, PPE procedures, etc.). It is important to prevent exposure to fentanyl-based substances. Be sure to assess the area for your safety. Always wear nitrile gloves when caring for a person you suspect is experiencing an opioid overdose. If a powdery substance is found, avoid touching as much as possible. Wear appropriate level PPE if contact risk is high and practice contamination control measures. Appropriate level PPE would include nitrile gloves, face masks (preferably N-95), face and eye protection (face shield), and wrist/arm protection to cover skin. Patients who may be contaminated and healthcare personnel who are exposed to illicit fentanyl should immediately remove clothing and use soap and water to thoroughly wash and rinse potentially contaminated skin. They should cover all open wounds and avoid breaking the skin during the decontamination process. Do not use alcohol-based hand rubs or bleach solutions to clean contaminated skin. Be sure to remove contaminated gloves and other PPE properly and placed into labeled durable 6 mil polyethylene bags and dispose of appropriately. Use soap and water to thoroughly wash and rinse hands and other potentially contaminated skin.

NOTE: Alcohol-based hand sanitizers do not get rid of the presence of fentanyl-based substances.

OBJECTIVE

1. If a person displays any or all the symptoms that follow, CALL 911 IMMEDIATELY:
   a. Face extremely pale and/or clammy
   b. Limp body
   c. Fingernails or lips have a purple or blue color
   d. Vomiting or making gurgling noises
   e. Cannot be awakened or unable to speak
   f. Pinpoint pupils
   g. Low blood pressure
   h. Breathing or heartbeat slows or stops

ASSESSMENT: Suspected Opioid Overdose

NOTE: The auto-injector and intranasal naloxone may be administered to infants and neonates. However, in neonates with known or suspected exposure to maternal opioid use, consider using another form of naloxone (IM) to allow dosing according to weight and titration to effect.

NOTE: Do Not Administer Naloxone Hydrochloride to Persons with Known Sensitivity.

PLAN

THERAPEUTIC

1. CALL 911 IMMEDIATELY or designated support person if you suspect a person is experiencing an opioid overdose.
2. Support staff should notify delegating physician and on-site clinical supervisor.
3. If at any time the person stops breathing, use a bag-valve mask device to maintain oxygenation. The bag-valve mask device will help prevent responder exposure to fentanyl or other harmful substances.
4. If at any time the person has no pulse, begin CPR.
5. Always utilize appropriate PPE to prevent absorption of fentanyl-related substances. These substances are designed to be readily absorbed though inhalation, transdermal transmission, contact with mucous membranes, oral ingestion, and injection.
   a. Always wear nitrile gloves when caring for a person you suspect is experiencing an opioid overdose.
   b. **If a powdery substance is found, do not touch it without wearing nitrile gloves, face mask (preferably N-95), and eye/face protection**.
   c. Also, be sure to remove and dispose gloves properly after caring for patient and wash hands with soap and water.

NOTE: If the patient responds to naloxone administration, additional dose(s) may need to be re-administered at a later interval. Patients who are given naloxone are at risk for repeated respiratory depression; additional doses may be needed depending on type/duration of opioid.

6. Administer Naloxone Hydrochloride:

    a. Administer naloxone hydrochloride either intramuscularly or intranasally every 2-3 minutes until the person responds. If a total of 10 mg is administered and no improvement is seen, do not administer additional naloxone as opioid overdose may not be the cause of symptoms. Continue monitoring vital signs, administer rescue breathing or CPR, if necessary, until EMS arrives.

    b. Naloxone hydrochloride solution:

        1) Adults, adolescents, and children older than 5 years or weighing more than 20 kg: Naloxone hydrochloride injection 2 mg IM every 2-3 minutes until person is spontaneously breathing and/or condition improves. Can give subcutaneously if dose cannot be administered IM. If no response is observed after 10 mg total dosage, consider other causes of respiratory depression.
        2) Infants and children younger than 5 years or weighing less than 20 kg: Initial dose is 0.1 mg/kg/dose; maximum dose is 2mg/dose; repeat every 2 to 3 minutes if needed. Monitor closely; may need to repeat doses (e.g., every 20 to 60 minutes) if duration of action of opioid is longer than naloxone. May give IM or subcutaneously in divided doses.

OR

1) Autoinjector (for neonates, infants, adolescents, and adults) Naloxone hydrochloride auto-injector 0.4 mg or 2 mg IM every 2-3 minutes until person is spontaneously breathing and/or condition improves. If no response is observed after 10 mg total dosage, consider other causes of respiratory depression.

NOTE: Autoinjector (naloxone hydrochloride) for IM use should be placed against the outer thigh, through clothing if needed. Press firmly and hold in place for 5 seconds.

OR

c. Intranasally (for neonates, infants, adolescents, and adults):

NOTE: In adults, onset of action is slightly delayed compared to IM.

1) Naloxone hydrochloride intranasal (e.g., Kloxxado, Narcan Nasal Spray). Do not prime or test the device prior to administration:
    a) Infants, children and adolescents (< 18 years of age): 4 mg or 8 mg (contents of 1 nasal spray) as a single dose in one nostril
    b) Adults: 4 mg or 8 mg (contents of 1 nasal spray) as a single dose in one nostril

2) Place the patient in the supine position and administer contents of one nasal spray as a single dose: 1 squirt in one nostril. Provide support to the back of the neck to allow the head to tilt back.

3) Following administration, turn the patient on their side. May repeat dose every 2-3 minutes in alternating nostrils until spontaneously breathing and/or condition improves and/or EMS arrives.

4) If the patient responds to intranasal naloxone spray and relapses back into respiratory depression before emergency assistance arrives, administer an additional dose of intranasal spray using a new nasal spray and continue surveillance of the patient.

NOTE: A new unit of intranasal naloxone spray must be used with each administration as each unit of naloxone nasal spray contains a single dose. Do not prime or test the device prior to administration.

NOTE: Alternating between dosage forms is acceptable.

NOTE: If patient responds to naloxone administration, after reversal, may need to re-administer dose(s) at a later interval (e.g., 20 to 60 minutes) depending on type/duration of opioid.

d. Following naloxone hydrochloride administration:
   1) Remain with the patient until EMS arrives.
   2) Place patient in recovery position if spontaneously breathing.
   3) Monitor vital signs every 5 minutes until EMS arrives.
   4) Complete Opioid Overdose Record (Attachment A)

e. The administration of naloxone hydrochloride can cause sudden opioid withdrawal symptoms, including agitation or combativeness; ensure the safety of patient and staff. Additional symptoms include body aches, diarrhea, tachycardia, fever, runny nose, sneezing, piloerection, sweating, yawning, nausea or vomiting, nervousness, restlessness, or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.

Note: Guidelines suggest that at least 20 to 40 mg of naloxone be stocked. Suggested amount is stated to be enough to treat 1 patient weighing 100 kg for an initial 8- to 24-hour period.

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ATTACHMENT A: OPIOID OVERDOSE RECORD

1. Call 911 and notify on-site supervisor and delegating physician.
2. Administer naloxone hydrochloride every 2-3 minutes until spontaneous respirations/conditions improves.
3. Place person in recovery position. Check vital signs every 5 minutes until EMS arrives.
4. If necessary, administer 2-person rescue breathing or CPR with bag-valve mask device.

Patient name: _____
Patient DOB/age: _____
Time 911 called: _____
Rescue breaths needed: Yes No
Time initiated: _____
CPR needed: Yes No
Time initiated: _____
CPR discontinued (time): _____
Oxygen started: Yes No

Naloxone Dosage Info

Administer naloxone hydrochloride every 2-3 minutes until spontaneous respirations/ conditions improve. If a total of 10 mg has been administered and no improvement is seen, do not give additional naloxone.

Naloxone HCl Solution:

Adults, adolescents, and children older than 5 years or weighing more than 20 kg: Naloxone hydrochloride injection 2 mg IM every 2-3 minutes until person is spontaneously breathing and/or condition improves. Can give subcutaneously if dose cannot be administered IM.

Infants and children younger than 5 years or weighing less than 20 kg: Initial dose is 0.1 mg/kg/dose; maximum dose is 2 mg/dose; repeat every 2 to 3 minutes if needed. Monitor closely; may need to repeat doses (e.g., every 20 to 60 minutes) if duration of action of opioid is longer than naloxone. May give IM or subcutaneously in divided doses.

OR

Naloxone HCl Autoinjector:
0.4 mg or 2 mg IM

OR

Intranasal: 4 mg or 8 mg single dose (1 nasal spray per individual dispenser). Administer 1 squirt of naloxone in one nostril. May repeat every 2-3 minutes in alternating nostrils. Do not prime or test the device prior to administration.

Naloxone Administration

Dose: _____ Route: ☐ Nasal ☐ IM/Auto
If IM, indicate site _____

Time Dose 1 given _____
Time Dose 2 given _____
Time Dose 3 given _____
Time Dose 4 given _____
Time Dose 5 given _____

NOTE: If a total of 10 mg has been administered and no improvement, opioid overdose may not be the cause of symptoms. Continue to monitor vitals, administer rescue breathing or CPR, if necessary, until paramedics arrive.

Vital Signs every 5 minutes

Time	B/P	Pulse	Respirations	Pulse Oximetry	Comments

EMS arrival _____ EMS departure _____ Hospital name _____
Patient condition when transported to hospital: _____

Signature of RN/APRN:
_____

CHILD HEALTH

2023 CHILD HEALTH STANDARD NURSE PROTOCOLS
CLINICAL REVIEW TEAM

Elin Brumbaugh, BSN, RN **Deputy Chief Nurse of School Health** **DPH**	**Kay Davis, RN, MSN** **Assistant Clinical Coordinator** **Immunization Coordinator** **District 9-2**
Susie Kim, RD, LD **WIC Outer County Dietitian** **District #2**	**Sierra Peebles** **Pediatric Nurse Practitioner** **District 9-1**

2022 CHILD HEALTH STANDARD NURSE PROTOCOLS
CLINICAL REVIEW TEAM

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Kay Davis, RN, MSN Assistant Clinical Coordinator Immunization Coordinator District 9-2	Sierra Peebles *Pediatric Nurse Practitioner* District 9-1
Selina G. Moon, RPh Pharmacist District 3-1	Susie Kim, RD, LD WIC Outer County Dietitian District #2

BRIGHT FUTURES, NEWBORN SCREENING, LEAD SCREENING

Public Health nurses will utilize the current edition of the American Academy of Pediatrics (AAP) Bright Futures Guidelines and periodicity schedule as their policy for providing well-child assessments in the public health setting.

Information about the current Bright Futures Guidelines is available on AAP's website: https://brightfutures.aap.org/materials-and-tools/guidelines-and-pocket-guide/Pages/default.aspx

The current Bright Futures Guidelines periodicity schedule is available online: **https://downloads.aap.org/AAP/PDF/periodicity_schedule.pdf**

Additional guidance for routine screening and follow-up of certain conditions will be provided through the Georgia Department of Public Health programs listed below:

1. Newborn Screening Program:

   Most babies appear healthy and show no signs of illness right after birth. However, some infants may be born with certain heritable diseases that can lead to disability or death. When detected early, many of these disorders can be managed and can prevent the occurrence of adverse health outcomes.

   The Newborn Screening (NBS) Program coordinates a multi-partner system for the early detection and intervention of congenital and heritable conditions. The Georgia Newborn Screening Policy and Procedure Manual will provide guidance on the implementation of newborn screening for genetic/metabolic, hearing, and critical congenital heart disease (CCHD) screening. This manual is also intended to be used as a resource guide for newborn screening in Georgia.

   The GA Newborn Screening Policy and Procedure Manual can be found on the DPH website: https://dph.georgia.gov/sites/dph.georgia.gov/files/MCH/NBS/Georgia_Newborn_Screening_Manual_b_0.pdf

2. Lead Screening/Healthy Homes Program:

   Screening for lead poisoning helps identify children who need interventions to reduce their blood lead levels. Many children who may have been exposed to lead or who are at risk for lead poisoning go without being screened. This increases their chance of being harmed neurologically and developmentally. A blood test is the preferred method for lead screening. There are two tests used to obtain blood lead specimens, capillary blood test or venous blood test.

   Lead Screening, Case Management, Lab Submissions, and Reporting Guidelines can be found on the GA DPH website: **Lead Screening, Case Management, Lab Submissions, Reporting Guidelines | Georgia Department of Public Health**

STANDARD NURSE PROTOCOL FOR MILD ACNE

DEFINITION

Comedones (blackheads, whiteheads), pimples and tender red bumps on the face, chest or back, or any combination. Usually occurs during puberty and can last until age 20-30.
Whiteheads are closed comedones. They are small white raised bumps blocked by a thin layer of epithelium.
Blackheads are open comedones. They are small plugs of darkened sebum and dead skin cells that fill a skin pore.

ETIOLOGY

Due to increasingly active androgenic hormones, there is increased activity of sebaceous glands. Obstruction of some sebaceous glands leads to rupture of the gland and release of sebum **(**a fatty acid**)** into the surrounding tissue resulting in an inflammatory reaction producing an acne nodule. Bacterial colonization of the trapped sebum with Cutibacterium acnes may produce further inflammation and/or superficial infection.

SUBJECTIVE

1. Patient may complain of blackheads, whiteheads, pimples to face, chest, and/or back.

2. Patient may report:
   a. Use of acne inducing medications (e.g., corticosteroids, phenytoin, greasy cleansing creams, cosmetics, oils).
   b. History of ~~u~~nderlying endocrinopathy (e.g., polycystic ovary syndrome, congenital adrenal hyperplasia/androgens).
   c. Condition often worsens during periods of stress or cyclic menstrual flares.
   d. Psychological distress caused by presence of facial lesions.
   e. Family history of acne.

OBJECTIVE

1. Physical examination may reveal the following criteria that are useful in classifying acne as noninflammatory or inflammatory:
   a. Noninflammatory, or Comedonal Acne, are closed and/or open comedones without tenderness or erythema.
   b. Inflammatory acne has inflammatory components consisting of erythematous papules, pimples, small pustules or nodules.
      1) Mild inflammatory acne: scattered small (<5 mm) whiteheads, with minimum blackheads, and tender red bumps on face; most common in early teens and adult women in their 20s. Consists of less than 20 comedones and less

than 15 inflammatory lesions. There is absence of nodules, absence of near confluent skin involvement and no scarring. There is limited skin involvement – presentation is isolated to individual body areas with relatively few lesions.

2) Generalized inflammatory acne: generalized eruption of pimples and whiteheads on the face and trunk.
3) Severe inflammatory acne: large, deep inflammatory nodules associated with pimples and whiteheads. May also leave scarring There is involvement of multiple body areas with more than a few scattered lesions (multiple comedones or inflamed papules or pustules are present).

2. It is necessary to assess female's pregnancy status by either asking last menstrual period or performing pregnancy test.

ASSESSMENT Acne, (Mild**,** generalized, or severe Inflammatory)

PLAN THERAPEUTIC

PHARMACOLOGIC

1. Non-prescription products
   a. If 12 years of age or older, for mild acne (fewer than 20 papules and non-pustular pimples):
      1) Benzoyl peroxide gel, lotion, foam, solution or cream, 5-10%, topically. Available over-the-counter (e.g., Benziq, BP Gel, Acne Medication 5, Acne Medication 10, Neutrogena On-The-Spot etc.). Use gel for oily skin, cream for dry skin, solutions are drying but cover large areas more easily (e.g. trunk), and foams are good for applying to hair-bearing areas.
      2) Begin with 5% daily.
      3) Leave initial application on for 15 minutes. Increase exposure time in 15-minute increments as tolerance allows.
      4) Once tolerated for 2 hours, it can be left on the skin overnight.
      5) If necessary, advance to 2 times a day.
      6) Increase or decrease the strength and/or frequency of application depending on tolerance and response (such as excessive drying or peeling).
      7) Advise to use skin protection (e.g., sunscreen and minimize prolonged exposure to sun or tanning beds).

NOTE: For patients with predominantly whiteheads and blackheads (Noninflammatory or Comedonal Acne) with very few inflammatory components (erythematous papules, pimples or small pustules), this therapy will not be effective. Topical retinoids give the best results for comedonal acne, and referral is indicated if treatment is desired.

2. Prescription products:
   If non-prescription products listed above yields an insufficient response after a trial of at least 4-6 weeks, topical benzoyl peroxide and topical antimicrobial regimen are added to optimize efficacy:

a. If 12 years of age or older, for mild acne (fewer than 20 papules and non-pustular pimples):
   1) Each morning wash with Benzoyl peroxide, gel or cream, 5-10%, topically pat dry.
   2) Each evening apply Benzoyl peroxide gel or cream5-10%, topically as described above.
   3) May apply Clindamycin Topical Gel 1% or Erythromycin Topical Gel 2% either once daily or twice daily depending on irritation and effectiveness.

OR

b. Benzoyl peroxide plus erythromycin (Benzamycin®), contains 3% erythromycin and 5% benzoyl peroxide in gel form (alcohol base), generic available. Apply 1-2 times a day to clean, dry skin.

OR

c. 5% benzoyl peroxide plus 1% clindamycin gel (BenzaClin®), generic available. Apply 1-2 times a day to clean, dry skin.

NON-PHARMACOLOGIC MEASURES

1. Shampoo hair regularly.
2. Gently wash face with warm (not hot) water and mild soap or cleanser (e.g. Dove, Basis, Purpose, Cetaphil) no more than 1-2 times a day**,** and shower or bathe daily. Explain that cleansers result in less skin peeling, dryness and irritation than soap.

PATIENT EDUCATION/COUNSELING

1. Keep hands off face. Avoid picking lesions which may lead to scar formation and/or secondary infection.

2. Avoid greasy cleansing oils, mousse, and cosmetics because they block oil glands. Use noncomedogenic cosmetics, moisturizers, and hair products if needed. Cover face when using hair spray.

3. Avoid scrubbing skin, because it can increase aggravation of inflammatory acne and promote development of new acne lesions.

4. Do not expect to completely prevent any new lesions. It takes time for improvement which can take up to 12 weeks. Discuss expected first line goal is a noticeable decrease in active acne lesions (versus complete clearance). Having an upfront explanation of long-term consistent use of topical acne therapy reduces poor adherence to treatment.

5. Eat a well-balanced diet for general health and well-being. There is limited evidence that suggests using specific dietary strategies as adjuvant therapy to decrease acne symptoms or prevent acne. Specific strategies include having diets with low glycemic load index and decreasing ingredients such as whey protein content in milk.

6. Educate patient about increased photosensitivity with use of products listed above.

7. When applying medications listed above, avoid contact with eyes, inside of nose, mouth and all mucous membranes.

8. When applying medications listed above, avoid contact with bedding, clothing, or hair. Some bleaching/staining may occur.

9. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. Return to clinic in 2 to 4 weeks after initiating therapy, then every 1 to 2 months to assess improvement of acne.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present. After a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol.

1. Patient is less than 12 years of age. Presence of acne in a preadolescent, especially ages one to seven years, necessitates prompt evaluation for hyperandrogenism.

2. No improvement in mild acne in 8-12 weeks.

3. Secondary bacterial infection.

4. Acne is moderate, severe, or cystic, refer to MD or APRN.

5. An underlying condition suspected, refer to MD or APRN.

6. Blackheads and whiteheads are the predominant lesions (non- inflammatory acne).

7. Pregnant or breastfeeding patient.

8. Any female with acne, menstrual irregularities (primarily oligomenorrhea) or hirsutism, which may be suggestive of polycystic ovary syndrome.

9. Refer to Women’s Health Program if indicated. Adolescent females may benefit from oral contraceptives (in addition to care under this protocol).

10. Refer for counseling if acne is due to psychological stress in addition to care under this protocol.

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STANDARD NURSE PROTOCOL FOR PEDIATRIC ALLERGIC RHINITIS

DEFINITION

An allergic disease affecting the nasal mucosa and often the conjunctiva. It may be seasonal (due to pollens that depend on wind for cross-pollination), or it may be perennial (non-seasonal). Condition is uncommon in children under 2 years of age.

ETIOLOGY

1. Seasonal Allergic Rhinitis:
   In the Eastern U.S. the following are the most common causes of seasonal allergic rhinitis. Pollination time varies by several months depending on location:
   a. Ragweed, August – October
   b. Grasses, May - July
   c. Trees, March – July
   d. Combinations of a, b, and c

2. Perennial Allergic Rhinitis
   a. House dust/ house dust mites
   b. Feathers
   c. Mold spores
   d. Animal dander
   e. Foods **-** Most authorities believe that if foods are causative, other signs of hypersensitivity occur with allergic rhinitis (e.g., urticaria, asthma, gastro-intestinal symptoms).

3. Aggravating factors:
   a. Tobacco smoke
   b. Air pollutants
   c. Sudden temperature changes.
   d. Wood heaters, fireplaces, carpets, etc.
   e. Strong smells (perfumes, bleach)

SUBJECTIVE Patient may report:

1. Seasonal symptoms that tend to occur the same time each year:
   a. Nasal itching, congestion, sneezing and watery drainage.
   b. Itchy eyes with excessive tearing.
   c. Postnasal drip with sore throat, cough and itchiness.
   d. Younger children can exhibit repeated snorting, sniffling, coughing, clearing throat or palatal clicking sound (occurs when scratching at an itching palate with tongue)

2. Coexisting atopic diseases such as eczema, food allergies or asthma. or allergic conjunctivitis. Other coexisting conditions include sinusitis, eustachian tube dysfunction creating serous otitis media, migraine headaches and anosmia.

3. Significant impact on school performance and sleep patterns.

OBJECTIVE Physical examination may reveal:

1. Clear, thin nasal discharge.
2. Nasal mucosa may be normal to pink to pale gray and edematous.
3. Enlarged nasal turbinates.
4. “Allergic salute" - rubbing of the nose upward and outward (seen especially in children) and "wrinkling" of the nose
5. “Allergic crease” – transverse line across the nose causing a nasal crease.
6. Conjunctival injection with or without clear drainage and dark semi-circles (“allergic shiners") under the eyes.
7. Mouth breathing
8. Hyperplastic lymphoid tissue lining the posterior pharynx, which resembles cobblestones ("cobblestoning")

ASSESSMENT Allergic Rhinitis

1. Seasonal – rule out:
   a. Upper respiratory tract infection
   b. Infectious conjunctivitis
   c. Any food allergies.

2. Perennial – rule out:
   a. Recurrent upper respiratory tract infection
   b. Vasomotor rhinitis (of unknown cause, non-infectious, non-seasonal, and non-allergenic).
   c. Deviated nasal septum.
   d. Side effects of medications, such as overuse of vasoconstricting nose drops/sprays.
   e. Chronic sinusitis/rhinosinusitis.
   f. Chronic contact with tobacco smoke (smoke is a primary irritant, allergy not required).

PLAN Data review: Consider obtaining allergy panel specific for northern or southern Georgia dependent on patient’s residential region to improve patient outcome. Identifying the allergens can facilitate avoidance of the allergen plus identify if patient can be referred as a candidate for allergen immunotherapy.

THERAPEUTIC

PHARMACOLOGIC

1. Nasal Corticosteroids:

For age 2 and over with seasonal allergic rhinitis, a nasal corticosteroid is regarded as first-line therapy (before using oral antihistamines). For the following nasal sprays, prime pump prior to first use and when breaks in utilization of product occur, following the specific product directions. Inform the patient to not blow their nose for 15 minutes after using the spray, if possible. After use wipe the spray bottle with a clean, dry tissue or cloth and put the cap back on. Advise to take a few sips of water or liquid of their choice after use to decrease fungal infection in the throat.

a. Prescription:
    1) Mometasone furoate nasal spray, (Nasonex®)
        a) Children 2-11 years of age, 50mcg (1 spray) in each nostril once daily (total daily dose 100mcg).
        b) Children 12 years of age and older, 100mcg (2 sprays) in each nostril daily (total daily dose 200 mcg).

OR

    2) Ciclesonide nasal spray, (Omnaris®)
        a) Children 2-11 years of age, 50mcg (1 or 2 sprays) in each nostril once daily (total daily dose 50 to 100mcg).
        b) Children 12 years of age and older, 50mcg (2 sprays) in each nostril daily (total daily dose 100 mcg).

OR

    3) Fluticasone propionate nasal spray, (50mcg/actuation) or available as OTC products (Flonase® Allergy Relief, GoodSense Nasoflow)
        a) Adolescents and Children (aged 4 years to 11 years): 1 to 2 sprays per nostril once daily (total dose 100 to 200 mcg/day); maximum daily dose: 2 sprays per nostril once daily (total daily dose: 200 mcg/day). Once symptoms are controlled, reduce dose to 1 spray per nostril once daily (total daily dose: 100mcg/day).
        b) Children > 12 years and Adolescents: 2 sprays per nostril once daily (total daily dose:200 mcg/day).

OR

    4) Fluticasone furoate, Flonase Sensimist 27.5mcg/spray available as OTC product
        a) Children 2-11 years: initial 1 spray (27.5mcg/spray) per nostril once daily (55 mcg/day). Patients not adequately responding may use 2 sprays per nostril once daily (110 mcg/day). Once symptoms are controlled, dosage may be reduced to 55 mcg once daily. Total daily dosage should not exceed 2 sprays in each nostril (110 mcg) per day.
        b) Children 12 years of age and older: Initial: 2 sprays (27.5 mcg/spray) per nostril once daily (110 mcg/day). Once symptoms are controlled, dosage may be reduced to 1 spray per nostril once daily (55 mcg/day). Total daily dosage should not exceed 2 sprays in each nostril (110 mcg) per day.

OR

b. OTC:
    1) Triamcinolone acetonide aqueous suspension nasal spray**,**

(55mcg/actuation), available as OTC products GoodSense Nasal Allergy Spray, Nasacort Allergy 24HR, Nasacort Allergy 24HR Children)

a) Children 2-<6 years: 55 mcg (1 spray) each nostril once daily (total daily dose 110 mcg).
b) Children 6-<12 years: Initial: 110 mcg/day as 1 spray in each nostril once daily; may increase to 220 mcg/day as 2 sprays in each nostril if response is not adequate; once symptoms controlled may reduce to 110 mcg/day.
c) Children 12 years and older: initial 220mcg/day as 2 sprays in each nostril once daily; titrate to lowest effective dose once symptoms are controlled; usual maintenance dose: 110mcg/day as 1 spray in each nostril once daily.
d) Discontinue use if symptoms after 3 weeks are not adequately controlled.

NOTE: For the above list of inhaled nasal corticosteroids, it is recommended that once optimal symptomatic relief is achieved, dosage of the drug should be gradually reduced to the lowest effective dose.

The preparations listed above are preferred because of low systemic bioavailability and therefore less risk of systemic complications with chronic use**.** For best control of symptoms through the active allergen season, up to 4 to 8 weeks may be needed before trial off medication.

2. Antihistamines: helpful in reducing itching, sneezing, and rhinorrhea, but less effective for nasal congestion. Preference is second generation antihistamines they are minimally sedating, have similar efficacy and fewer central nervous system effects.

   a. Cetirizine/Zyrtec® Liquid 5mg/5mL, chewable 5mg tablet, tablet 5mg or 10 mg (available OTC):
      1) 2 years- 5 years: ½ - 1 teaspoon (2.5 to 5mg) PO every day or ½ teaspoon every 12 hours.
      2) 6 years-11 years: 5mg to 10mg PO every day.
      3) 12 years or older: 1tab (10mg) PO every day.

      OR

   b. Loratadine/Claritin® Liquid 5mg/5mL, chewable 5mg tablet, orally disintegrating 5mg tablet, tablet 10mg (available OTC):
      1) 2 years-5 years: 1 teaspoon (5mg) PO every day.
      2) 6 years-11 years: 10mg PO every day.
      3) 12 years or older: 10mg PO every day.

      OR

   c. Fexofenadine /Allegra Liquid 30 mg/5 ml, orally disintegrating tab 30 mg, tablet 30 mg, 60 mg, 180 mg
      1) 2 years – 11 years: 30 mg PO every 12 hours
      2) 12 years or older: 180 mg PO every day

NOTE: Manipulation of dosage within the prescribed ranges may be necessary to achieve symptomatic relief with a minimum of side effects (e.g., drowsiness, dry mouth, nervousness). Medication should be taken for several days/weeks at a time during symptomatic periods. Intermittent single dose usage will not be as effective in controlling symptoms as regular dosing. Use loratadine and cetirizine with caution in patients with hepatic and renal impairment.

NOTE: Some loratadine tablets may contain phenylalanine; use with caution in patients with phenylketonuria.

NON-PHARMACOLOGIC MEASURES

1. Infants and toddlers less than 2 years of age**:** If needed for nasal congestion use saline nose drops; 1 to 2 drops in each nostril, followed by gentle aspiration of nasal secretions with rubber suction bulb or NoseFrida, particularly before feeding. Caution: may aggravate nasal congestion if nasal mucosa is injured (Available products: Ayr Baby Saline; Ayr Saline Drops; NaSal Saline Drops; Simply Saline Baby).

2. Children 2 years and above: If needed for nasal congestion, use saline nose drops; 2 to 6 drops in each nostril every 2 hours. (Available products: Ayr Baby Saline, Ayr Saline, Little Noses, Simply Saline Baby, Ocean for Kids.

3. Children 4 years and above: Consider nasal irrigation as an adjunctive therapy one or two times a day: Isotonic saline or mild hypertonic saline packets mixed with distilled water (no tap water) for positive pressure irrigation. Safe and effective when used and cleaned properly and replaced every few months. (Neil's Sinus Rinse Kit).

PATIENT COUNSELING/EDUCATION

1. Identification and avoidance of the offending antigen.

2. Most antihistamines cause drowsiness. Cetirizine and loratadine are known to be the least sedating. Counsel against driving or other activities that would present a risk if drowsy.

3. Cetirizine may cause photosensitivity reactions. Avoid sun exposure. Wear protective clothing and sunscreen while taking this medication.

4. For nasal corticosteroids, educate on the importance of priming and shaking the containers before administering medication; Optimal technique:
   a. Gently blow nose prior to use,
   b. Direct away from the septum, and
   c. Tilt head slightly forward to prevent swallowing the spray. ("Look toward your toes to spray your nose" and "If you taste it, you waste it.")

5. The patient should be instructed to consult their primary care provider of any recurrent epistaxis, nasal septum discomfort, irritation burning and/or stinging.

6. Females of child-bearing potential should inform clinician if they are or plan to become pregnant or plan to breastfeed.

7. Remind patient to drink a few sips of water or liquid after using nasal spray to help reduce throat irritation.

8. Some loratadine tablets may contain phenylalanine. Use with caution in patients with phenylketonuria (PKU) and patients with renal and hepatic impairment.

9. Take the following measures as appropriate:
   a. Seasonal
      1) Avoid areas with heavy concentration of ragweed, trees or grass during pollinating season. Can check allergy count through Atlanta Allergy & Asthma Pollen Counting Station (website).
      2) Strategize time outdoors: pollen counts can be higher in early morning between 5 am and 10 am and late evening.
      3) Sleep with bedroom windows closed during the appropriate pollinating seasons.
      4) Use an air conditioner with an electrostatic precipitating filter to avoid pollen. Clean filter often.
      5) Change clothes and bathe after long periods outside.
      6) Do not hang clothes or bedding outside.
   b. Perennial
      1) Create a dust-free bedroom. Use a mouth-and-nose mask when cleaning.
      2) Remove everything from the room, including floor coverings, curtains, drapes, and closet contents. Keep door closed always.
      3) Clean the room thoroughly - walls, woodwork, ceiling, floor and closet. Wash the floor.
      4) Cover the mattress, box spring, and pillows with plastic dust-proof covers.
      5) Make sure the room contains a minimum of furniture, washable rugs and curtains. Avoid bed pads, heavy rugs, drapes, upholstered furniture, stuffed toys and knick-knacks. No carpet floors are preferred
      6) Clean the room daily using a vacuum cleaner, damp cloth or damp mop. Do not use a broom or duster.
      7) Keep bedroom windows and doors closed. If hot-air heating is used, cover vents with coarse muslin which is changed frequently.
      8) Change furnace air filter frequently.
      9) Vacuum stuffed furniture and rugs frequently.
      10) Keep pets (dogs and cats) outside, if possible.
      11) Avoid damp and dusty places (e.g., attics, basements, closets, storerooms).
      12) No stuffed toys if patient is dust sensitive.
      13) Use an air conditioner with an electrostatic precipitating filter to avoid dust.
      14) No smoking inside the house, especially in child’s bedroom.

c. Contact clinic if any problems obtaining medications.

FOLLOW-UP

Return visit in one week, and periodically as needed to assess resolution and/or improvement of symptoms.

CONSULTATION/REFERRAL

NOTE**:** Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present (When a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. Failure to respond to treatment, or severe/prolonged periods of symptoms not controlled by the above treatment measures (especially persistent interference with sleep or school performance), consult with physician.

2. Consideration for immunotherapy (desensitization), or other alternate less used therapies. Leukotriene receptor antagonist are now being used with caution.

3. Inability to tolerate antihistamines.

4. Patient requiring almost daily medication for perennial symptoms.

5. Patient requiring more than three orders for nasal corticosteroids per-season.

6. Patients who are pregnant or breastfeeding.

7. Complications:
   a. Otitis media.
   b. Sinusitis.
   c. Nasal or sinus polyps from longstanding perennial allergic rhinitis.
   d. Asthma.
   e. History of anaphylaxis.
   f. Hepatic or renal impairment.

8. Consult registered dietitian nutritionist (RD/RDN) if food allergy related. Children ages 0-5 years of age may be eligible for nutrition assessment, education, and counseling through the WIC Program.

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STANDARD NURSE PROTOCOL FOR IMPACTED CERUMEN/EARWAX

DEFINITION

Ear wax is a protective waxy secretion produced in the ear canal. It is a lubricant that in most cases eliminates naturally. Because it is a hydrophobic agent (repels water) it serves to protect the delicate skin of the ear canal from maceration secondary to over-hydration. Cerumen impaction is an accumulation of cerumen in the ear canal that causes symptoms (e.g., ear pain, tinnitus, fullness in the ear, hearing loss or vertigo) or prevents assessment of the ear, or both. By this definition, cerumen impaction can occur when cerumen in the ear canal prevents needed assessment even if the canal is only partially occluded. When visualization of ear canal anatomy or the tympanic membrane is not essential to good care**,** and the presence of excessive wax is not associated with symptoms, cerumen in the ear canal is NOT considered "impacted". Excessive or impacted cerumen occurs in 1 in 10 children

ETIOLOGY

An excessive production of sebum by the sebaceous glands and apocrine sweat glands may cause occlusion in the external auditory canal. Impaction often occurs after objects are inserted into the ear canal in attempts to clean the ear.

SUBJECTIVE

1. Patient/caregiver may describe:
   a. Observed soft, yellow wax or a drier, black and brown wax on the outer surface of the external auditory canal.
   b. Noticed hearing impairment, ear pain, tinnitus, vertigo, itching, odor or discharge from the ear, or ear fullness.

OBJECTIVE

1. Physical examination may reveal:
   a. Yellow wax or a drier black and brown wax on the outer surface of the ear, or in the auditory canal.
   b. May or may not detect hearing impairment.

ASSESSMENT Excess Cerumen or Impacted Cerumen

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Cerumenolytics are preferred first line over irrigation (less risk of tympanic

membrane perforation.

a. Carbamide peroxide product:
   1) For child 3 to less than 12 years: Tilt head sideways and instill into the affected ear(s) 1 to 5 drops (individualize based on child's size) of carbamide peroxide product, e.g., Debrox or Auro, twice daily for up to 4 days. Allow the drops to remain in the ear for several minutes by keeping the head tilted. Then tilt head in opposite direction to allow fluid to drain from ear**.**
   2) For child 12 years and older: Tilt head sideways and instill 5 to 10 drops of carbamide peroxide product, e.g., Debrox or Auro, into affected ear(s) twice daily for up to 4 days. Allow the drops to remain in the ear for several minutes by keeping the head tilted. Then tilt head in opposite direction to allow fluid to drain from ear.

NOTE: These agents should be avoided if there is a reason to believe that the tympanic membrane is not intact (such as H/O ventilation tube placement, ear perforation or recent ear discharge). Do not use if there is ear pain, irritation, rash in the ear, or any suspicion of ear drum perforation.

NON-PHARMACOLOGIC

1. Home remedy (For children 3 years and older who are cooperative): Can soften the wax using a few drops of, mineral oil, glycerin, docusate sodium (Colace) or diluted hydrogen peroxide. After a day or two of softening, tilt head, straighten ear canal by pulling outer ear up, and using a rubber bulb syringe, can irrigate by squirting warm water into the ear. Tip head to side to let water drain out and gently dry outer ear If symptoms do not improve after one to two trials, return for evaluation.

NOTE: Do Not Perform if there is a presence of ear tube or ear perforation.

PATIENT COUNSELING/EDUCATION

1. Instruct to clean the ears properly, preferably with a washcloth.

2. Instruct not to insert Q-tips or other objects in ears (hair pin, paper clip); explain that this can cause further impaction or injury to the lining of the ear canal or eardrum.

3. Offer reassurance that cerumen production is a normal process.

4. Excessive cerumen production does not equal impaction. If visualization of ear canal anatomy or the tympanic membrane is not essential to good care and is not associated with symptoms, there is no need to be aggressive about cerumen removal.

5. Instruct not to use ear candling because there is no evidence of positive effects

and ear candling may be associated with considerable risks, e.g., burns, occlusion, perforated tympanic membranes.

6. Contact clinic if any problems obtaining medications.

FOLLOW UP

1. As needed.

CONSULTATION/REFERRAL

NOTE**:** Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present (When a patient is REFERRED to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. If ear remains impacted and symptomatic, refer to MD/NP for cerumen removal and further evaluation.

2. If tympanic membrane is not intact, ear tube is in place, ear pain, irritation, rash in the ear, or any suspicion of ear drum perforation.

3. Diabetic or immunocompromised patient.

4. History of injury from syringing.

5. Foreign bodies.

6. History of ear surgery.

7. History of chronic otitis media or other middle ear diseases.

8. Uncooperative patient.

9. Pregnant patient.

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STANDARD NURSE PROTOCOL FOR CONJUNCTIVITIS

DEFINITION

Conjunctivitis is inflammation of the conjunctiva. The conjunctiva are the mucous membranes of the eyelids and the surface of the eye. The conjunctiva is normally transparent but when inflamed it appears pink or red. There are three common types of conjunctivitis: bacterial, viral and allergic. All conjunctivitis is characterized by a red eye, but not all red eyes are conjunctivitis.

1. Bacterial conjunctivitis: Patients with bacterial conjunctivitis typically present with redness and discharge from one eye that can spread to both eyes. The affected eye is often stuck shut in the morning with purulent or mucopurulent discharge. The purulent discharge continues throughout the day. The discharge may be white, yellow or green. The discharge appears at the lid margins and the corner of the eye. Discharge reappears soon after wiping the lids. Bacterial conjunctivitis is very contagious and spread by contact with secretions. Bacterial conjunctivitis is commonly caused by:
   a. *Streptocococcus pneumonia*
   b. *Hemophilus influenza*
   c. *Staphylococcus aureus*
   d. *Moraxella catarrhalis*

The following agents are of concern during the newborn period and require immediate referral:

a. *Neisseria gonorrhea*
b. *Chlamydia trachomatis*

NOTE: If purulent discharge started between 2 and 5 days of age, emergent referral is necessary. This could represent gonorrhea and may require systemic antibiotics without delay.

If the discharge started in the first 24 hours and clears within 48 hours, this is typical of chemical conjunctivitis secondary to the instillation of drops at birth to prevent gonorrhea infection and does not require referral of treatment.

2. Viral conjunctivitis is often accompanied by symptoms of an upper respiratory infection. Patients with viral conjunctivitis present with red eyes and watery or mucoserous discharge. They can describe a burning, sandy or gritty feeling in one or both eyes. They may report waking with crusty eyes from the dried discharge and then watery eyes throughout the day. It is very contagious and spreads by contact with secretions. Viral conjunctivitis has a self-limiting course much like the common cold. It can last from a few days to several weeks.

3. Allergic conjunctivitis is caused by airborne allergens that cause an inflammatory reaction in both eyes. It presents with bilateral redness, watery discharge and itching. Itching is the primary complaint. Patients with allergic conjunctivitis often

have history of atopic dermatitis, seasonal allergies or other allergies. This form of conjunctivitis is NOT contagious.

ETIOLOGY

1. Bacterial infection:
   a. Streptococcus pneumonia
   b. Hemophilus influenza
   c. Staphylococcus aureus
   d. Moraxella catarrhalis
   e. Neisseria gonorrhoeae (of particular concern during the newborn period)
   f. Chlamydia trachomatis

2. Viral infection:
   a. Adenovirus

3. Allergic reaction:
   a. Usually associated with such allergens as pollen, molds, animal dander and dust.
   b. Other irritants include smoke, ingredients in cosmetics, chlorine in swimming pools and contact lenses.
   c. Foreign body or trauma.

SUBJECTIVE

1. Patient may report:
   a. Eye irritation; sandy or gritty feeling in eyes
   b. Eye discharge
      1) Watery: suggestive of viral or allergic.
      2) Purulent (yellow, white, or green): suggestive of bacterial
   c. Itching of eyes (more suggestive of allergic conjunctivitis)
   d. Mild photophobia.
   e. Eyelid(s) stuck shut in the morning.
   f. No complaints of decreased vision.
   g. May have history of contact lens use (caution: high risk).
   h. History of seasonal allergies.
   i. Concurrent upper respiratory infection.

OBJECTIVE

1. Physical examination may reveal:
   a. Redness of one or both eyes
   b. Discharge:
      1) Bacterial: Purulent discharge from one or both eyes that continues throughout the day. Discharge will return within minutes of wiping away.
      2) Viral: Mucoid or watery discharge from one or both eyes
      3) Allergic: Stringy or watery discharge

c. Chemosis (edema of the bulbar conjunctiva that can, at times, be marked when allergy is the cause).

ASSESSMENT Conjunctivitis: Bacterial, viral, or allergic.

NOTE: The diagnosis of conjunctivitis is made in a patient with a redeye and discharge ONLY if vision is normal AND there is no evidence of keratitis, iritis, or angleclosure glaucoma.

PLAN

THERAPEUTIC

PHARMACOLOGIC

Bacterial Conjunctivitis Treatment Options [4]	
Erythromycin 5mg/gram ophthalmic ointment (Ilotycin)	Infants (birth to 12 months) and older: ½ inch (1.25 cm) 4 times daily for 5 to 7 days
OR	
Trimethoprim-polymyxin B 0.1% - 10,000 units/mL ophthalmic drops (Polytrim)	Pregnancy Risk Factor C 2 months of age and older: 1 to 2 drops 4 times daily for 5 to 7 days
OR	
Bacitracin-polymyxin B 500 units-10,000 units/gram ophthalmic ointment (Polytracin,Polysporin,Polycin B,AK-Poly Bac)	Pregnancy Risk Factor C Infants (birth to 12 months) and older: ½ inch (1.25 cm) 4 times daily, for 5 to 7 days
OR	
Bacitracin 500 units/gram ophthalmic ointment	½ inch (1.25 cm) 4 to 6 times daily, for 5 to 7 days
OR	
Ofloxacin 0.3% (preferred agent in contact lens wearers, but contact lenses should not be worn during treatment of infection	Pregnancy Risk Factor C 1 year of age and older: Instill 1 to 2 drops in affected eye(s) every 2 to 4 hours while awake for the first 2 days; then, instill 1 to 2 drops every 6 hours while awake for the next 5 days.
OR	
Ciprofloxacin 0.3% ophthalmic drops (preferred agent in contact lens wearer) Ciprofloxacin 0.3% ophthalmic ointment	Pregnancy Risk Factor C 1 year of age and older: (Solution) Instill 1 to 2 drops into the affected eye(s) every 2 hours while awake for 2 days; then, 1 to 2 drops every 4 hours while awake for 5 days.

	2 years of age and older:(Ointment) Apply $^1/_2$-inch ribbon into the affected eye(s) 3 times per day for the first 2 days, followed by $^1/_2$-inch ribbon into affected eye(s) twice daily for 5 days.
OR	
Azithromycin 1% ophthalmic drops	1 year of age and older: 1 drop in affected eye(s) twice a day (8 to 12 hours apart) for 2 days; then 1 drop in affected eye(s) daily for 5 days.
OR	
Moxifloxacin Hydrochloride	Pregnancy Risk Factor C 4 months of age and older: (Moxeza®) Instill 1 drop into affected eye(s) 2 times daily for 7 days. Birth to adult: Vigamox® Instill 1 drop into affected eye(s) 3 times daily for 7 days.
Viral Conjunctivitis Treatment Options Warm or cool compresses may provide some relief. Patients must be told that the eye irritation and discharge may get worse for three to five days before getting better, that symptoms can persist for two to three weeks, and that use of topical agents (antihistamine/decongestant combs) for that duration might result in irritation and toxicity, which can itself cause redness and discharge.	
Lubricating drops/ointment OTC Advanced Eye Relief™, HypoTears; LiquiTears, Murine Tears®, Natures Tears; OTCTears Again®; Tears Naturale® Free; other generics	Drops: 1 to 2 drops every 1 to 6 hours as needed Ointment: ½ inch (1.25 cm) at bedtime or four times daily as needed
Naphazolin-pheniramine (decongestant/antihistamine) Opcon-A®, Naphcon-A®, Visine®	6 years and older: 1 to 2 drops 4 times daily as needed for no more than 3 weeks
Allergic Conjunctivitis Treatment Options	
For short-term treatment: Antihistamine/vasoconstrictor ophthalmic preparations can cause temporary increased redness once medication is discontinued.	
Lubricating drops/ointment OTC Advanced Eye Relief™, HypoTears; LiquiTears, Murine Tears®, Natures Tears [OTCTears Again®; Tears Naturale® Free; other generics	Drops: 1 to 2 drops every 1 to 6 hours as needed. Ointment: ½ inch (1.25 cm) at bedtime or four times daily as needed.
For frequent episodes (occurring more than 2 days per month): Mast cell stabilizer/antihistamine ophthalmic Solutions. Itching should decrease within 24- 72 hours; may cause dry eye sensation or burning. It may take up to 2 weeks to see full efficacy of these agents. CHOOSE ONE FROM BELOW:	

Olopatadine 0.1% (Patanol), 0.2% (Pataday), 0.7% (Pazeo)	Pregnancy Risk Factor C 2 years and older: 1 drop per affected eye(s) twice daily allowing 6 to 8 hours between doses (Patanol). OR 1 drop per affected eye(s) once daily (Pataday and Pazeo)
OR	
Alcaftadine 0.25% (Lastacaft) May require Prior approval for Medicaid	2 years and older: 1 drop per affected eye(s) once daily
OR	
Bepotastine 1.5% (Bepreve)	Pregnancy Risk Factor C 2 years and older: 1 drop per affected eye(s) twice daily
OR	
Epinastine 0.05% (Elestat) May require Prior approval for Medicaid	Pregnancy Risk Factor C 2 years and older: 1 drop per affected eye(s) twice daily
OR	
OTC Ophthalmic Products: Ketotifen 0.025% (Zaditor, TheraTears, Alaway Children's Allergy, Claritin)	Pregnancy Risk Factor C 3 years and older: 1 drop per affected eye(s) every 8 to 12 hours
OR	
Emedastine 0.05% (Emadine) May require Prior approval for Medicaid	3 years and older: One drop per affected eye(s) up to four times daily
Cromolyn Sodium Ophthalmic Solution 4%	Pregnancy Risk Factor Category B 4 years and older: 1-2 drops in each eye 4 to 6 times daily at regular intervals

NOTE: Ointments are preferred to liquid drops in children, those with poor compliance, and for those with difficulty administering eye medications.

NON-PHARMACOLOGIC MEASURES

1. Warm or cool compresses may provide additional symptomatic relief of discomfort, if mild non-purulent conjunctivitis associated with an upper respiratory infection, allergic or viral conjunctivitis is present.

PATIENT EDUCATION/COUNSELING

1. Contact lenses should not be worn during times of infection of the eye or during treatment of infections of the eye. Lens wear can resume when the eye is white, and no discharge has been present for 24 hours after completion of antibiotic therapy (if bacterial) or no discharge present (if viral). The lens case previously used should be discarded as well as the lenses replaced if they are disposable.

2. Viral conjunctivitis may last up to 12-14 days. Irritation and discharge.

3. May initially get worse for 3-5 days before improving**.**

4. Bacterial conjunctivitis should respond to treatment within 2-3 days. Refer to primary care provider if no improvement or worsening of symptoms.

5. Hands must be washed before and after application of ophthalmic ointment or solution. Instruct in hand washing technique and disposal of contaminated tissues.

6. Avoid contact of medication tube or bottle tip with skin or eye.

7. Do not share medication.

8. Dispose of medication when treatment is completed.

9. Do not share bath cloths/towels/ cosmetics/ linens/ eating utensils/ sports equipment.

10. School or daycare attendance: Check with school. Most require 24 hours of topical therapy before returning to school or daycare, and, in good judgment, resolution of eye drainage.

NOTE: American Academy of Pediatrics' position is that children with infectious conjunctivitis under treatment may attend school provided reasonable precautions are taken to avoid close physical contact. Children with allergic conjunctivitis are not infectious and may attend school.

11. May use cold, wet compresses. To clean eyes, use clean towel moistened with water. Use a fresh side of the towel with each wipe. Also, always wipe eye from inner canthus toward outer canthus**.**

12. Contact clinic if any problems obtaining medications.

FOLLOW-UP:

1. Follow-up in 2-3 days if no symptom improvement.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present. (After a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. Infants less than three months of age (see paragraph in Definition section regarding possible infectious agents of concern during newborn period requiring immediate referral).

2. No improvement in 2 to 3 days after initiation of treatment, or if symptoms worsen.
3. Foreign body, trauma or chemical injury.
4. Severe eye pain.
5. Vision changes (double vision, blurry vision).
6. Severe sensitivity/reaction to light.
7. Any irregularities of pupil size or reaction to light.
8. All contact lens wearers (possible infected corneal abrasion).
9. Any redness of eyelids.
10. Ill appearing, other body systems symptomatic
11. Pregnant or breastfeeding patient.

REFER IMMEDIATELY patients with complaints of:

1. Severe foreign body sensation or severe eye pain.
2. Ciliary flush (Keratitis, iritis, glaucoma): Severe injection [redness] in the transition zone between cornea and sclera.
3. Corneal Opacity (Keratitis): Whitish, cloudy film over the cornea.
4. Reduction in visual acuity (Keratitis, Iritis, Glaucoma) or vision changes (photophobia, fixed pupil).
5. Foreign body, trauma or chemical injury.
6. Severe headache with nausea and with eye complaints.

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STANDARD NURSE PROTOCOL FOR CONSTIPATION

DEFINITION

Bowel movements which are associated with the passage of hard, dry, often painful, stools. Stool frequency is not a primary consideration when diagnosing constipation. Infrequent passage of stools that are soft and easily passed does not constitute constipation. In fact, in exclusively breastfed infants after the first month of life, this is common and not a concern. Constipation affects up to 30% of children. Acute constipation is defined by presence of symptoms eight weeks or less. Chronic constipation is defined by presence of symptoms over 3 months.

ETIOLOGY

1. Acute Constipation may be caused by:
   a. Insufficient amount of fiber and/or fluid in the diet
   b. Decreased physical activity
   c. Early introduction of solid foods in infants less than 4 months
   d. Emotional upset
   e. Uncomfortable circumstances for defecating
   f. Disruption of usual daily routine
   g. Aggressive toilet training techniques

2. Chronic Constipation may be caused by:
   a. Psychogenic stool-holding
   b. Chronic neuromuscular disorders
   c. Hirschsprung's disease
   d. Hypothyroidism.
   e. Acute constipation that has not been adequately treated, resulting in an enlarged colon with decreased contractile strength (known as the 'vicious cycle' of constipation).
   f. GI disorders (celiac disease, cow's milk intolerance or sensitivity)
   g. Bowel bladder dysfunction
   h. Lead exposure and elevation

SUBJECTIVE

1. Acute Constipation:
   a. Pain on defecation.
   b. Stools are hard, dry, and large caliber when passed.
   c. Straining on defecation.
   d. History of blood-tinged stools.
   e. Mild abdominal pain.
   f. Decrease in frequency (two or fewer per week) of defecation from usual pattern may be taken as a sign of constipation if it is associated with other symptoms such as hard, dry stools.

2. Psychogenic stool-holding:
   a. Onset in late infancy or early childhood.
   b. Large bowel movements at long intervals.
   c. Fecal incontinence (encopresis).
   d. Behavior problems.

3. Chronic neuromuscular disease:
   a. Other developmental problems.
   b. Mild abdominal pain.

4. Hirschsprung's disease:
   a. Soiling and retentive behavior – rare.
   b. May present at any age but most become apparent at birth or in early infancy.
   c. Anorexia and bilious vomiting and abdominal distension in early infancy.
   d. Failure to pass meconium first stool after 48 hours of life
   e. Family History

5. Hypothyroidism:
   a. Poor feeding.
   b. Vomiting.

6. GI disorders:
   a. Celiac disease
   b. Milk Protein allergy/cow's milk protein intolerance

7. Bowel/bladder Dysfunction:
   a. Managed through treating the bladder dysfunction

OBJECTIVE

1. Acute Constipation
   a. Physical exam may be normal. Inspect for anorectal anomaly
   b. Anal fissure or perianal abscess.
   c. Mild abdominal distention with a palpable, firm stool apparent on abdominal and rectal exam.

2. Chronic Constipation
   a. Physical exam may be normal. Inspect for anorectal anomaly.
   b. Abdominal distention with a palpable firm stool apparent on abdominal and rectal examination. With Hirshprung's disease there will be no stool in the rectum on rectal examination. The obstruction is above the rectum. Abdominal distension is present and anal sphincter may be tight resulting in squirt sign on completion of rectal exam.
   c. Muscle weakness, sluggish reflexes (hypothyroidism), may have dimple on lower back.

ASSESSMENT

1. Constipation (Acute or Chronic)
   a. In most cases, physical exam will be within normal limits**.** Inspect for anorectal anomaly.
   b. May present with an intestinal obstruction, but this is rare (usually associated with abdominal pain and vomiting).

PLAN

1. Obtain stool diary of 5 to 7-day history of symptom, diet, stool frequency, appearance, and pain.
2. Assess for lead risk exposure and review lead screen results for 12 month and 24-month well check if available.
3. Hemoccult when considering milk protein allergy.

THERAPEUTIC

PHARMACOLOGIC

For patient with acute constipation (with symptoms such as pain, irritability, malaise):

1. Stimulation of stool passage
   a. Infants and children, 1 month to 2 years: Glycerin Suppository (not the liquid suppository): ½ to 1 infant suppository once per day until stool appears up to a maximum of 3 days.

   b. Children 2 through 5 years: 1 pediatric suppository (Fleet Pedialax or Colace Infant/Children) once per day until stool appears up to a maximum of 3 days

   OR

   c. Liquid glycerin suppositories e.g., Fleet Baby Lax: 2mL to 5 mL of rectal solution once per day until stool appears up to a maximum of 3 days.

   d. Children 6 years or older: 1 adult suppository (Fleet Glycerin, Colace Adult/Children,)

   OR

   e. 5mL-15 mL rectal solution as enema (Fleet Liquid Glycerin Suppositories) once per day until stool appears up to a maximum of 3 days.

2. For use after initial relief from above. A brief course of Polyethylene Glycol 3350 Powder**,** Sorbitol 70% solution or Docusate sodium (as below) may be helpful to restore regularity. Should not use for more than 5-7 days.

   a. Polyethylene Glycol 3350 Powder (MiraLax, GlycoLax) must be mixed in water or another non-carbonated beverage.
      1) Children younger than 18 months: ½ tsp-1tsp daily mixed in 2 to 8 (60 to 240mL); 18 months-3 years: 2-3 tsp once daily mixed in 4 to 8 ounces (120 to 240mL); older than 3 years: 2-4 tsp once daily mixed in 8 oz (240mL); Greater than 3 years: 17 grams powder (1 heaping tbsp per day mixed in 8

oz water or another non-carbonated beverage)

b. Sorbitol 70% Solution:
   1) Children 1-11 years: Oral: 1 mL/kg once or twice daily with max of 30 mL
   2) Children 12 years of age and older: Oral: 15-30 mL once or twice daily (60 ml max)

OR

c. Docusate sodium- 5 mg/kg/day.
   1) Infants and children 5mg/kg/day.in one to 4 divided doses

OR

d. 6 months to 2 years: 12.5mg three times daily
   1) 2 years to 11 years: 50 to 150mg/day in single or divided doses
   2) Greater than 12 years of age: 50 to 360 mg/day in single or divided doses.

NOTE: This softens and prevents excessive drying of the stool. It is effective unless there is voluntary stool retention. Effect should be apparent 1-3 days after the first dose.

NON-PHARMACOLOGIC MEASURES

1. Encourage increased water intake for children older than 1 year of age.

2. For infants less than 4 months, can give 1 ounce a day of juice for every month of life up to about 4 months (a 3-month-old baby would get 3 ounces).

   For infants greater than 4 months, offer 100% juice containing sorbitol such as prune, pear, plum and/or apple juices. Due to a heavy concentration of sugar, add 1-2 oz. of water with 1-2 oz. of juice (apple, prune, plum, pear) per day until stool has softened. Do not exceed 4 total ounces of juice per day. Discontinue offering juice once constipation resolves.

   Sorbitol containing juices (apple, prune, pear) may be offered at full strength to children greater than 1 year of age. Do not give more than 4-6 ounces of 100 % fruit juice per day to children between 1 and 6 years of age. Children 7 years and older may drink up to two 4 oz. servings per day.

3. If anal fissure, suggest warm Sitz baths, gentle cleansing, petroleum jelly to anus.

4. Increase the amount of fruits, vegetables and other high fiber foods such as, whole grains (age 6 months and above).

5. Recommend giving normal volume of milk for age**:**
   a. Formula fed: 2 months (21-32oz.), 4 months (26-32oz), 6 months and older whenever he/she displays signs of hunger (usually 5-6 times in 24 hours).
   b. Breastfed infants: feed ad lib as infant displays signs/symptoms of hunger. May have need to nurse more frequently during growth spurts.
   c. In children > 1 year of age: limit milk intake to no more than 16-24 oz. daily.

This includes cow's milk and plant-based alternatives.

PATIENT EDUCATION/COUNSELING

1. Infants (Infants and toddlers up to age 2):
   a. Explain the need for adequate fluid intake.
      1) Provide breastmilk and/or formula ad lib as the infant displays signs/symptoms of hunger. Infants less than 6 months should be able to receive adequate fluids through breast milk and/or formula alone. Infants less than 6 months should not be offered plain water without consulting their primary care provider.
      2) For infants, greater than 6 months and who are eating solid foods, plain fluoridated water may be given as recommended by a doctor.
   b. Counsel on overall quality of diet and dietary needs appropriate for the age of the infant:
      1) If breastfeeding, continue to breastfeed
      2) If feeding formula, ensure proper mixing/concentration and that 24-hour intake is appropriate for age (On average, infants take in approximately 2.5 ounces of formula for every pound of body weight):
         a) Formula fed 2 months (21-32oz.),
         b) 4 months (26-32oz),
         c) 6 months and older whenever he/she displays signs of hunger (usually 5-6 times in 24 hours).
      3) Encourage fruit juices with sorbitol such as prune, pear**,** plum and some apple juices. See Non-Pharmacologic Measures section, #2, for appropriate amounts for age & recommended limits and educate that routinely giving an infant (less than 1 year old) juice outside of the treatment of constipation is not recommended**.**
      4) Discontinue solids if introduced too early, prior to 4 months of age.
   c. For infants, greater than 4 months who are tolerating complementary foods, puree fresh fruits and vegetables to make homemade baby foods that are high in fiber. Commercially jarred baby foods have little to no fiber.
   d. Increased fiber intake without adequate fluids will only worsen constipation.
   e. DO NOT use laxatives such as Castoria or Fleet Phosphate enemas; do not use mineral oil for infants (risk of aspiration pneumonia).
   f. Honey or homegrown herbal teas should not be served to an infant less than 1 year of age since it may contain botulism spores that may cause infantile botulism.
   g. Controlled trials with infant formula have not shown a relationship between iron in the formula and constipation.
   h. Explain the vicious cycle:
      1) Constipation enlarges the colon and an enlarged colon is weaker, leading to more constipation.
      2) If the cycle of constipation is not interrupted, the result can be debilitating for a child and their family.

2. Children (greater than 2 years of age):

a. Offer water during meals and snack times and provide additional water during physical activity.
b. Offer apple or prune juice (limit to 4-6 oz./day).
c. Limit milk intake to no more than 16-24 oz per day.
d. Increase intake of whole grains/cereals, dried beans, fresh/dried fruits and vegetables, nuts/seeds (if age appropriate):
    1) Add high fiber foods gradually.
    2) Encourage a wide variety of foods.
    3) Consume fruits and vegetables with peel or skin whenever possible.
    4) AAP recommends daily fiber intake that equals age of patient + 10 grams.
e. Increase and encourage regular physical activity when appropriate.
f. Continuous treatment and follow up may be required for several weeks. Acute constipation can evolve into a major problem if not treated properly. (Explain 'vicious cycle' as described above for infants.)
g. Contact clinic if any problems obtaining medications.
h. Toilet training age: Counsel that a relaxed approach to toilet training includes providing foot support for sitting on toilet (For comfort and to relax the pelvic floor and reduce anal pressure which helps to expel stool).

FOLLOW UP

1. In 2 to 3 days if no improvement.

2. Seek prompt medical attention if symptoms worsen.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present (When a patient is referred to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. If no improvement in 2-3 days.
2. Pain or other symptoms, if secondary to constipation, should be entirely relieved with the passage of stool. If this is not the case, then the cause of the child's symptoms may not be constipation and prompt diagnosis is required. Acute constipation with symptoms should be referred to MD/APRN promptly (same day) if there is not relief of symptoms with the acute therapy described above or if symptoms worsen.
3. Chronic constipation (greater than 3 months) with additional signs and symptoms.
4. Signs of emotional/family issues.
5. Infants with any of the following: recurrent constipation, history of first bowel movement after 48 hours of age, any systemic signs such as vomiting or failure to gain weight**,** abdominal distension.
6. Exclusively breastfed infants who exhibit signs of chronic constipation.
7. Substantial rectal bleeding such as blood throughout the stool or blood clots equivalent to one teaspoon or more of blood.

8. Pregnant or breastfeeding.
9. Neonates.
10. Consult a Registered Dietitian Nutritionist if in depth dietary guidance is needed, or if there is low access to the recommended fiber rich foods. Children aged 0-5 years of age may be eligible for vouchers for fresh fruits/vegetables, beans, and whole grain foods, and nutrition education and counseling through the WIC Program.

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STANDARD NURSE PROTOCOL FOR CRADLE CAP

DEFINITION

A form of seborrheic dermatitis that most babies show at some time during infancy from 3 weeks to 12 months. It is a result of excessive discharge from the sebaceous glands, but the cause is not understood. The lesions are usually multiple, discrete, circumscribed oval or nummular patches covered with fine, yellowish, slightly oily scales on an erythematous base found on the scalp.

ETIOLOGY

The actual cause is unknown. The fungus, Malassezia Furfur, has been implicated as a causative agent.

SUBJECTIVE

1. As described by the parent/caregiver:
   a. Rash on scalp.
   b. Dry, scaly flakes that do not resolve with normal shampooing of the head.

OBJECTIVE

1. Physical examination may reveal:
   a. Dry, scaly, sometimes greasy flakes on the scalp.
   b. Running the finger firmly across the scalp surface will loosen the flakes.
   c. Thick, yellowish, crusted lesions on the scalp, with scaling.
   d. Papules or fissuring behind the ears and on the face.
   e. Examine other body areas, seborrheic dermatitis can be focal or spread. Other common sites include forehead, eyebrows, nasolabial folds, neck, axillae, and diaper area.
   f. Mild to moderate underlying inflammation**.**

ASSESSMENT Cradle Cap

PLAN

THERAPEUTIC

NON-PHARMACOLOGIC MEASURES

1. Initial treatment should include applying emollient to loosen scales (white petrolatum, vegetable oil, olive oil, jojoba oil, mineral oil, baby oil) to the scalp (overnight if necessary), followed by removal of scales with a soft brush (e.g., a soft bristle hairbrush or soft unused toothbrush).

2. Frequent shampooing with a mild, nonmedicated shampoo followed by removing of

scales with a soft brush (soft toothbrush) or fine-toothed comb is another conservative measure.

PHARMACOLOGIC MEASURES

1. First Preference: If inflamed, low potency topical corticosteroid (Hydrocortisone 1%) applied once daily for 1 week

OR

2. If the use of topical corticosteroids is a concern or lesions are diffuse, topical antifungal (e.g., Ketoconazole 2% cream or shampoo) applied twice per week for 2 weeks.

NOTE: In clinical practice, brief use without adverse effects.

PATIENT EDUCATION/COUNSELING

1. Review instructions for management.
2. Teach parents that gentle scrubbing over the fontanels is safe.
3. Teach parent to continue treatment for several days after condition clears.

FOLLOW-UP

1. In 1 to 2 weeks if no improvement.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present (After a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. If no improvement after 10 to 14 days of proper management.

2. If presence of secondary infection as evidenced by weeping, fissuring or maceration of the skin.

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STANDARD NURSE PROTOCOL FOR ATOPIC DERMATITIS (ECZEMA)

DEFINITION

A chronic inflammatory disorder of the skin manifested by some or all of the following: pruritic, erythematous, papular, vesicular, weeping lesions with scaling or crusting. It tends to occur in patients with an inherited allergic predisposition.

ETIOLOGY

In part, atopic dermatitis is an atopic allergic response. The exact etiology is unknown. It is probably the most common problem in pediatric dermatology. It is not present at birth and usually does not occur before the age of three months. The onset of Atopic Dermatitis usually occurs between 3 and 6 months of age, with 60% of patients developing symptoms within the first year of life, and 85% to 90% having developed symptoms before the age of 5 years. Dry skin resulting in a 'pruritus-scratching-inflammation-more pruritus' cycle clearly plays a role in the etiology of atopic dermatitis. Evidence suggests that food allergy is a very uncommon cause of atopic dermatitis. Manifestations are usually secondary to pruritus and scratching of the sensitive skin.

The following may initiate and aggravate the itching and inflammation:

1. Dry skin/cold weather
2. Perspiration/hot humid weather
3. Irritating clothing (wool, silk)
4. Certain soaps, detergents, or cosmetics
5. Respiratory infections
6. Frequent bathing

SUBJECTIVE

1. Patient/caregiver may complain of:
   a. Pruritus, rash, dry skin.
   b. Often, family history of allergic diseases (asthma, allergic rhinitis, urticaria) or atopic dermatitis.
   c. Onset after two months of age.
   d. History of asthma or allergic rhinitis (about 50% of cases).
   e. Rapid alternation between quiescent periods and exacerbations.
   f. Assess for severity of seven symptoms (itch, sleep disturbance, dryness, flaking, weeping or oozing, bleeding and cracking).

OBJECTIVE

1. Infancy (0–24 months)
   a. Rough, erythematous, papular and occasionally vesicular or scaling eruption, which frequently progresses to weeping and crusting.
   b. Location: commonly on cheeks, scalp, post-auricular area, neck, and extensor

surface of forearms, and legs; occasionally trunk and diaper area.
c. Frequent rubbing of involved areas by infant.

2. Childhood
   a. Less weeping and crusting, drier, papular, scaling eruption with hyperpigmentation.
   b. Intensely pruritic and excoriated lesions with lichenification due to scratching.
   c. Location: Commonly on flexor surfaces of wrist and neck and on antecubital and popliteal areas.

3. Adolescence and Adulthood
   a. Dry, thickening skin, with accentuation of normal lines and folds; often hyperpigmentation.
   b. Location: commonly on flexor areas of extremities, eyelids, back of neck and dorsum of hands and feet.

ASSESSMENT

1. Atopic Dermatitis (eczema)

2. Consider for differential diagnosis:
   a. Seborrheic dermatitis (sometimes impossible to differentiate in infancy).
   b. Fungal infections of the skin.
   c. Contact dermatitis (e.g., poison ivy).
   d. Irritant dermatitis (e.g., diaper dermatitis).
   e. Xerotic dermatitis (dry skin).
   f. Rare systemic diseases of infancy associated with atopic dermatitis-type rash.
   g. Scabies.
   h. Psoriasis

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Mild to Moderate Atopic Dermatitis: Mainstay of Therapy consists of topically applied corticosteroids and emollients.
   a. Apply a low-potency steroid sparingly.
   b. Do not use on the face, underarms, or groin areas.
   c. Use the smallest amount for the shortest period of time to avoid Hypothalamic-pituitary-adrenal (HPA) axis suppression.
   d. Therapy should be discontinued when control is achieved.
   e. Base dosage on disease severity and patient response.

      1) Hydrocortisone butyrate 0.1% (Locoid Lipocream, Locoid Lotion)
         a) 3 months or older: Apply a thin film to affected area twice daily, if no

improvement within 2 weeks, reassess. The patient should be counseled to contact the clinic for a referral so that treatment can be adjusted or prolonged. Do not use on the face, underarms, or groin areas.

2) Hydrocortisone cream or ointment
   a) Infants: 0.5%-1% hydrocortisone cream or ointment, twice daily, preferably after bath (cream during hot humid weather, otherwise ointment is best during the drier seasons of late fall and winter).
   b) Children 1 year of age and older: 1%-2.5% hydrocortisone cream or ointment twice to three times daily, preferably after bath (cream during hot humid weather, otherwise ointment is best).

NOTE: Apply until controlled. If treatment is required for more than 2-4 weeks for improvement of symptoms, the patient should be counseled to contact the clinic for a referral so that treatment can be adjusted or prolonged.

OR

3) Alclometasone dipropionate 1 year of age and older:
   a) Apply a thin film of alclometasone cream or ointment to the affected skin areas two or three times daily; massage gently until the medication disappears.
   b) Do not use for longer than 3 weeks.
   c) If treatment is required for more than 2-3 weeks for improvement of symptoms, the patient should be counseled to contact the clinic for a referral so that treatment can be adjusted or prolonged.
   d) Do not use on the face, underarms, or groin areas.

OR

4) Fluocinolone acetonide 0.01% ointment or cream 3 months and older:
   a) Apply to the affected skin areas two or three times daily
   b) massage gently until the medication disappears
   c) Do not use for longer than 3 weeks
   d) If treatment is required for more than 2-3 weeks for improvement of symptoms, the patient should be counseled to contact the clinic for a referral so that treatment can be adjusted or prolonged.
   e) Do not use on the face, underarms, or groin areas.

OR

5) Triamcinolone (Triderm, Kenalog, Oralene,and generics) Cream 0.025% or 0.1% Cream and Ointment Children:
   a) If no improvement of symptoms, the patient should be counseled to contact the clinic for a referral so that treatment can be adjusted or prolonged.
   b) Do not use on the face, underarms, or groin areas.

2. To help control pruritus use an over-the-counter antihistamine such as diphenhydramine (e.g., Benadryl) orally. The non-sedating antihistamines (e.g., Claritin, Zyrtec, or Allegra) appear to have only a very modest influence on atopic dermatitis symptoms.
   a. Diphenhydramine hydrochloride elixir
      1) Children 2 through 5 years of age:

a) Diphenhydramine hydrochloride elixir 12.5 mg/5 mL.
b) May give 6.25 mg every 4 to 6 hours
c) Do not exceed 37.5 mg/day.

2) Children 6 through 11 years of age:
   a) Diphenhydramine hydrochloride elixir 12.5 mg/5 mL.
   b) May give 12.5 to 25 mg every 4 to 6 hours
   c) Do not exceed 150 mg/day.
3) Adults and children 12 years of age and older
   a) Diphenhydramine hydrochloride 25-50 mg orally 3 or 4 times a day
   b) Do not exceed 300 mg/day

NOTE: Dosing should be based on severity of symptoms. Do not use topical diphenhydramine. Contact delegating physician before administering diphenhydramine to a child under 2 years of age.

OR

b. Hydroxyzine (Atarax or Vistaril) 10mg/5ml or 10 or 25 mg tablet. NOTE: Contraindicated in prolonged QT interval.
   1) Children 1 year to less than 6 years:
      a) 2 mg/kg/day divided every 6 to 8 hours.
      b) Maximum single dose 12.5 mg.
      c) Can be started and given once daily at bedtime or twice daily in the morning and at night.
   2) Children 6 years to 12 years:
      a) 2 mg/kg/day divided every 6 to 8 hours.
      b) Maximum single dose: 25 mg.
      c) Can be started and given as once daily (at bedtime) or twice daily in the morning and at night.
   3) Children 12 years and older and weight > 40 kg:
      a) 25 to 50 mg once daily at bedtime or twice daily.

NON-PHARMACOLOGIC MEASURES

1. Dietary restrictions in atopic dermatitis are controversial for infants. If food allergy is a concern in infants, patient should be referred to their primary care provider for dietary guidance.

2. Bathe using mild non-perfumed soap (Dove or Cetaphil) with 1/2 to 1 capful of bath oil (Alpha-Keri or Aquaphor) added to water. Apply moisturizer to wet skin after bath. Apply additional moisturizer (see guidance in topical care below) three times or more daily. Avoid excessive bathing.

PATIENT EDUCATION/COUNSELING

1. Avoid factors that initiate pruritus and irritate skin. Key is the reduction or elimination of factors that promote dryness or increased scratching in order to prevent a severe rash. This includes:

a. An environment that is slightly cool and well-humidified is best.
b. Spend time indoors in warm weather. Humidify home in winter if heating system dries air.
c. Use warm water for brief baths or showers; hot water causes itching.
d. Use soft cotton clothing and bedding. Avoid wool, starched or rough clothing.
e. Keep fingernails short.
f. Recognize that emotional stress can worsen but not cause the disease.
g. Use liquid detergent when washing clothes plus a second rinse cycle.

2. Instructions for topical care of atopic dermatitis:
   a. Wet the skin for 5-20 minutes twice a day.
   b. Avoid excessive exposure to soap. Use a mild soap (e.g., Dove or Cetaphil) for cleaning dirty areas.
   c. Pat dry and quickly apply the steroid preparation to the wet skin. Apply the steroid only on the areas of dermatitis.
   d. Apply lubricant (Eucerin Cream, Cetaphil Cream, Aquaphor Ointment, Vaseline Intensive Care Ointment) while the skin is still wet, twice a day.
   e. Use cream and ointment lubricants to all areas prone to dermatitis, even those not currently inflamed. Avoid lotions (vs. creams and ointments) because their low oil content renders them poor moisturizers.
   f. The lubricant may be applied over the steroid if the steroid is a cream.
   g. Reapply the lubricant throughout the day frequently.
   h. As the skin improves, continue the lubricant twice a day, or more frequently.
   i. Decrease the topical steroid to once a day, or less frequently, as needed. It may also be possible to decrease the potency of the topical steroid, if a medium or high-potency steroid has been prescribed.
   j. Wash hands after applying steroid and lubricant.

3. Emphasize to child and family that this is a chronic condition and exacerbating factors must be controlled for successful management. Emphasize that good skin care, which includes very frequent moisturization, will decrease flare-ups and the need for topical steroids.

FOLLOW-UP

1. Return in one week, or periodically as needed.

CONSULTATION/REFERRAL

NOTE**:** Refer patient to a primary care provider OR consult with the delegating physician for care management if the following conditions are present (When a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. Children and adolescents with moderate to severe eczema. (A prescription for a medium or high-potency steroid may be necessary.)
2. Patient with dermatitis with crusting or weeping lesions. Oral and topical antibiotics

may be necessary to treat secondary infection.

3. Ocular complications.
4. Patient with mild dermatitis that worsens or does not improve after two weeks of treatment.
5. Patient with suspected bacterial or viral infection should be referred immediately to MD.
6. Patient with suspected underlying condition.
7. Pregnant or breastfeeding patient.
8. Consult registered dietitian nutritionist for food allergy related education and counseling. Children 0-5 may be eligible to nutrition education and counseling through the WIC program.

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STANDARD NURSE PROTOCOL FOR MILD CONTACT DERMATITIS

DEFINITION

Acute or chronic inflammatory reaction to substances that come in contact with the skin.

ETIOLOGY

1. Irritant contact dermatitis is caused by local absorption of an irritant through a break in the skin. The inflammatory response may result from a single exposure to a caustic agent or repeated minor damage to the skin, such as frequent handwashing. Primary irritant dermatitis usually develops within a few hours, reaches peak severity at 24 hours, and then disappears. Common offending agents include soaps, detergents and oral solvents. Everyone is at risk for developing irritant contact dermatitis, but people vary in their response to the irritant.

2. Allergic contact dermatitis is a delayed cell-mediated hypersensitivity reaction to an offending agent. During the sensitization phase, an allergen penetrates the epidermis and produces proliferation of T-lymphocytes. The T-lymphocyte cells enter the blood circulation, so that all the skin becomes hypersensitive to the allergen. This phase may take days or months, depending on the individual's sensitivity, the amount and concentration of the allergen, and the amount of penetration. In the elicitation phase, the antigen specific T-lymphocytes react to subsequent allergen exposure and produce the inflammatory response. Allergic contact dermatitis has a delayed onset of 18 hours, peaks at 48–72 hours, and often lasts as long as 2–3 weeks even if exposure to the offending antigen is discontinued. Poison ivy, oak and sumac produce many cases of allergic contact dermatitis. Other allergens include fur; leather; nickel; topical antibiotics, antihistamines, and anesthetics; shoe dyes or glue; hair dyes; adhesive tape; parabens (found in sunscreens and lotions); latex, soap and cleansers, plastics, fragrances, metal, or rubber.

SUBJECTIVE

1. Patient or caregiver may report:
   a. History of exposure to chemicals, detergents, medications, plants, lubricants, cleansers or rubber gloves, metal belt buckles and/or jewelry (zinc) at home or at work.
   b. Previous history of contact dermatitis.
   c. Itching, swelling, rash of varying severity and duration.
   d. Ask about response to any treatment used.

OBJECTIVE

1. Note character of eruption:

a. Irritant contact dermatitis usually causes an erythematous dry, scaling eruption with an indistinct margin. Fissures sometimes occur.
b. Chronic exposure may cause weeping lesions.
c. Allergic contact dermatitis usually causes more erythema and edema. Vesicles, characteristic in response to poison ivy, oak and sumac, often weep and form crusts but can also have a linear line or streak– like pattern, pruritic indurated scaly plaques.

2. Note location and pattern of the eruption, which suggest the cause:
   a. Scalp/ears: hair care products, jewelry.
   b. Eyelids: cosmetics, contact lens solution.
   c. Face/neck: cosmetics, cleansers, medications, jewelry.
   d. Trunk/axilla: deodorants, clothing especially belt buckles.
   e. Arms/hands: poison ivy/oak/sumac, soaps, detergents, chemicals, jewelry, rubber gloves.
   f. Legs/feet: clothing, shoes.

ASSESSMENT Contact Dermatitis

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Lesions occupy less than 2% body surface area (less than 2x size of patient's palm) and do not involve the face:
   a. Apply triamcinolone 0.1% Cream or Ointment 2 to 3 times daily until clear (usually at least 2 weeks).
      1) Use ointments on dry or cracked skin and creams on inflamed or weeping lesions. Many patients prefer the cream. May need to taper application (twice daily and once daily) to avoid flare-up.
   b. Calamine lotion can be applied as an astringent, protectant, or soothing agent, for conditions such as poison ivy, poison oak, or minor skin irritations. Apply 1 to 4 times daily, avoid if skin is dry. Do not use on open wounds. Educate patient to ensure that they do not obtain Caladryl which contains a topical analgesic. It is not generally recommended for use in children younger than 2 years of age.

      OR

   c. Zinc oxide can be applied several times a day as required to soothe and promote healing of chapped skin.

2. In the early stages, if drainage is occurring, wet dressings, using gauze soaked in Domeboro astringent, are an option to control itching when ointments and the measures described below are insufficient to control pruritus during the first day or two of therapy. These dressings have the advantage of blocking the child's ability

to scratch the area. For use as a wet dressing, saturate gauze in the solution; gently squeeze. Apply saturated cloth loosely to the affected area. Change dressing every 2-3 hours.

3. For relief of itching:
   a. Diphenhydramine hydrochloride elixir:
      1) Children 2 through 5 years of age: Diphenhydramine hydrochloride elixir 12.5 mg/5mL. May give 6.25 mg every 4 to 6 hours; do not exceed 37.5 mg/day.
      2) Children 6 through 11 years of age: Diphenhydramine hydrochloride elixir 12.5 mg/5mL. May give 12.5mg to 25 mg every 4 to 6 hours; do not exceed 150 mg/day.
      3) Adults and children 12 years of age and older: Diphenhydramine hydrochloride 25-50 mg orally 3 or 4 times a day (not to exceed 300 mg/day). Do not give in third trimester of pregnancy or to breastfeeding mother.

NOTE: Dosing should be based on severity of symptoms. Do not use topical diphenhydramine. (Contact delegating physician before administering diphenhydramine to a child under 2 years of age).

OR

   b. Hydroxyzine (Atarax or Vistaril) 10mg/5ml or 10 or 25 mg tablet Contraindicated in prolonged QT interval.
      1) Children 1 year to less than 6 years: 2 mg/kg/day divided every 6 to 8 hours. Maximum single dose 12.5 mg. Can be started and given once daily (at bedtime) or twice daily (in the morning and at night).
      2) Children 6 years to 12 years: 2 mg/kg/day divided every 6 to 8 hours. Maximum single dose: 25 mg. Can be started and given as once daily (at bedtime) or twice daily (in the morning and at night).
      3) Children 12 years and older and weight > 40 kg: 25 to 50 mg once daily at bedtime or twice daily.

NON- PHARMACOLOGIC MEASURES

1. Apply cold, wet compresses for 15-20 minutes 3-4 times a day during the blistering and weeping stage.

2. Cool tub baths, with or without colloidal oatmeal (e.g., Aveeno), to decrease inflammation and itching.

3. Dress the area, if necessary, to control scratching. A wet dressing is least likely to aggravate pruritis (Domeboro solution preferred).

PATIENT EDUCATION/COUNSELING

1. Educate on potential causes. Remove or avoid the irritant/allergen. Wear protective clothing and gloves.

2. For poison ivy, oak, etc:
   a. As soon as possible after exposure, wash the skin with lots of cold water and soap. To wash within 15 minutes is the most effective. If soap and water are not available, alcohol may be used.
   b. Poison ivy dermatitis is not spread elsewhere on the body or to another person, by fluid in the blister. It is spread by any oil from the plant still on the skin, clothes or tub. (Taking a shower rather than a bath is less likely to leave resin around the tub).
   c. A rash will appear first on areas of skin which are thinner, or where the plant oil was more concentrated.
   d. Teach how to identify poison ivy, oak and sumac.
   e. Topical steroids do not work well on vesicles or weeping rashes but may be used after the blistering stage.
   f. Remind of potential for delayed hypersensitivity reaction

3. Avoid use of topical preparations with benzocaines or other -caines.

4. Emollients (e.g., Eucerin, Lubriderm) can be used to protect and care for dry skin.

5. Advise that patch testing may be required to identify the irritant or allergen if more than one is possible.

6. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. Re-evaluate in 2-3 days, if no improvement or signs of bacterial infection occur.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present. (When a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. If moderate to severe dermatitis (greater than 2% body surface area) or significant involvement of the face (oral steroids can bring about dramatic improvement; the sooner oral steroids are started, the more effective they will be).
2. For suspected secondary bacterial infection (significant extension of erythema and/or tenderness beyond the initial border of the rash; fever [not always present], malaise).
3. If no response to treatment.
4. Pregnant or breastfeeding patient.

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STANDARD NURSE PROTOCOL FOR DIAPER DERMATITIS (DIAPER RASH)

DEFINITION

Inflammation of the skin within the area usually covered by the diaper.

ETIOLOGY

It can be caused, and aggravated by, many factors acting separately or in combination. Contact irritants such as urine, stool and chemicals may be involved. Bacterial, fungal or viral infections may also cause diaper dermatitis. Other causes include seborrheic dermatitis or atopic dermatitis.

SUBJECTIVE

1. Patient or caregiver may complain of:
   a. Pruritus
   b. Irritability
   c. Erythema
   d. Rash

OBJECTIVE

1. Irritant contact diaper dermatitis will show mild erythema, especially on the buttocks, genitalia and lower abdomen with sparing in the creases.

2. Bacterial infection will show vesicles and/or pustules in the diaper area.

3. Monilial (candidal) infection will show smooth, shining, “fire-engine” red, papular and nummular rash, with well-circumscribed borders, that extends into creases, and satellite lesions that are outside the margin of the erythema. Oral thrush may also be present. Small pustules are often present on the periphery. Antibiotic use is a predisposing factor.

4. Affected area may be moist and exudative.

5. During healing of moderate to severe dermatitis, skin may be dry and scaly.

ASSESSMENT Diaper dermatitis.

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. For cases of diaper dermatitis that have the typical appearance of monilial infection

(satellite lesions, etc.) or for cases of diaper dermatitis that have been present for more than 3 days without improvement.

a. Apply nystatin 100,000 units/gm (e.g., Mycostatin©) cream lightly to affected area under a barrier ointment 3 to 4 times a day for 7-10 days. (May repeat cycle once).

b. Treat for oral thrush, if evident. See Standard Nurse Protocol for Thrush – Oral Candidiasis..

NOTE: Topical hydrocortisone and fixed-combination medications, Mycolog II and Lotrisone, should NOT be used. (Adverse systemic effects may occur due to use in an occlusive diaper area).

NON-PHARMACOLOGIC MEASURES

1. General Treatment and Prevention: Use ABCDE acronym for treatment protocol (Air, Barrier, Cleansing, Diaper and Education).
   a. Keep diaper area dry and free from urine and stool:
      1) Change diapers frequently.
      2) Cleanse diaper area with warm water with each diaper change. Avoid use of soap which can be irritating to skin, and use mild, non-perfumed, non-medicated soap only if necessary.
      3) Air drying is an important adjunctive treatment
      4) Avoid starch, other powders, and petroleum jelly.
   b. Apply protective barrier agent: bland ointment (e.g., A&D ointment) or a barrier cream (e.g., zinc oxide or Desitin©) after each diaper change.
   c. Avoid the use of commercial diaper wipes, which are often perfumed and irritating. Recommend using plain water and soft, non-abrasive towel for cleaning.
   d. Infants using super absorbent disposable diapers have a significantly lower frequency and severity of diaper rash when compared with infants using cloth diapers. These should be recommended if the dermatitis is recurrent or severe.
   e. Breastmilk in one study in 2013 showed efficacy as 1 % hydrocortisone ointment alone for 7 days course**.**

PATIENT EDUCATION/COUNSELING

1. Assure that parent/caregiver knows how to treat, as above.
2. Teach parent to promptly change diapers as needed.
3. Teach parent to gently wash area (do not scrub). If rash is severe and to avoid rubbing – to clean and rinse, use a water bottle to squirt warm water gently and pat dry.
4. Teach parent to use mineral oil on a cotton ball to remove dried feces.
5. Educate parent does not need to wipe off barrier paste completely at each diaper change.
6. For cases of recurrent or severe diaper dermatitis a change in the type of diaper used is a reasonable consideration. Diaper rash is less common with use of super

absorbent disposable diapers.

7. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. No follow-up needed if symptoms resolve within 2 weeks.

2. Reevaluate if symptoms persist or worsen beyond 2 weeks.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present. (When a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Failure to respond to treatment.

2. Signs of bacterial infection are present.

3. Any rash that is unusual or severe.

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STANDARD NURSE PROTOCOL FOR DYSLIPIDEMIA SCREENING

DEFINITION

Dyslipidemia is a condition marked by abnormal elevations of Total Cholesterol, Low-Density Lipoprotein cholesterol (LDL), Triglycerides, or deficiency of High-Density Lipoprotein cholesterol (HDL) in the blood.

ETIOLOGY

Research indicates that atherosclerosis (fatty deposits of plaque in arterial walls) begins in childhood and progresses over the lifespan. Exact causes of atherosclerosis are not known, but certain factors that may damage arterial walls and lead to atherosclerosis are smoking, high amounts of certain fats and cholesterol in the blood, high blood pressure and high amounts of sugar in the blood.

Dyslipidemias are disorders of lipoprotein metabolism that result in high levels of Total Cholesterol, LDL or Triglycerides and low levels of HDL. Dyslipidemia is a risk factor for cardiovascular disease (CVD) in adults. Early identification of youth with dyslipidemia can lead to interventions that may prevent or delay the progress of atherosclerosis and CVD.

Secondary causes are attributed to sedentary lifestyle, diets high in saturated fat and cholesterol, and conditions such as diabetes, nephrotic syndrome, hypothyroidism. Also, certain drugs may affect lipid profiles, e.g., progestins, anabolic steroids, corticosteroids, and protease inhibitors.

SUBJECTIVE

1. Risk Factors:
    a. Family history of parent with elevated blood cholesterol (level of 240 mg/dL or higher) or known dyslipidemia.
    b. Family history (parents, grandparents, aunt/uncle, or sibling with premature (before 55 years of age in males and before 65 years in females) cardiovascular disease (e.g., myocardial infarction, angina, stroke, coronary artery bypass graft/stent/angioplasty).
    c. Unobtainable family history.
    d. Personal history of tobacco use.
    e. Personal history of diabetes.
    f. Personal history of hypertension.
    g. Personal history of excess alcohol intake (defined as any alcohol intake in persons less than 21 years of age).
    h. Diet that includes excessive consumption of saturated (solid) fats and cholesterol. (Greater than 10 % of calories from saturated fatty acids).
    i. Low levels of physical activity (less than one hour of active play/physical activity most days of the week).
    j. Very high carbohydrate diet (greater than 60 percent of total energy).

k. Significant risk factors/conditions may include chronic renal disease/end-stage renal disease/post-renal transplant, post-orthotopic heart transplant, Kawasaki disease with current or regressed aneurysms, chronic inflammatory disease (systemic lupus erythematosis, juvenile rheumatoid arthritis), HIV infection, nephrotic syndrome, certain genetic conditions.

OBJECTIVE

1. Reasons to obtain lipid screening:
   a. Patient age falls within the recommendations for universal screening (between 9 – 11 years or between 17-21 years) as outlined in Bright Futures Periodicity Schedule.
   b. BMI at or greater than the 95th percentile for age (2 through 8 years old.)
   c. BMI at or greater than the 85th percentile for age (9 through 20 years old.)
   d. Patient is age 2-8 years of age or 12-16 years of age AND meets “high risk” criteria for significant risk factors/conditions

ASSESSMENT At Risk for Dyslipidemia

PLAN

DIAGNOSTIC STUDIES

1. BMI for age: check annually for patient 2 years and older. BMI: check annually for patient 21 years and older.

2. Blood Pressure: check annually for patient 3 years and above.

3. Per Bright Futures Periodicity Schedule**,** non-fasting dyslipidemia screening for all patients occurs once between ages 9-11 years and then again between ages 17-21 years.

4. High Risk Screening:
   a. Screen children ages 2-8 years of age and 12-16 years of age who meet any of the “high-risk” criteria (Refer to list under SUBJECTIVE for **“**high risk” criteria). Test only once during this age range.
   b. BMI at or greater than the 95th percentile for age (2 through 8 years old).
   c. BMI at or greater than the 85th percentile for age (9 through 20 years old).

   NOTE: Lipid Profile should include total Cholesterol, LDL cholesterol, HDL cholesterol and Triglycerides. Ideally, lipid profile and glucose should be obtained in the fasting state for those patients in the high-risk group. If not possible, non-fasting samples may be obtained.

5. Retest as needed if there are abnormal values or clinical concerns.

6. Evaluate laboratory results per the following reference tables:

Lipid Laboratory Results Parameters						
Youth: 2 through 19 years of age						
	Total Cholesterol (mg/dL)	LDL (mg/dL)	Non-HDL cholesterol (mg/dL)	Triglycerides (mg/dL) 0-9 years	Triglycerides (mg/dL) 10-19 years	HDL (mg/dL)
Acceptable	less than 170	less than 110	less than 120	less than 75	less than 90	greater than 45
Borderline	170-199	110-129	120-144	75-99	90-129	40-45
High	200 or greater	130 or greater	145 or greater	100 or greater	130 or greater	**
Low	**	**	**	**	**	less than 40
Source: Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report						

Youth 20 years of age					
	Total Cholesterol (mg/dL)	LDL (mg/dL)	Non-HDL cholesterol (mg/dL)	Triglycerides (mg/dL)	HDL (mg/dL)
Acceptable	less than 190	less than 120	less than 150	less than 115	greater than 45
Borderline	190-224	120-159	150-189	115-149	40-44
High	225 or greater	160 or greater	190 or greater	150 or greater	**
Low	**	**	**	**	less than 40
Source: Expert Panel on integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Summary Report					

THERAPEUTIC

NON-PHARMACOLOGIC

1. Initiate Therapeutic Lifestyle Changes for all patients as follows:
   a. Patients 2 years of age or older follow nutritional guidance in accordance with Dietary Guidelines for Americans 2020-2025.
   b. Physical activity recommendations for youth 2 years of age and older are 60 minutes or more of moderate or high intensity active play/physical activity per day.
   c. Lifestyle changes to include smoking avoidance, tobacco use cessation, healthy sleep volume and pattern, healthful food and beverage intake, and by increasing physical activity and reducing screen time.

PATIENT EDUCATION/COUNSELING

1. Counsel patients and families:
   a. To balance caloric intake with physical activity to achieve or maintain a healthy weight.
   b. To consume more fruits, vegetables, fish, whole grains, beans/lentils**,** and low-fat dairy products.
   c. To reduce the intake of calories from solid fats, saturated fat, trans fats, and cholesterol.
   d. Solid fats are solid at room temperature and are primarily saturated and/or trans fats. Solid fats mainly come from animal sources but include some plant sources. Some common solid fats are:
      1) Butter
      2) Whole milk and whole milk dairy products
      3) Beef fat (tallow, suet)
      4) Chicken fat**/**poultry with skin
      5) Pork fat (lard)
      6) Coconut and palm oils.
   e. Trans fats are also solid fats. Check the food label for trans fats. Primary sources of trans fat include:
      1) Shortening and other solid fats
      2) Pastries (i.e., cakes, doughnuts, cookies)
      3) Icing/frosting
      4) Stick margarine and some, but not all, tub margarines
      5) Microwave popcorn.
   f. Animal food sources all contain cholesterol. Oils from plant sources (vegetable and nut oils) do not contain any cholesterol. In fact, no foods from plants sources contain cholesterol.
   g. To increase the intake of monounsaturated and polyunsaturated fatty acids. Most oils (liquid fats) are high in monounsaturated or polyunsaturated fats, and low in saturated fats. Foods made up mostly of monounsaturated and polyunsaturated fats include:
      1) Olives and olive oil
      2) Canola oil
      3) Safflower oil
      4) Peanut oil
      5) Corn oil
      6) Nuts, nut butters, and seeds.
      7) Avocados
      8) Fatty fish such as salmon and tuna

   h. On decreasing intake of added sugars. On the ingredient list, added sugars can be listed as sucrose, maltose, cane sugar, high fructose corn syrup, molasses, corn sweetener, syrup, raw sugar, honey, or fruit concentrate. Fruit and milk have naturally occurring sugars. However, added sugars can be commonly found in:
      1) Soft drinks and fruit drinks

2) Candies and cookies
3) Cakes and pies
4) Ice cream
5) Sweetened yogurt
6) Sweetened milk

i. On ways to increase physical activity and decrease sedentary lifestyles.
j. About associated risk factors such as, smoking, obesity, diabetes, and hypertension.
k. The following are sources of food that can increase soluble fiber intake: oatmeal, 100% whole wheat products, legumes, barley, quinoa, brown rice, corn, beans/lentils, sweet potato, broccoli, turnips, carrots, brussel sprouts, spinach, cabbage, kale, onions, artichokes, all berries, citrus fruits, peaches, pears, apples, bananas, grapes, avocado.

2. Encourage family members with dyslipidemia risk factors to obtain medical evaluations as appropriate.

FOLLOW-UP

1. For patients screened with a fasting or non-fasting lipid profile with abnormal results, refer to a physician for follow-up.

CONSULTATION/REFERRAL

NOTE**:** Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present (When a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. For patient on oral contraceptives refer to Standard Nurse Protocol for Abnormal Lipid Tests While Using Hormonal Contraceptives.
2. If patient is a tobacco user, referral to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867).
3. Pregnant or lactating patient refer to APRN or physician.
4. Refer patients with significant risk factors to primary care provider.
5. Refer patients to a registered dietitian nutritionist (RDN) for consultation if lipid management requires individualized nutrition education and counseling. Children 1-5 years old may be eligible for nutrition education and counseling through the WIC Program.

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STANDARD NURSE PROTOCOL FOR FEVER

DEFINITION

Fever is an elevation in normal body temperature**.** A fever is generally harmless and can be considered a good sign that the immune system is working and that the body is trying to heal itself. Normal body temperature varies with time of day, activity level, age and general health. Infants tend to have higher temperatures than older children. In general, a person's temperature is highest during late afternoon early evening and lowest between midnight and early morning. The average normal body temperature is 98.6 degrees Fahrenheit (37 degrees Celsius). Most pediatricians consider a rectal temperature above 100.4 degrees Fahrenheit (38 degrees Celsius) a fever.

ETIOLOGY

Most fevers in children are seen in conjunction with an acute, infectious process. Fever control is of secondary importance to identification and control of its underlying cause.

SUBJECTIVE

1. Patient may have:
   a. History of exposure to other ill children or adults
   b. Be less active than usual or irritable
   c. Symptoms of illness, such as rhinorrhea, cough, tachypnea, ear pain, dysuria, pain, chills, rash, sore throat, headache, vomiting and/or diarrhea, increased urinary frequency or sudden enuresis
   d. A fever pattern that may be continuous, remittent, intermittent, or recurrent
   e. History of recent immunization. (However, caution is advised when attributing fever to an immunization. Immunized infants can also harbor an infectious process)
   f. Decreased appetite
   g. Complaint of pain or discomfort

OBJECTIVE

1. Elevated temperature greater than 100.4 degrees Fahrenheit (38° Celsius).
   a. Rectal Thermometry: Rectal temperatures are recommended for infants and children under 2 years of age. Bright Futures guidelines for Health Supervision suggests rectal temperatures can be obtained up to 4 years of age. Do not perform rectal thermometry in a patient with neutropenia.
   b. Oral Thermometry: If child is more than 2 years old and is cooperative, oral thermometry is preferred.
   c. Axillary Thermometry: Will be lower than rectal thermometer but there is no need for adjustment. The National Institute for Health and Care Excellence allows for use of electronic axillary thermometry for children younger than four weeks and up to five years of age due to its ease of use, quicker completion

and better acceptance by parents and caregivers. Preferred for the neutropenic patient who cannot use an oral thermometer.

d. Infrared Thermometry (Tympanic Membrane and Temporal Artery): These devices are commonly used in offices, homes and hospitals but accuracy may be affected by sweating or vascular changes. Readings may be lower or higher than rectal temperatures which is the standard reference measurement for risk of serious infections in febrile infants and young children. In these situations, temporal artery temperatures should not be used to make clinical decisions.

2. Pulse and**/**or respiratory rate may be elevated.

ASSESSMENT Fever/Elevated body temperature.

1. Perform complete physical exam (must rule out a more serious infection).

NOTE**:** The decision on whether to treat fever is individualized to each child. Antipyretics do not alter the course of disease and can cause side effects and toxicity. Temperature elevations do not correlate with severity of cause. The most common reason for treating fever is that fever makes the child uncomfortable. The decision to treat for comfort's sake should be based on how the child looks and behaves, not a temperature threshold.

PLAN

DIAGNOSTIC STUDIES

1. Laboratory tests as indicated by history and physical findings.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Aspirin should not be given to children and adolescents 19 years and under because of its association with Reye's syndrome especially when used during episodes of fever -causing or viral illnesses. Use of any medication in children which contain salicylates (such as Alka-Seltzer and Pepto Bismol) should be avoided.

If you do choose to treat a fever, the two recommended medications are:

1. Acetaminophen (less prone to GI irritation)

NOTE: Children with phenylketonuira (PKU) should <u>not</u> take Children's Anacin-3©, Children's Tylenol©, Double Strength Tempra©, Junior Strength Tylenol© and Tempra© in the chewable form. These products, in this dosage form, contain <u>aspartame</u>, which is metabolized in the GI tract to phenylalanine following oral administration.

NOTE**:** Caution in children with liver impairment

OR

a. Dosage Recommendations for Relief of Fever and Pain in Children Acetaminophen:

NOTE: Healthcare professionals should verify product concentration prior to providing dosing information. Dose is 10 to 15 mg/kg/dose every 4 to 6 hours as needed. Do not give more than 5 doses in 24 hours. Maximum of 75 mg/kg/day (not to exceed 4 g daily).

Acetaminophen dosage

Child's weight		Liquid (suspension*)	Meltaways	Junior meltaways
Lbs	Kg	160 mg per 5 mL	80 mg tablet	160 mg tablet
12-17	5.4-7.7	2.5 mL	Do not use	Do not use
18-23	8.1-10.4	3.75 mL	Do not use	Do not use
24-35	10.9-15.9	5 mL	2 tablets	1 tablet
36-47	16.3-21.3	7.5 mL	3 tablets	1½ tablets
48-59	21.8-26.8	10 mL	4 tablets	2 tablets
60-71	27.2-32.3	12.5 mL	5 tablets	2½ tablets
72-95	32.7-43.1	15 mL	6 tablets	3 tablets

*You may see the word suspension on your child's medicine bottle. Suspension means the medicine is loose in the liquid. This type of medicine needs to be shaken well before it is given to your child.
*Lbs = pounds; kg=kilograms; mg=milligrams; mL=milliliters

2. Ibuprofen (only for children 6 months and older due to potential harmful effects on kidneys).

NOTE: Only for children 6 months and older due to potential harmful effects on kidneys. Healthcare professionals should verify product concentration prior to providing dosing information. 5 to 10 mg/kg/dose. Dose may be repeated every 6 to 8 hours, not more than 4 doses in 24 hours**.** Use only the dropper provided for infant drops.

a. Ibuprofen dosage for 12 years of age and older is 400mg every 6 to 8 hours as needed. (Maximum: 2,400mg/24 hours); treatment beyond 3 days is not recommended. To reduce the risk of adverse cardiovascular and GI effects, use the lowest effective dose for the shortest period of time and take with food.
b. Dosage Recommendations for Ibuprofen Children's Suspension & Chewable Tablets:

Ibuprofen dosage

Child's weight		Infant's drops	Liquid (suspension*)	Chewable tabs	Junior chewable tabs
Lbs	Kg	50 mg per 1.25 mL	100 mg per 5 mL	50 mg	100 mg
18-23	8.1-10.4	1.875 mL	Do not use	Do not use	Do not use
24-35	10.9-15.9	2.5 mL	5 mL	2 tablets	Do not use
36-47	16.3-21.3	Do not use	7.5 mL	3 tablets	1½ tablets
48-59	21.8-26.8	Do not use	10 mL	4 tablets	2 tablets
60-71	27.2-32.3	Do not use	12.5 mL	5 tablets	2½ tablets
72-95	32.7-43.1	Do not use	15 mL	6 tablets	3 tablets

*You may see the word suspension on your child's medicine bottle. Suspension means the medicine is loose in the liquid. This type of medicine needs to be shaken well before it is given to your child.

*Lbs = pounds; kg=kilograms; mg=milligrams; mL=milliliters

NOTE: For anti-pyretic use, refer to recommendations in the dosage charts above. Under no circumstances should these two medications, Acetaminophen and Ibuprofen, be given in alternating fashion to reduce fever. Failure of fever to respond to antipyretics is not predictive of severity of illness.

NON-PHARMACOLOGIC MEASURES

1. Give extra clear liquids such as Pedialyte, Enfalyte, water, juices, and popsicles to prevent dehydration and replenish electrolytes when severe vomiting or diarrhea occurs. Observe urinary frequency, volume, and color for early signs of dehydration.
2. Avoid overdressing the febrile child.

PATIENT EDUCATION/COUNSELING

1. Comfort measures.
2. Children with fever may not feel hungry and it is not necessary to force them to eat.
3. Offer fluids frequently.
4. How to take rectal and oral temperatures (depending on age of child) and to observe for other signs and symptoms which may develop.
5. Safety measures and keeping all medications out of reach of children always.
6. Teach parents to read labels and find other sources of acetaminophen that are often in over-the-counter medications, like cough and cold preparations, and can cause toxicity.
7. Reinforce when parents should seek further medical evaluation.
8. Infants and children with fever should not attend daycare or school until afebrile without the use of medication for 24 hours.
9. Educate parent on appropriate dosage of Acetaminophen and Ibuprofen to give child when at home. Reinforce that these medications should not be given in alternating fashions.

10. Discourage the use of alcohol sponging and physical cooling to reduce child's temperature. Never use alcohol for sponging, alcohol can be absorbed through the skin.
11. Physical cooling, like sponging, is usually unnecessary and may even be harmful, causing discomfort and chilling. Sponging allows heat to escape without adjusting the hypothalamic thermostat. As cooling begins, the hypothalamus directs the body to produce more heat, causing muscular shivering and an increase in metabolic rate.

FOLLOW-UP

1. Return visit in 24-48 hours if no improvement.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the or delegating physician for care management if the following conditions are present. (After a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. All infants under 3 months old with a temperature elevation.

2. Any child with decreased mental awareness.

3. Any child that appears toxic (e.g., lethargic or irritable, noninteractive, poor perfusion, hypotension, petechial rash, cardio-respiratory distress, rigors).

4. Any child with signs of acute illness accompanying the fever, such as meningeal signs, alteration in neurologic status, lethargy, pain, rash, petechiae, dysuria, swollen joints, or tachypnea after fever control or other signs of respiratory distress.

5. Fever greater than 102.2° Fahrenheit (39° Celsius) and any of the following (high-risk UTI and bacteremia criteria):
   a. Age 3-6 months.
   b. Age 6-12 months, uncircumcised male.
   c. Age less than 24 months and female unless obvious source.

6. Child has a history of febrile seizures.

7. Any child who has a fever that lasts more than 3 days.

8. Child with immunosuppression, history of chronic conditions such as heart disease or sickle cell disease.

9. Child with prosthetic devices.

10. Child with an unusual exposure history (examples: tick bite, foreign travel, unusual

animal exposure, etc.).

11. Pregnant or breastfeeding patient.

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STANDARD NURSE PROTOCOL FOR IMPETIGO

DEFINITION

A condition involving bacterial infection in the superficial layer of the skin and characterized by honey-colored, crusted lesions or seropurulent vesicles surrounded by a narrow margin of erythema. It occurs in two forms: bullous and non-bullous.

Impetigo may be a complication of insect bites, abrasions or dermatitis. Peak incidence is in late summer and early fall. Impetigo is most common in infants and children.

ETIOLOGY

Virtually 100% of bullous impetigo and 75% of non-bullous impetigo is caused by *Staphylococcus aureus*. Methicillin-resistant *Staphylococcus aureus* infection may be present in impetigo. The remainder is caused by group A beta-hemolytic *Streptococcus*. Staphylococci normally spread from the nose to the skin and then infect the skin. It is commonly found on the face.

In non-bullous impetigo (greater than 70% of cases), skin lesions start as small erythematous macules and papules that develop into discrete, thin-walled vesicles, which become pustular and quickly rupture. As the vesicles rupture, a yellow fluid forms an exudate, which dries to form a stratified golden yellow crust that can spread the infection to other parts of the body. Cellulitis follows about 10% of cases of non-bullous impetigo.

Bullous impetigo infection occurs primarily in newborn infants and young children. The characteristic skin lesions of bullous impetigo are superficial, flaccid, thin-walled bullae that occur most often on the extremities but can occur anywhere.

Impetigo may be spread by direct contact with infected persons or it may be secondary to infections of the upper respiratory tract. The incubation period is 2-10 days. The untreated patient is contagious until lesions are healed; treatment shortens the period of contagiousness.

Acute glomerulonephritis (AGN) can follow streptococcal infections of either the skin or pharynx. It can occur at any age and the incidence is variable, ranging from 0 to 28%. The median latent period between infection and the development of AGN is 10 days. It is characterized by hematuria and hypertension. Treatment, even early treatment, does little to prevent the occurrence of AGN in the patient suffering from impetigo; however, it does reduce the spread of impetigo and therefore the development of AGN in other children.

SUBJECTIVE

1. Patient/caregiver complain of:

a. Superficial lesions, anywhere on the body, commonly begin on face.
b. Itching is common, and scratching may spread the infection.
c. Often a history of minor trauma (such as insect bites or scratches), or other skin conditions (such as scabies, chicken pox or herpes simplex lesions), provide a point of entry for the bacterial organisms.

OBJECTIVE

1. Superficial clear vesicles are present, containing serous fluid that becomes purulent. The base is erythematous, and lesions are surrounded by areas of erythema. May also observe ruptured pustules that have dried centrally and formed a honey-colored crust.
2. Lesions may vary in size from a few millimeters to several centimeters.
3. May have regional lymphadenopathy, which occurs more often in streptococcal than in staphylococcal infections.
4. Bullous impetigo is characterized by very large vesicles (bullae) that rupture and form circular, raw lesions resembling a second-degree burn; these eventually form a crust. It is very infectious and may be present on multiple sites of body and even on other family members.
5. MRSA impetigo: Considered when impetigo is not improving despite the use of standard antibiotics

ASSESSMENT Impetigo

PLAN

DIAGNOSTIC STUDIES

1. Check urine for blood and protein if there is any history of unusually dark (smoky) urine.

2. Check blood pressure.

3. Consider skin culture for identification and sensitivity testing:
    a. If there is reason to suspect Methicillin-resistant staphylococcus aureus (MRSA).
    b. History of MRSA infection in the household.
    c. Cellulitis.
    d. If there is an outbreak of impetigo in the community.
    e. Failure to respond promptly to treatment.
    f. If poststreptococcal glomerulonephritis is present.

THERAPEUTIC

PHARMACOLOGIC

1. Local treatment may be adequate when only one or two lesions are present and there is no fever present.

a. Remove crusts by soaking and gentle washing with warm water and antiseptic soap before applying antibiotic ointment.
b. Mupirocin 2% ointment (prescription required) should be applied to lesions 3 times a day for 7-10 days.

OR

c. Retapamulin 1% ointment (prescription required).
    1) Topical for children 9 months of age and older: Apply to affected area twice daily for 5 days. Total treatment area should not exceed 2% of total body surface area.

Reevaluate patient not showing a response in 2 to 3 days. May need culture for identification and sensitivity testing.

2. Systemic treatment is used for multiple lesions (e.g., 3 or more), widely separated lesions or lesions that are not showing rapid response to local therapy. If infection is severe (e.g., multiple large lesions with fever or other systemic symptoms refer to a physician. Before starting systemic antibiotic, obtain culture for identification and sensitivity testing.
    a. Infants, children, and adolescents: Cephalexin (Keflex), suspension of 125 mg/5mL or 250 mg/5 mL, or 500 mg capsules. Give 25-50 mg/kg/day orally, divided into 4 equal doses for 7 days.
        1) If younger than 1 year of age, divide into 3-4 doses.
        2) 15 years and older: cephalexin 500 mg orally twice daily for 7 days.

OR

a. Infants, children, and adolescents: Dicloxacillin orally 25-50 mg/kg/day in 4 divided doses
b. Adults: Dicloxacillin orally 250 mg-500 mg 4 times daily

OR

3. For PCN and/or Cephalosporin allergy or hypersensitivity. Do not use if allergic to any macrolides. Avoid use of erythromycin with infants under 6 months of age due to potential risk for infantile hypertrophic pyloric stenosis (IHPS).

    a. For 6 months and older: Erythromycin ethylsuccinate (EryPed, EES, Pediamycin) 200 mg/5 mL or 400 mg/5 mL suspension, or 200 mg chewable or 400 mg film-coated tablets.

    b. Erythromycin ethylsuccinate 30-50 mg/kg/day, orally in four equally divided doses every 6 hours for 10 days. If twice-a-day dosage is desired, ½ of the total daily dose may be given every 12 hours. Doses may also be given three times daily by administering one-third of the total daily dose every 8 hours.

    c. Adolescents and Adults weighing 100 lbs or more: Erythromycin ethylsuccinate 400 mg by mouth every 6 hours for 10 days.

NOTE: Give after meals to decrease gastric upset.

OR

a. Adults: Clarithromycin orally 250 mg BID for 7 days

b. 6 months and older: Clarithromycin orally 15mg/kg/day in 2 divided doses for 7 days

4. If MRSA is suspected or confirmed, give:
   a. Clindamycin:

      1) Infants, children, and adolescents: Clindamycin 30 mg/kg/day (maximum dose: 450mg/dose) in three divided doses for 7 days.
      2) Adult dose: Clindamycin 450 mg three times per day for 7 days.

      OR

   b. Trimethoprim-sulfamethoxazole
      1) 2 months and older: Trimethoprim 8-12 mg/kg per day (maximum 160mg trimethoprim/dose) in two divided doses for 7 days.
      2) Adult dose: Bactrim DS 1-2 tablets twice per day for 7 days.

NOTE: Treat or refer all family/household members in close contact who also have impetiginous lesions, to avoid reinfection and further spread.

PATIENT EDUCATION/COUNSELING

1. Instruct family and child in importance of handwashing.
2. Instruct in handling of linen and clothing separate from the rest of household.
3. Instruct in trimming and keeping nails clean.
4. Instruct in soaking and removal of crusts from lesions: gently wash the affected areas with clean gauze and antiseptic soap every day. Soak any areas of crusted skin in warm soapy water to help remove the layers of crust. It is not necessary to completely remove all crust.
5. Give parent information about symptoms of glomerulonephritis to observe for: hematuria; periorbital edema; headache; fever; malaise; or tea or “smoky”-colored urine.
6. May return to school 24 hours after starting antibiotic treatment. Children with draining or open lesions should have lesions covered with a clean, dry dressing (gauze and tape or a loose bandage). Close contact with other children should be avoided.
7. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. Reevaluate in 2-3 days if infection is not showing a response to medication, is worsening, or is spreading.
2. Recheck in 18-21 days or sooner if rash/infection gets worse while on treatment. Note any signs or symptoms of glomerulonephritis (brown colored urine, hematuria, periorbital edema, headache, malaise). Check blood pressure. If indicated, check urine for blood and protein (dipstick adequate).

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with the delegating physician for care management if the following conditions are present. (When a patient is referred to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. If rash is not completely resolved at end of medication regimen.
2. Infants under the age of 2 months.
3. Non-adherence with medication or instructions.
4. Severe infections (e.g., multiple large lesions with fever or other systemic symptoms).
5. If extensive local inflammation or cellulitis.
6. If any signs/symptoms of glomerulonephritis.
7. If multiple recurrences, to evaluate child for nasopharyngeal carriage state of *S. aureus.*
8. If progression after 24 hours of treatment or a culture positive for MRSA.
9. Pregnant or breastfeeding.

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STANDARD NURSE PROTOCOL FOR TREATMENT OF IRON DEFICIENCY ANEMIA

DEFINITION

Iron deficiency is a condition in which there is a reduction of iron in the body to less than normal. Iron depletion is the earliest stage of deficiency, where iron storage is decreased but serum iron concentration and blood hemoglobin levels are normal. Iron deficiency anemia is the most advanced stage of iron deficiency with low serum iron concentration and low blood hemoglobin concentration.

ETIOLOGY

Anemia occurs when there is a reduction in hemoglobin concentration or red blood cells, resulting in decreased oxygen carrying capacity of blood. Anemia may result from excessive blood loss, excessive blood cell destruction, or decreased blood cell formation. The latter anemia may result from inhibition of or loss of bone marrow function, defective nucleoprotein synthesis (as in pernicious anemia) or deficiency of iron in the diet. The most common anemia in children is iron deficiency anemia. Iron deficiency occurs most commonly in late infancy, early childhood, and adolescence.

Iron deficiency anemia represents the most severe end of the iron-deficiency spectrum. There is evidence that substantial iron deficiency during infancy and early childhood can have long term neurocognitive implications**,** and it is likely that by the time iron-deficiency progresses to anemia the neurological consequences have already occurred. Some of these neurodevelopment and behavior effects may be irreversible. It is, therefore, imperative that iron deficiency be prevented, and if not prevented then diagnosed early and treated aggressively.

Subsets at increased risk for iron deficiency include: infants of diabetic mothers, preterm infants and infants with growth restrictions; breastfed infants older than 6 months not receiving iron supplementation, children with elevated lead levels, children living at or below the poverty level, children and adolescents on low-meat or no-meat diets and post-menarche females.

NOTE: For female patient 18 years and over in Women's Health Program, see Standard Nurse Protocol for Iron Deficiency Anemia in Non-Pregnant Women.

SUBJECTIVE

1. Patient or caregiver may report:
   a. Asymptomatic
   b. Poor appetite, inadequate diet, or anorexia
   c. Irritableness or fussiness
   d. Poor weight gain
   e. Headaches
   f. Easily fatigued, listlessness, decreased social interaction, poor attention to tasks, developmental delays

g. Pica (can be a symptom of iron deficiency anemia and/or lead poisoning; iron deficiency anemia increases risk for lead poisoning)
h. Excessive milk/dairy intake (more than 24 oz. per day) and limited intake of iron-containing foods
i. Infants six months and older and exclusively fed human milk without iron supplementation (e.g., iron fortified cereals, oral iron, pureed meats)
j. Consumption of cow milk in infancy
k. Gestational severe maternal iron deficiency, maternal hypertension and maternal diabetes mellitus
l. History of intestinal parasites
m. History of sickle cell anemia or thalassemia
n. History of blood loss including GI bleeding or nose bleeds
o. Heavy menstrual blood loss (greater than or equal to 80mL per month)
p. Excessive aspirin or antacid consumption
q. History of splenectomy or cholecystectomy

OBJECTIVE

1. Physical exam findings may include:
   a. Hemoglobin/hematocrit below acceptable values (table follows).
   b. Skin pallor and/or pale mucous membranes
   c. Tachycardia
   d. Elevated blood lead level. (Obtain lead level if indicated; reference Georgia Childhood Lead Poisoning Prevention Program Guidelines).
   e. Premature (less than 37 weeks gestation) or low birth weight (less than 2,500 gm).
   f. Check Georgia newborn screening results (and other states as available) for sickle cell and other hemoglobin variants.

ASSESSMENT Iron deficiency anemia

1. Assessment for iron deficiency anemia should be performed at the 12-month health check following Bright Futures/American Academy of Pediatric Recommendations for preventative Pediatric Health Care periodicity table. Assessment should also occur during other age-based health checks when there are positive findings within the Bright Futures risk assessment questions that suggest anemia.

PLAN

DIAGNOSTIC STUDIES

1. For obtaining hemoglobin value, follow the HemoCue® Hemoglobin System standard operating procedure guidelines.

DIAGNOSTIC CRITERIA

1. Iron deficiency anemia, presumptive if hemoglobin or hematocrit are below acceptable values and if:
   a. No suggestion of sickle cell, thalassemia or other chronic illness including recurrent nosebleeds,
   b. No recent infections or inflammatory conditions**,**
      AND
   c. 3 negative stools for occult blood (if performed).

2. A diagnosis of iron deficiency anemia can be confirmed following a presumptive diagnosis, if, after iron supplementation, the hemoglobin increases by at least 1 gm/dL, or the hematocrit increases by more than 3% in one month.

NOTE: Check stool for occult blood if abnormal stool history (tarry, bloody, chronic diarrhea).

3. Iron deficiency anemia may coexist when there is GI bleeding, chronic nosebleeds, lead poisoning or other chronic illness. However, these underlying causes should be addressed through a referral. The diagnosis of iron deficiency will commonly include a full CBC and reticulocyte count a serum iron measurement and a TIBC, as well as a ferritin level. Simple dietary iron-deficiency anemia is most common under 30 months of age. When iron deficiency anemia is identified after 30 months of age, more aggressive efforts should be made to identify causes other than simple dietary deficiency such as occult GI blood loss or malabsorption.

AGE-SPECIFIC LOWEST NORMATIVE RED BLOOD CELL VALUES

NOTE: If patient's hemoglobin/hematocrit is less than the values in this table, begin therapeutic treatment as listed below:

Age[5]	Hemoglobin (g per dL)	Hematocrit (%)
6 months - 11 months	11	33
12 months - 23 months	11	32.9
24 months - 5 years	11.2	33
6 - 12 years	11.5	33
12 - 18 years (male) 12 – 18 years (female)	13 12	39 36

THERAPEUTIC

PHARMACOLOGIC

1. For Iron Deficiency Anemia (infants and children) give Ferrous Sulfate (Elemental Iron), 4 mg/kg/day by mouth given once or divided into 2 doses daily.
   a. A range of 3 mg/kg/day to 6 mg/kg/day is acceptable. Maximum dose should not exceed 150 mg of elemental iron.
   b. Treat for 2-3 months after hemoglobin/hematocrit return to normal to replenish total body stores. If adherence is a problem, the entire daily dose may be given as a single dose, with a meal. Do not give if patient has sickle cell or hemoglobin variants. Available OTC. See chart for a list of elemental iron products.
   c. Ideally, take iron supplement 30 to 45 minutes before meals or two hours after meals, and only with juice or water, rather than with food or milk. If gastric upset occurs, may take supplement after a meal or on a full stomach. Avoid taking with dairy. See Patient Education section for more information.

NON-PHARMACOLOGIC MEASURES

1. Dietary counseling for iron deficiency anemia in children.
   a. Give list of iron-rich foods (recommend at least 2 servings of iron rich foods daily).
   b. Encourage vitamin C-rich foods to improve iron absorption of non-heme iron (iron from plant sources).
   c. Reduce excessive dairy and dairy alternative intake to 3 servings per day (1 serving is equivalent to 8 oz milk, 8 oz yogurt, or 1.5 oz cheese).

PATIENT EDUCATION/COUNSELING

1. Poison control safety counseling because large doses of iron are poisonous. Store all medications out of reach of children. If drug is taken by accident call the poison control center right away.
2. The appropriate dose should be taken on an empty stomach. If unable to tolerate (GI upset occurs), advise to take after meals with 4 oz. of vitamin C-rich juice (orange, pineapple, tomato, grapefruit, or apple juice fortified with vitamin C) to increase absorption of iron and decrease gastric irritation. Taking iron with food can decrease the iron absorption by at least 50%. However, this may be preferred if compliance becomes a problem because of gastric discomfort when taking iron between meals. If iron must be given with food for improved compliance, then avoid milk (including soymilk), milk products (i.e., yogurt, cheese), tea, and cereals.
3. Iron can interfere with many drugs' absorption into the body. If the patient takes other medications, please check with pharmacist or healthcare professional.
4. For children ages 1 to 5 years: their daily total intake of milk containing products should not exceed 24 oz. per day (including cow's milk, goat's milk, soy milk, yogurt, ice cream, cheese, and breast milk).
5. Do not feed cow's milk before 1 year of age.
6. The American Academy of Pediatrics supports exclusive breastfeeding for the first 6 months of life; if formula fed, only iron-fortified formula should be used.

7. Iron products stain teeth. Instruct parents on importance of brushing teeth and rinsing the mouth after iron supplement is given.
8. Eat nutritious meals and snacks and limit low nutrient dense foods**.** Encourage iron rich foods with vitamin C rich foods at each meal, while avoiding dairy foods or tea with meals to maximize iron absorption.
9. Iron can cause black stools, constipation, or diarrhea.
10. Some iron products contain tartrazine. If allergic to tartrazine, please check product ingredients.
11. For tablets, have the child swallow whole.
12. For liquid drops or elixir, use the measuring device that comes with the drug and measure carefully.

FOLLOW-UP

1. Recheck hemoglobin/hematocrit after 4 weeks of treatment to assess for therapeutic progress and emphasize compliance.
   a. Iron Deficiency Anemia: An increase in Hgb of 1gm/dL or more; or Hct 3% or more confirms the diagnosis of iron deficiency anemia.
   b. If confirmed, reinforce dietary counseling, continue iron treatment and recheck hemoglobin or hematocrit in one month.
2. Continue iron supplementation for 2 to 3 months after hemoglobin/hematocrit has normalized.
3. Reassess approximately 6 months after successful treatment is completed.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is referred to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. For patient with presumptive iron deficiency anemia, refer to physician if treatment has been given as directed and Hgb/Hct levels are not improving or have not returned to normal values after one to two months.
2. Refer if known HIV infected patient.
3. Chronic nosebleeds and/or GI bleeding.
4. For prevention of iron deficiency, in a term breastfed infant at least 6 months of age and not receiving sufficient iron from complementary foods (e.g., greater than or equal to 2 servings of iron-fortified infant cereal), refer to physician for consideration of iron supplementation to prevent deficiency.
5. For prevention of iron deficiency, in breastfed preterm or low birth weight infant between 1 and 12 months of age and not receiving oral iron supplementation, refer to physician for iron supplementation evaluation.
6. For prevention of iron deficiency, in formula fed preterm infant in first year of life, and not receiving oral iron supplementation or vitamin preparation with iron, refer to physician for evaluation.
7. Infant less than 6 months of age with abnormal hemoglobin or hematocrit.

8. All ages with hemoglobin less than 9 grams or hematocrit less than 27%.
9. Presence of sickle cell or other hemoglobin variants.
10. Refer to nutritionist and/or WIC if child is under 5 years old and meets criteria.
11. Consult with physician for any irregularity in response to therapy.

Elemental Iron Products and Dosages:

Weight	Elemental Iron Dosing by body weight is preferred. Acceptable dosing range is 3mg/kg/day to 6mg/kg/day (up to 150mg per day max dose)	Supplements should generally produce a hemoglobin rise of greater than 1 g/dL within four weeks. Check concentration closely prior to ordering/dispensing. Orders written in milliliters (mL) should be clarified by indicating the amount of elemental iron.	
Lbs (kg)	Dosages below are estimated ranges based on 4 mg/kg/day	Suggested Product Options	
15-25 (7-11kg)	28mg-44mg	220 mg (44 mg iron) per 5 mL[6]	Ferrous Sulfate Elixir
		300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		75 (15 mg iron) per mL	Ferrous Sulfate Solution
		125mg (25mg iron) per mL	Ferrous Sulfate Drops (Fer-Gen-Sol®Drops)
		75 (15 mg iron) per mL	Ferrous Sulfate Drops e.g., Fer-In-Sol® (with alcohol 0.02%)
26-32 (12-14kg)	48mg-56mg	220 mg (44 mg iron) per 5 mL [6]	Ferrous Sulfate Elixir
		300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		75 (15 mg iron) per mL	Ferrous Sulfate Solution
		125mg (25mg iron) per mL	Ferrous Sulfate Drops (Fer-Gen-Sol®Drops)
		75 (15 mg iron) per mL	Ferrous Sulfate Drops e.g. Fer-In-Sol ®(with alcohol 0.02%)
33-39 (15-17kg)	60mg-68mg	300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		220 mg (44 mg iron) per 5 mL [6]	Ferrous Sulfate Elixir
		15 mg iron	Carbonyl Iron Tablets, chewable Iron Chews Icar® Pediatric
		15 mg iron per 1.25 mL	Carbonyl Iron Suspension Icar® Pediatric
40-43 (18-19kg)	72mg-76mg	220 mg (44 mg iron) per 5 mL [6]	Ferrous Sulfate Elixir
		300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		15 mg iron per 1.25 mL	Carbonyl Iron Suspension Icar® Pediatric

[6] Available from one or more manufacturer, distributor, and/or repackager by generic (nonproprietary) name.

Weight	Elemental Iron Dosing by body weight is preferred. Acceptable dosing range is 3mg/kg/day to 6mg/kg/day (up to 150mg per day max dose)	Supplements should generally produce a hemoglobin rise of greater than 1 g/dL within four weeks. Check concentration closely prior to ordering/dispensing. Orders written in milliliters (mL) should be clarified by indicating the amount of elemental iron.	
Lbs (kg)	Dosages below are estimated ranges based on 4 mg/kg/day	Suggested Product Options	
44-52 (20-23kg)	80mg-92mg	15 mg iron per 1.25 mL	Carbonyl Iron Solution Icar Pediatric
		300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		325 mg (65 mg iron) [6]	Ferrous Sulfate enteric-coated tablets
		325 mg (65 mg iron) [6]	Ferrous Sulfate film-coated tablets
		160 mg (50 mg iron)	Ferrous Sulfate, Dried: Tablet, extended-release Slow FE®
		200 mg (65 mg iron)	Ferrous Sulfate, Dried: Tablet Feosol®
		45 mg (of iron)	Carbonyl Iron Tablets Feosol® Caplets
53+ (24kg+)	96mg-150mg	300 mg (60 mg iron) per 5 mL	Ferrous Sulfate Syrup
		325 mg (65 mg iron) [6]	Ferrous Sulfate enteric-coated tablets
		325 mg (65 mg iron) [6]	Ferrous Sulfate film-coated tablets
		160 mg (50 mg iron)	Ferrous Sulfate, Dried: Tablet, extended-release Slow FE®
		200 mg (65 mg iron)	Ferrous Sulfate, Dried: Tablet Feosol®
		45 mg (of iron)	Carbonyl Iron Tablets Feosol® Caplets
		324 mg (106 mg iron) [6]	Ferrous Fumarate Tablet Hemocyte®

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STANDARD NURSE PROTOCOL FOR OTITIS EXTERNA

DEFINITION

Inflammation of the external auditory canal and auricle caused by a variety of infectious agents.

ETIOLOGY

The most common cause of otitis externa is accumulation of water in the ear, leading to maceration and desquamation of the lining and conversion of the pH from acid to alkaline (e.g., swimming or frequent showers). It also may be initiated by trauma from scratching (fingernail or cotton-tipped applicator) or poorly fitting earplugs for swimming. It may also accompany the chronic drainage from a perforated eardrum.

NOTE: It is unusual for an infant to be diagnosed with otitis externa. Before making this diagnosis in an infant, other causes of ear drainage and pain should be ruled out, including perforated otitis media and mastoiditis.

Common causative agents are *Staphylococcus*, *Pseudomonas* species and fungi, such as *Candida albicans*.

SUBJECTIVE

1. Patient may report:
   a. Pain and itching in ear(s).
   b. Purulent discharge from ear.
   c. Occasionally, decrease in hearing, or a sensation of obstruction in the ear(s).

OBJECTIVE

1. Pain aggravated by movement of the pinna or tragus (the most common finding).
2. Ear canal may be swollen and erythematous. The patient may be resistant to any attempt to insert an ear speculum.
3. Debris and exudate may be seen in the canal; the drum may be impossible to visualize in severe cases due to swelling.
4. Pre-auricular and/or post-auricular lymph nodes may be enlarged.
5. Swelling or pain over the mastoid should NOT be observed in uncomplicated otitis externa.

ASSESSMENT Otitis externa

PLAN

DIAGNOSTIC STUDIES

NOTE: Tympanogram is contraindicated due to pain and need to avoid pressure.

THERAPEUTIC

1. Therapy centers around the basic principles of 1) local cleaning of debris and drainage of infection, 2) restoration of the normal acidic protective barrier, 3) judicious use of appropriate local and/or systemic antibiotics, and 4) patient education to prevent recurrent infection.

PHARMACOLOGIC

NOTE: Desquamated epithelium and moist cerumen may need to be removed by gentle irrigation before treatment.

1. For patients with an intact tympanic membrane:

    a. Children 1 year of age or older: Cortisporin otic suspension (not the solution), instill 3 drops in affected ear canal(s) 3-4 times a day for 10 days.

    OR

    b. Children 1 year of age or older, Cipro HC otic suspension, 3 drops in the affected ear canal(s) twice daily for 7 days.

For each medication above, the bottle of medication should be warmed in hands for 1-2 minutes to assist with decreasing dizziness that can happen when cold medications are instilled. Shake suspension well immediately before use. The head should lie with the affected ear upward for medication instillation and stay in that position for 1- 5 minutes to facilitate penetration of the drops into the ear canal.

Proper installation of ear drops entails tilting the head toward the opposite shoulder, pulling the superior aspect of the auricle upward, and filling the ear canal with drops. In young children, the earlobe should be pulled downward to fill the canal.

2. May take age-appropriate doses of acetaminophen or ibuprofen for pain.

NON-PHARMACOLOGIC

Local cleaning is regarded by most otolaryngologists as an essential component of treatment. This is not easily accomplished in small children because of the tenderness of the ear canal. If the child will tolerate gentle irrigation with warm, dilute (1:1) peroxide solution that would be beneficial.

If not tolerated, but the canal is not totally obscured by exudates, it is reasonable to treat with antibiotic drops as advised below and follow-up by telephone in 24 hours. If there has been no improvement, then referral for debridement and instillation of a wick would be indicated.

PATIENT EDUCATION/COUNSELING

1. Preventing external otitis may be necessary for individuals susceptible to recurrences, especially children who swim. The most effective prophylaxis is to place 2 or 3 drops ethyl alcohol 70% 1:1 solution with acetic acid 2% (household white vinegar) in the ear canal immediately after swimming or bathing. OTC commercially prepared drops (such as Swim Ear and Auro-Dry) are also available. Place 4-5 drops into affected ears after bathing, showering, and swimming.
2. Counseling is provided regarding the causes of otitis externa, administration of ear drops, and signs and symptoms which indicate the need for further evaluation.

3. Swimming, particularly during the acute phase, should be avoided for at least 7-10 days. Bathing should be done in such a way as to keep the head out of the water, to avoid introducing soapy water and dirt into the ear canal.

4. Keep fingers and instruments (e.g., cotton swabs) out of the ear canals. There is no need to clean canals with swabs.

5. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. Follow-up visit in one to two weeks to assess and document effectiveness of treatment.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Severe pain, fever or swelling of canal extensive enough to prevent instillation of drops. A cotton wick may be required.
2. Cellulitis of ear or surrounding tissue.
3. Patients with diabetes or other conditions predisposing them to more severe infection.
4. Failure to respond to treatment in 3 days (24 hours if significant exudate was present and local debridement was not tolerated).

5. More than one recurrence.
6. Tympanic membrane is perforated, not intact or not visualized.
7. Refer child less than 1 year of age.

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STANDARD NURSE PROTOCOL FOR PEDICULOSIS CAPITIS (HEAD LICE)

DEFINITION

Pediculosis Capitis is the infestation of the scalp and hair by head lice (Pediculus humanus capitis). Most commonly occurs in school-age children because they have very close head to head contact. Head lice are not a sign of poor hygiene nor are they a health hazard. Lice do not cause the spread of any disease.

ETIOLOGY

An adult head louse measures 2-3mm long (the size of a sesame seed), is greyish white to tan in color and has 6 legs. The female louse can live up to 3-4 weeks and can lay up to 10 eggs per day. The eggs are firmly attached to the hair very close to the scalp usually within 4-5 mm by a glue-like substance produced by the female louse. The eggs are difficult to see because they are camouflaged by pigment to match the hair color. They are most easily identified at the posterior hairline. Empty egg casings (nits) are easier to see because they are white in color. The eggs require body heat to incubate and usually hatch within 7-12 days. After hatching a nymph will reach adult stage in 9-12 days. Females can begin laying eggs 1.5 days after reaching adulthood. Head lice survive by feeding on small amounts of human blood. They cannot survive if away from the scalp for more than a day. In addition, their eggs cannot hatch if away from the warm temperatures near the scalp.

Transmission occurs primarily by direct head-to-head contact with an actively infested person, and much less frequently by contact with infested objects such as hairbrushes, head gear, clothing, carpets, upholstered furniture and beds. Lice can only crawl; they do not jump or hop. Pets do not play a role in transmission of human lice. Combing dry hair can generate static electricity that may eject an adult louse up to 1 meter. Control measures should focus reducing the number of live lice on the head and limiting head-to-head contact.

SUBJECTIVE

1. Patient reports:
   a. Itching.
   b. Rash.
   c. Nits or adult lice seen.
   d. May give history of exposure to lice.

OBJECTIVE

1. Identifying adult lice, nymphs or nits on the scalp establishes the diagnosis.
2. Identification of live lice or eggs attached to head hair, eyebrows or eyelashes. Adult lice are hard to find, often less than 12 per patient. Eggs are

grayish to brown in color (pigmented). Hatched nits (empty egg cases) are translucent or whitish in color.

3. Common sites are the back of the head and behind the ears. Eggs are firmly attached to the hairs and cannot be moved up and down the hair shaft like hair casts, scales and dandruff. Recently laid nits are usually, but not always close to the scalp within 1 cm.
4. Small red papules or secondary excoriations to the scalp, nape.
5. Occipital or cervical lymphadenopathy may be present.

ASSESSMENT Pediculosis capitis (Head lice)

PLAN

THERAPEUTIC

PHARMACOLOGIC

Pediculicide resistance, particularly to pyrethroids and malathion, is an increasing concern.

The treatment choice should consider local resistance patterns (follow CDC Guidelines), agent-specific side effects, patient age, and treatment cost.

NOTE: Only patients with live infestations should receive treatment.

Instruct pregnant or breastfeeding females to consult with their physician before using any pediculocides. Instruct person applying pediculocide to wear gloves, to avoid direct contact with product.

1. Front-line treatment options (for patients with active infestations who are not suspected to have head lice that are resistant to permethrin or pyrethrins):

    a. Permethrin 1% cream (NIX). Although NIX is FDA approved for infants at least 2 months old, non-pharmacologic methods should be attempted first. Do not use NIX on patients who are allergic to synthetic pyrethroid, or pyrethrin, or any of its components, or chrysanthemums.
        1) Apply NIX to shampooed, rinsed and towel dried hair (make sure to use non-conditioning shampoo). Hair should be damp, not wet.
        2) Saturate the hair and scalp with NIX crème rinse. Not using enough pediculocide can result in treatment failure. Keep NIX out of eyes, nose, and mouth. Keep eyes closed and protect with a washcloth.
        3) Leave on for 10 minutes but not longer. Use a timer.
        4) Rinse NIX out with warm water and towel dry.
        5) Follow Therapeutic measures in non-Pharmacologic section.

Treatment with NIX may temporarily exacerbate pruritus, erythema, or edema. Patients may experience mild transient burning/stinging, tingling, numbness, or scalp discomfort. If any reaction persists, refer patient to a private care provider.

NOTE: Re-treatment on day 9 is recommended to kill any surviving hatched ice.

OR

b. Pyrethrins with piperonyl butoxide (such as nonprescription A-200, Pronto and RID shampoo). Do not use on patients allergic to pyrethrins, chrysanthemums or ragweed.

NOTE: Only FDA approved for children aged 2 years and older. Keep away from fire, open flame, or excessive heat.

1) Begin with completely dry hair. First apply behind the ears and to the back of the neck. Saturate hair and scalp with solution. Not using enough pediculocide can result in treatment failure.
2) Wait 10 minutes, but no longer; use a timer.
3) Add warm water to form lather, and rinse thoroughly. Keep product out of eyes, nose and mouth. Keep eyes closed and protect with a washcloth.
4) Follow Therapeutic measures in Non-pharmacologic section.

NOTE: Re-treatment is recommended on day 9 to kill any hatched lice.

2. If front line therapy medications are ineffective, the following medications are alternative options that can be used to treat head lice that may be resistant to previous treatments. (Safety concerns and side effects of these medications can be eliminated or reduced if used appropriately).

a. Sklice® (Ivermectin lotion). Patients 6 months of age or older; do not use in pregnant patients.
   1) Apply enough (up to 1 tube) to completely cover dry scalp and hair; for single dose use only. For external use only.
   2) Apply to dry scalp and hair closest to scalp first, then apply outward towards ends of hair; completely covering scalp and hair.
   3) Leave on for 10 minutes (start timing treatment after the scalp and hair have been completely covered).
   4) The hair should then be rinsed thoroughly with warm water. Avoid contact with the eyes. Nit combing is not required, although a fine-tooth comb may be used to remove treated lice and nits. Lotion is for one-time use; discard any unused portion. May cause skin or eye irritation.

OR

b. Malathion (e.g., prescription Ovide®, prior authorization may be required). Do not use on patients under age 6 years or those with asthma. Direct

supervision by an adult is required. Maximum of 2 fl. oz.

1) Apply carefully to dry hair; completely saturate the scalp and hair. Change child into clean clothing once the malathion has been applied. Keep product out of eyes, nose and mouth. Keep eyes closed and protect with a washcloth.
2) Allow hair to dry naturally; do not use a hair dryer or another electric heat source. Malathion is flammable. Warn to stay away from lighted cigarettes, open flames, and electric heat sources. Do not cover head with a cap or other occluding material.
3) Consider applying at bedtime and covering the sleeping pillow with a towel. Leave 8 hours, then shampoo and rinse thoroughly. Set a reminder to shampoo and rinse thoroughly.
4) Malathion is highly ovicidal but may not kill all lice eggs. If live lice are seen in 7 to 9 days, repeat Malathion treatment.

3. For itching, may give diphenhydramine (Benadryl) which may cause drowsiness. (Contact physician before administering diphenhydramine to a child under 2 years of age).

   The non-sedating antihistamines appear to have only a very modest influence on itching.

   a. Children 2 through 5 years of age: Diphenhydramine hydrochloride elixir 12.5 mg/5mL. May give 6.25 mg every 4 to 6 hours; do not exceed 37.5 mg/day.
   b. Children 6 through 11 years of age: Diphenhydramine hydrochloride elixir 12.5 mg/5mL. May give 12.5mg to 25 mg every 4 to 6 hours; do not exceed 150 mg/day.
   c. Adults and children 12 years of age and older: Diphenhydramine hydrochloride 25-50 mg orally 3 or 4 times a day (not to exceed 300 mg/day). Do not give in third trimester of pregnancy or to breastfeeding mother.

4. Evidence of secondary infection requires systemic antibiotic treatment. The patient should be assessed for impetigo treatment or physician referral.

NOTE: Manual removal of nits is advised because pediculocides are not 100% ovicidal, because resistance to pediculocides is increasing, and to avoid diagnostic confusion, which can result in overtreatment with pediculocides. Successful elimination and prevention of head lice infestation is important in effort to limit exposure to pediculocides, which are costly and, in some cases, ineffective. Additionally, in a recent study, these products were found in the urine of school children in Georgia, and the long-term effects of exposure to pediculocides is unknown.

NON-PHARMACOLOGIC MEASURES

1. Remove nits with a nit comb working through very small sections of hair at a time. Fine toothed metal combs specifically made for removing nits work better for most persons. Be sure to comb the hair close to the scalp where most unhatched nits will be located. Wet hair combing is recommended over dry hair combing.

2. When rinsing, rinse over a sink to limit skin exposure and rinse with warm water (not hot water) to minimize vasodilation and systemic absorption

NOTE: Wet hair may slow the lice making them easier to find and remove. Dry combing can cause a build-up of static electricity which has been reported to physically eject an adult louse from the head more than 1 meter.

Check for lice and nits on the comb and clean the comb often. The hair should be combed thoroughly and meticulously with fine tooth comb, focusing on small areas of hair at a time. Use good lighting and look carefully for lice and nits by parting off small sections of hair and drawing firmly down from the scalp and examined for lice after each stroke . If possible, check outside in daylight. Continue daily nit combing on wet hair with the entire head combed systematically at least twice per day. Combing is done until no lice are found in each session; Repeat every 3-4 days for several weeks and an additional 2 weeks after last large adult louse is found.

Wet combing is an alternative intervention primarily for very young infants and for patients who prefer to avoid pediculocides.

3. It is important that all other close contacts are checked by a trained person and treated if active infestation is found. If possible, treat all infested persons at the same time. If checking close contacts by a trained person is not practical, advise combing wet hair with a nit comb and then checking the teeth of the comb, to improve detection of live lice and nits.

4. Environmental interventions are directed towards items that the infested person has been in contact with during the 48 hours prior to treatment.
   a. Launder clothing, bedding, towels and other items that have been used by the infested person in the past 2 days in hot water and/or dry on high heat for 20 minutes. Items that are not washable can be dry cleaned or sealed in a plastic bag and stored for 2 weeks.
   b. Vacuum furniture, floorings, car seats and other fabric covered items. Fumigation of the home is not recommended and can be toxic.
   c. Soak brushes, combs and hair accessories in hot water (at least 130 degrees Fahrenheit) for 10 minutes.

5. Mild topical antipruritic/anti-inflammatory cream or ointment may be obtained over the counter for itching. May interfere with effectiveness of topical ointment.

6. Evidence of secondary infection requires systemic antibiotic treatment. The patient should be assessed for impetigo treatment or physician referral.

PATIENT EDUCATION/COUNSELING

1. Instructions vary for pediculocide products. Follow product instructions. If re-treatment is recommended in 7 to 10 days, re-treat on day 9. Exception: Natroba -re-treat if live lice are seen 7 days after first treatment.

2. Stress importance of checking all other close contacts and treating infested contacts at the same time to prevent re-infestation.

3. Do not use conditioners, shampoo/conditioner combinations or crème rinses on hair prior to treatment Do not re-wash hair for 1-2 days after the lice medication is removed. Exception: If using Natroba may shampoo hair immediately after treatment. Exception: can use if just using wet combing technique only.

4. Teach importance of using pediculocides as instructed. It is important to completely saturate the hair and scalp with pediculocide, be sure to include behind the ears and at the back of the neck.

NOTE: Inadequate treatment can sometimes be mistaken for drug resistance.

5. Do not get pediculocides and other chemicals in the eyes, nose, or mouth. Cover eyes and face with towel. Instruct child to close eyes tightly. If pediculocide gets in the eyes, flush the eyes with large amounts of cool water immediately and seek medical care.

6. All topical pediculicides should be rinsed from the hair over a sink rather than in the shower or bath to limit skin exposure. Instruct patient to rinse with warm rather than hot water to minimize absorption.

7. Using vinegar: water solutions and other products after NIX may interfere with effectiveness and are not recommended.

8. Using a hair dryer alone, will not eliminate a head lice infestation. Malathion is flammable.

9. Home remedies to control head lice, (e.g., vinegar, mayonnaise, petroleum jelly, olive oil, isopropyl alcohol, butter, and water submersion up to 6 hours**)** have not been proven effective in killing lice or eggs. Lice do not have air sacs or lungs and are not easily suffocated. Lice can survive for prolonged periods without air.

10. Chemicals such as gasoline and kerosene, or animal products should never be used.

11. Do not use more than one pediculocide product at a time.

12. Itching may persist for 1-2 weeks even after adequate treatment and should not be considered a reason for reapplication of medication.

13. Avoid head-to-head or hair-to-hair contact. This is the most common mode of transmission. Other ways to prevent transmission include:
    a. Do not share combs, brushes, or head gear/coverings with other persons.
    b. Hang coats where they do not touch those of other persons.
    c. Do not lie on furniture, pillows, stuffed animals, or other items that have recently been used by an infested person.
    d. Practice good handwashing and cleaning under fingernails to prevent transmission especially after scratching.
    e. Avoid sleepovers and slumber parties during lice outbreaks.

14. General Hair Care Recommendations:
    a. Shaving a child's head or cutting the hair very short is not necessary to eliminate the infestation.
    b. Modest shortening of the hair to a length acceptable to both the child and the parent will make combing easier.

15. Assure that head lice infestation is a common problem in the school-age population and affects children of all socio-economic groups.

16. Instruct caregiver that child may return to daycare or school the next day after first treatment for head lice. It is not recommended that child be excluded from school based on the presence of nits.

17. Teach as with all medications, to keep pediculocides safely stored, locked out of reach of children. Pediculocides should be used under direct adult supervision.

18. Do not swallow pediculocides. If swallowed, contact Poison Control Center immediately.

19. Contact clinic if any problems obtaining medications or questions about treatment.

20. Return to clinic if active infestation is suspected after completion of treatment.

FOLLOW-UP

1. Assess if infestation is active.

2. Evaluate adherence with treatment plan and response to therapy. Possible reasons for treatment failure include inadequate treatment, resistant lice, re-infestation. Re-treatment may be necessary. Reinforce teaching. Consider use of an alternate regimen if not responding to treatment.

CONSULTATION/REFERRAL

NOTE**:** Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (When a patient is REFERRED to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Consult with physician regarding any question of management or multiple reoccurrences.

2. Refer patient if pregnant or breastfeeding.

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STANDARD NURSE PROTOCOL FOR PINWORMS

DEFINITION

Pinworms are parasitic nematodes causing infestation of the intestines and rectum. Pinworms are the most common human worm infection in the United States and worldwide**.** Pinworms are indigenous to the climate of the southern United States, usually affecting young children and their families. Adult worms are 2-13 mm long and live in the intestines. Females deposit eggs on the perianal area, primarily at night, causing intense pruritus. Scratching contaminates the fingers and allows transmission back to the host or to contacts.

ETIOLOGY

The nematode, *Enterobius vermicularis.*

SUBJECTIVE

1. Patient may complain of the following symptoms:
   a. No symptoms
   b. Nocturnal perianal pruritus is the primary symptom.
   c. Restlessness and disturbed sleep are common.
   d. Young females may experience genital irritation with vulvovaginitis and dysuria.
   e. History of caretaker's observation of worms in anal area at night while child is sleeping.
   f. Anorexia, enuresis, insomnia, and grinding teeth during sleep.

OBJECTIVE

1. Observation of pinworm(s) during exam
2. May have local irritation or secondary infection of scratched skin
3. Normal exam

ASSESSMENT Pinworms

PLAN DIAGNOSTIC STUDIES

NOTE**:** Diagnosis based on symptoms and exam findings is sufficient; diagnostic test is optional.

1. Laboratory identification of eggs from perianal area: Apply transparent adhesive tape to the perianal area to pick up any eggs; apply tape to a glass slide and examine under a low-power microscope. A single test will usually detect 50% of infestations, 3 tests should detect 70%, and 5 tests should detect 100%. (Obtain specimens in the early morning before patient bathes or

defecates).

THERAPEUTIC

PHARMACOLOGIC

If not taking piperazine or theophylline, and patient does not have liver disease, anemia or malnutrition, the following is an option but may have the following side-effects: anorexia, nausea, vomiting, diarrhea.

1. Pyrantel pamoate (Pin-X, Reese's Pin Worm Medication, Pyrantel Pamoate Suspension), available as a suspension of 144 mg/mL (equivalent to pyrantel base 50 mg/mL) or a Chewable tablet 720.5 mg (equivalent to pyrantel base 250 mg).

   Dosing: 11mg**/**kg pyrantel base/kg (maximum 1 gram). Administered orally as a single dose. Dosage should be repeated after 2 weeks. Dosing chart is below.

Pyrantel Dosing (Give as a Single Dose) in Children [7]		
Weight range lb (kg)	Number of chewable tablets (250mg)	Amount of suspension (mL) (50mg/mL)
25-37lb (11-16 kg)	½	2.5
38-62lb (17 -28kg)	1	5
63-87lb (29-39 kg)	1½	7.5
88-112lb (40-50kg)	2	10
113-137lb (51-62kg)	2½	12.5
138-162lb (63-73kg)	3	15
163-187lb (74-84kg)	3½	17.5
188lb and greater (85kg and greater)	4	20

NOTE: If patient weighs less than 25lbs or is younger than 2 years old, refer to physician.

NOTE: The chewable tablet contains aspartame which is metabolized to phenylalanine and must be avoided in patients with phenylketonuria.

   a. The chewable tablet must be chewed thoroughly before swallowing.
   b. Dose may be taken with or without food. Drug may be mixed with milk or fruit juice.
   c. Repeat treatment once in 14 days.

d. Treat all household members simultaneously even if other household members are asymptomatic, with one of the above regimens, or refer for simultaneous treatment.
e. Other alternatives such as Abendazole or Mebendazole are cost prohibitive without adequate prescription drug coverage. In contrast, Pyrantel Pamoate without prescription is estimated to cost approximately $20 per course.

PATIENT EDUCATION/COUNSELING

1. Instruct parent to contact health department or consult their physician if medication side effects such as anorexia, abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness persist.
2. Hygienic precaution is essential to prevent reinfection. Emphasize the importance of personal hygiene, particularly hand washing before eating or preparing food and after using the toilet/changing diaper; do not scratch the infected area or place fingers in mouth.
3. Daily used bed linens, towels, underclothes, and clothes of symptomatic family members should be washed in hot water at time of treatment and daily until infection is cleared.
4. Upholstered furniture and carpet should be vacuumed. Other flooring should be wet mopped.
5. Shower immediately upon rising for several mornings after treatment. Showering is preferred over bathing because it avoids contaminating bath water with pinworm eggs. Also, discourage co-bathing.
6. Keep fingernails trimmed short.
7. Wear snug fitting underwear to deter direct contact by scratching.
8. Petroleum jelly applied at the perianal area may decrease egg dispersal.
9. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. If no improvement in 1 month.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Child under 2 years of age or weighing less than 25 pounds.
2. Pregnant or lactating.
3. Patients with any that are contraindications for treatment; patients who are on medications that adversely interact with pyrantel pamoate.
4. Patients who develop side effects from treatment.

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STANDARD NURSE PROTOCOL FOR RINGWORM: NON-HAIRY SKIN (TINEA CORPORIS)

DEFINITION

Superficial fungal infection involving the face, trunk or limbs.

ETIOLOGY

Several different fungi. Transmitted by direct contact with an infected person, animal, or contaminated articles.

SUBJECTIVE

1. Pruritus (common) but patient may be asymptomatic.

OBJECTIVE

1. Erythematous scaling patches to the skin on body (usually 1-2) that are round or oval. The lesions start small, then expand outward with clearing of the eruption in the center of the patch and activity restricted to the border of the lesion, as a ring. The border of the lesion is usually raised and scaly but may include small pustules or vesicles. Appearance of lesions are sometimes altered by prior application of topical corticosteroids and can mislead the examiner. Lesions are most common on the trunk, face, and arms.

2. Granuloma annulare can mimic tinea corporis. The distinguishing feature of tinea is the scale which may be subtle and delicate but will always be present with untreated tinea. If the scale is not present and there is only one isolated lesion, refer patient to their pediatrician to rule out Lyme Disease (not the most common cause of Granuloma Annulare but the most serious cause).

ASSESSMENT Tinea corporis (ringworm of the skin)

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Apply a non-prescription topical anti-fungal preparation. May choose one of the following for patients 2 years of age and older:

    a. Clotrimazole 1% (e.g., Lotrimin, available as Lotrimin AF, cream, or solution). Apply to affected areas twice daily for 4 weeks.

OR

b. Miconazole nitrate 2% (e.g., Micatin), cream. Apply to affected areas twice daily for 4 weeks.

OR

c. Patient's 12 years of age and older: Ketoconazole 2% cream. Apply to affected areas once daily for 2-4 weeks.

2. If patient can't use any of the above:
   a. Tolnaftate 1% (e.g., Tinactin), cream or solution. Apply to affected areas twice daily for 4 weeks.

   OR

   b. Naftifine (Naftin®) 2% cream: Apply a thick layer once daily to affected area and healthy surrounding skin (1/2 inch margin) for 2 weeks.

PATIENT EDUCATION/COUNSELING

1. Contacts of infected persons should perform periodic inspections for signs of infection and seek medical evaluation as needed.
2. Avoid direct contact with known sources of infection. Infected animals need veterinary examination.
3. Do not share clothing. Launder and dry clothing on hottest acceptable temperatures.
4. Advise against OTC corticosteroid topical medications, they will exacerbate lesions.
5. Keep lesions dry. Fungi thrive in moist areas.
6. Avoid tight fitting clothing and clothing that restricts air movement. Cotton clothing is preferable.
7. Children generally can return to school after applying medication to affected area(s) for at least 24 hours.
8. It is important to apply the topical antifungal for the length of therapy ordered**,** even if the rash clears in less than the length of therapy ordered, to prevent recurrence.
9. Return to clinic if no significant improvement in 7 to 9 days.
10. Return to clinic sooner if lesions worsen.
11. Contact clinic if any problems obtaining medication.

FOLLOW-UP

1. 1-2 weeks if no improvement.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (When a patient is REFERRED to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Children less than 2 years of age.

2. Severe or widespread infection.

3. Secondary bacterial infection.
4. Failure to respond to treatment may require oral therapy. Also, several skin conditions can closely mimic ringworm, these include: granuloma annulare, nummular eczema, pityriasis rosea, psoriasis, seborrheic dermatitis, tinea versicolor, erythema chronicum migrans, and early Lyme disease.

NOTE: If there has been tick exposure, refer to physician immediately. Early Lyme disease is an urgent diagnosis.

5. If present on scalp (tinea capitis).

6. Pregnant or breastfeeding patient.

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STANDARD NURSE PROTOCOL FOR RUBRAL/HEAT RASH

DEFINITION

Heat rash ("prickly heat") is characterized by an erythematous papular rash, distributed in areas where sweat glands are concentrated. Obstruction of the eccrine sweat ducts occurs often in neonates and often produces one or two clinical pictures depending on the level of obstruction:

1. Miliaria crystallina is characterized by tiny (1-2 mm), superficial grouped vesicles, without erythema, over intertriginous areas and adjacent skin (neck, upper chest). Obstruction occurs in the stratum corneum portion of the eccrine duct.

2. Miliaria rubra is more common. Obstruction of the eccrine duct deeper in the epidermis results in erythematous, grouped papules in the same area. Rarely, these may progress to pustules.

ETIOLOGY

This rash result from obstruction of the ducts of the sweat glands. The ducts become distended and break, leaking sweat into the skin, which causes the irritation. Heat and high humidity in the external environment cause sweating that leads to swelling and plugging of the sweat gland orifice.

SUBJECTIVE

1. Patient (or parent/guardian) may complain of:

    a. Fine, red raised rash on child. Pustules under neck and armpits may be present.
    b. Itching.
    c. History of over-dressing.
    d. History of predisposing environmental factors (e.g., hot spells in summer or house kept too warm).

OBJECTIVE

1. Rash is erythematous and vesiculopapular. Lesions are pinhead size and may coalesce on an erythematous patch or remain isolated. The sudden appearance of red patches of small papules and/or vesicles are discrete and accompanied by red areolae.

2. Rash is distributed in areas of sweat gland concentration and friction: over the trunk, neck, back of head, shoulders, chest, axillae, face, antecubital and popliteal fossae, and intertriginous areas.

ASSESSMENT Rubral/heat rash, according to lesion appearance and history (hot, humid environment).

1. Differentiate from:
   a. Contact dermatitis (history of contact, distribution in area of contact, edematous, erythematous, and vesicular lesions)

   b. Viral rashes (history of elevated temperature or other systemic symptoms)

   c. Candidiasis (shiny, intensely inflamed, sharply defined border, and satellite lesions)

   d. Erythema toxicum neonatorum (raised yellow or white spots surrounded by red skin, usually appears within 2 days of life and self resolves by 14 days of life)

   e. Neonatal acne

   f. Bacterial folliculitis (Staphylococcus, Pseudomonoas) or sterile folliculitis

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. In severe cases especially with miliaria rubra, may nonprescription 1% hydrocortisone cream as a thin film and rub in gently two times a day for 1-2 weeks. This regimen can reduce significant inflammation.

NON-PHARMACOLOGIC MEASURES

1. Avoid overdressing the child. The parent should dress the child as she/he would dress self for weather conditions.
2. Avoid hot, humid conditions. Keep patient in cool and dry environment as much as possible. Use air conditioner, fan and/or dehumidifier, if possible.
3. Keep patient's skin clean and dry.
4. Bathe patient in tepid water for cooling.

PATIENT EDUCATION/COUNSELING

1. If hydrocortisone cream used, apply sparingly.
2. Use mild or hypoallergenic soap for bathing.
3. Use mild detergents to launder clothes and avoid bleach and fabric softeners.
4. Keep patient's fingernails short.
5. Avoid dressing patient with **(**or placing patient in contact with**)** irritating

clothing (e.g., synthetic fabrics, wool, nylon, plastic liners). Light cotton clothing is preferred.
6. Avoid extended sun exposures.
7. Return for reevaluation if condition does not improve with proper management.

FOLLOW-UP

1. No follow-up needed if symptoms resolve within 2 weeks.
2. Re-evaluate if symptoms persist or worsen beyond 2 weeks.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. If there is no improvement with treatment.

2. Exacerbation of the rash (increased inflammation/ appearance of bacterial superinfection).

3. Pregnant or breastfeeding patient.

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STANDARD NURSE PROTOCOL FOR SCABIES

DEFINITION

Infestation with the *Sarcoptes scabiei* mite. The initial skin lesion is a burrow made by an impregnated female to lay her eggs. It appears as a fine, wavy, dark line boring from a few mm to 1 cm in length, with a minute papule at the open end. Papules or vesicles contain the mite. After several days, sensitivity to the mite results in intense pruritus followed by punctate excoriations from scratching, and possible development of impetiginous and eczematous changes at the site of the lesions. A generalized urticarial rash may also develop.

The condition is highly contagious and is spread predominately by skin-to-skin contact and to a lesser degree by contact with contaminated clothing or linens. Transmission to household members and sexual contacts is frequent. Outbreaks in schools, day care centers and nursing homes have occurred.

ETIOLOGY

The *Sarcoptes scabiei* mite. The female is about 0.44 mm long and has 4 sets of legs. The male is about half her size. Fertilization occurs on the skin surface. The impregnated female burrows into the stratus corneum and lays 1-3 eggs daily throughout her 30-day life cycle. Mites do not survive more than 3 days away from the skin. The eggs hatch in 3-5 days and the larvae return to the skin to grow, molt and mature.

In persons without previous exposure the incubation period is approximately 4 to 6 weeks. Thus, itching and lesions may be unapparent during the initial infestation and these persons are asymptomatic carriers. Repeat infestations generally lead to more rapid development of symptoms within 1 to 4 days.

Pruritus is secondary to a delayed hypersensitivity reaction to mite feces and eggs, not to the physical presence of the mite itself. Once sensitized, the host reacts much more quickly with an immune response.

SUBJECTIVE

1. Patient has:
   a. Intense itching, most severe at night
   b. Rash
   c. History of known exposure to scabies or of several family/group members having a similar itchy rash

OBJECTIVE

1. Observation of burrows and red papular vesicles or pustules, distributed

according to age:

a. Infants: palms, soles, neck, face, scalp, legs, and buttocks are commonly affected. Burrows are absent and vesicles, pustules, bullae and eczematous lesions are common.

b. Older children, adolescents, and adults: The lesions begin in the interdigital spaces and spread to the wrist, elbows, ankles, buttocks, umibilicus, belt line, groin, genitalia, areola, female breast and axillae. The upper back, neck, face, scalp, palms and soles are usually spared.

    1) Red, itchy rash, pustules and excoriation.

    2) Secondary infection from scratching.

NOTE: Atypical forms of scabies do occur and can be related to such things as personal hygiene, by the presence of another skin disease or in altered immunologic response in patients suffering from malnutrition, or other neurologic or physical disorders/diseases (Norwegian scabies).

ASSESSMENT Scabies, based on history and suspicious lesions.

1. With appearance varying, differential diagnosis depends on the type of lesion present. Papulovesicular lesions can appear like: papular urticaria, chicken pox, drug eruptions, canine scabies, viral exanthems, dermatitis herpetiform, contact dermatitis from poison ivy, poison sumac, and folliculitis.

2. If the lesions are eczematous, atopic dermatitis, and seborrheic dermatitis must be ruled out. Nodular scabies may be misdiagnosed as urticaria pigmentosa, histiocytosis, and insect bite granuloma.

NOTE: Confirmatory diagnosis can be made microscopically.

PLAN

DIAGNOSTIC STUDIES

1. Microscopic visualization of the mite.
    a. The suspected lesion is immobilized between the forefinger and the thumb, and the top is removed with a Number 15 scalpel blade laid parallel to the skin surface, after a drop of mineral oil is placed on the skin. No anesthesia is required.
    b. The specimen is then placed on a glass slide, with a coverslip, and examined under low power for the mite, eggs or larvae.

NOTE**:** A scraping is not necessary when there is an intensely pruritic rash in the typical locations that meets any of the following additional criteria:

1) History of close contact with a known case of scabies
2) Burrows

THERAPEUTIC

PHARMACOLOGIC

1. Permethrin 5% Cream single application for children 2 months and older.
   a. Do not bathe or shower before applying the cream.
   b. Thoroughly massage into all skin from the neck down to the soles of the feet including under the fingernails and toenails avoiding contact with mucous membranes, eyes, and mouth. Also, include the head, scalp face and neck in infants and toddlers.
   c. Remove by washing after 8-14 hours. Thirty grams or half of a 60-gram tube should be sufficient for a child.
   d. Wear gloves when applying.
   e. One application is generally curative; however, the treatment may be repeated once one week later. Optimal time to repeat is at day 9 based on the life cycle of lice. Demonstrable living mites after 7 days indicate that retreatment is necessary.

NOTE: Patients often experience pruritus after treatment. This is rarely a sign of treatment failure and is not an indication for retreatment.

NOTE: Worsening of asthma has been reported.

2. Cool baths with mild soap, nonprescription hydrocortisone cream topically or diphenhydramine (e.g., Benadryl) or hydroxyzine (not available over the counter) orally for itching, which may persist for several weeks.

   a. Topical Hydrocortisone cream OTC:
      1) Children greater than 2 years of age: Apply hydrocortisone cream to affected area(s) 2-4 times/day. Apply cream as a thin film and rub in gently. Avoid contact with eyes. May need medium to high potency cream or ointment to address pruritis that occurs after eradication of mites

      2) If medium potency cream or ointment is needed:
         a) Medium potency: Do not apply to face, groin (including diaper area), underarms, or areas with skin folds. Do not wrap, cover, or bandage affected area.
         b) 2 years and older: Hydrocortisone valerate ointment 0.2%, Apply to the affected skin areas once or twice daily for 5 to 7 days.

OR

c) 2 years and older: Mometasone furoate cream 0.1%, Apply a thin film to the affected skin areas once daily for 5 to 7 days

3) If high potency cream or ointment is needed:
   a) 2 years and older: Mometasone furoate ointment 0.1%, Apply a thin film to the affected skin areas once daily for 5 to 7 days

b. Diphenhydramine
   1) Children 2 years-5 years of age: Diphenhydramine hydrochloride elixir 12.5 mg/5 mL. May give 6.25 mg every 4 to 6 hours as needed for itching. Maximum Dose: 37.5 mg/day.
   2) Children 6-11 years of age: 12.5mg every 4 to 6 hours as needed for itching. Maximum Dose: 150mg/day.
   3) Children 12 years and older: 25-50mg every 4 to 6 hours as needed for itching. Maximum Dose: 300mg/day.

OR

c. Hydroxyzine (Vistaril®) 10mg/5ml or 10 or 25 mg tablet:
   1) 40kg or less: Oral: 2 mg/kg/day by mouth in divided doses every 6 to 8 hours only as needed; maximum dose 25mg/dose. Greater than 40kg: Oral: 25 to 50 mg by mouth once daily at bedtime or twice daily
   2) Contraindicated in prolonged QT interval.

NOTE: Dosing should be based on severity of symptoms. Do not use topical diphenhydramine. Contact physician before administering diphenhydramine or hydroxyzine to a child under 2 years of age.

NOTE: Lindane is no longer used due to risk of systemic toxicity that could lead to seizures, death.

NON-PHARMACOLOGIC MEASURES

1. Keep fingernails clean and well-trimmed.

2. While receiving pharmacologic treatment, launder all bedding, towels, wash cloths and clothing that have been in contact with the patient for the previous 4 days prior to treatment. Laundering should be done in hot water and drying in the hot cycle of the clothes dryer. If washing/drying is not possible, store the items (including shoes) in a plastic bag for 3 days to one week to avoid re-infestation.

PATIENT EDUCATION/COUNSELING

1. Encourage to wash hands often, clean under fingernails, wear clean clothes daily and not to exchange clothes with others.
2. Permethrin may temporarily increase itching, edema and redness. Mild and transient stinging and/or burning of the skin may also occur. These reactions are associated with the severity of the infestation.

3. The rash and pruritus of scabies may persist for up to 2 weeks after treatment.
4. Children should be allowed to return to school or child-care 24 hours after treatment has been completed.
5. Disinfecting the environment is unnecessary and unwarranted.
6. All close personal and household contacts within the preceding month need examination and prophylactic treatment at the same time as the patient. Manifestations of scabies infestation may not appear for as long as 2 months after exposure, during which time they can be transmitted.

FOLLOW-UP

1. Re-examine in one week. May re-treat once if no improvement, though single application of permethrin 5% cream is usually curative.
2. A patient symptomatic longer than 4 weeks after treatment should be re-evaluated for possible re-exposure.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. Severe/widespread infection, or secondary bacterial infection.

2. Infection of the scalp (usually infants).

3. Less than 2 months of age.

4. Pregnant or lactating.

5. Failure to respond to 2 rounds of permethrin treatment.

6. Immunocompromised patient.

7. Refer close personal contacts of index case for examination and prophylactic treatment at the same time as the index case.

8. Public Health Employees are required to report suspected child abuse including sexual abuse. All suspected child abuse must be reported in accordance with DPH Policy 09014: Mandatory Reporting of Suspected Child Abuse for Public Health Personnel.

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STANDARD NURSE PROTOCOL FOR TEETHING

DEFINITION

Inflammation of the gum tissue caused by eruption of primary teeth.

ETIOLOGY

In general, an infant's first tooth erupts at 6 months and one each month thereafter until all 20 have erupted. However, this is highly variable from child to child. One child might begin teething as early as 3 months, while another would not begin until age 12 months. The central lower incisors are usually the first to erupt.

SUBJECTIVE

1. Symptoms:
   a. The infant may be irritable and fretful.
   b. The infant may have decreased appetite.
   c. The infant may suck his fist, fingers, or other objects, more than usual.
   d. Some parents report increased drooling.

OBJECTIVE

1. Erupting teeth are sometimes preceded by a bluish discoloration of the proximal gum, a benign process.
2. Gums proximal to erupting tooth may be swollen.
3. Erupting tooth felt with finger or seen.
4. Teething associated with diarrhea, fever, and other illness is likely coincidental and further examination is warranted.
5. With increased drooling, rule out lesions in mouth and/or rash on hands and feet reflective of Hand, Foot and Mouth Disease.

ASSESSMENT Teething

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Systemic analgesia (acetaminophen or ibuprofen) in appropriate doses as listed in tables below. Ibuprofen preferred for teething if infant is older than 6 months, due to anti-inflammatory effect. Do not give acetaminophen and ibuprofen in an alternating fashion.

a. Ibuprofen children's solutions for children ages 6 months and older due to risk of harmful effects on kidneys. 5 to 10 mg/kg/dose. Dose may be repeated every 6 to 8 hours, not more than 4 doses in 24 hours.

NOTE: Treatment for more than 3 days is not recommended. No more than 4 doses in 24 hours should be given. Use the lowest effective dose for the shortest amount of time to reduce risk of adverse cardiovascular and GI effects. For infant drops use only the dropper provided.

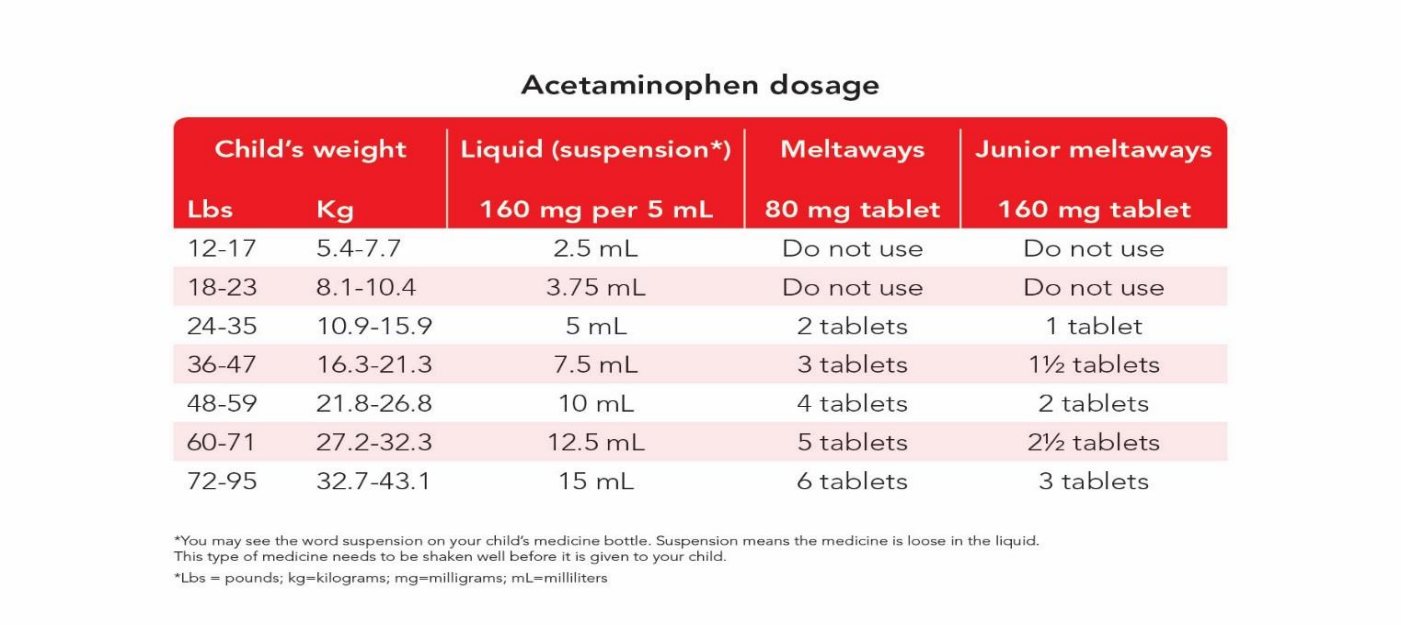
Ibuprofen dosage

Child's weight		Infant's drops	Liquid (suspension*)	Chewable tabs	Junior chewable tabs
Lbs	Kg	50 mg per 1.25 mL	100 mg per 5 mL	50 mg	100 mg
18-23	8.1-10.4	1.875 mL	Do not use	Do not use	Do not use
24-35	10.9-15.9	2.5 mL	5 mL	2 tablets	Do not use
36-47	16.3-21.3	Do not use	7.5 mL	3 tablets	1½ tablets
48-59	21.8-26.8	Do not use	10 mL	4 tablets	2 tablets
60-71	27.2-32.3	Do not use	12.5 mL	5 tablets	2½ tablets
72-95	32.7-43.1	Do not use	15 mL	6 tablets	3 tablets

*You may see the word suspension on your child's medicine bottle. Suspension means the medicine is loose in the liquid. This type of medicine needs to be shaken well before it is given to your child.

*Lbs = pounds; kg=kilograms; mg=milligrams; mL=milliliters

b. Acetaminophen children's liquid suspension 160mg/5mL dosage as listed in table below.
c. Dose is 10 to 15 mg/kg/dose every 4 to 6 hours as needed. Do not give more than 5 does in 24 hours. Use of weight to select dose is preferred.



Acetaminophen dosage

Child's weight		Liquid (suspension*)	Meltaways	Junior meltaways
Lbs	Kg	160 mg per 5 mL	80 mg tablet	160 mg tablet
12-17	5.4-7.7	2.5 mL	Do not use	Do not use
18-23	8.1-10.4	3.75 mL	Do not use	Do not use
24-35	10.9-15.9	5 mL	2 tablets	1 tablet
36-47	16.3-21.3	7.5 mL	3 tablets	1½ tablets
48-59	21.8-26.8	10 mL	4 tablets	2 tablets
60-71	27.2-32.3	12.5 mL	5 tablets	2½ tablets
72-95	32.7-43.1	15 mL	6 tablets	3 tablets

*You may see the word suspension on your child's medicine bottle. Suspension means the medicine is loose in the liquid. This type of medicine needs to be shaken well before it is given to your child.
*Lbs = pounds; kg=kilograms; mg=milligrams; mL=milliliters

NOTE: Healthcare Professionals should be aware that acetaminophen infant drops products with both the new and old concentrations may be available on pharmacy shelves and in the clinic medication room. Either product may be continued to be used, but the concentration must be verified and used according to labeled dosing directions. Healthcare professionals should verify product concentration prior to providing dosing information.

NON-PHARMACOLOGIC MEASURES

1. Be patient and soothe the infant**.** Gently rub or massage the child's gums with one of your fingers.

2. Offer infant chilled teething rings of firm rubber, or a clean, cold, wet washcloth for chewing on.

FOLLOW-UP

1. As needed.

PATIENT EDUCATION/COUNSELING

1. Counsel parent about the above therapeutic measures.

2. Be sure that the infant/child does not chew on things that would break or splinter in the mouth. Avoid offering teething necklaces, bracelets, or anklets due to the risk of choking, strangulation, and infection.

3. Teach parent to read labels and be aware of other sources of acetaminophen

that are often in over-the-counter medications to avoid toxicity/overdose. Teach parent not to give acetaminophen and ibuprofen in alternating fashion to control pain/discomfort due to increased risk of adverse effects from toxicity.

4. Teach parent not to give homeopathic teething tablets or teething products with benzocaine (Baby Orajel, Hurricaine, Anbesol, Cepacol, Chloraseptic) due to recent FDA warning linking benzocaine with methemoglobinemia.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol):

1. Child under 3 months old.
2. Eruption cysts or hematomas.
3. Systemic symptoms- fever, diarrhea, other acute symptoms occurring simultaneously.

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STANDARD NURSE PROTOCOL FOR THRUSH (ORAL CANDIDIASIS)

DEFINITION

Superficial fungal infection of the mouth, frequently occurring in healthy newborns and young infants. Can develop as early as 7 to 10 days of age. Uncommon in children 12 months and older, except those receiving antibiotic therapy, inhaled glucocorticoids, or with other underlying conditions and/or immune suppression.

ETIOLOGY

1. The causative organism is usually *Candida albicans*, which is acquired from the following sources:
   a. In newborns and infants, from infected mother's vagina during birth and/or from infected mother's breast via breastfeeding.
   b. By contamination of caretaker's hands or objects shared by infected infants.
   c. Adult with vulvovaginal candidiasis, through contamination of her hands. (Refer to Standard Nurse Protocol for Vulvovaginal Candidiasis).
   d. Infants/children with candidal diaper dermatitis, through contamination of hands.

SUBJECTIVE

1. Symptoms:
   a. Creamy white patches in the mouth, may be curd-like in nature.
   b. May have pain during feeding and difficulty swallowing.
   c. May have history of recent steroid, antibiotic or chemotherapy treatment.
   d. Mother may have history of or concurrent candida infection of vaginal area and/or breasts.

OBJECTIVE

1. White filmy coating or patches covering all or part of the tongue, gingiva, buccal mucosa and, occasionally, the lips, that does not remove easily with scraping. Distinguish from milk curds left on the tongue after feeding, which are easily removed. If patches are removed they leave a painful, red bleeding lesion.

2. The patient may have candidal diaper dermatitis that needs treatment (Refer to Standard Nurse Protocol for Dermatitis Diaper).

3. May have an inadequate oral intake because of mouth pain. Assess for dehydration, which is uncommon (assess intake, urine output and weight loss).

ASSESSMENT Oral Candidiasis (Thrush)

PLAN

DIAGNOSTIC STUDIES

1. Optional: Potassium hydroxide preparation of scrapings of lesions to detect budding yeast with or without hyphae. This study is usually not needed; diagnosis can be made based on examination and signs/symptoms listed above.

THERAPEUTIC

PHARMACOLOGIC

1. Nystatin oral suspension 100,000 units/mL. Nystatin is preferred to oral fluconazole because Nystatin is less expensive.
   a. For infants greater than 28 days old: Nystatin dosage is 200,000 units (2 mL) divided as 1mL in each side of the mouth 4 times a day for up to 14 days. Continue treatment for at least 3 days after perioral symptoms disappear.
   b. For infants ages 0-28 days old: Nystatin dosage is 100,000 units (1mL) divided as ½ mL in each side of the mouth 4 times a day. Continue treatment at least 3 days after perioral symptoms disappear.
   c. The suspension should be retained in the mouth as long as possible. One way to accomplish this is to apply a portion of the dose to two Q-tips and gently massage these Q-tips against the plaques. Avoid feeding for 5-10 minutes after the dose.
   d. For Mother: Nystatin oral suspension 100,000 units/mL; swab 1 mL on each nipple of breasts 4 times daily after feeding, for 2 weeks.
   e. Avoid nursing for 5-10 minutes after application, if possible.
   f. If diaper rash is present, treat per Nurse Protocol for Diaper Dermatitis due to candidiasis.

NOTE: Gentian Violet is no longer a recommended alternative due to increased risk of cancer and staining of infant's lip and clothing.

FOLLOW-UP

1. In 2 weeks if no improvement or sooner if worsens.

PATIENT EDUCATION/COUNSELING

1. Continue Nystatin treatment for 2 weeks, even if mouth appears to have cleared prior to the 14th day.

2. Properly treated, thrush should not be a cause for weaning from the breast.

3. Breast-fed infants and their mothers are to be treated simultaneously.

4. Household members and caretakers should practice good handwashing, especially when caring for infant.

5. Rubber/plastic nipples and pacifiers should be boiled for 10 minutes or replaced after beginning treatment. Do not allow infants to share pacifiers or nipples.

6. Seek prompt medical evaluation if infant refuses liquids.

7. Contact clinic if any problems obtaining medications.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Failure to respond after two weeks of Nystatin therapy.
2. Weight loss or suspected dehydration.
3. Recurrent or resistant breast infections.
4. Persons with recurrent infections are to be evaluated for HIV infection.
5. Children 12 months old or older with symptoms of thrush.

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STANDARD NURSE PROTOCOL FOR TINEA PEDIS

DEFINITION

Dermatophyte infections of the skin of the feet and toes.

ETIOLOGY

Trichophyton rubrum is the most common pathogen. *Trichophyton mentagrophytes* causes more inflammatory lesions.

The fungus is transmitted by direct contact with contaminated surfaces in moist areas such as swimming pools, community showers or baths and locker rooms. Tinea pedis occurs most frequently in adolescents and adults. Risk factors include sweaty feet and occlusive footwear.

SUBJECTIVE

1. Patient may be/have:
   a. Asymptomatic.
   b. Mild itching.
   c. Burning, stinging, and other sensations.

OBJECTIVE

1. On the sole and heel: usually non-inflammatory scaling, occasionally with thickening and cracking of the skin. May have groups of vesicles or exfoliation of the skin. Foul odor is common.

2. Between the toes: scaling or fissuring, fine vesicles or pustules, maceration.

3. Potassium hydroxide (KOH) skin-scraping: hyphae demonstrated

4. Severe cases can present with interdigital erosions and ulcers, sometimes painful vesicular or bullous eruption with underlying erythema.

ASSESSMENT Tinea pedis

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Order 1 of the following products. Continue treatment for 1-2 weeks after clinically cleared. Apply to normal skin 2 cm beyond affected area.

a. Over-the-counter products, applied twice daily in a thin layer for 4 weeks to the affected area(s):
   1) Miconazole (e.g., Micatin) 2% cream, ointment, powder
      a) Effervescent tablet: Dissolve 1 table in approximately 1 gallon of water; soak feet for 15 to 30 minutes; pat dry; twice daily

OR

   2) Clotrimazole (e.g., Lotrimin) 1% cream or ointment

OR

   3) Tolnaftate 1% (e.g., Tinactin) Cream, Powder, Solution

OR

   4) Terbinafine 1% Cream, gel, or solution. Must be 12 years of age or older. Apply once or twice daily for 1 week.

b. Prescription products
   1) 12 years of age and older: Ketoconazole 2% cream (e.g., Nizoral). Apply once daily for 6 weeks.

OR

   2) Econazole 1% cream. Apply once daily for 4 weeks.

   3) Burrow's solution may be used as a foot soak, 20-30 minutes twice daily, for lesions between the toes to relieve itching or discomfort.

PATIENT EDUCATION/COUNSELING

1. Wear rubber or wooden sandals in community showers and locker rooms.

2. Carefully dry between the toes after bathing/showering. Dry the groin area before drying feet to avoid inoculating tinea pedis dermatophytes into the groin area. A hair dryer on low setting may be used after toweling dry.

3. Change socks frequently. Avoid occlusive footwear. Remove shoes and socks, when possible, to allow air circulation for feet and toes.

4. Apply dusting or drying powders as necessary. Using antifungal powders may prevent recurrence of infection.

5. Completion of therapy is important. Use the medication for the full treatment time even though the symptoms may have improved.

6. Avoid spreading the infection to others. Good handwashing, thorough cleaning of bathrooms and avoidance of sharing bath towels and wash clothes may inhibit transmission.

7. Medications are for external use only.

8. Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away.

9. Contact clinic if any problems obtaining medications.

FOLLOW-UP

1. Recheck in 2 weeks if not improved.

CONSULTATION/REFERRAL

NOTE: Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (When a patient is REFERRED to the primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. No improvement after 2 weeks of treatment.

2. Severe infection or secondary bacterial infection.

3. Extension of the disease to the nails.

4. Pregnant or breastfeeding patient.

5. Under 2 years of age.

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STANDARD NURSE PROTOCOL FOR UPPER RESPIRATORY INFECTION (COMMON COLD)

DEFINITION

An acute viral infection of the upper respiratory tract involving the nose, pharynx, sometimes the paranasal sinuses and, perhaps, the middle ears. It lasts several days. Since the activity of the viruses in the upper respiratory tract can impair local defense mechanisms, invasion by bacteria may occur and cause secondary bacterial infections of the ears and sinuses.

ETIOLOGY

Numerous viruses. In the U.S., peak incidences in children occur in early fall (when schools open), midwinter and early spring. Colds occur most commonly during the second and third years of life, and the average child has from three to eight infections per year. Malnutrition seems to increase susceptibility to colds.

SUBJECTIVE

1. Patient may complain of:
   a. General malaise.
   b. Nasal stuffiness, nasal discharge, sneezing, cough.
   c. Mild sore throat.
   d. Watery eyes.
   e. Decreased appetite, particularly in infants.

OBJECTIVE

1. Low-grade fever (less than 101°Fahrenheit or less than 38.5° Celsius) occurs more commonly in children under 3 years old and lasts from a few hours to a few days. Older children usually have no fever. If they have a fever, evaluate for other causes, such as strep throat, otitis media, or pneumonia.

2. Erythematous, edematous nasal mucosa, with clear, thick nasal discharge initially. The discharge may become mucoid or purulent as the illness resolves.

3. Mildly erythematous pharynx.

4. Mild conjunctivitis.
5. Erythematous tympanic membranes in infants. (Rule out otitis media).

ASSESSMENT Common cold/upper respiratory infection (URI)

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Sodium Chloride nasal solution
   a. Infants - use saline nose drops if needed for congestion: 1-2 drops in each nostril, followed by gentle aspiration of nasal secretions with rubber suction bulb or Nose Frida, particularly before feeding. Caution: may aggravate nasal congestion if nasal mucosa is injured. (Available products: Ayr Baby Saline; Ayr Saline Drops; NaSal Saline Drops; Simply Saline Baby)
   b. Children - use saline nose drops for congestion: 2-6 drops in each nostril every 2 hours if needed for sinus congestion. (Available products: Ayr Baby Saline; Ayr Saline Drops; NaSal Saline Drops; Simply Saline Baby).

2. Ipratropium intranasal solution 0.06% (42mcg/spray). Use beyond 4 days has not been established for symptomatic relief of rhinorrhea.
   a. Children 5 years to 11 years of age: 2 sprays (84mcg) per nostril 3 times daily; maximum dose 504mcg/day
   b. 12 years of age and older: 2 sprays (84mcg) per nostril 3 to 4 times daily; maximum dose 672mcg/day

3. Acetaminophen or Ibuprofen orally - Pediatric (See dosage chart with Nurse Protocol for Fever) if fever is associated with discomfort or decreased fluid intake. Do not use aspirin.

4. Treatment of cough is discouraged because cough is a protective mechanism that helps clear the lung of infectious particles.

NOTE: The American Academy of Pediatrics position is that over-the-counter cough and cold medicines do not work for children younger than 6 years and in some cases, may pose a health risk.

NON-PHARMACOLOGIC MEASURES

1. Increase oral fluid intake.
2. Cool mist humidifiers may be used.
3. Avoid environmental respiratory irritants (e.g., cigarette smoke in the home).
4. Elevate head of bed slightly, for infants older than 6 months of age. Elevating head of bed is discouraged for infants younger than 6 months of age due to risk of SIDS/sudden unexpected infant death syndrome (SUIDS).
5. Nasal dilator strips are adhesive bands placed on the nose that dilate nasal air passages thus relieving nasal congestion. Over the counter strips (e.g., Breathe-Right® Strips) are FDA-approved for use in children 5 years and older. Do not use if allergic to latex.

PATIENT EDUCATION/COUNSELING

1. Rest and increased fluid intake.

2. Seek prompt medical evaluation if chest pain, dyspnea, signs of dehydration, wheezing, moist frequent cough, persistent abdominal pain or vomiting, persistent lethargy, agitation, behavioral changes, or confusion occur.

3. Seek prompt medical evaluation for child less than 3 months of age with temperature elevation.

4. Stress importance of good hand washing technique and proper disposal of tissues.

5. Caution parent not to use OTC cough and cold medications, including Zicam and Vicks VapoRub® under 6 years of age without consulting physician. If 12 years of age or older, may use OTC decongestant if necessary.

6. Do not give cough drops to young children. They are a choking hazard.

7. Breathe-Right strips may present a choking hazard.

8. Reinforce symptoms associated with viral illness can last for 2 weeks.

9. Educate that this is a viral illness and is not an indication for antibiotics.

FOLLOW-UP

1. No follow-up needed if symptoms resolve within one week.

2. Reevaluate if: symptoms persist beyond 7-10 days, deterioration with return of fever or increased work of breathing, dehydration or worsening coughing after apparent improvement after 4-6 days of illness (suspect pneumonia).

CONSULTATION/REFERRAL

NOTE**:** Refer patient to primary care provider OR consult with APRN or delegating physician for care management if the following conditions are present. (After a patient is REFERRED to a primary care physician, the Public Health RN may no longer care for the patient under this nurse protocol).

1. Any infant or child with suspected secondary infection (e.g., pneumonia, sinusitis) or URI symptoms persisting longer than 2 weeks.
2. Persistent lethargy or irritability for longer than 2 hours despite adequate treatment of fever.
3. Any infant/child:

   a. under 3 months of age with a temperature elevation.
   b. 3 to 6 months of age with temperature over 102.2°F.
   c. 6 to 24 months of age with temperature over 102°F and less than 2 pneumococcal immunizations.
4. Pregnant or breastfeeding patient.

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TYPE II DIABETES MELLITUS IN ADULTS

2023 STANDARD NURSE PROTOCOL FOR TYPE II DIABETES MELLITUS IN ADULTS CLINICAL REVIEW TEAM

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Latronda Davis, MPH, RN, BSN **Hypertension and Diabetes Nurse Program Manager** **DPH**	**Whitney Goggans, DNP, APRN, FNP-BC** **Deputy Chief Nurse of Nurse Protocol & QA/QI** **Department of Public Health**
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2022 STANDARD NURSE PROTOCOL FOR TYPE II DIABETES MELLITUS IN ADULTS CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR TYPE II DIABETES MELLITUS IN ADULTS

DEFINITION

Diabetes mellitus is a group of metabolic diseases characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. Diabetes is characterized by fasting plasma glucose (FPG) equal to or greater than 126 mg/dL or random plasma glucose equal to or greater than 200 mg/dL (with testing on two separate days) accompanied by symptoms. Symptoms of diabetes mellitus are frequently due to the osmotic diuresis associated with hyperglycemia. Complications of diabetes may be acute and/or chronic. Acute complications include hyperglycemia, hypoglycemia, diabetic ketoacidosis (DKA) and hyperosmolar hyperglycemic syndrome (HHS). The chronic complications of diabetes are most often the result of sustained hyperglycemia and include damage, dysfunction, and failure of various organs, such as eyes, kidneys, nerves, heart, and vascular system.

NOTE: This protocol is for Type II diabetes and does not include treatment for patients with impaired kidney function or chronic kidney disease, heart failure, pregnant or lactating women, suspected secondary hypertension, evidence of end organ damage, history of stroke, or other complicating factors***.***

ETIOLOGY Type II Diabetes Mellitus

1. Cause: combination of insulin resistance and/or inadequate insulin production. Increased hepatic glucose production and decrease of glucose uptake in the skeletal muscle contributes to elevated fasting blood glucose levels. Insulin resistance in the liver and muscle and impaired insulin secretion also contribute to hyperglycemia.

2. Risk factors:
   a. Overweight or obese: BMI equal to or greater than 25 kg/m^2 and BMI equal to or greater than 23 kg/m^2 for Asian Americans.
   b. Waist circumference greater than 102 cm (40 inches) for men and greater than 88 cm (35 inches) for women.
   c. Sedentary lifestyle, such as sitting for more than 30 minutes at a time or little to no moderate to vigorous activity in the past 30 days.
   d. Age equal to or greater than 45 years old.
   e. First degree relative with diabetes.
   f. Race: African American, Latino, Native American, Asian and Pacific Islander at greater risk.
   g. History of giving birth to babies greater than 9 pounds or history of gestational diabetes diagnosis.
   h. History of A1C equal to or greater than 5.7%, impaired glucose tolerance: 2-hour plasma glucose in 75–g Oral Glucose Tolerance Test of 140 mg/dL to 199 mg/dL, or fasting plasma glucose of 100 mg/dL to 125

mg/dL.

i. Hypertension: blood pressure equal to or greater than 140/90 mmHg or on therapy for hypertension.
j. HDL cholesterol level less than 35 mg/dL and/or triglyceride level greater than 250 mg/dL.
k. Polycystic ovary syndrome.
l. Clinical conditions associated with insulin resistance, such as severe obesity and acanthosis nigricans.
m. History of cardiovascular disease.

SUBJECTIVE

1. History may or may not reveal the following:
   a. Symptoms of hyperglycemia: polyuria, polydipsia, polyphagia, blurry vision, extreme fatigue, slow healing, and/or tingling, pain, or numbness in feet and hands.
   b. Unexplained weight loss or gain.
   c. Previously diagnosed with borderline diabetes or pre-diabetes, gestational diabetes, or impaired glucose tolerance.
   d. Past or current symptoms of coronary heart disease, heart failure, cerebrovascular disease, peripheral vascular disease, renal disease, gout, or sexual dysfunction.

2. Type II diabetics may be asymptomatic. Elevated glucose levels are discovered during routine lab work, evaluations for surgery, or work-up for other conditions. Persons suspected to have type I diabetes may report rapid onset of symptoms.

3. There may or may not be a family history or obvious risk factors.

4. Current diabetes self-management routine, if previously diagnosed, to include:
   a. Duration of diabetes, including age and characteristics of onset, such as diabetic ketoacidosis (DKA) or asymptomatic.
   b. Current and prior medications for diabetes.
   c. Assess medication-taking behaviors, such as compliance and barriers to medication adherence.
   d. Eating patterns for all meals during the day, weight history, and nutritional status.
   e. Prior self-management education/training, including nutrition education.
   f. Self-monitoring of blood glucose (SMBG) pattern and results and A1C results if available.
   g. Current physical activity: type, frequency, **and** duration.
   h. Frequency of usage and indications for OTC medications, prescriptions, and alternative medications, home remedies, nutritional supplements, and herbal supplements.

5. Acute complications: severe hypoglycemia (glucose of 70mg/dL or less is an alert value; glucose of 54mg/dL or less is clinically significant), DKA, severe hypoglycemia requiring assistance of another, hypoglycemia unawareness, hypoglycemia frequency and causes, **p**rior emergency room visits, and hospitalizations related to diabetes.

6. History of infections: type, treatment, **and** resolution time.

7. Family history of diabetes, chronic kidney disease, premature cardiovascular disease.

8. CHD risk factors: hypertension, abnormal lipids, high sodium intake, tobacco use, prior myocardial infarction, coronary revascularization, heart failure, stroke, transient ischemic attacks, peripheral arterial disease, and sleep apnea.

9. History of target organ damage: retinopathy (visual disturbances, changes-loss or fluctuation of visual acuity, blurry vision, floaters or history of cataracts, macular degeneration, or ophthalmic procedures); nephropathy (history of renal disease, ankle edema, fatigue, hypertension); peripheral (stocking and glove pattern of numbness, tingling, pain or weakness) and/or autonomic neuropathy (resting tachycardia, fixed heart rate, postural hypotension, syncope, urinary frequency, urgency, incontinence, male or female sexual dysfunction, gastrointestinal complaints such as gastroparesis, nausea, vomiting, early satiety, abdominal bloating, and weight loss).

10. History of foot ulcers and deformities. Patients should be asked if they perform at home foot checks to reduce complications.

11. Psychosocial and social situation, including economic factors, work environment and type of work (to assess activity level).

12. Smoking or other tobacco use including e-cigarettes, alcohol, and recreational drug use. Number of cigarettes per day, number of drinks per day and frequency of drug use should be noted.

13. Female reproductive history including menstrual history, method of contraception, pregnancies, and pregnancy outcomes.

14. Current immunization status.

15. Presence of dental disease.

OBJECTIVE

1. Routine assessment of blood pressure (standing and sitting or sitting and lying) to assess for dehydration and autonomic neuropathy. Blood pressure may be greater than 140/90 mmHg.

2. **Calculate the patient's 10-year risk of heart disease or stroke using the ASCVD algorithm published in 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk.**

3. Appearance: Frequently overweight or obese.

4. Extremities: changes in color, deformity, injury, sensation, temperature changes, muscle strength and deep tendon reflexes (use a 128-Hz tuning fork and a monofilament).

5. Mouth: gum problems, tooth decay and oral candidiasis.

6. Feet: thickened nails, signs of fungal or bacterial infections, and signs of compromised blood flow. Assess for decreased or absent deep tendon reflexes; numbness or burning sensation or sensory loss may be present. **Check pedal pulses. Determine temperate, vibration, and 10-g monofilament exam initially and annually.**

7. Sites of previous insulin injections, shiny spots over tibial bones, loss of hair over lower legs and toes, ulcerations of feet/legs, carbuncles and ulcers, lipohypertrophy or lipoatrophy at insulin injection sites. In type II diabetes, early hyperinsulinemia may be evidenced by acanthosis nigricans around the neck, waist, inguinal and axillary skin folds (dark velvety hyperpigmentation).

8. Orthostatic hypotension, hypertension, decreased capillary refill, absent pedal pulses, impaired circulation.

9. Possibly enlarged liver.

10. Hands may have deformities and decreased mobility.

DIAGNOSTIC FINDINGS Non-Pregnant Adults:

1. Confirmed A1C equal to or greater than 6.5%.
   OR
2. Confirmed fasting plasma glucose level equal to or greater than 126 mg/dL on at least two different occasions (on subsequent days)
   OR
3. Confirmed random plasma glucose level equal to or greater than 200 mg/dL (with classic symptoms of diabetes), on two different occasions.

ASSESSMENT Type II Diabetes Mellitus

PLAN

DIAGNOSTIC AND FOLLOW-UP STUDIES

Provide abnormal findings and results and discuss implications. Referrals should be provided for follow-up if indicated. If a service is not available in the clinic, the patient should be given resource and/or referral information. Document all referrals appropriately in the individual health record. Outcomes and follow-through of referrals and recommendations should be documented at the next visit.

1. A1C – Initially and every six months for well controlled patients on diet therapy or oral medication. Every three months for patients poorly controlled or when medications have been changed.

2. A1C target goals should be individualized based on patient desires, values, and willingness to participate in management, potential risks of hypoglycemia and other adverse events, patient's age and duration of diabetes, comorbidities (such as cardiovascular disease) and established vascular complications. Treatment goal is generally less than 7%, however, any lowering of A1C levels has benefit.

    a. As an example, A1C goals may be more aggressive by setting goal at less than 6.5% for those who may have a short duration of diabetes or no significant CVD. A1C goals may also be less aggressive by setting goals of less than 8% for those who may have a history of severe hypoglycemia or hypoglycemia unawareness or extensive comorbid conditions.

3. **Fingerstick blood glucose, either fasting or non-fasting, at initial visit and as indicated in a patient with known diabetes.**

4. **Total cholesterol and l**ipid profile **initially and annually**. Lipid management is an integral part of diabetes management.

    a. **Fasting lipids are not required as total cholesterol and HDL are minimally affected by fasting.**
    b. **If the non-fasting plasma triglyceride component of the lipid profile returns at > 400 mg/dL, obtain a fasting lipid profile.**

5. **Comprehensive** metabolic profile **initially and annually**.

6. **EKG/**ECG annually (or as indicated).

7. Annual dilated eye or **RetinaVue** exam.

8. Provide patients with adequate information about frequent foot checks at

home during each follow-up.

9. **Urinary** albumin to creatinine ratio, **initially and annually.**

10. **Vitamin B12 if on metformin, initially and annually.**

11. TSH as indicated by findings on physical examination or suggestive history.

12. Annual dental examination.

13. Calculate **height**, weight, and BMI at each visit.

14. Referral to other specialties and services as needed.

15. Refer women of reproductive age to Women's Health.

THERAPEUTIC

PHARMACOLOGIC

DISCLAIMER: Drug Shortages can occur for many reasons, including manufacturing and quality problems, delays, discontinuations, and supply chain interruptions. The FDA maintains a list of current drug shortages which may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm. Please contact the Hypertension and Diabetes Nurse Program Manager and the Georgia DPH Office of Pharmacy for assistance with specific drug shortage concerns.

Diabetes Medication Management, Type II Diabetes

NOTE: In persons markedly symptomatic and/or elevated blood glucose levels (equal to or greater than 300-350 mg/dL) or A1c (greater than or equal to 10-12 %) consider initiating insulin therapy. If insulin therapy is indicated, please refer these patients to an outside provider.

NOTE: Be familiar with local discount drug programs and maintain a current list (may change frequently). To the extent possible, order medications from these lists. Consult with the delegating physician as indicated.

1. Monotherapy: Metformin is the preferred first agent unless it is contraindicated or not tolerated.

    a. Biguanides: Metformin (Glucophage):

        i. Initial Dose: Take with meals; due to GI side effects start

once daily with the evening meal and titrate up as tolerated (500 mg per week or 850 mg increases every 2 weeks). Patients should be counseled on side effects and reminded that adverse GI effects are transient and will subside once the patient is stabilized.

ii. Contraindications: Avoid in renal impairment (Men: SCr ≥ 1.5 mg/dL, Women: SCr ≥ 1.4 mg/dL). **Contraindicated with eGFR < 30 mL/min/1.73 m^2**

iii. **Caution: Metformin use is associated with the development of vitamin B12 deficiency. Check vitamin B12 levels if taking metformin, initially and annually.**
   1. **If lab results indicate vitamin B12 deficiency, recommend over-the-counter supplementation: B12 (cyanocobalamin) 1,000 mcg once daily PO or sublingual.**

iv. Consider adding additional agents if A1C goal is not reached after 3 months of monotherapy OR if A1C is equal to or greater than 9%. Please see list below for additional agents.

v. A sulfonylurea or meglitinide (see below) may be used as first line therapy in patients unable to take Metformin.

NOTE: Elderly persons should not be titrated to maximum dose.

NOTE: Significant responses may not be seen at doses less than 1,500 mg/day. Start at low dose and titrate.

Drug	Initial Dose	Max Dose	Supplied
Metformin (Glucophage)	500 mg once or twice daily with meals or 850 mg once daily with meals	Immediate-release 2,550 mg/day (for doses > 2,000mg per day, consider administering in 3 divided doses to avoid GI adverse effects)	500, 850, 1000 mg tab
		ER: 2000 mg/day Glucophage XR, Glumetza) ER: 2,500 mg/day (Fortamet)	ER: 500, 750,1000 mg tab

2. Dual Therapy: sulfonylureas, DPP-4 inhibitors, **or** meglitinides may be added as second line therapy if patient is not meeting glycemic goals. Use appropriate monitoring of FPG and A1C measurements to ensure that the patient is not subjected to excessive drug exposure or increased probability of

secondary drug failure. If glucose targets are not achieved after a suitable trial of combination therapy and lifestyle changes, consider discontinuing these drugs and refer to an outside provider for initiation of insulin therapy.

a. Dipeptidyl Peptidase- 4 (DPP-4) inhibitors: Alogliptin (Nesina); Linagliptin (Tradjenta); Sitagliptin (Januvia); Saxagliptin (Onglyza)

DRUG GENERIC NAME	BRAND NAME	INITIAL DOSE
Alogliptin	Nesina	25 mg once daily with or without food
Linagliptin	Tradjenta	5 mg once daily with or without food
Saxagliptin	Onglyza	2.5-5 mg once daily with or without food.
Sitagliptin	Januvia	100 mg once daily with or without food

i. Individuals who do not achieve A1c less than 6.5% after 3 months of monotherapy with another agent, present with A1c between 7.5% and 9%, or present with A1c above 9% without symptoms, a DPP-4 inhibitor is acceptable as add-on to monotherapy.

ii. Combination therapies should include medications with mechanisms of action that complement each other.

1. When used in combination with a sulfonylurea, the sulfonylurea dose should be halved.

iii. Contraindications to Dipeptidyl Peptidase- 4 (DPP-4) inhibitors:

1. Hypersensitivity (eg, anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity) to the drug or any component of the formulation.
2. Type I diabetes
3. Diabetic ketoacidosis

iv. Adverse Reactions:

1. Hypoglycemia, arthralgia, headache, signs of common cold, rhinitis, pharyngitis, rhinorrhea
2. Severe and disabling arthralgia has been reported with dipeptidyl peptidase-4 (DPP-4) inhibitor use; onset may occur within one day to years after treatment initiation and may resolve with discontinuation of therapy

v. Caution:
1. Use with caution in persons with a history of pancreatitis.

Discontinue immediately if pancreatitis is suspected. Caution is advised with the use of DPP-4 inhibitors in patients with preexisting heart failure.

2. Use with caution in patients with abnormal serum transaminases or symptoms of hepatic injury (jaundice, dark urine, anorexia or abdominal pain). DPP-4 inhibitor use has been associated with development of bullous pemphigoid; cases have typically resolved with topical or systemic immunosuppressive therapy and discontinuation of DPP-4 inhibitor therapy.

3. Advise to report development of blisters or erosions. Discontinue therapy if bullous pemphigoid is suspected and refer to a physician.

vi. Drug Interactions:

1. Potentially significant drug interactions may exist with DPP-4 inhibitors. These interactions may be serious and require dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information

b. **Sulfonylureas (SU):**

DRUG GENERIC NAME	BRAND NAME	INITIAL DOSE	TITRATION	MAXIMUM DAILY DOSE	Notes
GLIPIZIDE	Glucotrol	2.5 mg once a day 30 min before a meal, preferably before breakfast*****	2.5-5 mg every 1-4 weeks	20 mg/day	More than 15 mg per day should be administered in 2 divided doses (may have a more satisfactory response)
GLIPIZIDE XL	Glucotrol XL	2.5-5 mg once a day with breakfast or first meal of the day*****	5-10 mg based on glycemic control	20 mg/day	Do not halve, crush, or chew tablets.
GLIMEPIRIDE	Amaryl	1-2 mg once daily with breakfast*****	1-2 mg every 1-2 weeks	8 mg once daily	
GLYBURIDE	Glynase	2.5-5 mg/day with breakfast or first meal of the day***** (patients sensitive to hypoglycemia	2.5 mg every week	20 mg/day	If receiving more than 10 mg per day: twice daily dosing may result in a more

		should start at 1.25 mg)			satisfactory response
GLYBURIDE MICRONIZED	Micronase	1.5-3 mg/day with breakfast or first meal of the day***** (patients sensitive to hypoglycemia should start at .075 mg)	1.5 mg every week	12 mg/day	If receiving more than 6 mg per day: twice daily dosing may result in a more satisfactory response

*Persons that are NPO or require decreased caloric intake may need doses held to avoid hypoglycemia.

i. The 20**21** AACE/ACE treatment algorithm suggests sulfonylureas as a last-line add-on therapy for either dual- or triple-therapy regimens for all patients.

ii. When used in combination therapy, sulfonylureas should be combined with medications that complement the mechanism of action.

   a. When sulfonylureas are added to a DPP-4 inhibitor, sulfonylurea dosage should be halved.

   b. There is little difference among the various sulfonylureas except perhaps in duration of action, with glyburide having a longer duration of action than glimepiride or glipizide.

      a. The 2009 ADA/EASD consensus statement recommends all sulfonylureas except glyburide as an addition to metformin if metformin monotherapy fails. Glyburide is not recommended because of an increased risk of hypoglycemia.

iii. If insulin treatment is warranted, sulfonylureas should be discontinued, and referral to a physician should be done.

iv. Sulfonylureas cross the placenta and are present in breast milk. Individuals who are pregnant to lactating should be referred to a physician.

v. Contraindications to Sulfonylureas:
   a. Hypersensitivity to sulfonylureas or sulfonamides
   b. Diabetic ketoacidosis
   c. Type I diabetes mellitus
   d. Severe renal impairment

vi. Common Adverse reactions:
   a. Hypoglycemia, dizziness, headache, nausea, diarrhea, allergic skin reactions, weight gain

vii. Caution:
   a. Disulfiram-like reaction is possible. Avoid alcohol consumption.
   b. Sound-alike/look alike issues: Glimepiride may be confused with Glipizide.
   c. Use and titrate with extreme caution.
   d. Avoid use in elderly.

viii. Drug Interactions
   a. Potentially significant drug interactions may exist with sulfonylureas. These interactions may require dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information

NOTE: Meglitinides (See below under Specific Situation therapy) may be used in place of Sulfonylureas in patients with a sulfa allergy and/or irregular meals schedules or who have late rise in postprandial glucose levels on SU's.

c. **Meglitinides**:

NOTE: Meglitinides may be used in place of Sulfonylureas in patients with a sulfa allergy and/or irregular meals schedules or who have late rise in postprandial glucose levels on SU's.

DRUG GENERIC NAME	**BRAND NAME**	**RECOMMEND DOSE**	**DOSE TITRATION**	**Maximum Dose**
Repaglinide	Prandin	A1c < 8%: 0.5 mg before each meal (2, 3, or 4 times per day depending on number of meals) A1c ≥ 8%: 1-2 mg before each meal (2, 3, or 4 times per day depending on number of meals)	May double the dose with each meal at intervals of ≥1 week until adequate glycemic control is achieved	Maximum dose: 4 mg/ meal or 16 mg/day

Nateglinide	Starlix	120 mg 3 times daily before meals; 60 mg dose may be used in patients who are near A1c goal when treatment is initiated		

i. Meglitinides are generally *not* used in patients with type 2 diabetes *except* for the following special situations:
   a. Irregular meal schedules
   b. Development of postprandial hypoglycemia when taking a sulfonylurea
   c. Unable to take a sulfonylurea due to sulfa allergy

ii. Contraindications
   a. Hypersensitivity to nateglinide, repaglinide, or any component of the formulation; Concurrent gemfibrozil therapy (repaglinide only)
   b. Type I diabetes mellitus
   c. Ketoacidosis

iii. Adverse Reactions
   a. Hypoglycemia, upper respiratory infections, dizziness, headache, increased uric acid levels, weight gain

iv. Caution
   a. Use with caution in adrenal or pituitary impairment.
   b. Use with caution in hepatic impairment.
   c. Use with caution in renal impairment.
   d. Stress-related states: It may be necessary to discontinue nateglinide and administer insulin if the patient is exposed to stress (e.g., fever, trauma, infection, surgery). If insulin use is warranted, refer to a physician.

v. Drug Interactions
   a. Potentially significant and serious interactions may exist requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information

3. <u>Triple Therapy:</u>

   a. Consider initiating triple therapy:
      i. In persons who do not achieve A1c less than 6.5% after 3

months with dual therapy
ii. In persons with A1c equal to or greater than 10 to 12%
iii. In persons with blood glucose equal to or greater than 300 to 350 mg/dL.

b. Triple therapy combinations within the drug classes covered by this protocol:
i. Metformin + Sulfonylurea + DPP-4 inhibitor
1. When sulfonylureas are added to a DPP-4 inhibitor, sulfonylurea dosage should be halved.

OR

ii. Metformin + Meglitinides + DPP**-4 inhibitor**

1. Cholesterol management:

Hyperlipidemia is classified as:

a. Total cholesterol is 200 mg/dL or higher
b. LDL is 130 mg/dL or higher (higher than 100 mg/dL in persons with diabetes)
c. HDL is 40 mg/dL or lower
d. Triglycerides are 200 mg/dL or higher (higher than 150 mg/dL in persons with diabetes)

NOTE: Provide nutrition counseling and promote adherence to a low cholesterol/low fat diet to decrease cholesterol level.

2. Calculate the patient's 10-year risk of heart disease or stroke using the ASCVD algorithm published in 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk.

3. Statin therapy is a highly recommended treatment for the following individuals, as they are most likely to benefit from moderate- or high-intensity statin therapy. Initiate pharmacologic treatment based on the following criteria and guidelines:

a. **Initiate a moderate-intensity statin for the following patients:**
i. Individuals aged 40-75 without clinical atherosclerotic cardiovascular or diabetes, with LDL 70-189 mg/dL, and estimated 10-year CVD risk of greater than 10% but less than 20%.

b. Initiate a high-intensity statin for the following patients:
i. Individuals aged 40-75 with diabetes and LDL ≥ 70 mg/dL.
ii. Individuals aged 40-75 without clinical atherosclerotic cardiovascular or diabetes, with LDL 70-189 mg/dL, and estimated 10-year CVD risk of ≥ 20%.
iii. Individuals with primary elevation of LDL ≥ 190 mg/dL.

iv. Individuals with clinical atherosclerotic cardiovascular disease, coronary heart disease, cerebrovascular disease, peripheral artery disease, or aortic atherosclerosis.

4. The clinical judgement to lower LDL-C in persons 75 years of age and older should be based on patient characteristics and should occur after a full discussion of the potential benefits and costs. Consider comorbidities, safety considerations, and priorities of care. Shared decision making is important in this setting. Data supports the continuation of use of statins beyond 75 years of age in persons who are already taking and tolerating the drug. Also, some data supports use of moderate intensity statin for secondary prevention. Data is less supportive for use in primary prevention.
    a. If therapy is elected for persons older than 75 years, treat with a medium potency statin.

5. Follow-up Labs

a. After initiating a statin, repeat lipid panel (can be fasting or non-fasting) and CMP at 6 weeks to assess adherence and response to statin (i.e., general impact on LDL levels & liver enzymes). Repeat lipids and CMP every 12 months.

NOTE: If an individual encounters difficulty obtaining a recommended agent due to cost, explore patient assistance or similar programs, Medicaid eligibility and any community programs to get the preferred medication. If no assistance is available, a less potent but more affordable medication can be substituted.

PHARMACOLOGIC

High Potency Statins and Therapeutic Doses = 50% or greater LDL-C reduction	**Moderate Potency Statins and Therapeutic Doses = 30-49% LDL-C reduction**	**Low Potency Statins and Therapeutic Doses = less than 30% LDL-C reduction**
Atorvastatin 40-80mg daily	Atorvastatin 10-20mg daily	Simvastatin 10mg daily
Rosuvastatin 20-40mg daily	Rosuvastatin 5-10mg daily	Pravastatin 10-20mg daily
	Simvastatin 20-40mg daily	Lovastatin 20mg daily
	Pravastatin 40-80mg daily	
	Lovastatin 40mg daily	
NOTE: Initial doses are listed below, then double doses as discussed below.		

6. When initiating statin medications, recommended starting doses are:
   a. Rosuvastatin 10mg daily,
   b. Atorvastatin 20mg daily,
   c. Simvastatin 20mg daily,
   d. Pravastatin 20mg daily,
   e. Lovastatin 20mg daily.

      1) Doses can be doubled every 2-4 weeks until the target dose is achieved. If a patient has difficulty tolerating an agent, consult with the delegating physician.

NOTE: If known or suspected liver disease, a statin should not be initiated without physician consultation. If a patient on statins develops elevated liver enzymes or muscle pain, the drug should be stopped immediately and notify delegating physician immediately. Statins are not to be used in pregnant or lactating women; consult with delegating physician. Potentially significant drug interactions may exist with statins (HMG-CoA Reductase Inhibitors), requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information.

NOTE**: P**ersons of reproductive **age** should be counseled to avoid pregnancy during **statin** therapy. Side effects **of statins** may include constipation, nausea, abdominal pain, headache, insomnia, vertigo, and upper respiratory infections. Advise patient to immediately report symptoms of myopathy or rhabdomyolysis, especially when accompanied by fever or malaise, or if symptoms persist after discontinuation of drug. Instruct patient to immediately report symptoms of liver injury. Instruct patient to avoid grapefruit juice while taking **simvastatin, atorvastatin, or lovastatin**.

NON-PHARMACOLOGIC

PATIENT EDUCATION/COUNSELING

1. Diabetes Self-Management Education/Training (DSME/DSMT) is considered an essential element for persons with diagnosed diabetes. DSME/T provides the knowledge, skills, and support necessary for diabetes self-care. For Medicare reimbursement, DSMT coding must be used.

2. Nutrition Therapy: evidence suggests that there is no ideal percentage of calories from carbohydrate, protein, and fat for all persons with diabetes. More emphasis is placed on a pattern approach rather than specific macronutrient and micronutrient recommendations. Macronutrient distribution should be based on individualized assessment of current eating patterns, preferences, and metabolic goals. The goals of nutrient therapy are:

a. Promote and support healthful eating patterns, emphasizing a variety of nutrient-dense foods. Nutrient-dense foods are naturally lean or low in solid fats and have little or no added solid fats, sugars, refined starches, or sodium. These foods include vegetables, fruits, whole grains, low-fat and fat-free dairy, and lean meats.
b. Attain individualized glycemic, blood pressure and lipid goals.
c. Achieve and maintain body weight goals. Body weight management is important for overweight and obese people with type II diabetes.
d. Delay or prevent complications of diabetes.
e. Address individual nutrition needs based on personal and cultural preference, health literacy, access to healthy food choices, desire, and ability to make behavior changes, and barriers to change.
f. Provide positive, nonjudgmental messages about food choices and limit food choices only when indicated by scientific evidence.
g. Provide practical tools for developing healthy eating patterns rather than focusing on individual macronutrients, micronutrients, or single foods. A variety of meal planning tools, DASH Eating Plan, Therapeutic Lifestyle Changes Diet, USDA Choose My Plate, Mediterranean style diet, and vegetarian and vegan eating plans may be used.

3. Physical activity has been shown to improve blood glucose control by decreasing insulin resistance and increasing metabolism, reducing cardiovascular risk factors, contributing to weight loss and improved sense of well-being.

    a. Reduce sedentary time by breaking up bouts of sedentary activity (greater than 30 minutes) by briefly standing, walking, or performing other light physical activities.
    b. Perform at least 150 minutes per week of moderate-intensity aerobic physical activity **(e.g., walking, jogging, cycling, yoga, or swimming)** spread over at least 3 days per week with no more than 2 consecutive days without exercise. Shorter durations (minimum 75 minutes/week) of vigorous-intensity or interval training may be sufficient for younger and more physically fit individuals.
    c. Perform muscle strengthening activities that involve all major muscle groups 2 or more days per week. Examples include weight training, working with resistance bands, push-ups, pull-ups, sit-ups, and heavy gardening.
    d. Persons over the age of 65 or those with disabilities should follow the above guidelines to the extent possible. If it is not possible to follow the guidelines, they should be encouraged to be as physically active as possible.
    e. Consideration of existing diabetes related health issues identified during the patient's assessment, such as cardiovascular disease, hypertension, peripheral and/or autonomic neuropathy, and microvascular changes, should be considered when recommending a physical activity program.

NOTE: In individuals taking insulin and/or insulin secretagogues, during physical activity, closer glucose monitoring is recommended as increased physical activity may lead to hypoglycemia. Individual may need to eat some added carbohydrate if pre-exercise glucose levels are < 100 mg/dL.

4. Monitoring:

   a. Self-Monitoring of Blood Glucose (SMBG):
      1) Used to assess effectiveness of meal plan, exercise, and medication.
      2) Individuals with Type II diabetes being treated with medication should perform SMBG on a regular, consistent basis until blood glucose targets are reached. One example of a testing schedule is performing a fasting and one other test during the day on an alternating routine, such as pre-meal testing on alternate days (pre-lunch one day, pre-evening one day and at bedtime on the third day). If fasting and pre-meal values are within target values but A1C values do not correlate, post-prandial blood glucose values may provide guidance in reviewing composition and portion sizes of meals. Once 50% of blood glucose values are within target blood glucose range, SMBG frequency can be modified to treatment (e.g., meal planning only, 2-3 times per week; oral medications once per day on alternating fasting and pre-meal schedule). Frequency of monitoring may depend on compliance, physical limitations, financial resources, comorbid conditions, and ability to act when abnormal values occur.
      3) Individualized target blood glucose ranges are based on treatment regimen, age, and presence of complications such as hypoglycemia unawareness. The recommended target goals for most individuals are pre-meal glucose between 80-130 mg/dL and peak post-prandial glucose less than 180 mg/dL. Discuss target glucose levels and encourage individuals to write them in their SMBG logbook.
      4) SMBG logbook/records should be reviewed on each visit to identify patterns of blood glucose levels to consider adjustments in the management plan. Provide feedback to support and encourage continued monitoring as well as behavior and lifestyle changes as indicated.
      5) Additional testing may be indicated during times of stress, especially infection/illness.

   b. Hypoglycemia:
      1) Individuals taking medications for diabetes must be counseled on risks for hypoglycemia: delaying or skipping meals, physical activity, taking too much medication, or drinking alcohol.
      2) Symptoms of hypoglycemia include sweating, palpitations, pallor, tremors, behavior change, confusion, drowsiness, tachycardia, and hunger. Severe, untreated hypoglycemia can lead to loss of

consciousness, seizure, coma, or death.

3) Treatment of hypoglycemia (blood glucose alert value of 70 mg/dL or less) for the conscious individual is 10-15 grams of easily absorbed carbohydrate such as 3-4 glucose tablets or 4 ounces of juice or regular soda. 15 minutes after treatment, if SMBG shows continued hypoglycemia, the treatment should be repeated.

c. Hyperglycemia:
   1) Counsel on risks for hyperglycemia including binge eating, consumption of carbohydrate-rich processed foods, omission of prescribed medications, lack of physical activity, infection, or illness, and taking medications that may increase blood glucose levels.
   2) Symptoms of hyperglycemia include increased thirst and urination, increased hunger, fatigue, blurry vision, and headaches.
   3) Counsel on the importance of testing blood glucose level when symptoms occur and to contact their healthcare provider when blood glucose levels are 250 mg/dL or greater on 2 occasions or if experiencing symptoms of illness or infection.

d. Sick Day Management:
   1) Counsel on importance of drinking 8 oz. of fluid per hour.
   2) Test blood glucose at least every 4 hours or more frequently if it continues to rise.
   3) Continue medications as possible.
   4) Persons who live alon**e**, especially the elderly should have someone check on them on a regular basis when they are not feeling well.
   5) Notify health care provider if any of the following occurs:
      a) Vomiting on more than one occasion and unable to retain liquids
      b) Diarrhea lasting more than 6 hours
      c) If symptoms of hyperglycemia become worse

e. A1C testing, which reflects average blood glucose concentration over the past 90-120 days, should be performed at least two times per year in patients meeting target treatment goals and quarterly in patients whose therapy is changed or who are not meeting treatment goals. Reduction of A1C to 7% or less has been shown to reduce microvascular complications and long-term reduction in macrovascular disease.

A1C	Average mg/dL
6.5%	140 mg/dL
7%	150 mg/dL
8%	183 mg/dL

f. Weight monitoring. Weight loss has been shown beneficial for persons with type II diabetes to improve glycemic control and reduce the need for glucose-lowering medications. Nutritional interventions and increased

physical activity can promote controlled weight loss. Weight gain should be monitored, and possible reasons explored, such as medications and need for additional nutritional counseling.

g. Regularly assess for cardiovascular risk factors and the presence of macrovascular disease.
   1) Monitor blood pressure and ensure that hypertension is being treated to target goal of systolic blood pressure less than 140 mmHg and diastolic blood pressure less than 90 mmHg.
   2) Assess for symptoms of macrovascular disease:
      a) chest pain
      b) decreased tolerance for physical activity
      c) chronic fatigue
      d) shortness of breath
      e) swelling of feet and ankles
      f) sudden numbness or weakness on one side of the body
      g) inability to walk or weakness, paralysis on one side of the body
      h) pain in the calves when walking or pain in feet when at rest
      i) coolness of lower extremities

h. For smokers, e-cigarette users, or other nicotine users utilize Ask, Advise and Refer (AAR) model and provide cessation counseling and referral to the Georgia Quit Line 1-877-270 STOP (7867) using the Quit Line Fax Back Form as appropriate.

i. Foot evaluation and care: early recognition and appropriate management of patients with insensate feet is important to reduce risk of amputation.
   1) All persons with diabetes should have an annual comprehensive foot examination as described in the Objective Section. Individuals with insensate feet, foot deformities, ulcers, and complaints of numbness and/or burning, should, at minimum, have a visual inspection of their feet at each visit.
   2) All persons with Type II diabetes should receive general foot care instructions. Those with neuropathy, insensate feet, history of foot ulcers, or deformities as well as those with visual impairment, should be given enhanced foot care instructions and/or referral to a specialist or podiatrist. See Patient Education/Counseling Section for additional information.

j. Psychological assessment and care: Depression is not uncommon in persons with diabetes and may affect their ability to perform self-management activities.
   1) Routinely ask how diabetes and its care is impacting their lives including feeling anxious, depressed, helpless, changes in sleep patterns, and concerns about the financial cost of diabetes care.
   2) The Patient Health Questionnaire (PHQ)-9 is a brief depression self-

report scale that is a useful screening tool and can be found at: http://med.stanford.edu/fastlab/research/imapp/msrs/_jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9%20id%20date%2008.03.pdf

3) Referral to mental health resources may be appropriate for patients who might benefit from a more comprehensive evaluation and when poor glycemic control persists despite ongoing adjustments in management regimen.

k. Diabetics, especially if poorly controlled, are at greater risk for periodontal disease. This can lead to difficulty chewing, pain, possible loss of teeth, and persistent bad breath. Encourage daily brushing and flossing, routine dental care, good glucose control, and avoidance of tobacco products.

l. Immunizations are important preventive services for persons with diabetes to reduce diabetes-related hospitalizations and to prevent morbidity and mortality.

1) Assess and administer vaccines indicated by the current Advisory Committee on Immunization Practices (ACIP) adult immunization schedule including those recommended for persons with chronic medical conditions. Review the Georgia Immunization Program Manual's Recommended Schedule and Guidelines for current ACIP schedules and administration guidelines for each vaccine. The Georgia Immunization Schedule may be accessed at https://dph.georgia.gov/immunization-section/immunization-schedules.

1. People with type 2 diabetes are at higher risk for serious problems from certain vaccine-preventable diseases. Important vaccines to review with patients and administer per ACIP guidelines include influenza, pneumococcal, Tdap, hepatitis B, and zoster vaccine.

REFERRAL/CONSULTATION

1. Smokers, e-cigarette users, or other nicotine users- Utilize Ask, Advise and Refer (AAR) model and provide cessation counseling and referral to the Georgia Quit Line 1-877-270-STOP (7867) using the Quit Line Fax Back Form as appropriate.

2. Referral to mental health resources may be appropriate for patients who might benefit from a more comprehensive evaluation and when poor glycemic control persists despite ongoing adjustments in management regimen.

3. In individuals with markedly symptomatic and/or elevated blood glucose levels (300-350 mg/dL or higher) or A1c (10-12 % or higher) consider

initiating insulin therapy. If insulin therapy is indicated, please refer these patients to an outside provider.

4. All persons diagnosed with type II diabetes should have, at minimum, a nutritional evaluation including development of an appropriate meal plan by a Registered Dietitian or Public Health Nutritionist, if available. Nutrition therapy has an integral role in overall diabetes management and when it is delivered by a Registered Dietitian is associated with A1C decreases.

5. Refer to a Diabetes Self-Management Education/Training Program and/or Chronic Disease Self-Management Program and local diabetes support groups.

6. Those diagnosed with prediabetes should be referred to lifestyle change programs or Diabetes Prevention Programs.

7. Medical Referral - In addition to periodic review by a physician, special consultation with delegating physician is indicated for:
   a. **Failure to** reach and/or maintain target blood glucose and/or A1C levels with the limited pharmacologic agents and dosing covered by this Nurse Protocol.
   b. **Patients** present**ing** with blood glucose levels equal to or greater than 300 mg/dL and/or A1C level equal to or greater than 10%.
   c. Recurrent episodes of hypoglycemia (glucose level less than 70 mg/dL) or after one episode of severe hypoglycemia (loss of consciousness or glucose level less than 54 mg/dL).
   d. Present with features suggestive of type I diabetes.
   e. Positive ketonuria.
   f. Pregnancy.
   g. Systolic pressure is 180 mmHg or greater.
   h. Diastolic pressure is 110 mmHg or greater.
   i. Abnormal, total cholesterol is 200 mg or higher, LDL is 100 mg/dL or greater, HDL equal to or less than 40 mg/dL in men and less than 50 mg/dL in women, fasting triglyceride is 500 mg/dL or greater, serum creatinine of 1.4 mg/dL or greater for women and 1.5 mg/dL for men or greater, serum potassium of 3.5 mEq or less or 5.5 mEq or greater, or positive urinary albumin creatinine ratio equal to or greater than 30 mg/dL.
   j. New onset angina, intermittent claudication, acute vision loss, acute foot injury or ulceration and/or abnormal ECG.
   k. Presence of complications or other medical conditions.

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HIV

2023 HIV STANDARD NURSE PROTOCOLS
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2022 HIV STANDARD NURSE PROTOCOLS
CLINICAL REVIEW TEAM

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RECOMMENDATIONS FOR USE OF HIV STANDARD NURSE PROTOCOLS

The HIV Nurse Protocol Committee recommends the following HIV Standard Nurse Protocols for use by public health registered nurses. In the following HIV Standard Nurse Protocols, the term "provider" refers to a primary HIV care provider, e.g., physician or APRN. In an effort to provide comprehensive care, the use of Standard Nurse Protocols from other areas is encouraged.

Due to the rapidly evolving management of HIV disease, the HIV Nurse Protocol Committee recommends updates to individual protocols as Department of Health and Human Services (DHHS) HIV-related guidelines are revised. Compliance with all DHHS HIV-related guidelines is a requirement of the Health Resources and Services Administration (HRSA) for sites receiving Ryan White HIV/AIDS Program funding. DHHS guidelines are considered "living" documents and are available online at Clinical Info HIV.gov https://clinicalinfo.hiv.gov/en/guidelines; therefore, changes in DHHS guidelines supersede information in the following HIV nurse protocols.

The HIV Nurse Protocol Committee recommends knowledge and application of HIV-related guidelines and references from sources such as:

- Clinical Info HIV.gov: https://clinicalinfo.hiv.gov/en/guidelines,
- The National HIV Curriculum, National STD Curriculum, Hepatitis C Online, Hepatitis B Online all available at: https://idea.medicine.uw.edu,
- AETC AIDS Education and Training Center Program: http://www.aidsetc.org,
- Stanford University HIV Drug Resistance Database: https://hivdb.stanford.edu/
- Georgia CAPUS Resource Hub: https://www.gacapus.com/r/,
- Georgia Department of Public Health Hepatitis C Testing Toolkit for Primary Care Providers in Georgia: http://dph.georgia.gov/hepatitis-c,

STANDARD NURSE PROTOCOL FOR SHORT TERM CONTINUATION OF ANTIRETROVIRAL THERAPY IN ADULT WITH HIV

DEFINITION

Antiretroviral therapy refers to a combination of medications used to treat HIV infection. These drug combinations are commonly called antiretroviral therapy (ART). Classes and subclasses of HIV ART approved by the Food and Drug Administration (FDA) include: nucleoside reverse transcriptase inhibitor (NRTI), non-nucleoside reverse transcriptase inhibitor (NNRTI), protease inhibitor (PI), integrase strand transfer inhibitor (INSTI), attachment inhibitor, post-attachment inhibitor, chemokine receptor 5 (CCR5) antagonist, and fusion inhibitor. ART regimens for treatment experienced patients vary based on clinical findings and to optimize treatment. Further details on ART regimens can be found at https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/introduction?view=full.

ETIOLOGY

Antiretroviral therapy (ART) has reduced HIV-related morbidity and mortality at all stages of HIV infection and has reduced HIV transmission. Clinical evidence has established that 'undetectable equals untransmittable U=U' meaning that persons with HIV who consistently take ART and maintain undetectable HIV RNA viral load levels do not transmit HIV sexually to others. Maximal and durable suppression of plasma viremia delays or prevents the selection of drug-resistance mutations, preserves, or improves CD4 T lymphocyte (CD4) cell numbers, and confers substantial clinical benefits, all of which are important treatment goals.

The key to successfully maintaining viral suppression is continuous access to ART and adherence to the prescribed regimen. Lack of adherence or intermittent access to ART can result in treatment failure and the emergence of drug resistance mutations that may compromise future treatment options. HIV is a chronic disease and patients generally remain on ART indefinitely. Throughout the lifespan, there are many reasons ART regimens may be changed, e.g., to simplify treatment, reduce effects of ART on co-morbid conditions, medication intolerance, unwanted side effects, adverse reactions, drug-drug interactions, treatment failure, and significant advances in ART treatment.

SUBJECTIVE

1. Established clinic patient currently taking ART regimen as prescribed.

2. Assess for adherence to prescribed antiretroviral treatment regimen.

3. Absence of adverse reactions, medication intolerance, or significant side

effects to current ART regimen.

4. Obtain a complete medication profile from current pharmacy to determine whether there are any clinically significant drug-drug interactions, especially to new medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications, (including prescribed medications from outside providers).

NOTE: See the latest Department of Health and Human Services (DHHS) antiretroviral guidelines, "Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV," for recommendations including antiretroviral regimens, agent formulations and dosing, adverse events, and drug-drug interactions. Read: **https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/whats-new-guidelines?view=full**

OBJECTIVE

1. Verify established clinic patient and current ART treatment regimen.

2. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

3. No evidence of virologic failure, e.g., HIV RNA viral load level greater than or equal to 200 copies/mL. https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv/virologic-failure?view=full.

4. If adherence assessment is indicated, contact pharmacy for a refill history. Maintain current signed release of information for pharmacy reviews as needed.

5. If ordering abacavir (may be present in fixed combination formulations such as Epzicom®, Triumeq®, Trizivir®.), no evidence of Human Leukocyte Antigen - B*5701 (HLA-B*5701) positive test result.

6. If ordering a CCR5 antagonist (e.g., maraviroc), no evidence of Chemokine receptor 4 (CXCR4) or dual/mixed coreceptor tropism.

   NOTE: Maraviroc should only be considered a fully active antiretroviral agent in treatment-experienced patients who have only CCR5 virus and who are naïve to CCR5 inhibitors. A tropism assay must be obtained before a CCR5 inhibitor is used and maraviroc not initiated if CXCR4 or dual/mixed virus (CCR5/CXCR4) is present.

ASSESSMENT Candidate for Continuation of Antiretroviral Regimen

PLAN

DIAGNOSTIC STUDIES

1. Complete pregnancy test for individuals of childbearing potential, if indicated.

2. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:
   a. HIV RNA viral load,
   b. CD4 cell count,
   c. Comprehensive metabolic panel,
   d. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

3. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:
   a. CBC with differential,
   b. Random or fasting lipid profile,
   c. Hepatitis A total antibody, for assessment of immune status,
   d. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
   e. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
   f. Pap smear,
   g. TB screening test or risk assessment, as indicated.

4. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

   a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
   b. Lexicomp, http://www.wolterskluwercdi.com/lexicomp-online/
   c. Drugs.com, Drug Interactions Checker, https://www.drugs.com/drug_interactions.php

THERAPEUTIC

PHARMACOLOGIC

1. Order one-month supply of the complete drug regimen containing each antiretroviral medication the patient is currently taking. In extenuating circumstances, wherein the patient has not yet completed a prescribing provider visit, this nurse protocol may be enacted a second time for a maximum cumulative 60-day supply given in succession.

2. Assess for needed vaccinations and offer vaccinations per GA DPH Immunization Program and DHHS guidelines.

PATIENT EDUCATION AND COUNSELING

1. Review current drug regimen including drug storage, dose (including dose adjustments in kidney failure), schedule (e.g., once a day, twice a day, etc.), route of administration, food requirements or restrictions, side effects, and follow-up monitoring.

2. Counsel about potential drug-drug interactions with all medications and to check with their pharmacist or provider before taking a new medication, nutritional or herbal supplement, or OTC drug/product.

3. Explain the importance of adherence, goals of therapy, methods to prevent transmission, e.g., routine partner testing, condom use (also to decrease exposure to other sexually transmitted infections), remaining virally suppressed on ART, treatment as prevention, undetectable equals un-transmittable U=U, decreasing number of partners, and partner use of pre-or post-exposure prophylaxis, etc.

4. Provide measure to promote adherence such as written medication schedules, pillboxes, phone apps, alarms, etc.

5. Discourage patient from stopping any components of ART regimen without consulting prescribing provider first.

NOTE: Antiretroviral drugs have different half-lives, thus partial or complete discontinuance of drugs in an ART regimen may result in dual or monotherapy (e.g., data have shown that efavirenz or nevirapine drug levels may persist for 21 days or longer). If all components of the ART regimen are not taken as prescribed, e.g., taking only emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg (FTC 200mg/TDF 300 mg: Truvada®) or Dolutegravir (DTG: Tivicay®) this can result in treatment failure and the emergence of drug resistance mutations. Patients with hepatitis B coinfection receiving one or a combination of NRTIs (e.g., emtricitabine, lamivudine, or tenofovir) may experience an exacerbation of hepatitis upon drug discontinuation. Currently there are no guidelines for optimal discontinuation intervals between drugs. **If needed,** check with the physician concerning discontinuation instructions. Ask patient to immediately report adverse drug reactions, side effects or other changes in

health that he/she feels are important to his/her care provider.

NOTE: If patient experiences hypersensitivity reactions to abacavir, it should be discontinued, along with all other ARVs, immediately.

If abacavir is stopped due to hypersensitivity reaction, then contact the prescribing provider immediately and advise the patient to hold all ART until further recommendations are available. If the patient's symptoms are severe, advise the patient to present to the closest ER for an assessment. If able, have the patient or family ask the assessing provider to contact the ART prescribing provider. Patients who have an HLA-B*5701-positive screen should not be prescribed abacavir, and positive status should be recorded in the patient records as an abacavir allergy. Patients, including those with negative screening tests, should be warned to consult their provider immediately if they note two or more of the hallmark symptoms, including fever, skin rash, GI symptoms (nausea, vomiting, diarrhea, abdominal pain), respiratory symptoms (cough, dyspnea, pharyngitis) and/or constitutional symptoms (malaise, fatigue, myalgia) especially during the first month of therapy. If the patient stops taking abacavir because of adverse reactions, it should not be re-started. Abacavir hypersensitivity reactions can be fatal.

6. Counsel patient to not skip days to try to extend the medication supply; to not "borrow" or lend medications from or to friends or family or obtain prescription drugs outside the care of their physician (e.g., pre-exposure prophylaxis, non-occupational post-exposure prophylaxis, erectile dysfunction agents).

7. Instruct patient to bring all medications, nutritional or herbal supplements, and OTC drugs/products to their medical appointments.

NOTE: It is important to maintain a current signed release of information from the patient to verify medications filled at ALL pharmacies at any time.

8. Review barriers to care. Stress the importance of keeping scheduled appointments to minimize gaps in services and potential discontinuation of medications and services.

9. Instruct patient of childbearing potential to inform provider if planning pregnancy or if pregnant.

FOLLOW-UP

1. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition, family planning) and provide services and/or linkage as soon as possible, preferably during the visit.

NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

2. Check for any upcoming prescribing provider appointments:
   a. If no appointment scheduled or scheduled beyond 30 days, schedule with the provider as soon as possible (ideally in one to two weeks).

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Do not continue ART and refer without delay to the delegating physician or prescribing provider, patients with the following
   a. Most recent HIV RNA level greater than or equal to 200 copies/mL,
   b. Non-adherence with ART regimen,
   c. ART regimens that do not follow current DHHS treatment guidelines,
   d. Suspected treatment failure,
   e. History of adverse reactions to ART or severe/significant side effects,
   f. Pregnant and not on preferred DHHS ART regimen,
   g. Hepatitis co-infected patients not previously assessed by the prescribing provider,
   h. Patient on an abacavir-containing regimen is HLA-B*5701 positive,
   i. Patient on a CCR5 antagonist has CXCR4 or dual/mixed coreceptor tropism.

2. Refer to the delegating physician or prescribing provider, patients with the indications listed below. If any of the below conditions apply this protocol may only be used for one 30-day supply of ART. Ensure the patient is scheduled to see the provider within 30-days.
   a. Identification of mutations from previous resistance testing or outside records not previously reviewed by the prescribing physician,
   b. Patients planning pregnancy,
   c. Patients desiring treatment simplification.

3. If conditions exist that indicate an immediate need to discontinue or switch ART regimens, consult delegating or designated physician for instructions.

4. Consult delegating or designated physician concerning ART in patients with abnormal lab results not previously reviewed by the provider.

5. Consult delegating or designated physician when further medical guidance is needed, and HIV/AIDS nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR HERPES ZOSTER (SHINGLES) IN ADULT WITH HIV

DEFINITION

Herpes zoster is a viral illness that usually presents as a vesicular rash, in a unilateral dermatomal distribution that is painful, itchy, or tingly. These symptoms may precede rash onset by several days. Some people may also have headache, photophobia (sensitivity to bright light), and malaise in the prodromal phase. The duration of vesicles and crusts, as well as significant pain, is usually 2-3 weeks. Thoracic dermatomes are most frequently involved, followed by cranial nerve, cervical, lumbar, and sacral dermatomes. Involvement of the trigeminal nerve can cause infection of the eye, which may lead to blindness.

Herpes zoster can occur in adults with HIV at any CD4 cell count, but risk for disease is highest in those with CD4 counts less than 200 cells/mm^3 or with HIV viremia. Individuals with HIV may have additional increased risk of developing herpes zoster in the first four months after starting effective antiretroviral therapy, likely a result of immune reconstitution. In contrast, long-term use of suppressive antiretroviral therapy reduces the risk of developing zoster in persons with HIV, but the risk of herpes zoster remains three-fold higher in adults with HIV than the general population.

Postherpetic neuralgia is the most common complication of herpes zoster. Postherpetic neuralgia is pain that persists in the area where the rash once was for more than 90 days after rash onset. Post herpetic neuralgia can last for weeks or months, and occasionally, for years. Immunosuppression from HIV infection is associated with a two-fold increase in the risk of developing post-herpetic neuralgia when compared to persons without HIV. Patients with advanced HIV infection may present with prolonged lesion formation and viral dissemination. Cutaneous dissemination can result in hundreds of vesicles outside the primary dermatome and may be difficult to distinguish from primary varicella (e.g., chickenpox). Disseminated varicella-zoster virus (VZV) infection may appear as widespread blisters with or without an associated dermatomal eruption or may present as widespread ecthymatous ulcers. Viral dissemination may occur to the visceral organs (e.g., lungs) and the CNS. The CNS is the primary target for herpes zoster dissemination in patients co-infected with HIV. Various VZV-related neurologic syndromes may occur (e.g., CNS vasculitis, multifocal leukoencephalitis, ventriculitis, myelitis, myeloradiculitis, optic neuritis, cranial nerve palsies, focal brain-stem lesions, cognitive changes, and aseptic meningitis).

NOTE: Nosocomial transmission of VZV is well-recognized and can be life threatening to certain groups of patients. Reports of nosocomial transmission are uncommon in the United States since introduction of varicella vaccine.

Patients, healthcare providers, and visitors with varicella or herpes zoster can spread VZV to susceptible patients and healthcare providers in hospitals, long-term-care facilities, and other healthcare settings. In healthcare settings, transmissions have been attributed to delays in the diagnosis or reporting of varicella and herpes zoster and failures to implement control measures promptly. Healthcare providers should follow CDC standard precautions plus airborne precautions and contact precautions until lesions are dry and crusted. Patients with varicella should be isolated in closed rooms with no contact with people without evidence of immunity. Patients with varicella should be cared for by staff with evidence of immunity.

ETIOLOGY

Herpes zoster is caused by reactivation of VZV (e.g., reactivation of chickenpox).

SUBJECTIVE

1. May report numbness, itching or pain in a dermatomal distribution that precedes the appearance of lesions by many days (prodrome).

2. Complains of painful and/or itching skin blisters or ulcerations along one side of the face or body.

3. May complain of:
   a. Severe pain,
   b. Disseminated skin lesions,
   c. Loss of or change in vision,
   d. Respiratory symptoms,
   e. Symptoms of encephalitis (e.g., headaches, vomiting, lethargy, ataxia, tremor, and dizziness).

4. Conduct pain assessment using pain tool/scale (e.g., faces of pain or 0-10 numerical scale).

5. May report a history of:
   a. Chickenpox,
   b. Shingles.

6. Absence of allergies to acyclovir, valacyclovir or famciclovir.

7. Absence of known or suspected resistance to oral medications, e.g., previous clinical failure to standard therapy.

NOTE: All acyclovir-resistant strains are also resistant to valacyclovir and famciclovir. Anti-viral resistant varicella zoster infection should be managed by an infectious-disease specialist and alternate therapy should be administered.

8. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

9. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. Vesicular lesions with erythematous bases following dermatomes; may be bullous, hemorrhagic and/or necrotic.

   NOTE: Lesions in the eye area or tip of nose, along the trigeminal nerve, represent a therapeutic emergency and the patient should be evaluated immediately in the Emergency Room. Assessment, if available, by an experienced ophthalmologist is strongly recommended.

2. May have allodynia (e.g., pain provoked by normally innocuous stimuli) and/or sensory deficits.

3. May have dermatomal scarring and/or hypopigmentation.

4. May have signs of disseminated skin or visceral disease (e.g., respiratory signs, altered mental status).

5. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

ASSESSMENT Suspect Herpes Zoster

PLAN

DIAGNOSTIC STUDIES

1. Assessment is usually based on characteristic clinical presentation. May order polymerase chain reaction (PCR), direct fluorescent antibody (DFA), or culture. To collect the sample for DFA testing, unroof the lesion and scrape the base, since this optimizes collection of more cellular material. Although viral culture has been the gold standard for diagnosis, there is increasing evidence that it is suboptimal when compared with more modern molecular

techniques, such as PCR. If the lesions are already crusted, the sensitivity of any test is decreased, but in this situation, PCR testing provides the highest yield. If submitting specimens for testing, consult the laboratory performing the test in advance for sample requirements.

2. Complete pregnancy test for individuals of childbearing potential, if indicated.

3. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as **suspect syphilis,** elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:

    a. HIV RNA viral load,
    b. CD4 cell count,
    c. Comprehensive metabolic panel,
    d. CBC with differential,
    e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites). **Refer to the Standard Nurse Protocols for Sexually Transmitted Diseases.**

4. **Consider Mpox, refer to Standard Nurse Protocol for Mpox.**

5. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:

    a. Random or fasting lipid profile,
    b. Hepatitis A total antibody, for assessment of immune status,
    c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
    d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
    e. Pap smear,
    f. TB screening test or risk assessment, as indicated.

6. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
b. Lexicomp,

http://www.wolterskluwercdi.com/lexicomp-online/
c. Drugs.com, Drug Interactions Checker
https://www.drugs.com/drug_interactions.php

THERAPEUTIC

PHARMACOLOGIC

1. If patient does not have clinical features of disseminated or visceral infection, and if lesions are not in the eye area, tip of nose, or along the trigeminal nerve begin treatment:

   PREFERRED:

   a. Valacyclovir 1 gram by mouth three times/day for 7 to 10 days.
   OR
   b. Famciclovir 500mg by mouth three times/day for 7 to 10 days.

   ALTERNATIVE:

   c. Acyclovir 800mg by mouth 5 times/day for 7 to 10 days.

NOTE: Longer duration of therapy should be considered if lesions resolve slowly.

NOTE: Antiviral therapy should be instituted as soon as possible for all patients with HIV. Prompt treatment should be instituted in all immunosuppressed patients with herpes zoster if presentation occurs within 1 week of rash onset or any time before full crusting of lesions. Dose reductions are required for patients with renal impairment. Exercise caution when treating elderly patients who are more likely to have renal or CNS adverse reactions.

2. For pain management: May instruct patient to try over-the-counter analgesics but to avoid aspirin because of the risk of Reye syndrome.

3. May use calamine lotion to relieve pain and itching. Avoid using large amounts that result in caking and is difficult to remove.

NON-PHARMACOLOGIC

1. Try not to scratch or pick at lesions.
2. Loose clothing may be more comfortable.
3. May try oatmeal baths to relieve itching.
4. Placing cool, wet cloths on the area for about 20 minutes may relieve pain and itching. Do not use if blisters are no longer oozing.
5. Use a separate cloth for bathing affected area to avoid dissemination. Pat skin dry without rubbing it.

6. Do not use thick ointment, such as petroleum jelly, on the sores. This will keep them from drying and healing.
7. Warm saline wet-to-dry dressing can be applied 2-3 times/day to necrotic tissue and lesions gently debrided. Lesions should be kept clean and dry as much as possible.

PATIENT EDUCATION/COUNSELING

1. Inform patient that VZV is contagious, and contact or airborne spread from vesicle fluid may cause chickenpox in non-immune persons *(*e.g., no history of chickenpox or shingles). Patient should avoid exposing non-immune persons to VZV. If a non-immune person, especially a pregnant woman, some infants or immunocompromised individual, has been exposed, they should seek medical care as soon as possible (within 96 hours after exposure) to receive prophylactic assessment and treatment (e.g., VariZIG™, vaccine, etc.). Refer to the GA-DPH STANDARD NURSE PROTOCOL FOR CHILDHOOD AND ADULT IMMUNIZATIONS.

2. Counsel on importance of completing medication treatment even if symptoms are resolved. Review current drug regimen, including drug storage, dose, route of administration, schedule, side effects, drug interactions and follow-up monitoring.

3. Counsel on importance of taking antiretroviral therapy as ordered to improve immune function and decrease severity of herpes zoster.

4. Instruct patient to notify provider of any adverse drug reactions or side effects.

5. Instruct patient to report signs/symptoms of disseminated disease, secondary infections (e.g., fever, worsening skin lesions), and facial lesions, especially near eye or on tip of nose or recurrence of lesions to provider. Delays in assessment should be minimized and the patient should be instructed to present to the local Emergency Room for any severe symptoms or inability in reaching the clinic for recommendations.

6. Instruct patient to notify clinic if condition worsens or does not improve within seven days of initiation of therapy or if skin lesions have an atypical (e.g., verrucous) appearance that do not improve within seven days of treatment.

7. Explain that pain may continue even after skin lesions heal and patient should inform provider of continued pain.

8. Explain that recurrences may occur, and to notify provider of any recurrences.

9. Advise patient to check with their pharmacist or provider about interactions before taking a new medication, nutritional or herbal supplement, or over-the-

counter drug/product.

10. Instruct patient of childbearing potential to inform provider if planning pregnancy or if pregnant.

11. For patients **18** years of age or older, counsel patient on DHHS recommendation to receive **recombinant zoster vaccine (RZV, Shingrix®)** following provider evaluation and resolution of herpes zoster.

FOLLOW-UP

1. Schedule follow-up contact or visit (phone, in-person, telehealth, etc.) with patient near to completion of treatment to determine if further evaluation by provider is needed.

2. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

   NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Patients presenting with lesions on the face, tip of nose, near the eye, or complaints of visual disturbances should be evaluated immediately in the Emergency Room, as this represents a therapeutic emergency. Delays in evaluation should be minimized and the patient should be assessed the same day.

2. Refer without delay to delegating physician or prescribing provider:

   a. Pregnant patient,
   b. Patient with severe or suspected disseminated or visceral infection. Delays in evaluation should be minimized and patient should be assessed the same day with referral to the Emergency Room if needed,
   c. Patient with renal impairment,
   d. Patient with severe hepatic impairment,
   e. Patient with known or suspected VZV anti-viral resistance,
   f. Patient not on ART,
   g. Patient on ART and not virally suppressed, e.g., HIV RNA at or greater

than 200 copies per mL.

3. Refer to delegating physician or prescribing provider:

    a. Signs/symptoms of secondary infection are present,
    b. If longer duration of therapy is being considered due to slowly resolving lesions,
    c. Appropriate pain management, if needed,
    d. Patient with history of medication side effects and/or adverse events.

4. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR OROLABIAL HERPES SIMPLEX IN ADULT WITH HIV

DEFINITION

Herpes simplex virus (HSV) primarily infects the orolabia (e.g., mouth and lips), genitals, and anorectal area. Herpes simplex virus is categorized into two types: herpes simplex virus type 1 (HSV-1) and herpes simplex virus type 2 (HSV-2) . Orolabial herpes (commonly known as cold sores or fever blisters) is the most common manifestation of HSV-1. Both HSV-1 and HSV-2 can cause lesions anywhere on the body and are indistinguishable from a clinical perspective. Non-mucosal manifestations may include HSV keratitis, encephalitis, hepatitis, retinitis, herpetic whitlow and disseminated infection. HSV is a significant cause of proctitis in men with HIV who have sex with men and may not be associated with external anal ulcers.

HSV is a chronic lifelong viral infection. Infections with HSV are common. Initial infection with HSV-1 usually occurs in childhood. Oral herpes infection with HSV-1 may be asymptomatic and people may be unaware that they are infected. Approximately 95% of persons with HIV are seropositive for either HSV-1 or HSV-2 and 60-70% are seropositive for HSV-2. Severity and frequency of HSV recurrence may increase with advancing immunosuppression. HSV-2 infection increases the risk of HIV acquisition two- to three- fold. In coinfected patients, HSV-2 reactivation results in increases in HIV RNA levels in blood and genital secretions. HSV infection is characterized by periodic reactivation, during which shedding from orolabial, and genital mucosal surfaces is increased; shedding can occur even in asymptomatic individuals, and HSV shedding also persists despite highly active antiretroviral therapy among persons coinfected with HSV and HIV.

Classic manifestations of oral HSV-1 include a sensory prodrome in the affected area, rapidly followed by lesions on lips and oral mucosa that evolve in stages from papule to vesicle, ulcer, and crust. Recurrent herpes lesions usually appear on heavily keratinized mucosa, including the vermillion border of the lips, gingivae, hard palate, and tongue. The course of illness in untreated patients is 5 to 10 days. Lesions recur 1 to 12 times per year and can be triggered by sunlight or physiologic stress.

Anti-herpes therapy initiated at onset of the prodrome can shorten the symptomatic period or even abort the outbreak. Individuals with a CD4 count less than 100 cells/mm^3 may have deep, extensive, non-healing ulcers and are more likely to develop acyclovir-resistant HSV if they receive multiple courses of herpes treatment; repeated episodic therapy poses a greater risk than suppressive therapy. In addition, persons who have just started effective antiretroviral therapy may develop unusual ulcerative lesions as a manifestation of immune reconstitution syndrome.

ETIOLOGY

Primary infection, or recurrent disease from latent infection, with herpes simplex virus, HSV-1 or HSV-2.

SUBJECTIVE

1. Painful blisters followed by ulcers in or around the mouth.

2. May have:

    a. Sensory prodrome of pain, tingling, itching, or burning sensation,
    b. Persistent ulcers or large crusted erosion,
    c. Fever,
    d. Sore throat,
    e. Swollen lymph nodes in neck,
    f. Pain,
    g. Neurological symptoms, e.g., light sensitivity, headaches, vomiting, lethargy, sleepiness, ataxia, tremor, seizures, dizziness),
    h. Opthalmic symptoms, e.g., photophobia, eye redness, pain in and around one eye only, sensation of dirt or grit in eye, excessive tearing, rash near eyes.

3. May have a history of:
    a. Cold sores/fever blisters or genital herpes/ulcers,
    b. Partner with cold sores/fever blisters or genital herpes/ulcers.

4. Absence of allergies to acyclovir, valacyclovir or famciclovir.

5. Absence of known or suspected resistance to oral medications, e.g., previous clinical failure to standard therapy.

NOTE: Treatment failure due to oral medication resistance should be suspected if herpes-related lesions do not begin to resolve within 7 days to 10 days after initiation of anti-HSV therapy. All acyclovir-resistant strains are also resistant to valacyclovir and famciclovir. Anti-viral resistant HSV should be managed by an infectious-disease specialist and alternate therapy should be administered.

6. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new medication initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

7. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. May have:
   a. Erythematous ulcers with 'punched out' borders,
   b. Crusted erosions/ulcers,
   c. Deep, extensive, and non-healing ulcers,
   d. Unusual ulcerative lesions,
   e. Lymphadenopathy,
   f. Swelling and/or erythema of oral mucosa and/or pharynx,
   g. Altered mental status.

2. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

ASSESSMENT Suspect Orolabial Herpes Simplex

PLAN

DIAGNOSTIC STUDIES

1. May order a HSV DNA PCR assay (preferred) or HSV viral culture (secondary option) if needed to confirm HSV.

NOTE: When obtaining samples, the base of the lesion should be scraped to ensure an adequate number of cells are obtained. If submitting specimens for testing, consult the laboratory performing the test in advance for sample requirements.

NOTE: Mucosal HSV infections cannot be diagnosed accurately by clinical examination, especially in persons with HIV infection, a laboratory diagnosis should be pursued in all cases, but negative results do not rule out the possibility of HSV infection.

2. Complete pregnancy test for individuals of childbearing potential, if indicated.

3. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as **suspect syphilis,** elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:
   a. HIV RNA viral load,
   b. CD4 cell count,
   c. Comprehensive metabolic panel,
   d. CBC with differential,
   e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

NOTE: Any patient who presents with genital, anal, or oral ulceration, even if the suspicion of HSV is high, syphilis serologic testing should be done. Refer to the Standard Nurse Protocols for Sexually Transmitted Diseases.

4. **Consider Mpox, refer to Standard Nurse Protocol for Mpox.**

5. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:
   a. Random or fasting lipid profile,
   b. Hepatitis A total antibody, for assessment of immune status,
   c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
   d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
   e. Pap smear,
   f. TB screening test or risk assessment, as indicated.

6. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
b. Lexicomp, http://www.wolterskluwercdi.com/lexicomp-online/
c. Drugs.com, Drug Interactions Checker, https://www.drugs.com/drug_interactions.php

THERAPEUTIC
PHARMACOLOGIC

1. Episodic treatment (duration 5 to 10 days):

   a. Acyclovir 400mg by mouth three times/day,
   OR
   b. Valacyclovir 1 gram by mouth two times/day,
   OR
   c. Famciclovir 500mg by mouth two times/day.

NOTE: Dose reductions of these medications are required for patients with renal impairment.

2. May use over the counter oral pain relief medications, per manufacturer's recommendations.

PATIENT EDUCATION/COUNSELING

1. Provide the patient with emotional support, counseling, and education about HSV as needed.

2. Counsel patient that HSV is not curable and that recurrences may occur.

3. Counsel patient on preventing exposure and transmission of HSV. Inform patient that HSV can be transmitted to other persons and asymptomatic shedding/transmission of the virus often occurs. HSV shedding is increased in persons with HIV. Persons should specifically avoid contact with symptomatic herpetic lesions and during prodromal periods (e.g., no kissing and no oral-genital sex).

4. Counsel patient to inform partner(s) about herpes and to encourage them to obtain evaluation and counseling.

5. Counsel patient that some foods may be irritating (e.g., acidic, salty, spicy, etc.). and to avoid if needed.

6. Counsel on importance of completing medication treatment even if symptoms are resolved. Review current drug regimen including drug storage, dose, route of administration, schedule, side effects and follow-up monitoring.

7. Counsel on importance of taking antiretroviral therapy as ordered to improve immune function and decrease severity of HSV.

8. Instruct patient to notify provider if condition worsens or does not improve.

9. Instruct patient to notify provider of any adverse drug reactions or side effects.

10. Instruct patient of childbearing potential to inform provider if planning pregnancy or if pregnant.

11. Advise patient to check with their pharmacist or provider about interactions before taking a new medication, nutritional or herbal supplement, or over-the-counter drug/product.

FOLLOW-UP

1. Schedule follow-up contact or visit (phone, in-person, telehealth, etc.) with patient near to completion of treatment to determine if further evaluation by provider is needed.

2. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. If patient is reporting symptoms suggestive of encephalitis, neurological or ophthalmic sequelae and/or exhibiting altered mental status, contact the delegating physician immediately and send patient to the closest Emergency Room without delay.

2. Refer without delay to delegating physician or prescribing provider:

    a. Severe or persistent cases,
    b. Patient with known or suspected anti-viral resistant HSV,
    c. Patient with renal impairment,
    d. Patient with severe hepatic impairment,
    e. Pregnant patient,
    f. Patient not on ART,
    g. Patient on ART and not virally suppressed, e.g., HIV RNA at or greater than 200 copies per mL.

3. Refer to delegating physician or prescribing provider:
    a. Patient requesting or indicated for suppressive therapy evaluation,
    b. Patient with history of medication side effects and/or adverse events,
    c. Patient with pain management needs beyond OTC therapy.

4. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR PNEUMOCYSTIS PNEUMONIA PROPHYLAXIS IN ADULT WITH HIV

DEFINITION

Pneumocystis jirovecii pneumonia (PCP) prophylaxis is treatment given to individuals with HIV to prevent either a primary episode or recurrence of PCP. The taxonomy of the organism has been changed; *P. carinii* is now exclusive to the pneumocystis that infects rodents and *P. jirovecii* refers to the species that infects humans. However, the abbreviation PCP is still used to designate *Pneumocystis* pneumonia.

In patients with HIV, the most common manifestations of PCP are subacute onset of progressive dyspnea, fever, non-productive cough, and chest discomfort that worsens within days to weeks.

In mild cases, pulmonary examination while the patient is at rest usually is normal. With exertion, tachypnea, tachycardia, and diffuse dry (cellophane) rales may be observed. Oral thrush is a common coinfection. Fever is apparent in most cases and may be the predominant symptom in some patients. Extrapulmonary disease is rare but can occur in any organ and has been associated with use of aerosolized pentamidine prophylaxis. Hypoxemia is the most characteristic laboratory abnormality and can range from mild to severe.

ETIOLOGY

Pneumocystis jirovecii is a ubiquitous fungus acquired through inhalation. Initial infection with *Pneumocystis jirovecii* usually occurs in early childhood; two-thirds of healthy children have antibodies to *Pneumocystis jirovecii* by ages 2 to 4 years. Disease probably occurs by new acquisition of infection and by reactivation of latent infection with most cases occurring in patients who are unaware of their HIV infection or are not receiving ongoing care for HIV, and in those with advanced immunosuppression, e.g., CD4 counts less than 100 cells/mm^3.

SUBJECTIVE

1. May have a history of:
   a. Previous PCP episode,
   b. Oropharyngeal candidiasis,
   c. An AIDS defining illness.

2. No history of active tuberculosis (TB)

3. No complaints of symptoms suggestive of active PCP (e.g., non-productive cough, fever, shortness of breath).

4. Absence of allergies to sulfa drugs, dapsone, pyrimethamine or atovaquone.

5. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

6. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

2. Assess patient's indications for PCP prophylaxis per the table below:

Preventing First Episode of PCP (Primary Prophylaxis)
Indications for Initiating Primary Prophylaxis: • CD4 count <200 cells/mm^3 OR • CD4 percentage <14% of total lymphocyte count OR • CD4 count >200 cells/mm^3, *but* <250 cells/mm^3 if ART initiation must be delayed and if CD4 count monitoring (e.g., every 3 months) is not possible. NOTE: Patients who are receiving pyrimethamine/sulfadiazine for treatment or suppression of toxoplasmosis do not require additional prophylaxis for PCP.
Indication for Discontinuing Primary Prophylaxis: • CD4 count increased from <200 cells/mm^3 to ≥200 cells/mm^3 for ≥3 months in response to ART • Can consider when CD4 count is 100–200 cells/mm^3 and HIV RNA remains below limit of detection of the assay used for ≥3 months to 6 months
Indication for Restarting Primary Prophylaxis:

- CD4 count <100 cells/mm^3 regardless of HIV RNA
- CD4 count 100–200 cells/mm^3 and HIV RNA above detection limit of the assay used

Preventing Subsequent Episode of PCP (Secondary Prophylaxis)

Indications for Initiating Secondary Prophylaxis:

- Prior PCP

Indications for Discontinuing Secondary Prophylaxis:

- CD4 count increased from <200 cells/mm^3 to >200 cells/mm^3 for >3 months as a result of ART

OR

- Can consider if CD4 count is 100–200 cells/mm^3 and HIV RNA remains below limits of detection of assay used for ≥3 months to 6 months
- For patients in whom PCP occurs at a CD4 count >200 cells/mm^3 while not on ART, discontinuation of prophylaxis can be considered once HIV RNA levels are suppressed to below limits of detection of the assay used for ≥3 months to 6 months, although there are no data to support recommendations in this setting.

NOTE: If an episode of PCP occurs at a CD4 count >200 cells/mm^3 while a patient is on ART, it would be prudent to continue PCP prophylaxis for life, regardless of how high the CD4 cell count rises as a consequence of ART.

Indications for Restarting Secondary Prophylaxis:

- CD4 count <100 cells/mm^3 regardless of HIV RNA
- CD4 count 100–200 cells/mm^3 and HIV RNA above detection limit of the assay used.

3. Absence of pulmonary signs and symptoms.

4. Absence of Glucose-6-Phosphate Dehydrogenase (G6-PD) deficiency

NOTE: Whenever possible, patients should be tested for G6-PD deficiency before administration of dapsone. Alternative agent should be used if the patient is found to have G6-PD deficiency. Additionally, trimethoprim-sulfamethoxazole should be used with caution in patients with G6-PD deficiency.

ASSESSMENT Candidate for PCP Prophylaxis

PLAN

DIAGNOSTIC STUDIES

1. If previous results not available, test for G6-PD deficiency.

2. Complete pregnancy test for individuals of childbearing potential, if indicated.

3. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:

    a. HIV RNA viral load,
    b. CD4 cell count,
    c. Comprehensive metabolic panel,
    d. CBC with differential,
    e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

4. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:
    a. Random or fasting lipid profile,
    b. Hepatitis A total antibody, for assessment of immune status,
    c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
    d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
    e. Pap smear,
    f. TB screening test or risk assessment, as indicated.

5. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

    a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
    b. Lexicomp, http://www.wolterskluwercdi.com/lexicomp-online/
    c. Drugs.com, Drug Interactions Checker,

https://www.drugs.com/drug_interactions.php

THERAPEUTIC

PHARMACOLOGIC

1. Preferred Therapy:
   a. Trimethoprim-sulfamethoxazole* (TMP-SMZ 800mg/160mg): one double strength (DS) tablet by mouth daily†
      OR
   b. TMP-SMZ* (400mg/80mg): one single-strength (SS) tablet by mouth daily†

2. Alternative
   a. TMP-SMZ* (800mg/160mg): one DS tablet by mouth 3 times per week† (e.g., Monday, Wednesday, Friday)

3. Alternative if intolerant to TMP-SMX
   a. Dapsone Regimens

   NOTE: As of June 2015, pyrimethamine is no longer available in retail pharmacies in the United States. It is only available through a special pharmacy program (http://www.daraprimdirect.com/). If there is a delay in procuring pyrimethamine for a patient in whom it is needed, consult physician for guidance.

      1) Dapsone 200mg by mouth once per week
         PLUS
         Pyrimethamine 75mg by mouth once per week
         PLUS
         Leucovorin 25mg by mouth once per week†
         Given together once per week
         OR
      2) Dapsone 50mg by mouth two times/day or 100 mg by mouth daily‡
         OR
   b. Atovaquone suspension 1500mg by mouth daily with food †¶

   NOTE: For use of Atovaquone with Zidovudine, monitor for zidovudine adverse effects.

LEGEND

* Many patients become intolerant of sulfa medications. Severe reactions may include persistent neutropenia, fever, renal failure, severe erythroderma, and Stevens-Johnson syndrome (bullae & desquamation of the skin). Some patients with milder reactions can be desensitized.

† Regimen is also effective against toxoplasmosis.

‡ This regimen is not recommended for prevention of toxoplasmosis.
¶ Very expensive and should not be used if other alternatives are available.

PATIENT EDUCATION/COUNSELING

1. Counsel on importance of completing medication treatment even if symptoms are resolved. Review current drug regimen including drug storage, dose, route of administration, schedule, side effects and follow-up monitoring.

2. Counsel on importance of taking antiretroviral therapy as ordered to improve immune function and decrease potential for PCP disease.

3. Instruct patient to stop PCP prophylaxis medications immediately and notify provider of any adverse drug reactions or side effects (e.g., unexplained cough, shortness of breath, sore throat, unusual bleeding or bruising, changes in skin color, rash, fever, muscle weakness, etc.).

4. Instruct patient to notify provider of any other health changes of concern.

5. Inform patient of importance of attending follow-up provider and lab appointments to monitor health status and decrease potential for serious outcomes and complications.

6. Explain that prophylaxis may be discontinued due to sustained rise in CD4 cell count while on ART but may need to be re-started in the event of stopping ART, CD4 cell counts decreasing or if health condition worsens.

7. Inform that PCP can occur or recur despite prophylaxis or an elevated CD4 count and to call provider if patient develops symptoms, (e.g., cough, fever, shortness of breath, chest pain).

8. Advise patient to check with their pharmacist or provider about interactions before taking a new medication, nutritional or herbal supplement, or over-the-counter drug/product.

9. Instruct patient of childbearing potential to inform provider if pregnant or planning pregnancy.

10. For patient taking TMP-SMZ counsel on:
    a. Importance of keeping hydrated with fluids; take TMP-SMZ with a full glass of water to avoid development of urine crystals and kidney stones,
    b. Sun sensitivity and to practice sun protection as needed, e.g., limit direct sun exposure, cover up with clothing, hats and sunglasses that block UV light, apply sunscreen, avoid tanning beds.

FOLLOW-UP

1. Ensure patient has a follow-up provider visit scheduled as soon as possible and within 30 days.

2. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

NOTE: Timely provision of services (same day if possible) is important to reduce gaps in services and improve outcomes.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Refer without delay to delegating physician or prescribing provider:
    a. Pregnant patient,
    b. Patient with signs/symptoms of PCP disease,
    c. Patient with G6-PD deficiency,
    d. Patient with renal impairment,
    e. Patient with severe hepatic impairment,
    f. Patient not on ART.

2. Refer to delegating physician or prescribing provider patient with history of medication side effects and/or adverse events.

3. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for treatment of patient.

REFERENCES

1. American Cancer Society, "Spend Time Outside and Stay Sun-safe," April 15, 2020, <https://www.cancer.org/latest-news/stay-sun-safe-this-summer.html> (**November 2, 2022**).

2. David H. Spach, "*Pneumocystis* Pneumonia," September 2, 2020, *National HIV Curriculum*, <https://www.hiv.uw.edu/go/co-occurring-conditions/opportunistic-infections-prevention/core-concept/all#empneumocystisem-pneumonia> (**November 3, 2022**).

3. Department of Health and Human Services, "Pneumocystis Pneumonia" Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents **with HIV**, National Institutes of Health, **Centers for Disease Control and Prevention,** HIV Medicine Association, **and** Infectious Diseases Society of America, March 28, 2019, <**https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/pneumocystis-0?view=full** > (**November 3, 2022**).

4. Department of Health and Human Services, "Laboratory Testing **September 21, 2022**, **Panel on Antiretroviral Guidelines for Adults and Adolescents, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV** <**https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/tests-initial-assessment-follow-up?view=full** > (**November 1, 2022**).
.
5. Drugs.com, "Bactrim: 7 things you should know," **February 15, 2022**, <https://www.drugs.com/tips/bactrim-patient-tips> (**November 3, 2022**).

6. **Wolters Kluwer, "Lexicomp: Evidence-Based Referential Content**," **2022**, <http://www.wolterskluwercdi.com/lexicomp-online/> (**November 1, 2022**).

7. MedlinePlus, National Library of Medicine, *"*Glucose-6-phosphate dehydrogenase deficiency*,"* **May 1, 2017**, <https://ghr.nlm.nih.gov/condition/glucose-6-phosphate-dehydrogenase-deficiency> (**November 3, 2022**).

STANDARD NURSE PROTOCOL FOR TOXOPLASMOSIS PRIMARY PROPHYLAXIS IN ADULT WITH HIV

DEFINITION

All persons with HIV should be tested for IgG antibody to *Toxoplasma* soon after HIV diagnosis. Persons found to be *Toxoplasma*-seropositive and with CD4 counts less than 100 cells/mm^3 should be administered primary prophylaxis to prevent toxoplasmic encephalitis (TE). In addition, Toxoplasma IgG-negative patients, should be retested for IgG antibody to Toxoplasma when their CD4 counts decline to less than 100 cells/mm^3 to determine whether they have seroconverted and therefore are at risk for TE. Clinical disease is rare among patients with CD4 T lymphocyte (CD4) counts greater than 200 cells/mm^3 with the greatest risk in those patients with CD4 counts lesser than 50 cells/mm^3.

Persons with HIV who have completed initial treatment for TE should be administered secondary prophylaxis (chronic maintenance therapy) for life, until immune reconstitution occurs due to antiretroviral therapy (ART).

Toxoplasmosis is considered to be a leading cause of death attributed to foodborne illness in the United States. More than 40 million men, women, and children in the U.S. carry the *Toxoplasma* parasite, but very few have symptoms because the immune system usually keeps the parasite from causing illness. However, women newly infected with *Toxoplasma* during or shortly before pregnancy and anyone with a compromised immune system should be aware that toxoplasmosis can have severe consequences. Toxoplasmosis is not passed from person-to-person, except in instances of mother-to-child (congenital) transmission and blood transfusion or organ transplantation. People typically become infected by three principal routes: foodborne transmission- eating or accidentally ingesting raw or undercooked contaminated meat or shellfish, animal-to-human transmission- accidental ingestion of oocysts from cat's feces, contaminated soil and water, and congenital transmission.

ETIOLOGY

Toxoplasmic encephalitis (TE) is caused by the protozoan *Toxoplasma gondii*. Disease appears to occur almost exclusively because of reactivation of latent tissue cysts. Primary infection occasionally is associated with acute cerebral or disseminated disease.

It is estimated that approximately 11% of the United States population 6 years and older have been infected with *Toxoplasma.* In the era before antiretroviral therapy (ART), the 12-month incidence of TE was approximately 33% in patients with advanced immunosuppression who were seropositive for

Toxoplasma gondii and not receiving prophylaxis with drugs against the disease. A low incidence of toxoplasmosis is seen in patients who are seronegative for *Toxoplasma gondii*. If patients are truly seronegative, their toxoplasmosis presumably represents primary infection, re-activation of latent disease (most commonly due to immunodeficiency) in individuals who cannot produce detectable antibodies or testing with insensitive assays. *Toxoplasma gondii* can infect any tissue, but the most common sites are the brain, lungs, and eyes. In persons with HIV the most common presentation is focal encephalitis.

SUBJECTIVE

1. Does not have a history of TE and treatment for TE.

2. No history/complaints of neurological symptoms suggestive of TE (e.g., seizures, altered mental status, motor weakness, headaches, and/or cognitive impairment).

3. Absence of allergies to sulfa drugs, dapsone, pyrimethamine, atovaquone, folate derivatives and/or clindamycin.

4. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

5. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. May be *Toxoplasma* IgG seropositive.

NOTE: The absence of IgG antibody makes a diagnosis of toxoplasmosis unlikely but not impossible.

2. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

3. Assess patient's indications for TE prophylaxis per the table below:

Preventing 1st Episode of *Toxoplasma gondii* Encephalitis (Primary Prophylaxis)
Indication for Initiating Primary Prophylaxis: • *Toxoplasma* IgG positive patients with CD4 count <100 cells/mm^3 NOTE: All the recommended regimens for preventing 1st episode of toxoplasmosis are also effective in preventing PCP.
Indications for Discontinuing Primary Prophylaxis: • CD4 count >200 cells/mm^3 for >3 months in response to ART; OR • Can consider if CD4 count is 100-200 cells/mm^3 and HIV RNA levels remain below limits of detection for at least 3-6 months.
Indication for Restarting Primary Prophylaxis: • CD4 count <100 to 200 cells/mm^3

4. Absence of neurological signs of TE (e.g., altered mental status, aphasia, ataxia, hemiparesis, and cranial nerve palsies).

5. Absence of Glucose-6-Phosphate Dehydrogenase (G6-PD) deficiency.

NOTE: Whenever possible, patients should be tested for G6-PD deficiency before administration of dapsone. Alternative agent should be used if the patient is found to have G6-PD deficiency. Additionally, trimethoprim-sulfamethoxazole and sulfadiazine should be used with caution in patients with G6-PD deficiency.

ASSESSMENT Candidate for Toxoplasmosis Prophylaxis

PLAN

DIAGNOSTIC STUDIES

1. If previous positive results or recent IgG antibody testing for *Toxoplasma* not available, test for IgG antibody to *Toxoplasma*.

2. If previous results not available, test for G6-PD deficiency.

3. Complete pregnancy test for individuals of childbearing potential, if indicated.

4. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:

    a. HIV RNA viral load,
    b. CD4 cell count,
    c. Comprehensive metabolic panel,
    d. CBC with differential,
    e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

5. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:

    a. Random or fasting lipid profile,
    b. Hepatitis A total antibody, for assessment of immune status,
    c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
    d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
    e. Pap smear,
    f. TB screening test or risk assessment, as indicated.

6. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

    b. a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
    c. Lexicomp, http://www.wolterskluercdi.com/lexicomp-online
    d. Drugs.com, Drug Interactions Checker, https://www.drugs.com/drug_interactions.php

THERAPEUTIC

PHARMACOLOGIC

1. Primary Prophylaxis (Prevention of TE)
   a. Preferred Regimen:
      1) Trimethoprim-sulfamethoxazole* (TMP-SMZ-800mg/160mg): one double strength (DS) tablet by mouth daily†

OR

   b. Alternative Regimens:
      1) TMP-SMZ* (400mg/80mg): one single strength (SS) tablet by mouth daily†

OR

      2) TMP-SMZ* (800mg/160mg): one (DS) tablet by mouth 3 times per week† (e.g., Monday, Wednesday, Friday)

NOTE: TMP/SMZ may require dosage adjustment in patients with renal impairment. Consult with delegating physician regarding appropriate dosing.

OR

If patient cannot tolerate TMP-SMZ:

1) Alternative Regimens:
   a) Dapsone† 200mg by mouth once per week

PLUS

Pyrimethamine 75mg by mouth once per week

PLUS

Leucovorin 25mg by mouth once per week.
Given together once per week.

OR

   b) Atovaquone 1500mg by mouth daily with food†‡

NOTE: As of June 2015, pyrimethamine is no longer available in retail pharmacies in the United States. It is only available through a special pharmacy program (http://www.daraprimdirect.com/). If there is a delay in procuring pyrimethamine for a patient in whom it is needed, consult physician for guidance.

NOTE: For use of Atovaquone with Zidovudine, monitor for zidovudine adverse effects.

LEGEND:
* Many patients become intolerant of sulfa medications. Severe reactions may include persistent neutropenia, fever, renal failure, severe erythroderma, and Stevens-Johnson syndrome (bullae & desquamation of the skin). Some patients with milder reactions can be desensitized.

† Regimen is also effective against PCP. (Atovaquone dosed at 750mg every 12 hours is an alternative regimen for secondary TE prophylaxis, but not for PCP).
‡ Very expensive and should not be used if other alternatives are available.

PATIENT EDUCATION/COUNSELING

1. Counsel on importance of completing medication treatment even if symptoms are resolved. Review current drug regimen including dose, drug storage, route of administration, schedule, side effects, and follow-up monitoring.

2. Counsel on importance of taking antiretroviral therapy as ordered to improve immune function and decrease potential for TE.

3. Instruct patient to stop TE primary prophylaxis medications immediately and notify provider of any adverse drug reactions or side effects (e.g., unexplained cough, shortness of breath, sore throat unusual bleeding or bruising, changes in skin color, rash, fever, muscle weakness, etc.).

4. Instruct patient to notify provider promptly of any neurological signs/symptoms suggestive of TE and any other health changes of concern.

5. Inform patient of importance of attending follow-up provider and lab appointments to monitor health status and decrease potential for serious outcomes and complications.

6. Explain that prophylaxis may be discontinued due to sustained rise in CD4 cell count while on ART but may need to be re-started in the event of stopping ART, CD4 cell counts decreasing or if health condition worsens.

7. Instruct patient of childbearing potential to inform provider if pregnant or planning pregnancy.

8. For patient taking TMP-SMZ counsel on:
   a. Importance of keeping hydrated with fluids; take TMP-SMZ with a full glass of water to avoid development of urine crystals and kidney stones.
   b. Sun sensitivity and to practice proper sun protection as needed, e.g., limit direct sun exposure, cover up with clothing, hats and sunglasses that block UV light, apply sunscreen, avoid tanning beds.

9. Advise patient to check with his/her pharmacist or provider about interactions before taking a new medication, nutritional or herbal supplement, or over-the-counter drug/product.

10. Counsel *Toxoplasma* IgG-negative patients on ways to minimize risk of

acquiring toxoplasmosis, e.g., avoiding accidental contact with and eating raw or undercooked meats and shellfish, handwashing after contact with raw meat, soil, and cat litter boxes, etc.

FOLLOW-UP

1. Ensure patient has a follow-up provider visit scheduled as soon as possible and within 30 days.

2. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Refer without delay to delegating physician or prescribing provider:

    a. Pregnant patient,
    b. Patient with signs/symptoms of TE, e.g., seizures, altered mental status, motor weakness, headaches, and/or cognitive impairment,
    c. Patient with G6-PD deficiency,
    d. Patient with renal impairment,
    e. Patient with severe hepatic impairment,
    f. Patient not on ART.

2. Refer to delegating physician or prescribing provider:

    a. Patient with history of TE disease,
    b. Patient with history of medication side effects and/or adverse events.

3. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for therapeutic treatment of patient.

REFERENCES

1. American Cancer Society, “Spend Time Outside and Stay Sun-safe,” April 15, 2020, <https://www.cancer.org/latest-news/stay-sun-safe-this-summer.html> (**November 2, 2022**).

2. Centers for Disease Control and Prevention, “Parasites - Toxoplasmosis (Toxoplasma infection),” August 29, 2018, <https://www.cdc.gov/parasites/toxoplasmosis/> (**November 3, 2022**).

3. Centers for Disease Control and Prevention, “Toxoplasmosis: General FAQs,” September 3, 2020, <https://www.cdc.gov/parasites/toxoplasmosis/gen_info/faqs.html> (**November 3, 2022**).

4. David H. Spach, “*Toxoplasma* Encephalitis,” September 2, 2020, *National HIV Curriculum*, <https://www.hiv.uw.edu/go/co-occurring-conditions/opportunistic-infections-prevention/core-concept/all#emtoxoplasmaem-encephalitis> (**November 3, 2022**).

5. Department of Health and Human Services, “Toxoplasma gondii Encephalitis,” Panel on Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents **with HIV**, National Institutes of Health, **Centers for Disease Control and Prevention,** HIV Medicine Association, **and** Infectious Diseases Society of America, July 25, 2017, <**https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/toxoplasma-gondii?view=full**> (**November 3, 2022**).

6. Department of Health and Human Services, “Laboratory Testing” **September 21, 2022**, **Panel on Antiretroviral Guidelines for Adults and Adolescents, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV** <**https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/tests-initial-assessment-follow-up?view=full** > (**November 1, 2022**).

7. MedlinePlus, National Library of Medicine, *“*Glucose-6-phosphate dehydrogenase deficiency*,”* **May 1, 2017**, <https://ghr.nlm.nih.gov/condition/glucose-6-phosphate-dehydrogenase-deficiency> (**November 3, 2022**).

STANDARD NURSE PROTOCOL FOR SEBORRHEIC DERMATITIS IN ADULT WITH HIV

DEFINITION

Seborrheic dermatitis is a skin condition commonly seen in persons with HIV (**affects approximately 34 to 83% of persons with HIV, as opposed to 1 to 3% of the general population**.). It is chronic and usually undergoes periods of exacerbation and remission. The condition occurs in areas where sebaceous glands are concentrated, including the scalp, eyebrows, nasolabial folds, forehead, cheekbones, ears, hairline, chest, axilla, and groin.

ETIOLOGY

The probable cause of seborrhea is a yeast, *Malassezia* (formerly called *Pityrosporum ovale*). Overgrowth of the Malassezia yeast in the oily skin environment, failure of the immune system to regulate the fungus, and the skin's inflammatory reaction to the yeast overgrowth appear to be the chief factors that cause the dermatitis.

SUBJECTIVE

1. May report a rash, itchy, or "dry skin" that will not go away despite application of topical moisturizers.

2. May have a history of dandruff and/or seborrheic dermatitis.

3. Absence of allergies to topical treatments included in pharmacologic section.

4. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

5. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. Fine white scaling, without erythema, affecting the scalp (dandruff),
   and/or
   Scaly/crusty patches and plaques of erythema with indistinct margins and yellowish, greasy scale affecting one or more of the following areas: scalp, eyebrows, nose, nasolabial folds, forehead, cheekbones, ears, hairline, chest, breast folds, axilla, back and/or groin.

2. Absence of symptoms suggestive of secondary syphilis, (e.g., palmoplantar, and mucosal lesions, peripheral adenopathy, condylomata lata, patchy alopecia) see GA DPH STANDARD NURSE PROTOCOL FOR SYPHILIS, EARLY SYMPTOMATIC (PRIMARY and SECONDARY).

3. Review recent (within 6 months) CD4 cell count, HIV RNA viral load, and comprehensive metabolic panel (assess renal and hepatic function).

ASSESSMENT Suspect Seborrheic Dermatitis

PLAN

DIAGNOSTIC STUDIES

1. May perform a potassium hydroxide (KOH) preparation to rule out *Candida albicans* and other superficial yeast infections.

2. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:
   a. HIV RNA viral load,
   b. CD4 cell count,
   c. Comprehensive metabolic panel,
   d. CBC with differential,
   e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

3. Consider completing the following during the visit, if indicated to enhance care coordination and reduce missed opportunities:
   a. Random or fasting lipid profile,
   b. Hepatitis A total antibody, for assessment of immune status,
   c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
   d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
   e. Pap smear,
   f. TB screening test or risk assessment, as indicated.

4. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
b. Lexicomp, http://www.wolterskluwercdi.com/lexicomp-online/
c. Drugs.com, Drug Interactions Checker. https://www.drugs.com/drug_interactions.php

5. Complete pregnancy test for individuals of childbearing potential, if indicated.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Persons with HIV who start antiretroviral therapy often have major improvement or regression of seborrheic dermatitis.

1. For scalp conditions:

NOTE: Consult delegating or designated physician if patient has experienced a history of severe allergic reaction (e.g., severe rash, hives, difficulty breathing, dizziness) to sulfur, aspirin, nonsteroidal anti-inflammatory drug (NSAID [e.g., ibuprofen, naproxen, celecoxib]); and/or if patient is taking anticoagulants, (e.g., heparin, warfarin, apixaban, enoxaparin, rivaroxaban), aspirin, methotrexate, or sulfonylureas (e.g., glipizide) because the risk of side effects may be increased by Sebex shampoo.

a. Regular use of an over-the-counter dandruff shampoo that contains sulfur and salicylic acid (e.g., Sebex), selenium sulfide (e.g., Selsun Blue, Dandrex), ketoconazole (e.g., Nizoral-AD), coal tar, or zinc pyrithione (e.g., Head and Shoulders, Zincon). Instruct patient to shampoo per manufacturer's recommendations until condition resolves (2 to 4 weeks).

   Rotation of different classes of shampoos may improve and maintain efficacy of these formulations in clinical practice. Irritation and/or burning sensation have been reported in 1 to 3 percent of patients.

OR

b. Ketoconazole 2% shampoo (prescription strength) used daily or at least two or three times per week until condition resolves (2 to 4 weeks). Instruct patient to wet hair, massage well into scalp and leave on for 5 to 10 minutes and then rinse thoroughly.

OR

c. If shampoo alone is not adequate, a medium-potency topical corticosteroid solution (e.g., triamcinolone 0.1% applied once daily to the scalp for 2 to 4 weeks) may be used. Instruct patient to part hair, apply a small amount of the solution on the affected area, and rub it in gently. Protect the area from washing and rubbing until the solution dries. Hair

may be washed as usual but not right after applying the medicine.

NOTE: Avoid application of medium potency topical steroids to the face.

d. For individuals requiring maintenance therapy in preventing relapses: Use an over-the-counter dandruff shampoo listed above or ketoconazole 2% shampoo once per week.

2. For face conditions:
   a. First Choice: Apply ketoconazole 2% cream to affected areas once or twice daily until condition resolves (2 to 4 weeks).
   OR
   b. Second Choice: Apply hydrocortisone 1% cream to affected areas once or twice daily until condition resolves (2 to 4 weeks).
      1) Least potent topical corticosteroid creams should be used because of the potential adverse effects with prolonged use (e.g., permanent telangiectasia and atrophy). Long-term (months to years) continuous use of even mild topical corticosteroids can result in permanent telangiectasia and atrophy and should be avoided.
   c. For individuals requiring maintenance therapy in preventing relapses: Use an over-the-counter dandruff shampoo listed above or ketoconazole shampoo 2% as a facial wash once a week.
   OR
   Apply ketoconazole 2% cream to affected areas once a week.
   d. For patients with mustaches and/or beards:
      1) Apply over-the-counter dandruff shampoo listed above or ketoconazole 2% shampoo to facial hair daily until condition resolves (2-4 weeks) and then once per week if needed for maintenance therapy in preventing relapses.

3. For conditions on trunk and intertriginous areas:
   1) Apply topical 2% ketoconazole cream to affected area(s) 1 to 2 times per day until condition resolves (2 to 4 weeks).
   And/or
   2) Apply topical 0.1% triamcinolone cream to affected area(s) 1 to 2 times per day until condition resolves (2 to 4 weeks).
   3) To prevent relapses:
      a) Apply ketoconazole 2% cream to the involved area(s) once a week.
      OR
      b) Use ketoconazole 2% shampoo as a body wash once weekly.

PATIENT EDUCATION/COUNSELING

1. Review current drug regimen including drug storage, dose, route of administration, schedule, side effects, and follow-up monitoring. Include the following:

a. Treatment is for external use only. Avoid contact with eyes, inside nose and mouth. If contact occurs, rinse thoroughly with cool water.
b. If using over-the-counter dandruff shampoo, follow manufacturer directions and leave shampoo on for the recommended amount of time. Allow shampoo suds onto affected facial areas when possible.
c. Do not apply topical therapy to open wounds or weeping areas.
d. Wash and dry area before applying topical creams.
e. If using topical corticosteroid (e.g., hydrocortisone); counsel on possible sun sensitivity and to practice sun protection as needed, e.g., limit direct sun exposure, cover up with clothing, hats, sunglasses, apply sunscreen and avoid tanning beds.
f. Use products as ordered, and do not overuse. Counsel about potential adverse effects with prolonged corticosteroid cream use especially to the face (e.g., permanent telangiectasia and atrophy) and not to use corticosteroid creams ordered for conditions on trunk and intertriginous areas on the face.

2. Counsel that seborrheic dermatitis is a chronic condition, which often recurs. Patients should keep their skin as clean and dry as possible, and watch for recurrences, particularly in winter due to dry heat.

3. Counsel on the importance of taking antiretroviral therapy as ordered to improve immune function, which often leads to major improvement and regression of seborrheic dermatitis.

4. At the earliest sign of recurrence, instruct patient to restart shampoo and/or topical therapy to prevent progression and secondary infection.

5. Instruct patient to inform provider if condition worsens or does not improve, or if they have signs of secondary infection.

6. Advise patient to check with their pharmacist or provider about interactions before taking a new medication, nutritional or herbal supplement, or over-the-counter drug/product.

7. Instruct patient of childbearing potential to inform provider if pregnant or planning pregnancy.

FOLLOW-UP

1. Assess patient’s needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

2. Routine appointments with provider as indicated, at least every 3-6 months.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Refer without delay to the delegating physician or prescribing provider:
   a. Patient not on ART,
   b. Patient on ART and not virally suppressed, e.g., HIV RNA at or greater than 200 copies per mL.

2. Refer to delegating physician or prescribing provider:
   a. Pregnant patient,
   b. Patient with history of medication side effects and/or adverse events,
   c. Patient with suspected secondary infection,
   d. Patient with severe or recalcitrant episodes,
   e. Patient with symptoms that persist beyond four weeks with therapy.

3. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR ORAL CANDIDIASIS IN ADULT WITH HIV

DEFINITION

Oropharyngeal candidiasis is commonly caused by *Candida albicans.* It is characterized by painless, creamy white, plaque-like lesions that can occur on the buccal surface, hard or soft palate, oropharyngeal mucosa, or tongue surface, less commonly, erythematous patches without white plaques can be seen on the anterior or posterior upper palate or diffusely on the tongue. Angular cheilosis also can be caused by *Candida*.

ETIOLOGY

Oropharyngeal candidiasis is seen frequently among individuals with HIV and is an indicator of immune suppression. It occurs most often in patients with CD4 cell counts less than 200 cells/mm^3. *Candida albicans* is the most common species involved, but non-*albicans* species (*C*. *dubliniensis*, *C*. *glabrata*, *C*. *tropicalis*) can also cause disease. Fluconazole (or azole) resistance is predominantly the consequence of previous exposure to fluconazole (or other azoles), particularly repeated and long-term exposure. The introduction and widespread use of effective antiretroviral therapy has led to a marked decrease in the prevalence of oral candidiasis. Although HIV-related immune suppression is typically the most important risk factor for developing oral candidiasis, other causes for oral candidiasis include antibiotic use, corticosteroids, chemotherapeutic drugs, and diabetes. By maximizing immune status with effective antiretroviral therapy, most cases of candidiasis can be avoided.

SUBJECTIVE

1. May be symptomatic.

2. May complain of white patches anywhere on the oral mucosal tissues, smooth red areas on dorsal tongue (erythematous), burning or painful mouth areas, changes in taste sensation, sensitivity to spicy foods and/or decreased appetite.

3. Absence of signs/symptoms of esophageal candidiasis (e.g., esophageal candidiasis generally presents with retrosternal burning pain or discomfort along with odynophagia (painful or difficulty swallowing); occasionally esophageal candidiasis can be asymptomatic.

4. Absence of allergies to antifungal agents.

5. Obtain a complete medication profile to determine whether there are any clinically significant drug-drug interactions with treatment, especially to new

medications initiated since the previous assessment. Include over-the-counter medications, herbals, vitamins, and prescription medications (including prescribed medications from outside providers).

6. Assess for adherence to prescribed antiretroviral treatment regimen.

OBJECTIVE

1. May have white/off-white patches/lesions anywhere within the oral cavity. Among patients with HIV, manifestations of oral candidiasis are more commonly:
   a. Pseudomembranous candidiasis (thrush) appears as creamy white plaques or patches, which can be scraped off easily with a tongue depressor, (unlike oral hairy leukoplakia) at times revealing a bleeding, macerated surface below them. Lesions may be as small as 1-2 mm in size, or extensive plaques covering the entire hard palate.
   b. Erythematous candidiasis (atrophic candidiasis) typically presents as flat red patches that may present on any mucosal surface, but primarily is seen on the hard palate and dorsal tongue surface. The tongue may have depapillated red mucosal areas on its dorsal surface.
   c. Angular cheilitis (not exclusively due to *Candida*) presents with fissuring and redness at either one or both corners of the mouth and may appear alone or in conjunction with another form of oral Candida infection.

2. Review recent (within 6 months) CD4 cell count, HIV RNA viral load and comprehensive metabolic panel (assess renal and hepatic function).

ASSESSMENT Suspect Oral Candidiasis

PLAN

DIAGNOSTIC STUDIES

1. Complete pregnancy test for individuals of childbearing potential, if indicated.

2. Complete the following labs during this visit if needed, e.g., most recent labs greater than six months, or if closer monitoring needed, such as elevated HIV RNA, low CD4 cell count or percentage, renal and hepatic monitoring:
   a. HIV RNA viral load,
   b. CD4 cell count,
   c. Comprehensive metabolic panel,
   d. CBC with differential,
   e. Sexually transmitted infection screening (syphilis, gonorrhea, and chlamydia at all exposure sites).

3. Consider completing the following during this visit, if indicated to enhance care coordination and reduce missed opportunities:

a. Random or fasting lipid profile,
b. Hepatitis A total antibody, for assessment of immune status,
c. HBV serology, e.g., anti-HBs, anti-HBc and HBsAg, or HBV DNA for assessment of immune status or disease,
d. Hepatitis C antibody with reflex to RNA level OR Hepatitis C RNA, if previous antibody positive,
e. Pap smear,
f. TB screening test or risk assessment, as indicated.

4. Complete drug interactions checker for current and planned medications to evaluate for potential interactions.

NOTE: Antiretroviral medications frequently have drug-drug interactions that require dose modifications. Check with the physician, a pharmacist, drug, and HIV references, and/or the latest DHHS antiretroviral guidelines for appropriate dose modifications including for individuals with acute/chronic kidney failure. Other online references may be referenced as needed and available, such as:

a. University of Liverpool, *HIV Drug Interactions,* http://www.hiv-druginteractions.org/
b. Lexicomp, http://www.wolterskluwercdi.com/lexicomp-online/
c. Drugs.com, Drug Interactions Checker, https://www.drugs.com/drug_interactions.php

THERAPEUTIC

PHARMACOLOGIC

1. Mild to moderate cases (candidiasis anterior to the vibrating line - junction between the hard and soft palates).
   a. Clotrimazole one troche (10mg) dissolved in mouth 5 times/day for 7 to 14 days.

NOTE: Allow troche to dissolve slowly in the mouth. Dissolution is complete in approximately 30 minutes. The patient should not take anything else orally for 30 minutes after using the above topical agent. Adherence to these regimens is often poor because of time requirements.

2. Moderate to Severe Cases (candidiasis posterior to the vibrating line).
   a. Fluconazole 100mg PO once daily for 7 to 14 days.

3. Angular Cheilitis Topical Treatment:
   a. 2% ketoconazole cream applied to affected angles on the mouth four times/day for 14 days,

      OR

      1% clotrimazole cream applied to affected angles on the mouth four

times/day for 14 days.

b. May order chlorhexidine gluconate oral rinse 0.12% 1-pint (473 mL) bottle, if needed for denture soaking.

PATIENT EDUCATION/COUNSELING

1. Counsel on importance of completing medication treatment even if symptoms are resolved. Review current drug regimen, including drug storage, dose, route of administration, schedule, side effects and follow-up monitoring.

2. Counsel on importance of taking antiretroviral therapy as ordered to improve immune function and decrease frequency of candidiasis.

3. Instruct patient to notify clinic if condition worsens or does not improve.

4. Instruct patient to maintain good oral hygiene and to avoid mouth trauma (e.g., use a soft toothbrush, don't eat food or drink liquids that are too hot in temperature or too spicy).

5. Rinse mouth of all food before using topical agents and take nothing by mouth for 30 minutes after using agents.

6. For patients with oral candidiasis and dentures or partial denture plates, counsel on the importance of mouth care and cleaning to reduce the levels of potentially harmful bacteria and fungi. Instruct on the following:
   a. Dentures should be cleaned daily by soaking and brushing with an effective, nonabrasive denture cleanser. Toothpaste should not be used to clean complete or partial dentures.
   b. Disinfect the denture, when outside the mouth by soaking in a 50/50 mix of 0.12% chlorhexidine gluconate oral rinse and water during the course of the infection.
   c. Denture cleansers should ONLY be used to clean dentures outside of the mouth.
   d. Dentures should always be thoroughly rinsed after soaking and brushing with denture-cleansing solutions prior to reinsertion into the oral cavity. Always follow the product usage instructions.
   e. Do not wear dentures continuously (24 hours a day). To reduce or minimize *Candida*-associated denture stomatitis, remove dentures/partials at night.

7. Counsel tobacco users on cessation and refer to the Georgia Tobacco Quit Line https://dph.georgia.gov/chronic-disease-prevention/tobacco/ready-quit.

8. Counsel patient to rinse mouth after using corticosteroid inhalers.

9. Instruct patient to avoid high sugar and high carbohydrate foods when candidiasis is present.

10. Instruct patient of childbearing potential to inform provider if planning pregnancy or if pregnant. If taking fluconazole, counsel patient on the importance of using reliable contraception to avoid becoming pregnant while on fluconazole and to stop taking fluconazole if pregnant.

11. Advise patient to check with their pharmacist or provider about possible drug interactions before taking a new medication, nutritional or herbal supplement, or over-the-counter drug/product.

FOLLOW-UP

1. Schedule follow-up appointment with provider near to completion of treatment to assess response.

2. Assess patient's needs (e.g., case manager, social worker, eligibility, medication assistance plans, clinician, immunizations, laboratory, peer navigator, mental/behavioral health, oral health, nutrition) and provide services and/or linkage as soon as possible, preferably during the visit.

   NOTE: Timely provision of services (same day if possible) is important to minimize missed opportunities, reduce gaps in services and improve patient outcomes.

3. Ensure all abnormal laboratory results are reviewed by prescribing provider and follow-up completed within seven days of result reporting.

CONSULTATION/REFERRAL

1. Refer without delay to delegating physician or prescribing provider the following:
   a. Suspect candidiasis that is worsening or unresponsive following treatment,
   b. Suspect esophageal candidiasis (e.g., patient reports painful or difficulty swallowing, retrosternal burning pain),
   c. Pregnant patient,
   d. Patient with renal impairment,
   e. Patient with severe hepatic impairment,
   f. Patient not on ART,
   g. Patient on ART and not virally suppressed, e.g., HIV RNA at or greater than 200 copies per mL.

2. Refer to delegating physician or prescribing provider patient with history of medication side effects and/or adverse events.

3. Consult delegating or designated physician when further medical guidance is needed, and HIV nursing protocol is not applicable for therapeutic treatment of patient.

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PRE-EXPOSURE PROPHYLAXIS (PrEP)

2023 STANDARD NURSE PROTOCOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) CLINICAL REVIEW TEAM

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2022 STANDARD NURSE PROTOCOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL
PRE-EXPOSURE PROPHYLAXIS (PrEP) FOR USE IN THE PREVENTION OF HIV

DEFINITION

Pre-exposure prophylaxis (PrEP) is a course of HIV drugs taken by HIV-negative individuals to reduce their risk of acquiring HIV infection. PrEP can virtually eliminate the risk of getting HIV if taken consistently and correctly. **All sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition. This information will enable patients to both respond openly to risk assessment questions and to discuss PrEP with persons in their social networks and family members who might benefit from its use.**

ETIOLOGY

The anti-HIV drugs in PrEP stop the virus from replicating in the human body. If a person is exposed to HIV but has been taking PrEP correctly, there will be high enough levels of the drugs in the body to prevent the person from acquiring HIV.

ELIGIBILITY

This PrEP protocol may only be offered to eligible persons who meet the following requirements:

1. In combination with safer sex and other risk reduction practices for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of sexually and through drug injection acquired HIV-1 in at-risk adults and adolescents (13-17 years old) weighing at least 35kg (77lbs).

NOTE: PrEP does not prevent other infectious diseases, e.g., syphilis, gonorrhea, chlamydia, herpes simplex virus (HSV), human papillomavirus (HPV), hepatitis C virus (HCV), etc.

NOTE: The consent to the provision of medical or surgical care or services when such consent is given by a minor who is or professes to be infected with a STI or at risk for HIV infection shall be as valid and binding O.C.G.A. §31-17-7(a).

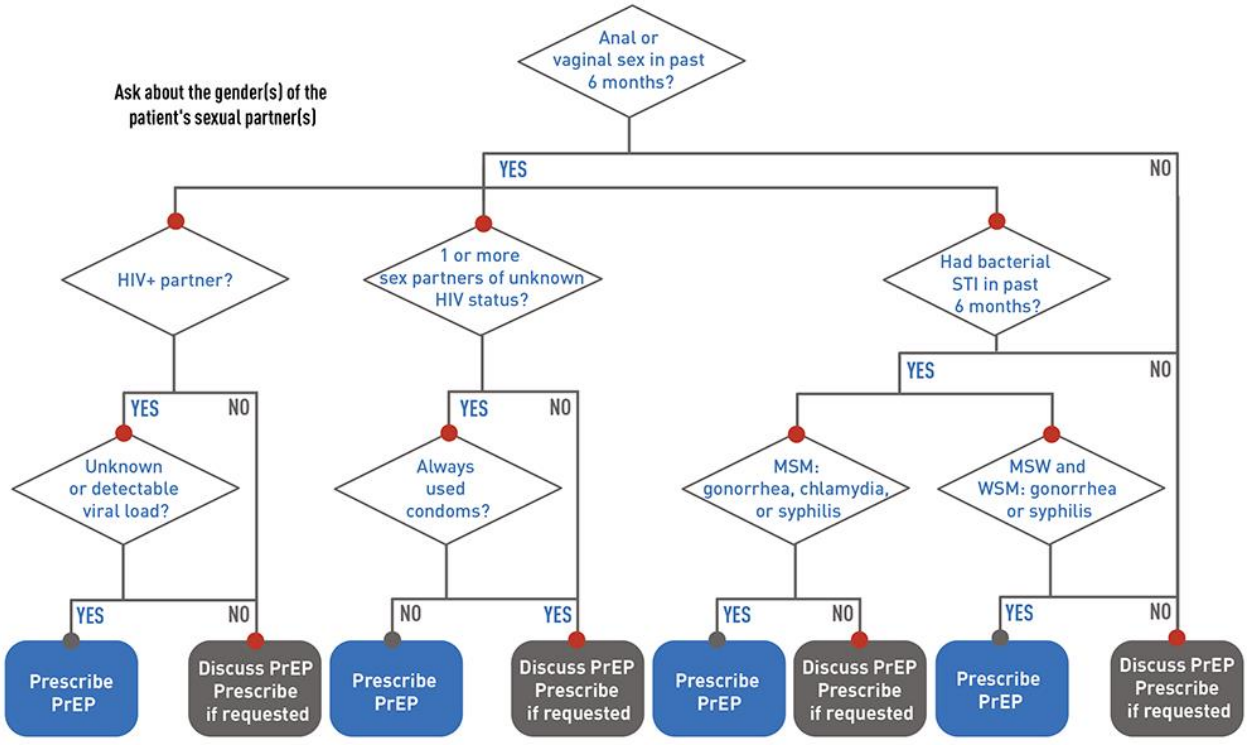
2. Individuals with documentation of HIV-negative status within 7 days of initiating or re-initiating PrEP (Appendix A). Documentation may include:
   a. Blood draw, such as routine HIV enzyme-linked immunoassay (EIA) OR
   b. Rapid, point-of-care, FDA-approved, fingerstick blood test.
      a. A rapid fourth generation HIV antibody/antigen test is preferred.

NOTE: Oral rapid tests should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests. Also, DO NOT accept patient-reported test results or documented anonymous test results.

c. A preliminary reactive HIV antibody test must be confirmed by an HIV-1/2 antigen/antibody immunoassay and a quantitative HIV RNA PCR viral load if confirmatory test negative or indeterminate. Immediately link all HIV-positive patients to care https://www.gacapus.com/r/resource-directory-2/

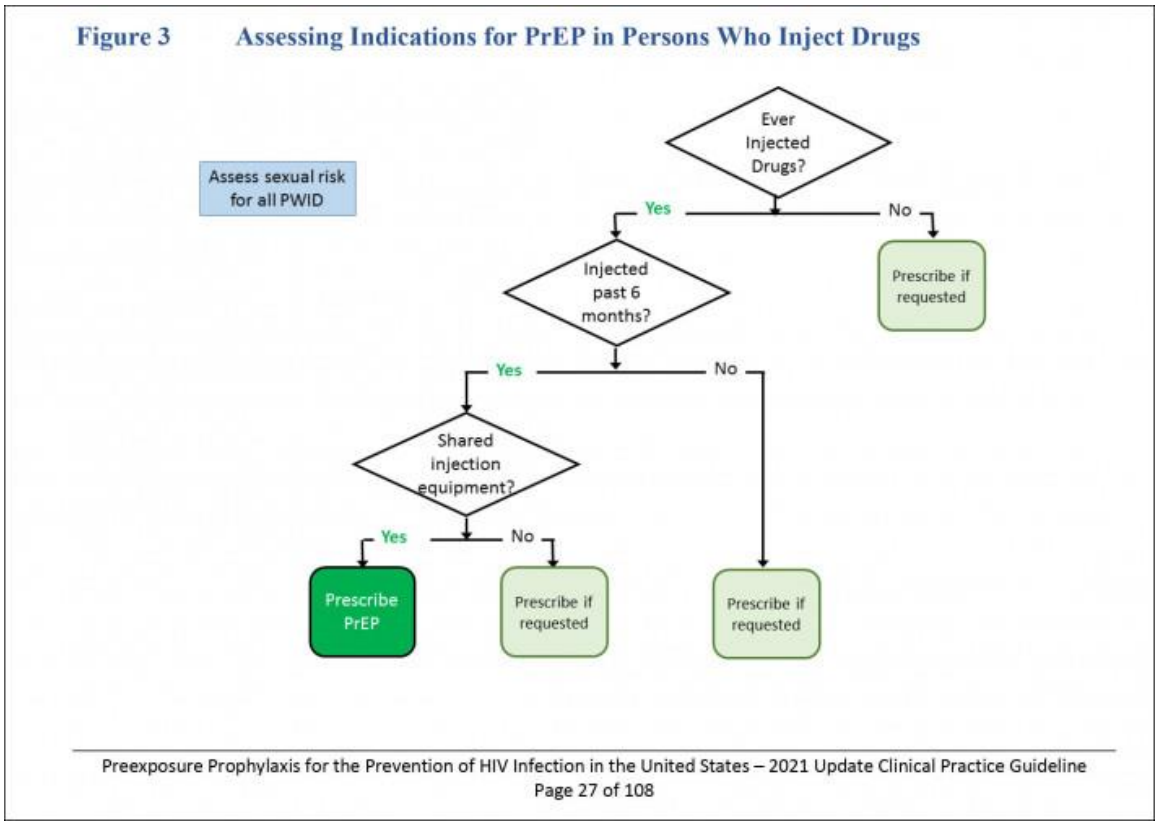
3. **Assess risk of HIV acquisition. See figures 2 and 3 below which outline a set of brief questions designed to assess a key set of sexual and injection drug practices that are associated with the risk of HIV acquisition. Only a few questions are needed to establish whether indications for PrEP are present, however, clinicians may want to ask additional questions to obtain a more complete sexual history. See CDC's Guide to Taking a Sexual History.**

a. **Assessing Indicators for PrEP in Sexually Active Persons:**



***Public health registered nurses and advanced practice registered nurses without prescriptive authority may order or dispense PrEP. They cannot prescribe PrEP.**

b. Assessing Indications for PrEP in Persons Who Inject Drugs



***Public health registered nurses and advanced practice registered nurses without prescriptive authority may order or dispense PrEP. They may not prescribe PrEP.**

4. **Providers should order or dispense PrEP to anyone who asks for it, including sexually active adults and adolescents who do not report behaviors that put them at risk for getting HIV.**
    a. **Patients may request PrEP because of concern about acquiring HIV but not feel comfortable reporting sexual or injection behaviors to avoid anticipated stigmatizing responses in health care settings. For this reason, after attempts to assess patient sexual and injection behaviors, patients who request PrEP should be offered it, even when no specific risk behaviors are elicited.**

NOTE: Persons without HIV and in a monogamous relationship with a person with HIV on antiretroviral therapy who is virally suppressed has no risk of acquiring HIV from their partner with HIV (Undetectable = Untransmittable; U=U).

- **PrEP for an HIV-uninfected patient may be indicated if a sexual partner with HIV has been inconsistently virally suppressed or his/her viral load status is unknown.**

- **PrEP may also be indicated if the partner without HIV seeking PrEP either has other sexual partners or wants the additional reassurance of protection that PrEP can provide.**

- **PrEP should not be withheld from HIV-uninfected patients who request it even if their sexual partner with HIV is reported to have achieved and maintained a suppressed viral load.**

- **For patients in an HIV discordant partnership for whom PrEP is being considered, especially where the partner with HIV is not virally suppressed, either CAB injections or daily oral PrEP are recommended options.**

NOTE: Pregnancy and breastfeeding: offer PrEP to individuals who are at risk for HIV and are trying to conceive or are pregnant, postpartum, or breastfeeding.

- Individuals who become pregnant while using Truvada™ or Generic FTC/TDF for PrEP can continue PrEP throughout their pregnancy
- Only **order or dispense** daily Truvada™ or Generic FTC/TDF under this circumstance (Eligibility: 3b)
- Mothers infected with HIV-1 should be instructed not to breastfeed, due to the potential for HIV transmission.

INELIGIBILITY Persons NOT eligible to receive PrEP:

1. Any acute high-risk HIV exposures (e.g., unprotected anal or vaginal sex or use of shared/unsterile injection equipment) in the past 72 hours. Immediately refer to the nPEP nurse protocol under these situations and if PrEP indicated following nPEP, refer to the nPEP appendix on nPEP to PrEP transition then back to this protocol on PrEP.

2. Have evidence of confirmed HIV infection by laboratory testing.

3. Have clinical signs and symptoms consistent with possible acute HIV infection, such as: fever, chills, rash, night sweats, headache**,** muscle aches, **headache**, sore throat, fatigue, swollen lymph nodes, and/or mouth ulcers.

   NOTE: Any individual with confirmed HIV infection (#2) or signs and symptoms of acute HIV infection (#3), as noted above, will require immediate referral or evaluation for HIV care.

4. Have underlying renal disease:
   a. eCrCl less than 60 mL/min for Truvada™ (TDF/FTC) or Generic Emtricitabine and Tenofovir Disoproxil Fumarate (Generic FTC/TDF)
   b. eCrCl less than 30mL/min for Descovy™ (TAF/FTC)]. (Refer to Consultation/Referral section below)

i. eCrCL should be calculated by using the Cockcroft-Gault formula. The following online calculator may be used: Creatinine Clearance (Cockcroft-Gault Equation) Calculator.

5. Are unwilling to adhere to Truvada™, Generic FTC/TDF or Descovy™, as **ordered**, AND attend follow up visits every 3 months.

6. Have known chronic, active Hepatitis B infection.

7. Will require further provider evaluation prior to initiating PrEP due to unstable comorbidities and/or history of severe allergic reaction to the components of PrEP.

8. For Descovy™ at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

SUBJECTIVE

1. Patient is eligible to receive PrEP according to the eligibility criteria listed above in the DEFINITION section.

2. Patient denies having symptoms to suggest acute HIV (fever, chills, rash, night sweats, muscle aches, **headache,** sore throat, fatigue, swollen lymph nodes, and/or mouth ulcers) within the past 2-4 weeks which resolved over a few days to several weeks.

3. Medical history negative for any medical, relative, or absolute contraindications to PrEP which may include complicated medical conditions or potential drug-drug interactions. Consult with Delegating Physician or Medical Director or visit www.gacapus.com for potential referral to PrEP clinic when assessing the safety of starting PrEP.

OBJECTIVE

1. **Collect a brief, targeted sexual history.**

2. **Physical exam within normal limits.**

ASSESSMENT Patient eligible to receive PrEP.

PLAN

DIAGNOSTIC STUDIES

NOTE: All diagnostic studies should be obtained 7 days prior to date of the initial PrEP prescription, unless same-day PrEP is being utilized (see Appendix E). Consult with Delegating Physician or Medical Director regarding any abnormal lab results. Do not initiate PrEP if patient has abnormal lab results without express approval of Delegating Physician or Medical Director.

1. HIV test. Routine HIV enzyme-linked immunoassay (EIA) or rapid, point-of-care, FDA-approved, fingerstick blood test. Nonreactive test result must be within 7 days of initiating and dispensing Truvada™, Generic FTC/TDF or Descovy ™.

2. Serum creatinine for creatinine clearance calculation (eCrCl must be 60 mL/min or greater for Truvada™ or Generic FTC/TDF and 30mL/min or greater for Descovy™). Test result must be within 60 days of initiating and dispensing Truvada™, Generic FTC/TDF or Descovy™.

NOTE: If the eCrCl is less than 60 mL/min and considering Truvada™ or Generic FTC/TDF or eCrCl less than 30mL/min and considering Descovy™, assess for nephrotoxic medications (e.g., NSAIDS, acyclovir, valacyclovir) and body building substances (e.g., creatinine, protein drinks) and repeat the eCrCl in 4 weeks. Truvada™ or Generic FTC/TDF cannot be **ordered or dispensed** if repeat eCrCl is less than 60 mL/min. Descovy™ cannot be **ordered or dispensed** if repeat eCrCl is less than 30 mL/min. Refer patients with eCrCl levels to their primary care provider and consider nephrology referral for individuals with eCrCl levels that prevent PrEP prescribing.

3. **Urinalysis to assess for proteinuria in patients with hypertension or diabetes every 6 months.**

4. Hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (HBsAb), and hepatitis B total core antibody (HBcAb), if not currently documented. **Test result must be within 60 days of initiating and dispensing Truvada or Descovy. If the patient reports a recent high-risk exposure for hepatitis, and is unvaccinated with no documentation of immunity, repeat testing at baseline is indicated.**
    a. Hepatitis B vaccination should be offered, if indicated based on HBV laboratory studies (Appendix 3,nPEP Nurse Protocol). Refer to the Georgia Department of Public Health's Immunization Program Manual for immunization schedule and administration information.

NOTE: All persons who test positive for hepatitis B surface antigen (HBsAg) may not be treated with PrEP under this protocol; they should be evaluated by an infectious disease or hepatic disease specialist.

5. Hepatitis C antibody (HCV Ab), if not previously documented. Appropriate referral to gastrointestinal, infectious disease, or a provider with HCV treatment experience for assessment should be made for individuals who are HCV positive.

6. Hepatitis A total antibody (HAV Ab), if not previously documented. HAV vaccination should be offered, if indicated based on HAV laboratory studies. Please refer to the GA Immunization Program manual for further guidance.

NOTE: The diagnosis of hepatitis A cannot be made on a clinical basis alone, but rather requires serologic testing. The presence of IgM antibody to HAV is diagnostic of acute HAV infection. A positive test for total anti-HAV indicates immunity to HAV infection but does not differentiate current from previous HAV infection.

7. STI screening, if not conducted within the prior 3 months, the individual has signs or symptoms of an active STI, or the individual has risk factors for an acute STI (see STD Nurse Protocols). This screening should include gonorrhea/chlamydia (**collect specimens for** all exposed sites: urine, rectal, and pharyngeal), syphilis (RPR or VDRL **if documented prior history of syphilis** or reverse algorithm testing **if no documented prior history of syphilis**) and trichomonas (cisgender women and transgender men).

8. Pregnancy test for cisgender women and transgender men of reproductive age, as appropriate. Counsel patient about the benefits of PrEP to reduce the risk of maternal HIV acquisition and perinatal HIV transmission. Offer PrEP to individuals who are at risk for HIV and are trying to conceive or are pregnant, postpartum, or breastfeeding.

9. **Patients taking F/TAF (i.e., Descovy) should have a lipid panel performed initially and annually.**

THERAPEUTIC

PHARMACOLOGIC

NOTE: As of March 15, 2018, the FDA approved Truvada™ as PrEP for adolescents at-risk for HIV, based on the ATN113 study. Recommended dosage in HIV-1 uninfected adults and adolescents weighing at least 35 kg (77 lbs) is one Truvada™ (200/300mg) tablet once daily taken orally, with or without food.

On October 3, 2019, the U.S. Food and Drug Administration (FDA) approved Descovy™ (200/25mg) in at-risk, uninfected adults and adolescents weighing at

least 35kg for HIV-1 pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection from sex, excluding those who have receptive vaginal sex. Descovy™ is not indicated in individuals at risk of HIV-1 infection from receptive vaginal sex because the effectiveness in this population has not been evaluated.

News release October 2, 2020 noted the release of Generic Emtricitabine and Tenofovir Disoproxil Fumarate (Generic FTC/TDF).

1. Initial medication order:
   a. Emtricitabine 200mg + Tenofovir DF 300mg (Truvada™)
      OR
   b. Generic Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300mg (Generic FTC/TDF)
      OR
   c. Emtricitabine 200mg + Tenofovir Alafenamide 25mg (Descovy™)
      1) 1 tablet orally daily for 30 days.
         a) In renally impaired HIV-uninfected individuals, Truvada™ or Generic FTC/TDF are not recommended if eCrCl is below 60 mL/min. http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf and https://www.tevahivgenerics.com/Truvada-generic/hcp
         b) In renally impaired HIV-uninfected individuals, Descovy™ is not recommended if eCrCl is below 30 mL/min. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf
         c) Schedule follow up visit to minimize gaps in PrEP
            OR
   d. Cabotegavir: Follow guidance in Appendix D

1. One month follow-up for patients initiated or re-initiated on PrEP who were dispensed an initial 30-day supply of Truvada™, Generic FTC/TDF or Descovy™. Only following documentation of adherence and no contraindications in continuing Truvada™, Generic FTC/TDF or Descovy™ provide:
   a. Emtricitabine 200mg + Tenofovir DF 300mg (Truvada™)
      OR
   b. Generic Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300mg (Generic FTC/TDF)
      OR
   c. Emtricitabine 200mg + Tenofovir Alafenamide 25mg (Descovy™)
      1) 1 tablet orally daily for up to 60 days.
         a) Schedule next visit to minimize gaps in PrEP

2. Following the initial dispense of Truvada™, Generic FTC/TDF or Descovy™ and 1 month follow up, schedule follow up every 3 months for patients only

following documentation of adherence and no contraindications in continuing Truvada™, Generic FTC/TDF or Descovy™. Provide:

a. Emtricitabine 200mg + Tenofovir DF 300mg (Truvada™)

OR

b. Generic Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300mg (Generic FTC/TDF)

OR

c. Emtricitabine 200mg + Tenofovir Alafenamide 25mg (Descovy™)
   1) 1 tablet orally daily for up to 90 days.
      a. Schedule three month visit to minimize gaps in PrEP

PATIENT EDUCATION/COUNSELING

1. Counsel patient regarding the basics of PrEP. Discuss the continued need for other measures in preventing other STIs and counsel that following the initiation of PrEP, medication levels are therapeutic at 7-days (rectal tissue) and 21-days (cervicovaginal tissue and blood). Also, stress the importance of adherence, especially for women as drug levels associated with significant protection against HIV infection require 6-7 doses per week (~85% adherence) for lower vaginal tract tissues.

2. Patients taking PrEP should be informed of side effects among HIV-negative participants in clinical trials. In these trials, side effects were uncommon and usually resolved within the first month of taking PrEP ("start-up syndrome"). Discuss the use of over-the-counter medications for headache, nausea, and flatulence should they occur. Patients should also be counseled about signs or symptoms that indicate a need for urgent evaluation (e.g., those suggesting possible acute renal injury or acute HIV infection).

3. Provide patient centered risk reduction counseling, (e.g., partner(s) testing and partner referral to care if at risk for HIV or HIV-positive and not in care, serosorting, seropositioning, decreasing the number of partners, etc.), condoms, and medication adherence counseling.

4. Refer to package insert and U.S. Department of Health and Human Services (HHS) guidelines for details on possible changes to bone mineral density (BMD) on Truvada™ as appropriate. For more information:

http://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf
https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/22/62/hiv-and-osteoporosis

Note: Decreases in bone mineral density (BMD): Consider assessment of BMD in individuals with a history of pathologic fracture.

5. Truvada™ or Generic FTC/TDF are not recommended in individuals with renal impairment (eCrCl below 60 mL per minute). No dosage adjustments of Truvada™ or Generic FTC/TDF are recommended in individuals with eCrCl greater than or equal to 60 ml per minute.

6. Descovy™ is not recommended in individuals with severe renal impairment (eCrCl below 30 mL per minute). No dosage adjustment of Descovy™ is recommended in individuals with eCrCl greater than or equal to 30 mL per minute.

7. The indication does not include use of Descovy™ in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated. Consult delegating physician for individuals at-risk for HIV from receptive vaginal sex who have a contraindication to Truvada™ or Generic FTC/TDF. Any use of Descovy™ in those at risk from vaginal sex is not indicated and therefore may not be **ordered or dispensed** PrEP under this protocol.

FOLLOW-UP

1. Patient follow-up:
   a. Follow-up visit 1 month after initial PrEP initiation or re-initiation visit for adherence counseling and any required additional assessment (e.g., clinical and/or laboratory tests). During this visit confirm HIV-negative test status, assess for early side effects of medications, discuss any difficulties with medication adherence, and answer questions.

   b. The following diagnostic tests should be performed a minimum of every 3 months:
      1) HIV screening assay in assessing HIV status and verifying an HIV negative status prior to authorizing additional Truvada™, Generic FTC/TDF or Descovy™ refills. (Appendix A and B)
      2) Conduct STI screening for urogenital, pharyngeal, and rectal site risk of STI for all sexually active persons and test for those with signs/symptoms as well as those with identified risk factors (e.g., those with syphilis, gonorrhea, chlamydia, or trichomonas diagnosed/treated at prior visits or multiple sex partners).
      3) Repeat pregnancy testing for cisgender women and transgender men who may become pregnant.

   c. The following diagnostic tests should be performed at least every 6 months:
      1) Serum creatinine for creatinine clearance calculation for eCrCl. If other threats to renal safety are present (e.g., hypertension, diabetes, etc.), renal function may require more frequent monitoring or may need to

include additional tests (e.g., urinalysis for proteinuria). An increase in serum creatinine is not a reason to withhold treatment if eCrCl remains 60 mL/min or greater for Truvada™ or Generic FTC/TDF and if eCrCl remains 30mL/min or greater for Descovy™. If eCrCl is declining steadily (but still 60 mL/min or greater for Truvada™ or Generic FTC/TDF and still 30mL/min or greater for Descovy™), consult with a Delegating Physician or Medical Director. May extend eCrCl to every 12 months for persons less than 50 years old with an eCrCl of **greater** than or equal to 90 ml/min at PrEP initiation.

2) STI testing (e.g., syphilis, gonorrhea, chlamydia, trichomonas) should be conducted. Testing may be indicated more often (e.g., every 3 months) based on risk factors and exposures (**collect specimens for** all exposed sites **to test** for gonorrhea and chlamydia: urine, rectal and pharyngeal).

d. **Assess interest in patient continuing or discontinuing PrEP at each visit. Discussion may include risk factors, adherence, and alternative PrEP regimens if needed.**

2. If a patient discontinues PrEP due to concern for possible acute retroviral syndrome, HIV viral load and HIV antibody testing should be conducted within 7 days before reinitiating PrEP.

3. Patients who discontinue PrEP because of non-adherence to laboratory follow-up, intolerance to Truvada™, Generic FTC/TDF or Descovy™ or reduction in HIV risk, should receive counseling on HIV risk reduction strategies and information on safely restarting PrEP.

4. Patients that are considering stopping PrEP but **have** not yet stopped, discuss the importance of continuing PrEP for 28 days after the last high-risk exposure.

Recommended Laboratory Testing/Screening for Individuals Taking PrEP					
Test/Screening	Baseline	Every 3 months	At least every 6 months	At least every 12 months	Notes
Provider assessment	✓	✓			Discuss adherence, side effects, barriers, etc.
Risk assessment	✓			✓	Consider discussing continued risk and need of PrEP at each appointment
HIV screening assay	✓	✓			Preliminary or confirmed HIV infection or signs and

					symptoms of acute HIV infection require immediate referral or evaluation for HIV care.
HAV, HBV, HCV screening	✓				Offer HAV & HBV vaccination if not immune
Serum creatinine **(eCrCl**)	✓		✓		Avoid PrEP if eCrCl less than 60 mL/min for Truvada™ or Generic FTC/TDF and if eCrCl is less than 30mL/min for Descovy™. May extend eCrCl to every 12 months for persons less than 50 years old or with an eCrCl greater than or equal to 90ml/min at PrEP initiation.
STI testing	✓		✓		Conduct STI screening for sexually active persons for signs or symptoms of infection. Offer testing for individuals with signs and symptoms of STI as well as asymptomatic MSM (include all exposed sites for gonorrhea and chlamydia; urine, rectal and pharyngeal) who are high risk for recurrent STIs (e.g. those with syphilis, gonorrhea, chlamydia, or trichomonas diagnosed/treated at prior visits or multiple sex partners).
Pregnancy test if childbearing potential	✓				Repeat testing as indicated.
Lipid Panel	✓			✓	**(Patients taking F/TAF only)**

Adapted from: https://www.hiv.uw.edu/go/prevention/preexposure-prophylaxis-prep/core-concept/all

CONSULTATION/REFERRAL

1. Refer to Delegating Physician, Medical Director and/or Primary Care Provider if any of the following occur:
   a. Abnormal lab results
   b. Side effects from PrEP
   c. Signs and symptoms of acute HIV infection; refer immediately to infectious disease/HIV specialist.
   d. Renal impairment (eCrCl less than 60 mL/min for Truvada™ or Generic FTC/TDF and eCrCl less than 30mL/min for Descovy™. In addition, if available, refer to nephrologist.
   e. Comorbidities and/or drug-drug interactions where PrEP is contraindicated.
   f. Chronic hepatitis B or hepatitis C infection. Also refer to infectious disease, hepatic disease specialist, or provider experienced in hepatitis C treatment, if able.
   g. Repeatedly non-adherent despite intensive counseling.
   h. History of pathologic fracture.
   i. PrEP discontinued due to HIV seroconversion: offer immediate linkage to care and antiretroviral therapy through the RAPID program. Linkage to care can be assisted through: **https://capus.dph.ga.gov/ehe/**
   j. Reactive HIV test: refer immediately to infectious disease/HIV specialist. Linkage to care can be assisted through: **https://capus.dph.ga.gov/ehe/**

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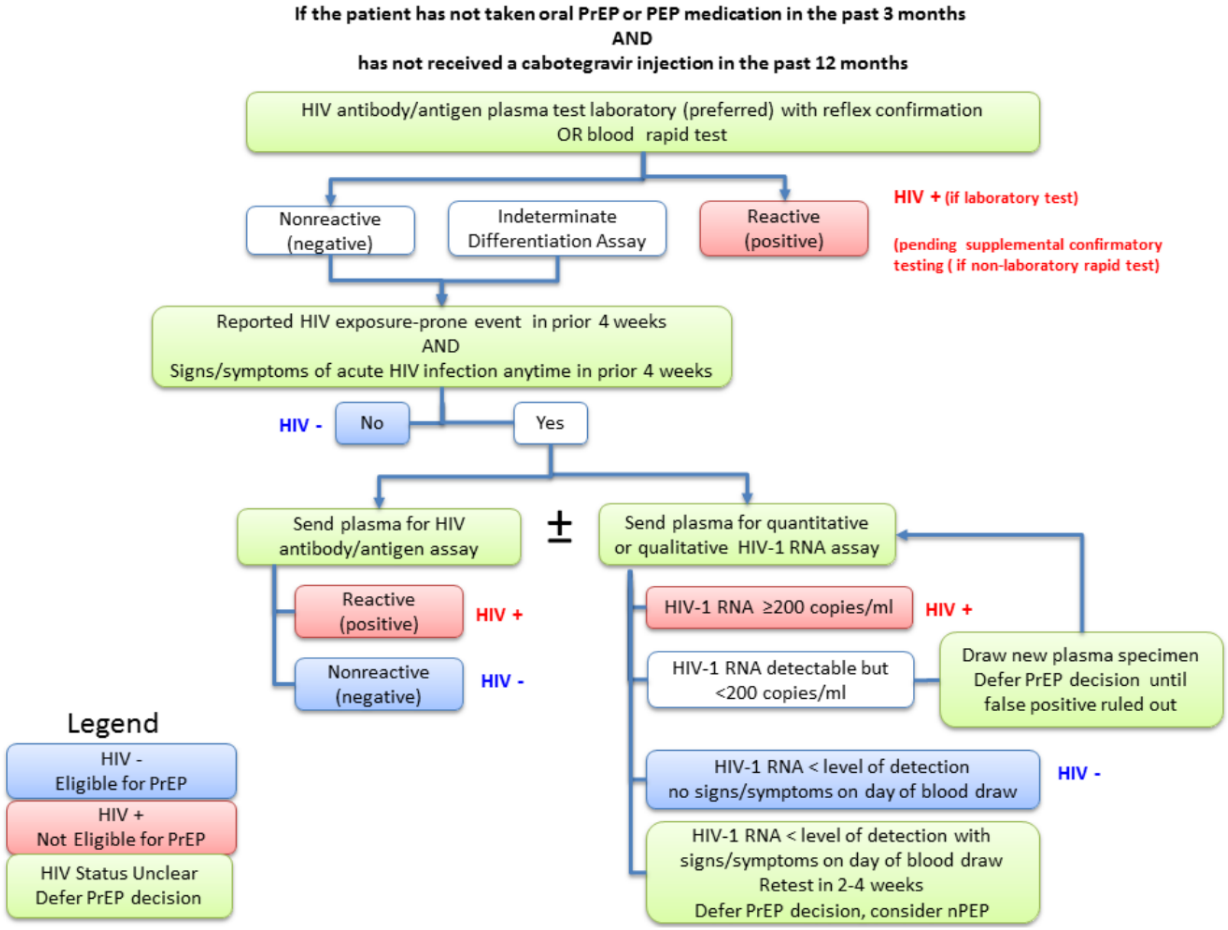
Appendix A

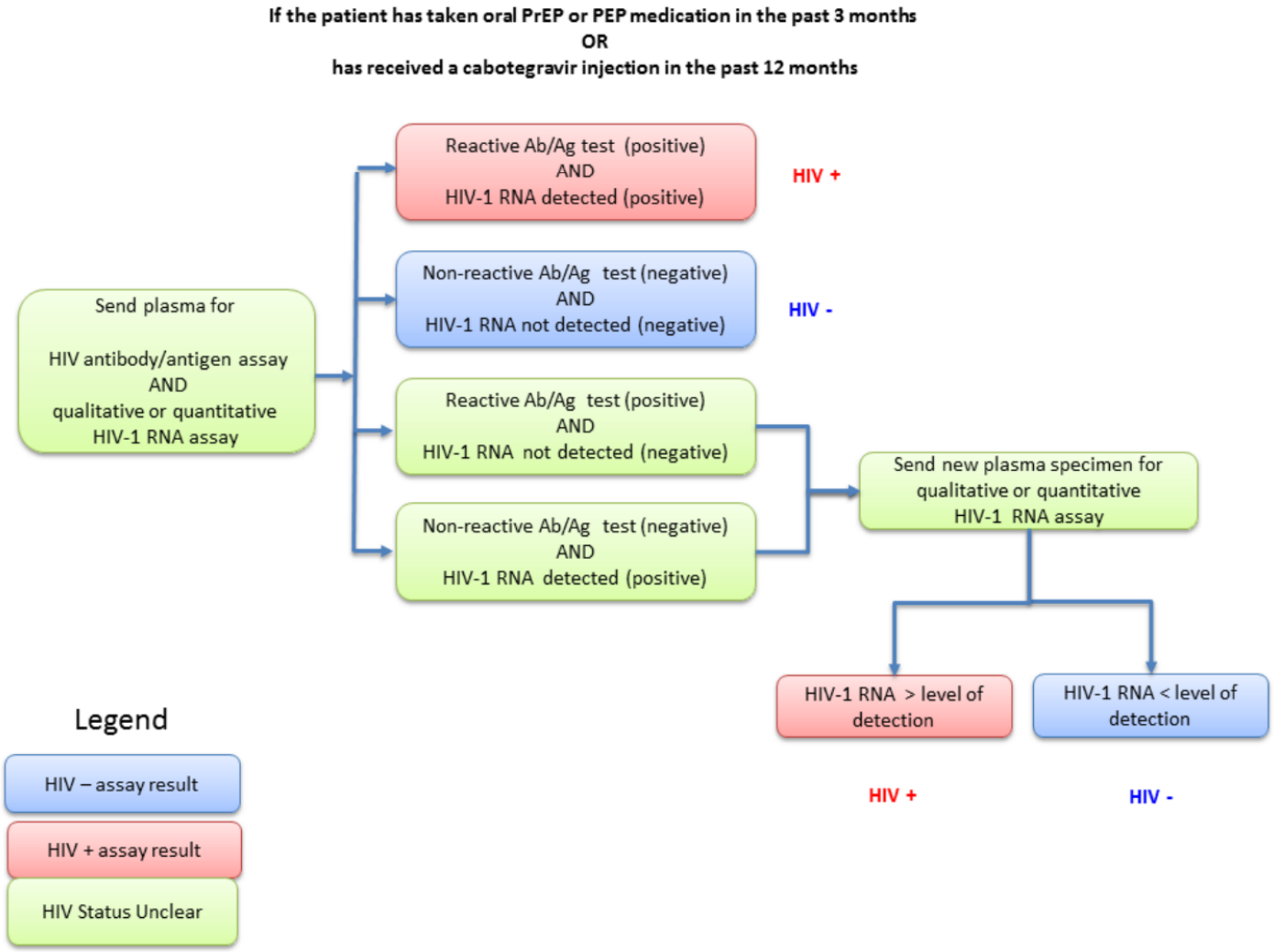
Determination of HIV Status for PrEP Provision to Persons without Recent Antiretroviral Prophylaxis Use



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Appendix B:

Determination of HIV Status for PrEP Provision to Persons with Recent or Ongoing Antiretroviral Prophylaxis Use



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Appendix C

Box #1: Risk Behavior Assessment for MSM and Transgender Women

In the past 6 months:

1. Have you had sex with men, women, or both?
2. (if men or both sexes) How many men have you had sex with?
3. How many times did you have receptive anal sex (you were the bottom) with a man who was not wearing a condom?
4. Is/Are any of your male sex partners of unknown HIV status or known HIV-positive not known to be taking anti-retroviral therapy or not known to be HIV virally suppressed?
    a. (if any positive) With these HIV-positive male partners, how many times did you have insertive anal sex (you were the top) without you wearing a condom?
5. Have you used methamphetamines (such as crystal or speed)?
6. Have you been diagnosed with an STI within the last 6 months (e.g. syphilis or trichomonas or gonorrhea or chlamydia of the urine, rectum and/or throat)?

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2021.pdf (p. 25)

Box #2: Risk Behavior Assessment for Heterosexual Men/Women and Transgender Men

In the past 6 months:

1. Have you had sex with men, women, or both?
2. (if opposite sex or both sexes) How many men/women have you had sex with?
3. How many times did you have vaginal or anal sex when neither you nor your partner wore a condom?
4. Is/Are any of your sex partners of unknown HIV status or known HIV-positive not known to be taking anti-retroviral therapy or not known to be HIV virally suppressed?
5. (if any positive) With these HIV-positive partners, how many times did you have vaginal or anal sex without a condom?
6. Have you been diagnosed with an STI within the last 6 months (e.g. syphilis or trichomonas or gonorrhea or chlamydia, etc. of the urine, rectum and/or throat)?

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf (p. 23)

Appendix D

Prescribing Cabotegravir (CAB) PrEP Injections:

1. Inform patient of all FDA approved options
2. CAB may be considered over oral regimens for PrEP in persons who:
   a. Have significant renal disease
   b. Have difficulty with adherent use of oral PrEP
   c. Prefer injections every 2 months instead of an oral PrEP dosing schedule
   d. Persons who inject drugs (PWID) and are sexually active should be assessed for sexual risk and provided the option of CAB for PrEP when indicated
3. Patients that have been taking daily oral PrEP, can initiate CAB injections as soon as HIV-1 RNA test results confirm that HIV test remains negative.
4. Avoid CAB in persons with a history of hypersensitivity reaction to CAB

CAB Precautions:

1. Efficacy is unknown for other injectable antiretrovirals (ARVs), injection sites, or dosing schedules
2. Do not **order or dispense** other ARV medications in combination with CAB for PrEP
3. Do not administer CAB injections at any site other than the gluteal muscle
4. Do not dispense CAB injections for use by patients for home administration
5. Do not **order or dispense** ongoing daily oral CAB

NOTE: No safety concerns were identified during clinical trials, therefore, an oral lead-in is not required when initiating CAB for PrEP. It may be optionally used for patients who are especially worried about side effects to relieve anxiety about using the long-acting CAB injection. However, continued daily oral CAB is not recommended or FDA-approved for PrEP.

Laboratory Testing for CAB PrEP Patients:

NOTE: Additional labs may be indicated on a case-by-case basis for routine care and not specific to the provision of CAB for PrEP

1. CAB consideration: HIV test results indicate no acute or chronic HIV infection
   a. If an oral lead-in is utilized, HIV testing can be performed in accordance with PrEP Protocol's Plan/Diagnostic Studies #1 and the following (1b)
   b. Use an HIV-1 RNA assay completed within 1 week of the CAB initiation visit

Note: Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay. Ideally, this testing will be done within 1 week prior to the initiation visit. If clinicians wish to provide the first injection at the first PrEP evaluation visit based on the result of a rapid combined antigen/antibody assay, blood should always be drawn for laboratory confirmatory testing that includes an HIV RNA assay.

2. All PrEP patients should have baseline STI tests:
   a. MSM and transgender women who have sex with men including those who inject drugs: Gonorrhea, chlamydia, and syphilis

   b. Heterosexual women and men including persons who inject drugs: Gonorrhea, **chlamydia** and syphilis
3. Testing not routinely indicated for CAB PrEP:
   a. Creatinine
   b. eCrCl
   c. Hepatitis B serology
   d. Lipid panels
   e. Liver function tests
4. See Timing of CAB PrEP-associated Laboratory Tests below and Summary of Clinician Guidance for Cabotegravir Injection PrEP Use at the end of the Appendix for additional details and summary.

Timing of CAB PrEP-associated Laboratory Tests:

Test	Initiation Visit	1 month visit	Q2 months	Q4 months	Q6 months	Q12 months	When Stopping CAB
HIV*	X	X	X	X	X	X	X
Syphilis	X			MSM^/TGW~ only	Heterosexually active women and men only	X	MSM/TGW only
Gonorrhea	X			MSM/TGW only	Heterosexually active women and men only	X	MSM/TGW only
Chlamydia	X			MSM/TGW only	MSM/TGW only	Heterosexually active women and men only	MSM/TGW only

* HIV-1 RNA assay
X all PrEP patients
^ men who have sex with men
~ persons assigned male sex at birth whose gender identification is female

Note: On each subsequent visit. Because of the long duration of drug exposure following injection, exclusion of acute HIV infection is necessary with the most sensitive test available, an HIV-1 RNA assay. Ideally, this testing will be done within 1 week prior to the initiation visit. Clinicians may base their decision on CAB continuation based on the result of a rapid combined antigen/antibody assay, blood should always be drawn for laboratory confirmatory testing that includes an HIV RNA assay.

Pharmacy And Therapeutics:

1. Initiation: CAB 600 mg injected into gluteal muscle one month apart for two consecutive months in adults and adolescents weighing at least 35 kg

NOTE: the second injection may be given up to 7 days before or after the individual is scheduled t receive the second injection

2. Maintenance: CAB 600mg (3mL) injected into gluteal muscle every 2 months in adults and adolescents weighing at least 35kg

NOTE: Cabotegravir injections may be given up to 7 days before or after the individual is scheduled to receive the injections

3. CAB 30 mg daily orally; optional for a 4-week lead-in prior to injections
   a. Oral Lead-in: Oral cabotegravir 30mg by mouth once daily for 30 days

Note: Current guidelines state that at least 28-day oral lead-in course is recommended. However, due to manufacturers requirements that the product must be dispensed in the original container, a 30-day supply should be written as directed in the protocol.

Example 1: Recommended dosing schedule with Oral Lead-in for PrEP in Adults and Adolescents weighing at least 35kg:

Oral Lead-in (at least 28 days)	Intramuscular (Gluteal) Initiation Injection (Month 2 and Month 3)	Intramuscular (Gluteal) Continuation Injection (Month 5 and every 2 months onwards)
Oral cabotegravir 30mg PO daily for 28 days	APRETUDE 600mg, 3 mL(a)	APRETUDE 600mg (3mL) (b)

a. Should be administered on the last day of oral lead-in or within 3 days thereafter
b. Individuals may be given **APRETUDE** up to 7 days before or after the date the individual is scheduled to receive the injections

Example 2: Recommended Dosing Schedule (Direct to Injection) for PrEP in Adults and Adolescents Weighing at Least 35 kg:

Intramuscular (Gluteal) Initiation Injection (Month 1 and Month 2)	Intramuscular (Gluteal) Continuation Injection (Month 4 and every 2 months onwards)
APRETUDE 600mg, 3 mL (a)	APRETUDE 600mg, 3mL(a)

a. Individuals may be given **APRETUDE** up to 7 days before or after the date the individual is scheduled to receive the injections

NOTE: Breastfeeding: Assess the benefit-risk of using APRETUDE to the infant while breastfeeding due to the potential for adverse reactions and residual concentrations in the systemic circulation for up to 12 months or longer after discontinuation.

NOTE: Pregnancy: There are insufficient human data on the use of APRETUDE during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. Pregnancy Exposure Registry There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to APRETUDE during pregnancy. Healthcare providers are encouraged to register individuals by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Recommended CAB Injection:

1. 3 ml suspension of CAB 600 mg IM in gluteal muscle (gluteus medius or gluteus maximus)

2. Recommend use of a 2-inch needle for intramuscular injection in patients with a BMI of 30 or greater and 1.5-inch needle should be used in patients with a BMI less than 30

NOTE: No data are yet available from clinical trials in men or women to estimate the time from initiation of CAB injections to maximal protection against HIV acquisition

Managing Injection Site Reactions:

1. Injection site reactions (pain, tenderness, induration) were frequent in clinical trials and were generally mild or moderate, lasted a few days, and occurred most frequently after the first 2-3 injections.
   a. Inform patient that reactions are common and transient.
   b. Patients should be managed as followed for the first 3 injections
      1) take an over-the-counter pain medication within a couple of hours before or soon after the injection and continue as needed for one to two days
      2) apply a warm compress or heating pad to the injection site for 15-20 minutes after the injection (e.g., after arriving back at home) and as needed for subsequent injections

Patient Education/Counseling:

1. Initial follow up following the first injection should be 1-month and then as per the table above.
2. Educate patient on the long “tail” of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug-resistant strain if HIV infection is acquired during that time
3. Importance of keeping follow-up appointments including if they decide not to continue CAB.

Clinical Follow-Up and Monitoring for CAB Injections:

1. Once CAB injections are initiated, patients should return for follow-up visits 1 month after the initial injection and then every 2 months. (Refer to Table #2: Clinical Summary Guidance)
   a. 1 month visit after initial injection (month 1, second injection):
      1) Repeat HIV-1 RNA test and assess for signs or symptoms of acute infection
      2) Administer CAB injection
      3) Respond to new questions
   b. At each bimonthly visit (beginning with the third injection, month 3):
      1) Repeat HIV-1 RNA test and assess for signs/symptoms of acute infection
      2) Administer CAB injection
      3) Provide access to clean needles/syringes and drug treatment services for PWID, if available
      4) Respond to new questions and provide any new information about CAB PrEP

5) Discuss benefits of persistent CAB PrEP use and adherence to scheduled injection visit

c. At least every 4 months (every other injection visit, beginning with the third injection - month 3)
   1) Conduct bacterial STI screening for MSM and transgender women who have sex with men: oral, rectal, urethral, blood
d. At least every 6 months (beginning with the fifth injection – month 7)
   1) Conduct bacterial STI screening for all heterosexually active women and men: (vaginal, rectal, urine - as indicated), blood
e. At least every 12 months (after the first injection)
   1) Assess desire to continue CAB injections for PrEP
   2) Conduct chlamydia screening for heterosexually active women and men even if asymptomatic

Discontinuing or Restarting CAB PrEP:

Council patient who wishes to discontinue CAB injections for PrEP or who are a month or more late for an injection as follows:

1. How to safely discontinue or restart CAB injections for PrEP
   a. Re-educate patients about the “tail” and the risks during declining CAB levels
   b. Assess ongoing risk/indications
   c. Educate about nPEP (see nPEP nurse protocol)
   d. Continue follow-up visits quarterly for 12 months
   e. Conduct HIV-1 RNA tests at each quarterly follow-up visit after CAB discontinuation
2. The risk of developing drug resistant HIV during the period of waning drug levels, i.e., the “tail period”. Refer to Table #1 below:Trade-off of PrEP Drug Levels and Risk of HIV Infection with Resistant Virus.
   a. Need for daily oral PrEP or other effective HIV prevention methods if ongoing risk of HIV exposure is anticipated
      1) See PrEP protocol for oral agents and begin within 8 weeks after last injection

NOTE: CAB levels slowly wane over many months after injections are discontinued. At some point (based on clinical trials) during the “tail phase” (44 weeks for men and 67 weeks for women) CAB levels will fall below a protective threshold and persist for some time at nonprotective levels exposing the patient to risk of HIV acquisition. These lower levels of CAB may be sufficient to apply selective pressure that selects for existing or de-novo viral strains with mutations that confer resistance to CAB or other HIV Integrase Inhibitor medications, thus complicating HIV treatment.

NOTE: Patients discontinuing CAB injections who may be at ongoing risk of sexual and injection HIV exposure should be provided with another highly effective HIV prevention method during the months following their last injection.

RESTARTING CAB INJECTIONS:

1. CAB for PrEP can be restarted at any point after determining HIV status with HIV-1 RNA testing completed within 1-week of the CAB re-initiation.

Table 1: Trade-off of PrEP Drug Levels and Risk of HIV Infection with Resistant Virus

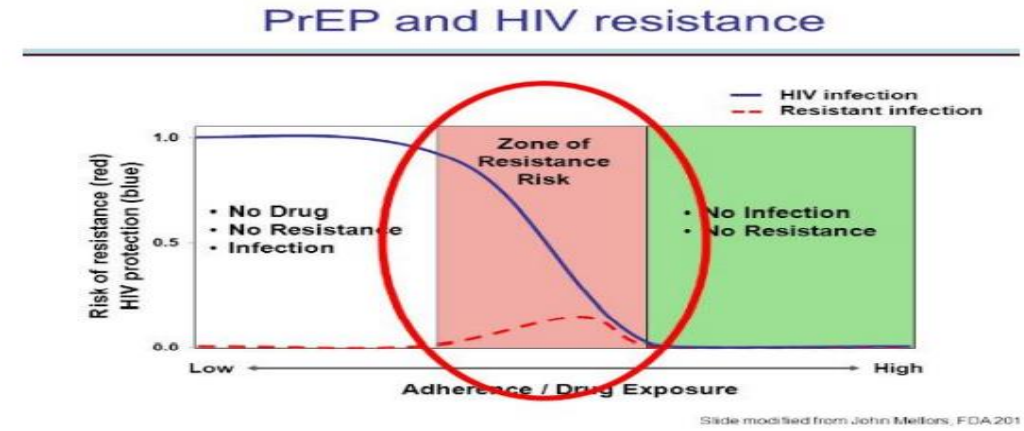


Table 2: Summary of Clinician Guidance for Cabotegravir Injection PrEP Use

	Sexually Active Adults	Persons Who Inject Drugs
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • Sexual partner with HIV (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months • History of inconsistent or no condom use with sexual partner(s)	Injecting partner with HIV OR Sharing injection equipment
Clinically eligible	**<u>All of the Following Conditions are MET:</u>** • Documented negative HIV Ag/Ab test result within 1 week before initial cabotegravir injection • No signs/symptoms of acute HIV infection • No contraindicated medications or conditions	
Dosage	600mg Cabotegravir administered as one 3mL intramuscular injection in the gluteal muscle: • Initial dose • Second dose 4 weeks after first dose (month 1 follow-up visit) • Every 8 weeks thereafter (month 3,5,7, follow-up visits etc.)	

Follow-up care	<u>At follow-up visit 1 month after first injection:</u> • HIV Ag/Ab test and HIV-1 RNA assay <u>At follow-up visits every 2 months (beginning with 3rd injection month 3) provide the following:</u> • HIV Ag/Ab test and HIV-1 RNA assay • Access to clean needles/syringes and drug treatment services for PWID <u>At follow-up visits every 4 months (beginning with the 3rd injection month 3) provide the following:</u> • Bacterial STI screening for MSM and transgender women who have sex with men: oral, rectal, urine, blood <u>At follow-up visits every 6 months (beginning with the 5th injection month 7) provide the following:</u> • Bacterial STI screening for all heterosexually-active women and men: blood (vaginal, rectal, urine as indicated) <u>At follow-up visits at least every 12 months (after the 1st injection) provide the following:</u> • Assess desire to continue injections for PrEP • Chlamydia screening for heterosexually active women and men (vaginal, urine) <u>At follow-up visits when discontinuing cabotegravir injections provide the following:</u> • Re-educate about the 'tail' and the risks during declining CAB levels • Assess ongoing HIV risk and prevention plans • If PrEP is indicated, **order or dispense** daily oral F/TDF or F/TAF beginning within 8 weeks after last injection • Continue follow-up visits with HIV testing quarterly for 12 months

References:

1. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021. Accessed December 27, 2021
2. Highlights of prescribing information; Apretude™ (Cabotegravir). Revised: 12/2021. https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Apretude/pdf/APRETUDE-PI-PIL-IFU.PDF Accessed December 27, 2021

Appendix E

PrEP ACQUISITION:

Inclusion/exclusion criteria change often, therefore the following links are provided that include applications, phone numbers up-to-date criteria for accessing PrEP through pharmaceutical assistance programs, co-pay cards, etc.

1. Truvada™ for PrEP Patient Support:
   a. https://www.truvada.com/how-to-get-truvada-for-prep/patient-support-resources
   b. https://www.gileadadvancingaccess.com/

2. Descovy™ for PrEP Patient Support:
   a. https://www.descovy.com/prep/
   b. Co-pay Support and Resources for DESCOVY® Cost
   c. https://www.gileadadvancingaccess.com/

3. APRETUDE™ (Cabotegravir): ViiV Connect
   a. 1-844-588-3288 (toll free) Monday-Friday 8AM-11PM (ET)
   b. About the Provider Portal | ViiVConnect

4. Ready, Set, PrEP:
   a. https://www.hiv.gov/federal-response/ending-the-hiv-epidemic/prep-program
   b. https://www.getyourprep.com/

5. Resource for any medication. RxAssist Patient Assistance Program Center:
   a. RxAssist: Patient Assistance Programs
   b. https://rxassist.org/

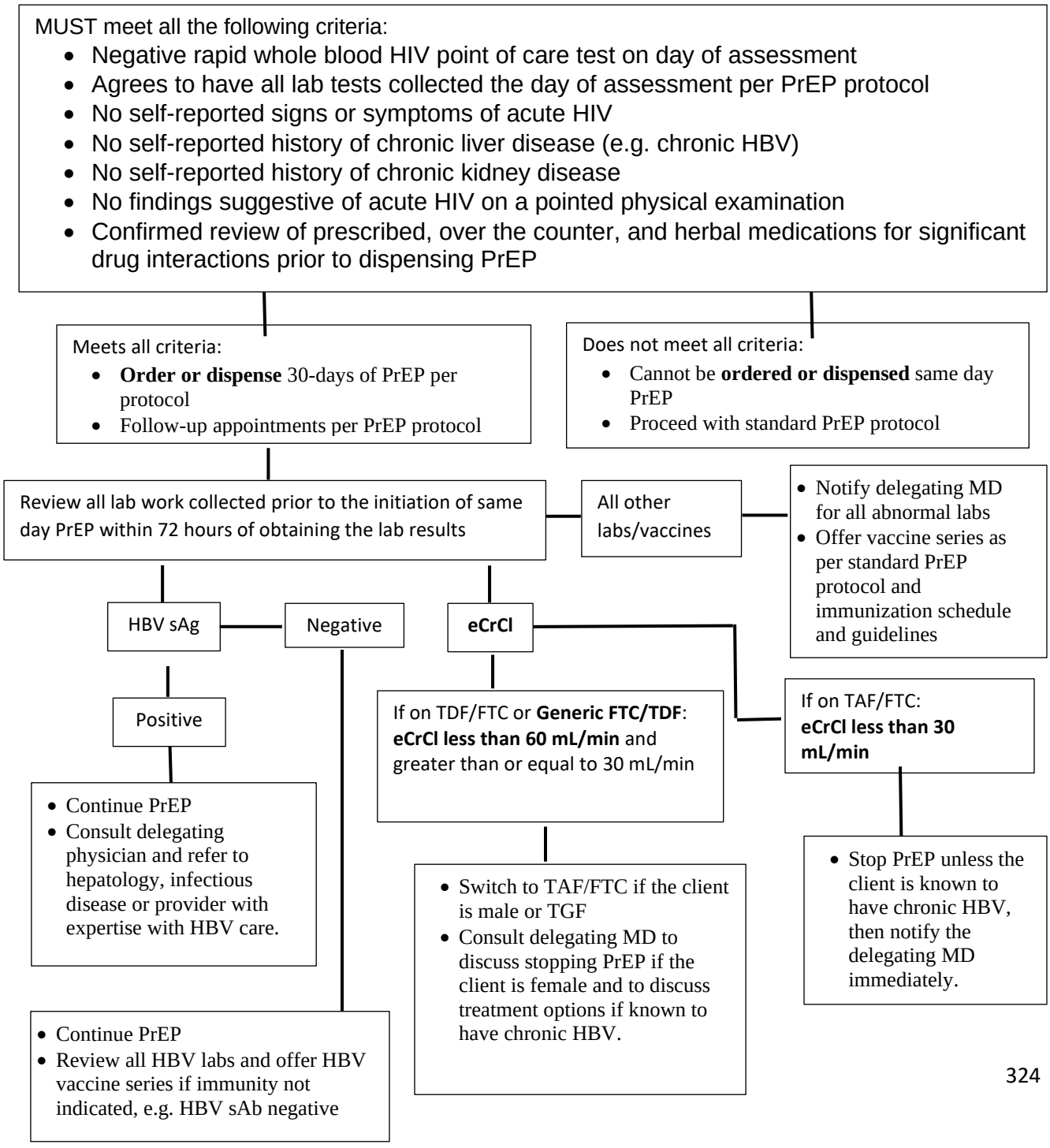
6. PAN Foundation:
   a. https://www.panfoundation.org/disease-funds/hiv-treatment-and-prevention/

7. Other resources for PrEP access:
   a. My PrEP Experience: http://myprepexperience.blogspot.com/p/truvada-track.html. Patients can e-mail problems in gaining access to myprepexperience@gmail.com. Website includes available online community that can help with access to PrEP.
   b. Clinical Trials: http://www.avac.org/trial-summary-table/prep. Access to enroll in ongoing clinical trials and access PrEP at no cost.

Appendix F:

Same day / Rapid PrEP:

To **order or dispense** PrEP medication for HIV prevention in a documented HIV negative individual pending lab test results collected on the day of assessment.



NOTE: Maximum intracellular concentrations of TDF are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervicovaginal tissues at approximately 20 days. No data are available about intracellular drug concentrations in penile tissues susceptible to HIV infection to inform considerations of protection for male insertive sex partners.

Descovy™ is not indicated for use in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated. In addition, Descovy™ is not FDA approved for on-demand PrEP.

NOTE: For individuals with active HBV infection (detectable HBsAg), discontinuation of TDF/FTC or Generic FTC/TDF PrEP could lead to acute HBV flares or hepatic decompensation, particularly for patients with hepatic cirrhosis. This may also occur with TAF/FTC; therefore, careful monitoring of HBV infection and liver function is recommended after discontinuation of TDF/FTC, Generic FTC/TDF or TAF/FTC. If appropriate, anti-hepatitis B therapy may be considered.

Acronyms:
1. HB: Hepatitis B:
    - sAg: surface antigen
    - sAb: surface antibody
2. TDF/FTC: Truvada™
    - TAF/FTC: Descovy™
    - TDF: Tenofovir disoproxil fumarate
3. eCrCl:
    - estimated creatinine clearance in mL/min
    - TGF: Transgender Female
4. TAF: Tenofovir alafenamide

REFERENCES

1. eCrCl calculation for individuals less than 18 years of age. Accessed January 20, 2021. *https://www.ebmconsult.com/app/medical-calculators/pediatric-gfr-calculator-renal-function*

2. Creatinine Clearance Calculator for Adults. Accessed January 20, 2021. https://clincalc.com/Kinetics/CrCl.aspx

3. Saag, M. et al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2018 Recommendations of the International Antiviral Society–USA Panel. JAMA July 24/31, 2018 Volume 320, Number 4. Accessed January 20, 2021. https://www.iasusa.org/wp-content/uploads/guidelines/arv/arv_2018.pdf

4. Truvada™ Highlights of Prescribing Information. Accessed January 20, 2021. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf. Revised 06/2020.

5. Descovy™ Highlights of Prescribing Information. Accessed January 20, 2021. https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/descovy/descovy_pi.pdf. Revised 01/2020.

6. Generic Emtricitabine/Tenofovir Disoproxil Fumarate 300mg Prescribing information. Accessed December 30, 2020. https://www.tevahivgenerics.com/Truvada-generic/hcp

7. **Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States, 2021 Update: A Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf Published December 2021. Accessed November 21, 2022.**

Appendix G

PrEP on-demand (2-1-1):

Definition:
Non-daily pericoital Truvada™ (TDF/FTC) PrEP, also known as on-demand, event-driven, or “2-1-1” dosing may be considered as an alternative to daily PrEP for MSM with infrequent sexual exposures.

Criteria:

a. Dosing: On-demand PrEP “2-1-1” dosing with TDF/FTC with or without food:
    1) 1st dose: (2) tablets by mouth once 2 to ideally 24 hours before sex
    2) 2nd dose: (1) tablet by mouth once 24 hours after the 1st dose
    3) 3rd dose: (1) tablet by mouth once 24 hours after the 2nd dose
b. If intercourse is planned in the context of 2-1-1 PrEP dosing, the first dose (2 tablets) of TDF/FTC should be taken closer to the 24-hour precoital time than the 2-hour time.
c. For consecutive sexual contacts, men should be instructed to take 1 tablet by mouth once daily with food until **48 hours** after the last sexual encounter.
d. See examples 1, 2, 3 in the chart below for further guidance.

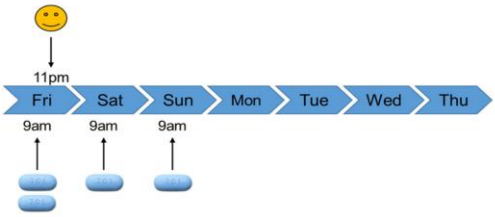
Contraindications:

a. This regimen is not recommended in other risk groups or in patients with active HBV infection because of the risk of hepatitis flare, hepatic decompensation and HBV resistance.
b. Lack of data among heterosexual men and women, transgender men, transgender women on estrogen, and people who inject drugs prevents recommendation of the “2-1-1” dosing in these populations.

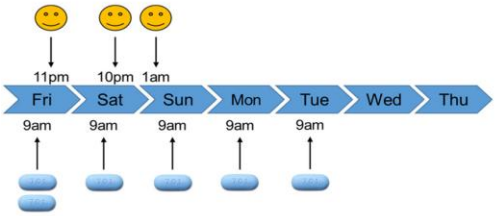
Follow-up:

a. 2-1-1 provides choice and convenience for men who have sex with men who may be at high HIV risk for brief periods or have sex once per week on average. Per PrEP protocol plus for individuals with 2 or more sexual encounters in a 7-day period, daily PrEP should be discussed.

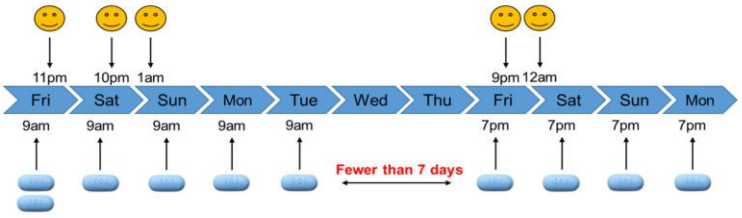
Example 1: One sex episode.
2 PrEP tablets 2-24 hours before sex; 1 PrEP tablet 24 hours after and another 48 hours after the double dose.



Example 2: Multiple sex episodes.
Continue 1 PrEP tablet every 24 hours until 2 days after last "sex day."



Example 3: Multiple sex episodes in one week.
If there are <7 days between end of one on-demand dosing period and beginning of another, take one single PrEP tablet to restart.
If there are ≥7 since last PrEP dose, start again with 2 PrEP tablets.



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1. Saag, m. et.al. Antiretroviral Drugs for Treatment and Prevention of HIV Infection in Adults 2018 Recommendations of the International Antiviral Society–USA Panel. JAMA. 2018;320(4):379-396. doi:10.1001/jama.2018.8431. https://www.iasusa.org/wp-content/uploads/guidelines/arv/arv_2018.pdf Accessed January 6, 2021.

2. Highlights Of Prescribing Information. Truvada™. Revised 06/2020 https://www.gilead.com/~/media/Files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

3. Technical Brief. What's The 2+1+1? Event Driven Oral Pre-Exposure Prophylaxis to Prevent HIV for Men Who Have Sex With Men: Update To WHO's Recommendation On Oral Prep. July 2019. https://apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf?ua=1

4. Saberi, P., et.al. On-Demand Oral Pre-exposure Prophylaxis with Tenofovir/Emtricitabine: What Every Clinician Needs to Know. J Gen Intern Med. Jan. 21, 2020. DOI: 10.1007/s11606-020-05651-2.

5. **Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States, 2021 Update: A Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf Published December 2021. Accessed November 21, 2022.**

Appendix H PrEP Management Checklist

<table>
<tr><td colspan="2">Prep Management Checklist: Pre-Prescription, Follow-Up, And Monitoring

* Refer to GA-DPH Nurse PrEP protocol for additional details, clarification and for medical decision making.</td></tr>
<tr><td>❑ Pre-Prescription:
• Discuss PrEP use; clarify inclusion/exclusion criteria
• (HIV risk, drug interactions, acute HIV, etc.)
• Assess PrEP medication coverage, Appendix C PrEP protocol
• Perform baseline laboratory testing:
▪ HIV test; positive tests immediately link to care
▪ Serum creatinine for eCrCl.
▪ STI testing (GC, CT, syphilis, trichomonas) if not done in previous 3 months
NOTE: MSM and TGF, 3-site testing (genital, rectal, pharyngeal) for GC and CT regardless of sites of reported exposure
▪ Pregnancy test; individuals of childbearing capacity
▪ HAV serology: offer vaccine as indicated (HAV IgG or total)
▪ HBV serologies: offer vaccine as indicated (HBsAg, anti-HBs, anti-HBc [IgG or total])
▪ HCV antibody</td><td>❑ After Drawing Appropriate Tests:
• Consult / Refer to delegating physician, medical director, PCP as directed by Nurse PrEP protocol
• Provide patient centered risk reduction counseling
• TDF/FTC (Truvada™) or Generic FTC/TDF: eCrCl of greater than or equal to 60 mL/min
• TAF/FTC (Descovy™): for cisgender MSM and TGF only (eCrCl of greater than or equal to 30 mL/min)
• CAB: see Appendix D
• Daily dosing is preferred, but On-demand PrEP is an acceptable alternative for cisgender MSM. Appendix E
• Assure HIV test <u>results</u> are available and acted upon within 7 days of initiation of PrEP
• Contact patient within 2 weeks to ensure:
▪ Prescription filled and taken as **ordered**
▪ Problems with payment for PrEP are solved
▪ Any side effects are addressed
• Instruct patient to report side effects immediately</td></tr>
</table>

❑ At Every Follow-Up Visit:

- Assess/ discuss strategies for maintaining adherence; explore/ address potential barriers to ongoing use of and adherence to PrEP
- Discuss risk reduction in the context of sexual health or injection drug use; offer condoms, syringe access, etc.
- Assess for possibility of pregnancy and offer birth control and pregnancy testing when appropriate
- Inquire about side effects and offer advice for management as needed
- Partner with providers in providing services; subspecialty medical care, mental health, substance use treatment, case management, navigation and linkage services, housing assistance, income/ benefits assessments, etc.
- Make every effort to avoid discontinuing PrEP or withholding it from a patient at risk of acquiring HIV
- Ask about symptoms suggestive of STIs and test those at risk
- Screen for symptoms of acute HIV and test at every follow-up visit

❑ Testing / Screening: Every 3 Months:

- Test for HIV infection (see PrEP nurse protocol for details)
- Conduct STI screening and proceed with testing if indicated, e.g., symptomatic or risk of new infection (GC, CT, syphilis, trichomonas)
- Perform NAATs for GC and CT infections for all patients at all sites of reported exposure.
- For all MSM and TGF, routinely perform 3-site testing (genital, rectal, and pharyngeal) for GC and CT regardless of sites of reported exposure, unless declined

❑ Every 6 Months:

- Conduct STI testing (GC, CT, Syphilis; as above)
- Obtain serum creatinine and eCrCl
  (May extend eCrCl to every 12 months for persons less than 50 years old or with an eCrCl of greater than or equal to 90ml/min at PrEP initiation)
  - Discontinue Truvada™ or Generic FTC/TDF if confirmed eCrCl less than 60 mL/min.
  - Discontinue Descovy™ if confirmed eCrCl less than 30 mL/min.
    Consult/ Refer: if client **develops** chronic active HBV **during course of PrEP usage, consult/refer** prior to **stopping** PrEP **due to risk of a hepatitis flare.**

❑ At Least Annually:

- Assess need for PrEP

Acronyms: anti-HBc: hepatitis B core antibody; anti-HBs: hepatitis B surface antibody; CT: Chlamydia; eCrCl: estimated creatinine clearance; FTC: emtricitabine; GC: gonorrhea; HAV: hepatitis A virus; HBsAg: hepatitis B surface antigen; HBV: hepatitis B virus; HCV: hepatitis C virus; IgG: immunoglobulin G; MSM: men who

have sex with men; NAAT: nucleic acid amplification test; PrEP: pre-exposure prophylaxis; STI: sexually transmitted infection; TAF: tenofovir alafenamide; TDF: tenofovir disoproxil fumarate; TGF: Transgender Female

REFERENCES

1. GA-DPH PrEP nurse protocol. https://dph.georgia.gov/office-nursing/nurse-protocols-and-quality-assurancequality-improvement

2. New York State Department Of Health Aids Institute, Clinical Guidelines Program, Appendices: PrEP Checklists**. https://www.hivguidelines.org/prep-for-prevention/prep/#tab_8**

3. **Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States, 2021 Update: A Clinical Practice Guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf Published December 2021. Accessed November 21, 2022.**

NON-OCCUPATIONAL POST EXPOSURE PROPHYLAXIS (nPEP)

2023 STANDARD NURSE PROTOCOL FOR NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (Npep) CLINICAL REVIEW TEAM

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Arthandreale Nicholas, APRN **District 5-2**	

2022 STANDARD NURSE PROTOCOL FOR NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP) CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR NON-OCCUPATIONAL POST-EXPOSURE PROPHYLAXIS (nPEP) USE IN THE PREVENTION OF SEXUALLY TRANSMITTED DISEASES AND BLOODBORNE PATHOGENS

DEFINITION

Non-occupational post-exposure prophylaxis (nPEP) is a course of prophylactic **therapy to prevent certain** sexually transmitted infection**s** (STI**s**) **and** bloodborne pathogens, including human immunodeficiency virus (HIV) drugs taken by HIV-negative individuals. nPEP and other aspects of case management are utilized for persons with isolated exposure(s) outside **of** health care settings to blood, genital secretions, or other potentially infectious body fluids that might contain STIs (i.e., HIV, syphilis, gonorrhea, chlamydia, trichomonas, hepatitis B, etc.) and/or other bloodborne pathogens. nPEP may include treatment of bacterial STIs and/or other bloodborne pathogens and **may** virtually eliminate the risk of getting HIV if anti-retroviral medications (ARVs) are taken timely (within 72 hours), consistently and correctly. nPEP is not taken for life; it is only taken for 30 days**, when** a person has had a **recent** substantial risk exposure to STIs and/or other bloodborne pathogens through sexual or injection drug use behavior.

NOTE: Current guidelines state that a 28-day course of prophylaxis is recommended. However, due to the manufacturers requirements that the product must be dispensed in the original container, a 30-day supply should be written as directed above.

ETIOLOGY

Immediate treatment, prophylaxis and vaccines can prevent long-term complications (PID, infertility, acquiring HIV, etc.). If HIV 3-drug antiretroviral medication nPEP is ordered, data supports that nPEP initiated as soon as possible within 72 hours after exposure and continued for 30 days with high medication adherence can reduce the risk for acquiring HIV infection after non**-**occupational exposures. The nPEP antiretrovirals (ARVs) stop the virus from replicating in the human body. If a person is exposed to HIV, initiates HIV nPEP as soon as possible within 72 hours of the exposure and takes nPEP correctly then nPEP can prevent the person from acquiring HIV.

NOTE: Delays in initiating therapy within the 72 hour period may decrease efficacy.

ELIGIBILITY

This nPEP protocol may only be offered to eligible persons who meet the following requirements:

1. Individuals 13 years of age and older who weigh at least 35kg (77lbs)
2. Exposure occurred within 72 hours of the nPEP assessment
3. Reported exposure presents a substantial risk for transmission; Appendix 1
   a. Exposure is based on sexual behavior, assault**,** and/or injection drug use
4. If HIV nPEP is considered, eligibility is only for individuals who are HIV negative

NOTE: The consent to the provision of medical or surgical care or services when such consent is given by a minor who is or professes to be afflicted with a venereal disease or at risk for HIV shall be as valid and binding as if the minor had achieved his or her majority. O.C.G.A. § 31-17-7(a).

NOTE: Pregnant women may obtain nPEP following the same assessment for a non-pregnant woman following any of the above noted eligibilities.

NOTE: Current guidelines recommend that nPEP be provided for infrequent exposures. Individuals presenting for nPEP more than once a month should be assessed for nPEP, if indicated for the current visit, and provided therapy, but should undergo further education on exposure prevention and undergo assessment for PrEP. See appendix 5 below on nPEP to PrEP transition and PrEP protocol.

NOTE: If the most recent recurring exposure is within the 72 hours prior to an evaluation, nPEP may be indicated with transition of the patient to PrEP after completion of 30 days of nPEP medication. (Refer to PrEP protocol and nPEP protocol Appendix #5 nPEP to PrEP section for more information)

NOTE: Staff should be aware of sexual assault organizations found at the GA Network to End Sexual Assault site https://www.gnesa.org/ and Georgia Mandatory Reporting of Suspected Child Abuse O.C.G.A. §19-7-5.

INELIGIBILITY

This nPEP protocol may not be utilized in the following situations:

1. The most recent exposure occurred beyond 72 hours of the nPEP assessment or therapy cannot be initiated within 72 hours of the exposure.
   a. Consult with an infectious disease provider in these cases
2. Individual with a baseline reactive rapid HIV test or is identified as having HIV
   a. Refer immediately to an HIV care provider for rapid anti-retroviral therapy (ART) initiation assessment
3. Index patient tests HIV negative after the exposure (if testing/results are available)
4. Patient has already been ordered, taking, and adherent to pre-exposure prophylaxis (PrEP)
5. Reported exposure presents no substantial risk of HIV transmission; Appendix 1.

6. Post-natal exposure of infants born to mothers with HIV
   a. Use of different ART regimen is required in these cases
7. Acute HIV is suspected:
   a. Fever, chills, rash, night sweats, muscle aches, sore throat, fatigue, swollen lymph nodes, and/or mouth ulcers
   b. Refer immediately to an HIV care provider for **further evaluation and guidance**.
8. Clinical staff being assessed for occupational postexposure prophylaxis (oPEP)

NOTE: If the exposure was beyond 72 hours, then evaluate symptomatically – see STD, Immunization and HIV nurse protocols.

NOTE: Discontinue HIV nPEP if the **index patient** is determined not to have HIV infection.

SUBJECTIVE

1. Patient is eligible to receive nPEP according to the eligibility criteria listed above.
2. Patient denies acute HIV signs and symptoms (i.e., fever, **chills,** fatigue, myalgia, skin rash, headache, pharyngitis, lymphadenopathy, arthralgias, night sweats, diarrhea) within the past 2-4 weeks.

NOTE: In most instances, acute HIV symptoms should resolve over 1 to 3 months from the acute infection but may be ongoing.

NOTE: Individuals eligible for nPEP who present with the common cold and influenza, influenza-like symptoms, COVID-19, etc. should undergo assessment as per this protocol, be started on nPEP and assessed in follow-up as outlined below.

3. Medical history negative for any medical, relative, or absolute contraindications to nPEP which may include complicated medical conditions or potential drug-drug interactions. Consult with Delegating Physician or Medical Director when assessing the safety of starting nPEP.

OBJECTIVE

1. Targeted physical exam based on exposure, i.e., skin, oral, genital, rectal exam

ASSESSMENT

1. Patient eligible to receive nPEP.

PLAN

DIAGNOSTIC STUDIES

NOTE: All diagnostic studies should be followed-up within 72 hours of results being reported. Consult with Delegating Physician or Medical Director regarding any abnormal lab results. Unless a severe reaction is occurring (i.e., Toxic epidermal necrolysis [TEN], Stevens-Johnson syndrome [SJS], Drug Rash with Eosinophilia and Systemic Symptoms [DRESS]), do not discontinue nPEP without express approval of Delegating Physician or Medical Director.

NOTE: Inquire about previous STIs and treatment for all individuals undergoing assessment for nPEP.

1. Initial/baseline nPEP Evaluation; Appendix 3
    a. Obtain history of potential exposure event
        1) HIV, hepatitis B virus (HBV), Hepatitis C virus (HCV) and other STI status of exposed person and source person, if available
        2) Timing of most recent potential exposure
        3) Type of exposure event and risk for HIV acquisition
        4) Make determination if nPEP is indicated; Appendix 1
    b. If nPEP is indicated, then
        1) Conduct baseline laboratory testing

2. HIV-1/2 blood test: rapid combined Ag/Ab test
    a. Preferably a rapid HIV-1/2 antigen/antibody test should be performed, but if not available, a rapid HIV antibody test or non-rapid HIV serum testing should be done. If non-rapid HIV-1/2 antigen/antibody immunoassay testing is performed, START nPEP immediately and arrange follow-up in 1-2 days for HIV results.

3. Initial RPR or Treponemal antibody with reflex to confirmatory syphilis test for assessment of syphilis
    a. Initial RPR reflexed to Treponemal antibody or
    b. Initial Treponemal antibody reflexed to RPR
        1) Preferred for high risk of acute syphilis

4. Gonorrhea nucleic acid amplification testing at site of exposure(s)
    a. Test all sites of sexual contact including oropharyngeal, rectal, and genital; urine testing may be considered in place of genital testing.

5. Chlamydia nucleic acid amplification testing at site of exposure(s)
    a. Test all sites of sexual contact including oropharyngeal, rectal, and genital; urine testing may be considered in place of genital testing.

6. Trichomonas for women and transgender men

7. Hepatitis A: IgM [for acute infection] and Total Ab [for chronic infection]: individuals with oral/anal exposure and/or “booty” meth use.
   a. Use of needleless syringes for rectal meth use

8. HBV; Appendix 4
   a. Surface antigen (sAg) with reflex to HBV DNA if sAg positive
   b. Surface antibody (sAb)
   c. Total and IgM core Ab

9. HCV Total Ab with reflex to HCV RNA if total Ab positive

10. Urine **p**regnancy test for women of childbearing capacity

11. Complete metabolic panel (CMP) to assess hepatic and renal function

THERAPEUTIC

PHARMACOLOGIC

1. Adults and adolescents 13 years of age and older (weighing at least 35kg [77lbs]), including pregnant women and women of childbearing capacity, with normal renal function (creatinine clearance ≥ 60 mL/min) and time between exposure and assessment having occurred within 72 hours.

2. Preferred: all components ordered as a 30-day course

NOTE: Current guidelines state that a 28-day course of prophylaxis is recommended. However, due to the manufacturers requirements that the product must be dispensed in the original container, a 30-day supply should be written as directed in the protocol above.

3. A 3-drug regimen consisting of:
   a. Emtricitabine 200mg + Tenofovir DF 300mg (Truvada™) 1 tablet orally once daily with or without food
      OR
   b. Generic Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300mg (Generic FTC/TDF) 1 tablet orally once daily with or without food
      PLUS
   c. Raltegravir 400 mg (Isentress™) 1 tablet orally twice daily with or without food
      OR
   d. Dolutegravir 50 mg (DTG / Tivicay™) 1 tablet orally once daily with or without food

NOTE: Avoid taking mineral supplements, including prenatal vitamins, within 2 hours of taking DTG.

4. Alternate 3-drug regimen consisting of (all components ordered as a 28-day course):
   a. Emtricitabine 200mg + Tenofovir DF 300mg (Truvada™) 1 tablet orally once daily with or without food
      OR
   b. Generic Emtricitabine 200mg + Tenofovir Disoproxil Fumarate 300mg (Generic FTC/TDF) 1 tablet orally once daily with or without food
      PLUS
   c. Darunavir 800 mg 1 tablet orally once daily with food
      PLUS
   d. Ritonavir 100 mg 1 tablet orally once daily with food

NOTE: For the latest data on neural tube defects (NTDs) in infants born to women prescribed dolutegravir (DTG), use of Folic Acid and counseling is found at https://clinicalinfo.hiv.gov/en/guidelines/perinatal/appendix-d-dolutegravir-counseling-guide-health-care-providers?view=full

NOTE: nPEP is not contraindicated for pregnant women, **as** pregnancy has been demonstrated to increase susceptibility to sexual HIV acquisition. All provided nPEP regimens are preferred in pregnancy (although dose adjustments, i.e. Darunavir [Must be used twice daily in pregnancy], would be recommended), however the delegating physician should be consulted for cases of nPEP in pregnant patients.

NOTE: If nPEP is ordered for a woman who is pregnant at the time of exposure or becomes pregnant while on nPEP, health care providers should enter the patient's information (anonymously) into the Antiretroviral Pregnancy Registry (http://www.apregistry.com).

NOTE: Women who are breastfeeding should be advised to continue to pump but discard the milk until 48 hours after completion of nPEP.

NOTE: There is an increased risk of drug interactions if a nPEP regimen using a boosting agent (i.e., ritonavir) is administered. Darunavir should generally be avoided in patients with a documented sulfonamide allergy.

5. Prophylaxis for other STIs and Hepatitis including exposure by sexual assault
   a. All adults and adolescents with exposures by sexual assault should be provided with prophylaxis routinely for other STIs, HAV, HBV and HPV. Adults and Adolescents not exposed sexually, but at risk for STIs, should be offered STI testing.

NOTE: Nonoccupational exposures should be provided with prophylaxis for GC, CT and trichomoniasis. Testing should be conducted prior to treatment.

NOTE: Refer to the STI Standard Nurse Protocol and the Penicillin Allergy Algorithm for additional guidance.

b. For gonorrhea: male and female adults and adolescents (also see STD nurse protocol)
   1) For persons weighing less than 150.6kg/330lbs:
      a) Ceftriaxone 500mg IM, single dose
   2) For persons weighing equal to or more than 150kg/330lbs:
      a) Ceftriaxone 1g IM, single dose

c. For chlamydia: male and female adults and adolescents (also see STD nurse protocol)
   1) Doxycycline 100mg po twice a day for 7 days

NOTE: Do not give Doxycycline to pregnant women or lactating patient(s). Patient(s) must be advised to discontinue breastfeeding or receive alternative regimen. Breastfeeding can be restarted 2 days after completion of treatment. Patient(s) who are nursing should be informed to use caution while nursing since treatment may be excreted in human breast milk in small amounts.

   2) For individuals who are pregnant Azithromycin 1g orally as a single dose

d. For trichomonas: female **or transgender male** adults and adolescents (also see STD nurse protocol)
   1) Metronidazole 500 mg orally twice a day for 7 days

6. Vaccines Stress HAV, HBV and HPV vaccines during the initial assessment. Otherwise, assess for and offer vaccinations per GA DPH Immunization Program and ACIP guidelines

7. Emergency contraception (Also see Women's Health Nurse Protocol)
   a. For women of childbearing capacity who have had genital exposure to semen and a negative pregnancy test when evaluated for possible nPEP, current contraception use should be assessed, and if a risk for pregnancy exists, emergency contraception should be discussed with the patient.

PATIENT EDUCATION / COUNSELING

1. Offer referral for Mental/Behavioral health counseling, **sexual assault** crisis center, primary care resources as applicable.

2. Current guidelines recommend that nPEP be provided for infrequent exposures. Individuals presenting for nPEP more than once a month should be assessed for nPEP acutely and undergo further education on exposure

prevention and undergo assessment for PrEP. See appendix 5 below on nPEP to PrEP transition and PrEP protocol.

3. Counsel patient regarding the basics of nPEP, including the importance of adherence, minimizing any gaps in therapy and stress the need to take all medications as ordered. Assess for safety in taking nPEP medications at place of residence (i.e., any interpersonal violence risk if found to be taking anti-HIV medications) and provide harm reduction counseling and support.

4. Review nPEP drug regimen with patient, including, drug storage, dose, route of administration, schedule, potential side effects, clinically significant drug interactions and follow-up monitoring.

NOTE: Any unusual or severe toxicities from antiretroviral drugs should be reported to the manufacturer or FDA.1-800-FDA-1088 [1-800-332-1088] or http://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm)

5. When necessary, assist patients with obtaining nPEP medication through a medication assistance program for the ordered regimen. See resource section below. Ensure the patient is able to obtain and initiate nPEP prescriptions as soon as possible within 72 hours of exposure; order prescribed medications to a pharmacy that keeps nPEP medications on-hand (if possible) or ensure the prescription can be ordered, dispensed, delivered and initiated within the 72-hour window period.

NOTE: Best practice guidance is to identify and maintain list of local pharmacies who **are** available to provide/assist with nPEP medications.

6. Provide counseling related to STI prevention strategies, as appropriate.

7. The safety of nPEP with Truvada™ or Tenofovir disoproxil fumarate (TDF) alone for infants exposed during lactation has not been adequately studied. Therefore, women who are breastfeeding will need to continue to pump and discard until patient has completed HIV nPEP medications.

8. Counsel patient on the importance of adherence to the prescribed regimen, but if a dose of medication is late or missed:
    a. Daily dosing (depending on the time of original scheduled dose):
        1) Take the missed dose of medication as soon as remembered and adjust the timing of the next dose to that same time moving forward if the adjusted time is convenient for patient compliance for future daily doses
        2) If the missed dose time is not convenient for patient compliance of future daily doses, then take the next dose as early as convenient for the patient and adjust timing of the next daily dose to that same time moving forward unless the adjusted time is within 4 hours of the

scheduled dose, then skip the missed dose and take the scheduled dose when it is due.

b. Twice daily dosing (depending on the time of original scheduled dose):
   1) Take the missed dose of medication as soon as it is remembered unless it is more than 2 hours beyond the original time of the missed dose. Schedule the next dose 12 hours after the missed dose is taken and continue this time schedule moving forward. The patient may need to adjust dosing time if exactly 12 hours is not convenient for patient compliance (i.e., from midnight-to 5AM).

c. Counsel patient not to take a double dose to make up for any missed dose. This may increase the chance of unwanted adverse effects. Also, assist the patient to establish dosing times that are convenient for their lifestyle and daily reminders to help with compliance and adherence.

FOLLOW-UP: Additional information in Appendix 3

1. Initial patient follow-up:
   a. Schedule first follow-up to occur 72 hours following the initial assessment. This assessment should focus on answering questions, assessing early side effects of medications, discuss any difficulties with medication adherence and follow-up, review initial lab work, etc. Face-to-face is the best option, but the patient may be contacted via other means, based on the clinics policies and procedures, in minimizing gaps in services.

2. Four to 6 weeks after the exposure:

NOTE: Follow-up in 2 to 3 weeks if individual considering PrEP

   a. HIV-1/2 blood test: if the baseline test was negative
      1) Preferably a rapid HIV-1/2 antigen/antibody test should be performed, but if not available, a rapid HIV antibody test or non-rapid HIV-1/2 antigen/antibody immunoassay serum should be performed.

   b. RPR or Treponemal antibody with reflex to confirmatory syphilis test for assessment of syphilis, if the baseline test was negative
      1) RPR reflexed to Treponemal antibody
      OR
      2) Treponemal antibody reflexed to RPR (Preferred for high risk of acute syphilis)

   c. Gonorrhea at site of exposure, if not provided presumptive treatment at baseline, or if symptomatic at follow-up
      1) Test all sites of sexual contact including oropharyngeal, rectal, and genital; urine testing may be considered in place of genital testing.

d. Chlamydia at site of exposure, if not provided presumptive treatment at baseline, or if symptomatic at follow-up

e. Test all sites of sexual contact including oropharyngeal, rectal, and genital; urine testing may be considered in place of genital testing.

f. Urine **p**regnancy test
   1) If woman of childbearing capacity, not using effective contraception, and with vaginal exposure to semen

g. Complete Metabolic Panel (CMP) in assessing hepatic and renal function; preferred at 2 weeks if patient able to present for laboratory work.

3. Three months after exposure
   a. HIV-1/2 blood if the 4 to 6-week test was negative
      1) Preferably a rapid HIV-1/2 antigen/antibody test should be performed, but if not available, a rapid HIV antibody test or non-rapid HIV-1/2 antigen/antibody immunoassay serum should be performed

4. Six months after exposure
   a. HIV-1/2 blood test: if the 3-month test was negative and only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.
      1) Preferably a rapid HIV-1/2 antigen/antibody test should be performed, but if not available, a rapid HIV antibody test or non-rapid HIV-1/2 antigen/antibody immunoassay serum should be performed.

   b. Hepatitis A Total Ab and IgM if baseline studies indicated no acute HAV or no immunity indicated.

   c. Hepatitis B virus (HBV): if exposed person susceptible to HBV at baseline: Appendix 4
      1) Surface antigen (sAg) with reflex to HBV DNA if sAg positive
      2) Surface antibody (sAb)
      3) Total and IgM core Ab

   d. Hepatitis C virus (HCV) (both IgM [for acute infection] + Total Ab [for chronic infection]) with reflex to HCV RNA if total Ab positive; if exposed person susceptible to HCV at baseline

   e. RPR or Treponemal antibody with reflex to confirmatory syphilis test for assessment of syphilis, if the 4 to 6-week test was negative
      1) RPR reflexed to Treponemal antibody
         OR

2) Treponemal antibody reflexed to RPR (Preferred for high risk of acute syphilis)

5. If the patient discontinues nPEP secondary to concerns of side effects, personal choice, or acute retroviral syndrome, then continue testing as noted above.

6. All persons who report behaviors or situations that place them at risk for frequently recurring HIV exposures (e.g., injection drug use, or sex without condoms) or who report receipt of greater than or equal to 1 course of nPEP in the past year should be provided risk-reduction counseling and intervention services, including consideration of preexposure prophylaxis. See PrEP nurse protocol.

NOTE: Persons who engage in behaviors that result in frequent, recurrent exposures that would require sequential or near-continuous courses of nPEP should be offered PrEP. A gap is unnecessary between ending nPEP and beginning PrEP.

NOTE: Refer to PrEP appendix C on pharmaceutical company PAP/co-pay limits and the individual's insurance company in accessing nPEP more than once per year.

CONSULTATION

1. Consult with the Delegating Physician or Medical Director:
   a. If at any time patient's lab results are abnormal
   b. If patient is experiencing side effects from nPEP
   c. If patient has signs and symptoms of acute HIV infection
   d. If patient has renal impairment (eCrCl less than 60 mL/min for Truvada™ or Generic FTC/TDF) Also refer to nephrologist, if able.
   e. If patient has comorbidities and/or drug-drug interactions where nPEP is contraindicated
   f. If patient is repeatedly non-adherent despite intensive counseling
   g. Wants restart of HIV nPEP following discontinuation beyond 72 hours of last dose
   h. If index patient is HIV positive with detectable or unknown HIV viral load and records demonstrate ARV treatment experienced with or without documented ARV resistance

NOTE: If available, all resistance testing (genotypes, phenotypes tropisms ever completed) should be reviewed in assessing viable nPEP options for the exposed individual. A highly recommended resource for interpretation of ART mutations is the Stanford HIV Database (https://hivdb.stanford.edu/hivdb/by-mutations/)

i. HBV sAg positive: do not stop nPEP; immediately refer to Delegating Physician or Medical Director
j. HCV Total Ab positive: Appropriate referral to gastrointestinal, infectious disease, or a provider with HCV treatment experience for assessment should be made for individuals with a positive HCV RNA result.
k. If the initial/baseline exposed HIV test is reactive/positive, the patient should NOT be given HIV nPEP, but be provided supportive counseling and connected to an HIV primary care or specialty care (HIV/Infectious Disease specialist) provider immediately, e.g., before being discharged from care.

NOTE: All HIV indeterminate/positive tests should be immediately assessed or referred to a local HIV expert (https://www.gacapus.com/r/resource-directory-2/)

l. If the exposed follow-up HIV test is reactive/positive, stop nPEP immediately, provide supportive counseling and connect the patient to an HIV primary care or specialty care (HIV/Infectious Disease specialist) provider.
m. Patient requests HIV nPEP when presenting outside of the 72-hour exposure window period
n. Individuals less than 13 years of age who are requesting nPEP
o. Individuals greater than or equal to 13 years of age who weigh less then 35kg (77lbs)
p. Use of antiretroviral regimens for nPEP other than those listed in this protocol as preferred or alternative

Resources for Drug Assistance Plans:

1. Information for specific medications and manufacturers is available at: https://medicineassistancetool.org/ https://www.rxassist.org/

2. Persons being ordered nPEP after sexual assault can be reimbursed for medications and clinical care costs through state Crime Victim's Compensation Programs funded by the U.S. Department of Justice. Contact information for each state is available at http://www.ojp.usdoj.gov/ovc/map.html orhttp://www.nacvcb.org/index.asp?bid=16

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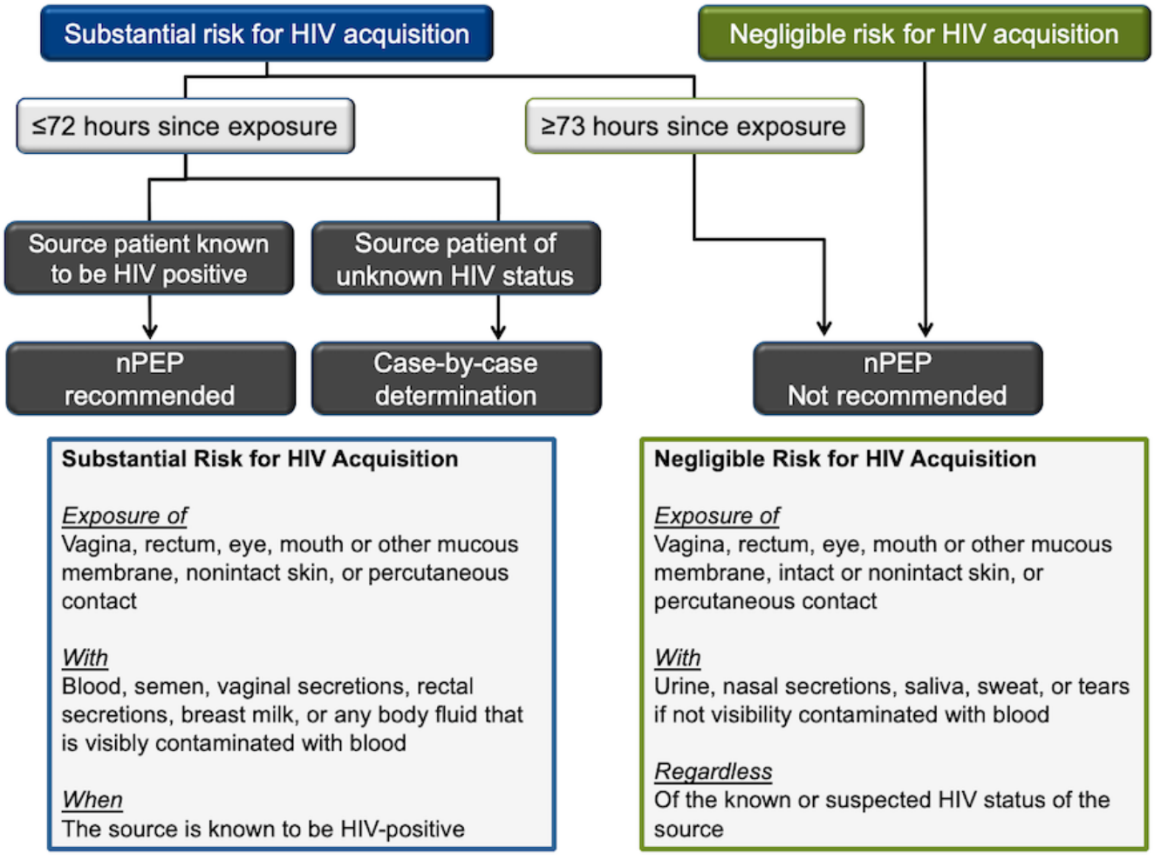
Appendix 1: Algorithm for evaluation and treatment of possible nonoccupational HIV exposures



Note: The HIV status of the index should be classified as HIV-negative, HIV-positive, or unknown at the time of the initial evaluation. Thus, treatment decisions should be made based upon the nature of the exposure and when the exposure occurred. Once the need for nPEP has been identified, the patient should receive a dose as soon as possible (MUST be within 72 hours of the exposure), even if HIV testing of the exposed patient and index have not yet been performed. After the initial dose has been administered, HIV testing, and a more detailed history can be obtained. At that time, patients should also be assessed for hepatitis A, B and C virus, sexually transmitted infections (depending upon the type of exposure) and pregnancy for women. See Diagnostic Studies Section above.

Appendix 2: Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act[a]

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other[b]	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

Source: http://www.cdc.gov/hiv/policies/law/risk.html

[a] Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

[b] HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Note: U=U means that people with HIV who achieve and maintain an undetectable viral load—the amount of HIV in the blood—by taking antiretroviral therapy (ART) daily as prescribed cannot sexually transmit the virus to others.
https://www.niaid.nih.gov/diseases-conditions/treatment-prevention

Note: A history should be taken of the specific sexual, injection drug use, or other exposure events that can lead to acquiring HIV infection. Eliciting a complete description of the exposure and information about the HIV status of the partner(s) can substantially lower (e.g., if the patient was exclusively the insertive partner or a condom was used) or increase (e.g., if the partner is known to be HIV-positive) the estimate of risk for HIV transmission resulting from a specific exposure.

Percutaneous injuries from needles discarded in public settings (e.g., parks and buses) sometimes result in requests for nPEP. Although no HIV infections from such injuries have been documented, concern exists that syringes discarded by PWID might pose a substantial risk. However, such injuries typically involve small-bore needles that contain only limited amounts of blood, and the infectiousness of any virus present might be low. Saliva that is not contaminated with blood contains HIV in much lower titers and constitutes a negligible exposure risk, but saliva that is contaminated with HIV-infected blood poses a

substantial exposure risk. HIV transmission by this route has been reported in greater than 3 cases.

Appendix 3 nPEP recommended schedule of laboratory evaluations of index and exposed persons

Test	Source	Exposed persons			
	Baseline	Baseline	4–6 weeks after exposure	3 months after exposure	6 months after exposure
		For all persons considered for or prescribed nPEP for any exposure			
HIV Ag/Ab testing[a] (or antibody testing if Ag/Ab test unavailable)	✓	✓	✓	✓	✓[b]
Hepatitis B serology, including: hepatitis B surface antigen hepatitis B surface antibody hepatitis B core antibody	✓	✓	—	—	✓[c]
Hepatitis C antibody test	✓	✓	—	—	✓[d]
		For all persons considered for or prescribed nPEP for sexual exposure			
Syphilis serology[e]	✓	✓	✓	—	✓
Gonorrhea[f]	✓	✓	✓[g]	—	—
Chlamydia[f]	✓	✓	✓[g]	—	—
Pregnancy[h]	—	✓	✓	—	—
		For persons prescribed tenofovir DF+ emtricitabine + raltegravir or tenofovir DF+ emtricitabine + dolutegravir			
Serum creatinine (for calculating estimated creatinine clearance[i])		✓	✓	—	—
Alanine transaminase, aspartate aminotranferase		✓	✓	—	—
		For all persons with HIV infection confirmed at any visit			
HIV viral load	✓	✓[j]			
HIV genotypic resistance	✓	✓[j]			

Abbreviations: Ag/Ab, antigen/antibody combination test; HIV, human immunodeficiency virus; nPEP, nonoccupational postexposure prophylaxis; tenofovir DF, tenofovir disoproxil fumarate.

[a] Any positive or indeterminate HIV antibody test should undergo confirmatory testing of HIV infection status.

[b] Only if hepatitis C infection was acquired during the original exposure; delayed HIV seroconversion has been seen in persons who simultaneously acquire HIV and hepatitis C infection.

[c] If exposed person susceptible to hepatitis B at baseline.

[d] If exposed person susceptible to hepatitis C at baseline.

[e] If determined to be infected with syphilis and treated, should undergo serologic syphilis testing 6 months after treatment

[f] Testing for chlamydia and gonorrhea should be performed using nucleic acid amplification tests. For patients diagnosed with a chlamydia or gonorrhea infection, retesting 3 months after treatment is recommended.

- For men reporting insertive vaginal, anal, or oral sex, a urine specimen should be tested for chlamydia and gonorrhea.
- For women reporting receptive vaginal sex, a vaginal (preferred) or endocervical swab or urine specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive anal sex, a rectal swab specimen should be tested for chlamydia and gonorrhea.
- For men and women reporting receptive oral sex, an oropharyngeal swab should be tested for gonorrhea. (http://www.cdc.gov/std/tg2015/tg-2015-print.pdf)

[g] If not provided presumptive treatment at baseline, or if symptomatic at follow-up visit.

[h] If woman of reproductive age, not using effective contraception, and with vaginal exposure to semen.

[i] eCrCl = estimated creatinine clearance calculated by the Cockcroft-Gault formula; eCrClCG = [(140 − age) x ideal body weight] ÷ (serum creatinine x 72) (x 0.85 for females).

[j] At first visit where determined to have HIV infection.

Source: https://stacks.cdc.gov/view/cdc/38856

NOTE: Serum creatinine, Alanine transaminase and Aspartate aminotransferase are included in the CMP noted within the protocol above.

NOTE: Perform HAV testing as noted within the protocol above.

Appendix 4: Hepatitis B virus screening serology

HBsAg	Anti-HBc	Anti-HBs	IgM Anti-HBc	Interpretation	Action
Negative	Negative	Negative	—	Susceptible	Vaccinate
Negative	Positive	Positive	—	Immune (natural infection)	Document
Negative	Negative	Positive	—	Immune (prior vaccination)	Document
Positive	Positive	Negative	Negative	Chronic hepatitis B virus infection	Evaluate for treatment
Positive	Positive	Negative	Positive	Acute hepatitis B virus infection	Follow and evaluate for treatment
Negative	Positive	Negative	—	Unclear—might be: • resolved infection (most common) • false-positive anti-HBc; susceptible • "low level" chronic infection • resolving acute infection	Case-by-case evaluation

Abbreviations: HBsAg, hepatitis B surface antigen; anti-HBc, hepatitis B core antibody; anti-HBs, hepatitis B surface antibody.

Source: https://stacks.cdc.gov/view/cdc/38856

Appendix 5 nPEP to PrEP Transition Checklist

nPEP to PrEP TRANSITION CHECKLIST: PRE-PRESCRIPTION, FOLLOW-UP, AND MONITORING
Refer to GA-DPH Nurse nPEP and PrEP protocol for additional details, clarification and for medical decision making

❑ 1-month nPEP FOLLOW-UP VISIT

▪ Obtain nPEP follow-up testing for: HIV, syphilis, CMP, urine pregnancy test (if applicable), GC and CT (if presumptive treatment was not provided at nPEP initiation)

▪ Screen for acute HIV
- Person is not PrEP eligible if HIV test is reactive or if signs and symptoms of acute HIV are present
- Contact delegating physician and immediately refer to HIV care if needed

▪ Discuss PrEP use; clarify inclusion/exclusion criteria per PrEP protocol

▪ Perform baseline PrEP laboratory testing (if not performed upon nPEP initiation)

▪ Obtain pharmaceutical co-pay assistance for PrEP as indicated
- Some insurance companies may require use of Generic FTC/TDF
- See PrEP protocol appendix C for medication acquisition

▪ Prescribe PrEP per PrEP protocol

▪ Schedule the patient to return for follow-up in 2 months for HIV testing and STI screening per PrEP protocol

❑ 3-MONTH nPEP/PrEP FOLLOW-UP VISIT

▪ Test for HIV infection (see PrEP nurse protocol for details)

▪ Conduct STI screening and proceed with testing if indicated, i.e. symptomatic or risk of new infection
(GC, CT, Syphilis, Trichomonas)

Note:
▫ Perform NAATs for gonococcal and chlamydial infections for all patients at all sites of reported exposure.

▫ Offer 3-site GC and CT testing (genital, rectal and pharyngeal) to all asymptomatic MSM and TGF who are high risk for recurrent STIs.

❑ 6-MONTH PrEP FOLLOW-UP VISIT AND WHILE CLIENT ON PrEP (testing only if 3-month tests are negative)

- Test for HIV infection (see PrEP nurse protocol for details)
- Hepatitis A, B and C testing (see above for details)
- Conduct STI screening and proceed with testing if indicated, i.e. symptomatic or risk of new infection
(GC, CT, Syphilis, Trichomonas)
- Refer to PrEP protocol for remainder of care

Note: CMP, complete metabolic panel; CT, chlamydia; FTC, emtricitabine; GC, gonorrhea; HIV, human immunodeficiency virus; MSM, men who have sex with men; NAAT, nucleic acid amplification test; nPEP, non-occupational postexposure prophylaxis; PrEP, preexposure prophylaxis; STI, sexually transmitted infection; TDF, tenofovir disoproxil fumarate; TGF, transgender female

PRIMARY HYPERTENSION IN ADULTS

2023 STANDARD NURSE PROTOCOL FOR PRIMARY HYPERTENSION IN ADULTS CLINICAL REVIEW TEAM

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2022 STANDARD NURSE PROTOCOL FOR PRIMARY HYPERTENSION IN ADULTS CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR PRIMARY HYPERTENSION IN ADULTS

Disclaimer:
The Department of Public Health recognizes the implications of the **2017** changes to hypertension treatment proposed by the American Heart Association and American College of Cardiology. Based on the non-endorsement of these guidelines by the American Academy of Family Physicians and considering the populations we serve across the state of Georgia, the following hypertension treatment guidelines align with those of the **2022** American Academy of Family Physicians **hypertension guidelines which are most consistent with the 2020 International Society of Hypertension Global Hypertension Practice Guidelines**.

DEFINITION

Primary (Essential) Hypertension is defined as systolic blood pressure (SBP) equal to or greater than 140 mm Hg **and/**or diastolic blood pressure (DBP) equal to or greater than 90 mm Hg on at least two subsequent occasions or taking antihypertensive medication with **a** goal of maintaining a normal blood pressure (BP). Secondary hypertension is a type of hypertension with an underlying potentially correctable cause.

NOTE: This protocol is for Primary Hypertension and **does** not include treatment for patients with impaired kidney function or chronic kidney disease, heart failure, pregnant or lactating women, suspected secondary hypertension, evidence of end organ damage, history of stroke or other complicating factors.

Classification of Hypertension Based on Office Blood Pressure Measurement

Blood Pressure Category	**Systolic Blood Pressure (mm Hg)**		**Diastolic Blood Pressure (mm Hg)**
Normal	**< 130**	**and**	**< 85**
High-normal	**130 – 139**	**and/or**	**< 85 – 89**
Grade 1 hypertension	**140 – 159**	**and/or**	**90 – 99**
Grade 2 hypertension	**≥ 160**	**and/or**	**≥ 100**

ETIOLOGY

1. Primary hypertension/high blood pressure (HBP) appears to be a multi-factorial disease/disorder in which several genes interact with each other and with the environment.

2. Contributing Risk Factors for Hypertension include:
   a. Family history of premature cardiovascular disease (men aged less than 55 and women aged less than 65).
   b. Age
   c. Race or ethnicity (African American)
   d. Overweight/obesity (BMI greater than **25**)
   e. Habitual high salt intake
   f. Sedentary lifestyle (little to no moderate to vigorous activity in the past 30 days)
   g. Alcohol intake greater than moderate drinking (more than one drink per day for women and more than 2 drinks per day for men)
   h. Any tobacco or nicotine use
   i. **Type II** Diabetes Mellitus
   j. Microalbuminuria
   k. Renal disease

SUBJECTIVE

1. Normally no symptoms. Headaches, dizziness, or nosebleeds do not occur more often in persons with hypertension.
2. May or may not have a personal or family history of hypertension.
3. The following medical history should be elicited:
   a. Known duration/levels of elevated blood pressure.
   b. Past or current symptoms of coronary heart disease, heart failure, cerebrovascular disease, peripheral vascular disease, renal disease, **type II** diabetes mellitus, dyslipidemia, sleep apnea or sexual dysfunction.
   c. History of symptoms of gout.
   d. Recent changes in weight, leisure-time activity, smoking or other tobacco use, or recreational drug use including stimulants, cocaine, amphetamines, marijuana, prescribed and non-prescribed opioids.
   e. Current and Past Medication History including:
      1) Current use of antihypertensive medications including reasons for use, length of use, and any adverse effects
      2) Previous antihypertensive therapy including impact on BP and adverse effects
      3) Other prescription medications
      4) OTC medications
      5) Alternative therapies, herbs, or supplements
      6) Homeopathies
4. Family history of hypertension.
5. Family history of cardiovascular disease, diabetes, elevated lipids (high blood cholesterol).
6. Family history of secondary hypertension
7. Results of previous medical assessments of possible causes of hypertension (e.g., labile hypertension or paroxysms of hypertension accompanied by headache, palpitations, pallor and perspiration; abdominal bruits or abdominal

or flank masses; delayed or absent femoral artery pulses or decreased BP in the lower extremities; hypokalemia; hypercalcemia; elevated creatinine).

8. Physical activity history and diet history, including intake of salt, alcohol, saturated fat, and caffeine.
9. Psychosocial and environmental factors (e.g., family situation, employment status, working conditions, educational level).
10. May have one or more of the following symptoms suggestive of target organ damage and/or clinical cardiovascular disease (e.g., left ventricular hypertrophy [LVH], angina, prior myocardial infarction [MI] or coronary revascularization, heart failure, stroke or transient ischemic attack [TIA], neuropathy, peripheral arterial disease, chronic kidney disease, retinopathy):
    a. Visual disturbances.
    b. Chest pain.
    c. Shortness of breath.
    d. Edema.
    e. Dizziness.
    f. Headache.
    g. Confusion or other neurological symptoms (e.g., difficulty with speech or movement, facial or one-sided numbness).
    h. Nocturia, urinary frequency, urinary incontinence.

OBJECTIVE

1. SBP equal to or greater than 140 mm Hg and/or DBP equal to or greater than 90 mm Hg (based on the average of at least two measurements separated by 2 minutes) **on at least two separate occasions.**
    a. Whenever possible, the diagnosis should not be made on a single clinic visit. Two to three clinic visits at 1-to-4-week intervals (depending on the blood pressure level) are needed to confirm a diagnosis of hypertension.
    b. **A diagnosis of hypertension may be made on a single clinic visit if blood pressure is 180/110 mm Hg and there is evidence of cardiovascular disease.**

NOTE: For SBP of 1**30**-1**39** mm Hg and/or DBP **of** 8**5**-**89** mm Hg with no cardiovascular risk, recommendations for lifestyle modifications should be provided as a preventative measure. **These patients should be encouraged to monitor their blood pressure at home and bring in a copy of readings to a follow-up visit. Patient should be advised to contact the clinic for an appointment if two or more readings are ≥ 140 and/or ≥ 90.**

NOTE: Accurate measurement of blood pressure is essential to the diagnosis and management of hypertension. Before taking blood pressure measurements, it is recommended that the patient's bladder be empty and patients avoid smoking, caffeine, and exercise for 30 minutes prior to measurement. Patients should remain seated and relaxed for 5 minutes

before taking blood pressure measurements. Neither patient nor staff should talk before, during, and between measurements. While measuring blood pressure, a patient's feet should be flat on the floor and the arm supported with the cuff at the level of the heart. Wrist blood pressure tests are not recommended.

NOTE: For BP measurement, be sure to indicate in the patient's record the arm with the higher reading. The arm with the higher reading is to be used for ongoing evaluation on subsequent visits.

2. **Calculate the patient's 10-year risk of heart disease or stroke using the ASCVD algorithm published in** 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk**.**

3. Triage assessment is performed at each visit and includes the information components listed below:
    a. Chief complaint.
    b. Physical examination includes:
        1) Weight, body mass index, and waist circumference.
        2) Sitting and standing BP (particularly for patients with diabetes or complaints suggestive of orthostatic hypotension, the elderly and patients taking diuretics). A drop in BP without an increase in pulse rate is suggestive of autonomic neuropathy in patients with diabetes, and of volume depletion in patients taking diuretics.
        3) Temperature and pulse rate.
        4) Heart and lung sounds.
        5) Assessment of extremities.
        6) Assess, advise and refer tobacco and nicotine users.
    c. Adherence to the treatment regimen, including lifestyle modifications and pharmacologic treatment. Note any side effects to medications. See Patient Education/Counseling section.
    d. ER/Hospital visits or change in medical history since the last visit.

NOTE: When HBP is identified early before target organ damage occurs, the physical examination is usually normal for the patient's age and sex.

ASSESSMENT Primary (Essential) Hypertension

NOTE: If subjective and objective findings do not indicate a cause of the hypertension and/or if secondary hypertension is suspected, refer to delegating physician and/or out for care.

PLAN

DIAGNOSTIC STUDIES

1. Baseline Evaluation:
    a. Complete blood count (CBC)
    b. Basic metabolic panel (BMP) which includes serum potassium, creatinine, sodium and calcium
        i. Comprehensive metabolic panel (CMP) should be ordered for clients taking a statin.
    c. Fasting blood glucose
    d. Hemoglobin A1C
    e. Total cholesterol and lipid profile
        i. Fasting lipids are not required as total cholesterol and HDL are minimally affected by fasting.
        ii. If the non-fasting plasma triglyceride component of the lipid profile returns at > 400 mg/dL, obtain a fasting lipid profile.
    f. Dipstick urinalysis including microalbumin, full urinalysis by laboratory for any positive results.
    g. ECG/EKG
    h. TSH
    i. Urinary albumin to creatinine ratio, **if patient has history of diabetes**
    j. Pregnancy test for women of reproductive age, as indicated.

    NOTE: If hypertension is identified early, diagnostic studies should be within normal limits. They may be abnormal if the BP has been elevated for a long time or is high to the point that it can cause target organ damage.

2. Complete routine follow-up lab studies to determine the effect of therapy and/or when complaints of concerning signs/symptoms:
    a. Thiazide-type diuretics, ACEIs, ARBS, and **spironolactone**
        i. Obtain BMP, serum potassium, blood urea nitrogen (BUN), and creatinine **within the first two to four weeks after initiating treatment and again at 6 months and 12 months.**
            1. **Closer monitoring may be needed as dosing of these medications are increased.**
        ii. Monitor abnormal serum potassium levels as described in the pharmacologic section.
        iii. If serum creatinine is elevated (1.4 mg/dL or greater for women and 1.5 mg/dL or greater for men) consult with physician for recommendation.

3. Annual Evaluation:
    a. If receiving anti-hypertensive therapy, **patients** should have the following labs performed annually:
        i. CBC
        ii. BMP
            1. Comprehensive metabolic panel (CMP) should be ordered for clients taking a statin.
        iii. Total cholesterol and lipid profile

iv. Dipstick urinalysis including microalbumin, full urinalysis by laboratory for any positive results.
v. Hgb A1C

4. **Every 5 years, perform an** EKG. **Perform an EKG sooner in the presence** of new signs and/or symptoms of heart disease (e.g., chest pain or abnormal heartbeats) or evidence of congestive heart failure (e.g., peripheral edema, shortness of breath).

THERAPEUTIC

The goal of therapy for hypertension is to minimize end-organ damage by lowering blood pressure. This may be accomplished with only lifestyle modification or a combination of lifestyle changes and medications.

PHARMACOLOGIC

DISCLAIMER: Drug Shortages can occur for many reasons, including manufacturing and quality problems, delays, discontinuations, and supply chain interruptions. The FDA maintains a list of current drug shortages which may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm**. Please contact the Hypertension and Diabetes Nurse Program Manager and the Georgia DPH Office of Pharmacy for assistance with specific drug shortage concerns.**

The general principles of drug therapy in the treatment of primary hypertension are based on the **2022 American Academy of Family Physicians Guidelines and the 2020 International Society of Hypertension Guidelines.**

Pharmacologic treatment should be initiated:
1. In the general population, **for all adults aged 18 to 80**, initiate pharmacologic therapy to lower BP to a SBP goal of less than 140 mm Hg and to lower BP to a DBP goal of less than 90 mm Hg.
2. In the general population, **for adults older than 80 years of age**, initiate pharmacologic therapy to lower BP to a SBP goal of less than 150 mm Hg and to lower BP to a DBP goal of less than 90 mm Hg.

NOTE: If medications are not available due to shortage or recall, please refer to another medication in that class as **noted in this nursing protocol** and/or consult with your delegating physician or pharmacist.

NOTE: Most patients with hypertension will require more than one blood pressure medication to reach goal blood pressure. Consider initiating monotherapy in frailer patients, in the very old (≥ 80), and in patients that decline to start dual therapy.

- **If there are no compelling reasons to select a specific drug class for monotherapy, an ACE inhibitor (or Angiotensin receptor blocker) or a dihydropyridine calcium channel blocker should be selected, rather than a thiazide diuretic.**
- **In African American patients, use of an ARB is preferred over an ACEI to decrease risk of angioedema.**
- **An ACEI or an ARB should be used for initial monotherapy in patients who have diabetes.**

For patients with hypertension, utilize the following medication selection and escalation algorithm:

Step 1: Initiate dual low dose* combination (ideally a single pill combination therapy, but not required)	**ACE-inhibitor (ACEI) or Angiotensin receptor blocker † (ARB) and Dihydropyridine-Calcium Channel Blocker (DHP-CCB)**
Step 2: If needed, titrate up to dual full dose combination	**ACEI or ARB and DHP-CCB**
Step 3: If indicated, add a 3rd medication. Initiate at low dose and titrate dose as needed.	**ACEI or ARB and DHP-CCB and thiazide-like diuretic**
Step 4: If indicated due to resistant hypertension, and after consultation and approval of delegating physician, add a 4th medication.	**ACE-I or ARB and DHP-CCB and thiazide-like diuretic and spironolactone** (12.5 – 50 mg)**

***Low-dose refers to the initial starting dose of the medication as listed in the nursing protocol.**

† In African American patients, use of an ARB is preferred over an ACEI to decrease risk of angioedema.

****An alternative medication to spironolactone includes a beta-blocker.**

NOTE: To improve adherence to antihypertensive treatment, it is preferred to use a single pill combination with once-daily dosing.

NOTE**: Before escalating antihypertensive drug therapy, it is prudent to confirm that the patient is adherent to the treatment regimen**. If goal BP cannot be reached using the drugs included in this protocol or due to any contraindication or the need to use more than 3 drugs to reach goal BP, refer to delegating physician and/or refer out for care.

NOTE**:** For those drugs listed with once or twice daily dosing, the antihypertensive effect may diminish toward the end of the dosing interval

especially with the lower dosing. An increased dosing may aid in extending the duration of antihypertensive effect or the need to divide the dose for twice-daily dosing should be assessed by monitoring peak and trough responses.

1. Angiotensin Converting Enzyme Inhibitor (ACEI)

NOTE: Avoid the combined use of ACEI and ARB. Do not give the following ACEI to patients with a known hypersensitivity to ACEIs or any component of the formulation.

NOTE: **Persons of reproductive age should be counseled to avoid pregnancy during therapy with an ACEI.**

NOTE: For patients with diabetes who are also taking an ACEI, they should not take Aliskiren if GFR is estimated to be below 60 mL/min (mild loss of kidney function) because the combination may enhance the nephrotoxic effect of the ACEI. Other patients should be monitored for serum potassium, serum creatinine, and blood pressure periodically.

a. Lisinopril
    1) Initial Dose: Lisinopril 10 mg tablet PO once daily if patient not maintained on a diuretic. Lisinopril 5 mg PO once daily if patient maintained on a diuretic or if patient is volume depleted. For older patients (aged 65 years or over), consider starting with a lower initial dose and titrating to BP response.

    2) Usual dose: Lisinopril 10 mg to 40 mg PO once daily. Maximum dose 40 mg/day

OR

b. Enalapril Maleate
    1) Initial Dose: Enalapril Maleate 5 mg PO once daily if patient is not maintained on a diuretic. Enalapril Maleate 2.5 mg PO once daily if patient is maintained on a diuretic or if patient is volume depleted. For older patients (aged 65 years or over), consider starting with a lower initial dose and titrating to BP response. May titrate at **2 to 4**-week intervals based on patient response.
    2) Usual dose: Enalapril Maleate 10-20 mg PO daily in 1 or 2 divided doses. Maximum dose 40 mg/day

OR

c. Benazepril HCL
    1) Initial Dose: Benazepril HCl 10 mg PO once daily if patient is not maintained on a diuretic. Benazepril HCl 5 mg PO once daily if patient is maintained on a diuretic or if patient is volume depleted. For older patients (aged 65 years or over), consider starting with a lower initial dose and titrating to BP response.

2) Usual dose: Benazepril HCl 10-40 mg PO daily in 1 or 2 divided doses. If patient is compliant after 2-3 weeks but BP is not decreasing, increase dosage until control is gained, side effects become intolerable, or maximum dosage is reached. Maximum dose 40 mg/day

2. Angiotensin Receptor Blockers (ARBs)

NOTE: Avoid the combined use of ACEI and ARB. Do not give the following ARBs to patients with a known hypersensitivity to ARBs or any component of the formulation.

NOTE: **Persons of reproductive age should be counseled to avoid pregnancy during therapy with an ARB.**

a. Losartan Potassium:
   1) Initial dose: Losartan Potassium 25 mg PO once daily if maintained on a diuretic or volume depleted. Losartan Potassium 50 mg PO daily if not maintained on a diuretic.

   2) Usual dose: Losartan Potassium 50-100 mg PO daily in 1 or 2 divided doses. Maximum dose 100 mg/day

OR

b. Valsartan:
   1) Initial dose: Valsartan 80 mg PO daily if not maintained on a diuretic or if Valsartan is used as monotherapy. Valsartan 40 mg PO once daily if maintained on a diuretic or volume depleted. Dose may be increased to achieve desired BP effect.

   2) Usual dose: Valsartan 80-320 mg PO daily. Maximum dose 320 mg/day

OR

c. Irbesartan:
   1) Initial dose: Irbesartan 150 mg PO once daily if patient is not maintained on a diuretic. Irbesartan 75 mg PO once daily, if patient is maintained on a diuretic or if patient is volume depleted.
   2) Usual dose: Ibesartan 150-300 mg PO daily. If patient is compliant after 2-3 weeks but BP is not decreasing, increase dosage until control is gained, side effects become intolerable, or maximum dosage is reached. Maximum dose 300 mg/day

3. Calcium Channel Blockers (CCBs)
   a. **Dihydropyridine**: Amlodipine Besylate
      1) Initial dose: Amlodipine Besylate 2.5 mg PO once daily may be used when adding amlodipine to other antihypertensive therapy. If used as

monotherapy, can initiate Amlodipine Besylate 5 mg PO once daily. Older patients (aged 65 years or over) should be initiated at Amlodipine Besylate 2.5 mg PO once daily. In general, titrate in 2.5 mg increments, wait **1 to 2 weeks** between titration steps.

2) Usual dose: Amlodipine Besylate 5-10 mg PO once daily. Maximum dose 10 mg/day

OR

b. Non-dihydropyridines: **Not preferred CCB medications, but a patient currently well tolerated on a non-dihydropyridine CCB may continue.**

NOTE**:** Non-dihydropyridine calcium channel blockers (e.g., diltiazem, verapamil) offer a small protective effect on proteinuria in diabetic nephropathy beyond their anti-hypertensive action. There is a small additional benefit on proteinuria from addition of non-dihydropyridine CCBs to ACEIs.

NOTE**:** Concomitant use of non-dihydropyridine calcium channel agents (e.g., verapamil, diltiazem) and beta-adrenergic blocking agents can have additive negative effects on myocardium contractility, heart rate, and AV conduction and they may inhibit the metabolism of certain beta-blockers.

1) Diltiazem Extended Release:
   a) Initial Dose: Diltiazem Extended Release 120-180 mg PO once daily (24-hour formulation) or 60 mg PO twice daily (12-hour formulation). For older patients, consider starting with 120 mg as an initial daily dose and titrating to BP response.
   b) Usual dose: Diltiazem Extended Release 240-360 mg PO once daily (24-hour formulation) or 120-180 mg PO twice daily (12-hour formulation). Anti-hypertensive effects usually are evident within the first week. If patient is compliant after 2 weeks but BP is not decreasing, increase dosage until control is gained, side effects become intolerable, or maximum dose is reached. May not see any benefit in doses higher than 360 mg/day.
   c) Various formulations exist with different dosing. For treatment of Hypertension (HTN) use extended-release capsules and tablets only.

      i. Extended-Release 24-hour capsules:
      Cardizem CD, Cartia XT: Maximum 360 mg/day
      Dilt-XR, Tiazac, Taztia XT: Maximum 360 mg/day
      ii. Extended Release 24-hour tablets:
      Cardizem LA, Matzim LA: Maximum 360 mg/day
      iii. Extended Release Capsule, 12 hours:
      Diltiazem HCL ER (generic Cardizem SR): Maximum 360 mg/day

OR

2) Verapamil HCl Sustained-Release (SR)
   a) Initial Dose: Verapamil HCl 180 mg PO given in the morning. Lower initial dosages of 120 mg daily may be warranted in patients who may have an increased response (e.g., elderly patients, patients of small stature.)
   b) If adequate BP response is not obtained with Verapamil HCl 180 mg, the dosage may be titrated upward in the following manner at weekly intervals until appropriate BP response achieved:

      i. Verapamil HCl 240 mg PO each morning. THEN if needed, Verapamil HCl 180 mg PO each morning, plus Verapamil HCl 180 mg PO each evening.

      OR

      i. Verapamil HCl 240 mg PO each morning plus Verapamil HCl 120 mg PO each evening.
      ii. Usual dose: Verapamil HCl 240-360 mg PO daily. Verapamil HCl sustained release 120-360 mg PO daily.

4. Thiazide-type Diuretics

NOTE: Do not give to patients with a known sensitivity to thiazide-type diuretics, any component of the formulation or sulfonamide-derived drugs or anuria. Be sure to read package insert for all side/adverse effects.

a. Chlorthalidone: preferred thiazide-like diuretic over indapamide and hydrochlorothiazide.
   1) Initial dose: 12.5 mg once daily. Maximum dose 25 mg/day. Evaluate response after 2 to 4 weeks and titrate dose, as needed. For older patients, consider starting with a lower initial dose of 6.25 mg and titrating based on BP response. Maximum: 25 mg/day.

OR

b. Hydrochlorothiazide (HCTZ):
   1) Initial dose: HCTZ 12.5 mg – 25 mg PO once daily. For older patients (aged 65 years or over), consider starting with a lower initial dose of 12.5 mg and **evaluate response after 2-4 weeks and titrate dose, as needed.**

   2) Usual dose: HCTZ 25 mg to 50 mg PO once daily in 1-2 divided doses. Maximum dose 50 mg/day

OR

c. Indapamide:

1) Initial dose**:** Indapamide 1.25 mg PO once daily. If inadequate BP response (no control of BP or BP does not steadily decrease after **2**-4 weeks of use), dosage may increase to 2.5 mg PO daily.

2) Usual dose: 1.25 mg to 2.5 mg PO daily. Maximum dose 5 mg/day

5. Potassium Supplementation:

Potassium loss associated with diuretic therapy is not commonly resolved with increasing dietary potassium. This is because dietary potassium is almost entirely coupled with phosphate and diuretic therapy is mostly associated with chloride depletion. Also consuming the amount needed in potassium-rich foods to increase serum potassium may be costly and may lead to weight gain.

Potassium chloride has been shown to be the most effective means of replacing acute loss. Strategies to minimize the risk of potassium depletion include minimizing the dosage of or discontinuing the non–potassium-sparing diuretics and restricting sodium intake. A high salt diet often results in excessive urinary potassium loss.

Use of diuretics for hypertension may result in hypokalemia. (This is generally counterbalanced by the potassium-raising effect of ACEI or ARB if they are used concomitantly). Normal serum potassium ranges from 3.5-5.5 mEq/L in most labs. A value of 4 mEq/L should be targeted in most patients. If a patient develops low potassium during therapy for hypertension, management depends on the severity of the potassium level.

i. Mild Hypokalemia: For potassium values of 3.0-3.4 mEq/L, a high-potassium diet should be provided. Potassium chloride supplementation should be considered. Potassium Chloride 10 to 20 mEq given BID (20-40 mEq/day). Potassium levels should be checked regularly, approximately every 2 weeks, until the value becomes normal.

ii. Moderate to severe Hypokalemia: For potassium values of 2.9 and below mEq/L, please consult with delegating physician, refer to appropriate office, or direct to nearest emergency room for immediate evaluation as appropriate based off potassium value.

iii. Oral potassium supplementation should consist of Potassium Chloride (KCl) 20 mEq BID to QID (40 to 80 mEq/day). Limit single dose to 20mEq to avoid GI discomfort. Take with 6 to 8 ounces of water to minimize GI irritation. This management should be reassessed if a potassium raising medication is added later or if the inciting diuretic is

changed. Potassium supplements should not be used to elevate the serum potassium over 4.5 mEq/L.

Note: Spironolactone is not recommended for initial BP management, or monotherapy, but may be considered, after consultation and approval of delegating physician, as additional therapy for resistant hypertension in patients who do not respond adequately to combination therapy with preferred agents (e.g., ACEI or ARB, dihydropyridine-CCB, and thiazide-like diuretic).

6. **Spironolactone: potassium sparing diuretic**
   a. **Initial dose: 12.5 mg once daily. Titrate as needed after 2 to 4 weeks based on response and tolerability up to 25 mg once daily. Max dose of 50 mg/day.**

7. Beta-Blockers

NOTE**:** Beta-Blockers should only be added after all other appropriate classes of anti-hypertensive agents have been given and titrated to their tolerated dose.

a. Metoprolol:
   i. (ALERT: US Boxed Warning for Ischemic heart disease. When discontinuing chronically administered metoprolol, particularly in patients with ischemic heart disease, gradually reduce the dosage over a period of 1 to 2 weeks and carefully monitor the patient).
   ii. Metoprolol (tartrate) is very commonly used and safe. Although it is available in a once daily formulation (metoprolol succinate, Toprol XL, etc.), its twice per day version is often utilized because it is very affordable for patients.
   iii. Initial dose: Metoprolol 25 mg BID. Titrate by doubling the dose every two weeks. Recommended maximum dose is 100 mg BID or as tolerated.

OR

b. Bisoprolol:
   i. Bisoprolol is less commonly used than other beta-blockers but is affordable and has the advantage of being dosed once daily.
   ii. Initial dose: Bisoprolol **2.5 mg to** 5 mg PO once daily; **titrate every 1-2 weeks as needed based on response. Usual dose: 2.5 mg to 10 mg once daily. Maximum dose is 20 mg/day.** It is available as a combination with HCTZ.

OR

c. Carvedilol:
   i. Carvedilol is a different type of beta blocker from the others in this protocol because it provides some blockade of alpha-adrenergic receptors in addition to beta-adrenergic receptors. This causes

additional vasodilation, which may be beneficial in hypertension and other conditions. It may also result in a slightly higher incidence of some side effects such as dizziness and syncope.

ii. Carvedilol is indicated for patients with hypertension who also have diabetes mellitus, and possibly for those with pre-diabetes in whom a small increase in blood glucose would be significant. Carvedilol may not be a good choice for those patients at risk of falls or for whom a BID medication would be difficult to maintain.

iii. Although carvedilol is available in a once-daily extended-release form, its twice per day version is often utilized because it is very affordable for patients.

iv. Initial dose: Carvedilol 6.25 mg BID and then titrated by doubling the dose every two weeks to a maximum dose of 25 mg BID or as tolerated.

NOTE**:** Public health nurses may encounter individuals who are already receiving atenolol, possibly having been treated under older protocols or from outside clinicians. Please see the section that follows, Currently Receiving Hypertensive Therapy, for guidance about management.

Currently Receiving Hypertensive Therapy:

1. Individuals seeking care for their blood pressure may already be receiving anti-hypertensive medications from other providers or may be receiving medications initiated under an older version of the DPH hypertension nurse protocol. This section clarifies how those individuals should be managed.
   a. If a patient is on medications for hypertension, the exact details of their regimen should be obtained.
   b. It is preferable to base the patient's medication list on actual medications/bottles brought to the clinic rather than on patient report or a written list.
   c. Please ask the patient if they are taking any herbs or supplements for managing their blood pressure or for any other reason.
   d. The evaluation of a hypertensive patient already on medication should be completed as described by other sections of the protocol.

NOTE: Any clinical questions not fully addressed here should be discussed with the designated hypertension program consultant, the District Health Director (DHD), or someone designated by the DHD.

NOTE: No medication changes, either of the older regimen or new agents, should be done except as listed here.

2. For patients receiving any medication initiated by a non-DPH provider (including those which may appear in the DPH hypertension protocol):

a. Anyone receiving medication initiated by a non-DPH provider should be reviewed with the delegating provider, the DHD, or someone designated by the DHD to develop a medication management plan.
   1) The plan developed with that provider can be implemented by the treating nurse under protocol.
   2) A plan for ongoing communication and follow-up between the nurse and consulting provider should be established.
   3) All discussions and plans should be fully documented in the medical record.

3. For patients receiving medications originally initiated under DPH hypertension nurse protocol:
   a. Everyone who is being treated by public health nurses should meet the standards of the current DPH hypertension protocol.
   b. If stable and controlled on a regimen previously allowed under protocol, and the treating nurse wishes for them to remain on the regimen despite it not being congruent with the current protocol, the patient should be reviewed with the designated hypertension program consultant, the DHD, or someone designated by the DHD to develop a medication management plan.
      1) The plan developed with the provider can be implemented by the treating nurse under protocol.
      2) A plan for ongoing communication and follow-up between the nurse and consulting provider should be established.
      3) All discussions and plans should be fully documented in the medical record.

Cholesterol management:

1. Hyperlipidemia is classified as:
   a. Total cholesterol is 200 mg/dL or higher
   b. LDL is 130 mg/dL or higher (higher than 100 mg/dL in persons with diabetes)
   c. HDL is 40 mg/dL or lower
   d. Triglyceride is 200 mg/dL or higher (higher than 150 mg/dL in persons with diabetes)

NOTE: Provide nutrition counseling and promote adherence to a low cholesterol/low fat diet to decrease cholesterol level.

2. Calculate the patient's 10-year risk of heart disease or stroke using the ASCVD algorithm published in 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk**.**

3. **Statin therapy is a highly recommended treatment for the following individuals, as they are most likely to benefit from moderate- or high-intensity statin therapy. Initiate pharmacologic treatment based on the following criteria and guidelines:**
    a. **Initiate a moderate-intensity statin for the following patients:**
        i. **Individuals aged 40-75 without clinical atherosclerotic cardiovascular or diabetes, with LDL 70-189 mg/dL, and estimated 10-year CVD risk of greater than 10% but less than 20%.**
    b. **Initiate a high-intensity statin for the following patients:**
        i. **Individuals aged 40-75 with diabetes and LDL ≥ 70 mg/dL.**
        ii. **Individuals aged 40-75 without clinical atherosclerotic cardiovascular or diabetes, with LDL 70-189 mg/dL, and estimated 10-year CVD risk of ≥ 20%.**
        iii. **Individuals with primary elevation of LDL ≥ 190 mg/dL.**
        iv. **Individuals with clinical atherosclerotic cardiovascular disease, coronary heart disease, cerebrovascular disease, peripheral artery disease, or aortic atherosclerosis.**

4. The clinical judgement to lower LDL-C in persons 75 years of age and older should be based on patient characteristics and should occur after a full discussion of the potential benefits and costs. Consider comorbidities, safety considerations, and priorities of care. Shared decision making is important in this setting. Data supports the continuation of use of statins beyond 75 years of age in persons who are already taking and tolerating the drug. Also, some data supports use of moderate intensity statin for secondary prevention. Data is less supportive for use in primary prevention.
    1) If therapy is elected for persons older than 75 years, treat with a medium potency statin.

5. **Follow-up Labs**
    a. **After initiating a statin, repeat lipid panel (can be fasting or non-fasting) and CMP at 6 weeks to assess adherence and response to statin (i.e., general impact on LDL levels & liver enzymes). Repeat lipids and CMP every 12 months.**

NOTE: If an individual encounters difficulty obtaining a recommended agent due to cost, explore patient assistance or similar programs, Medicaid eligibility and any community programs to get the preferred medication. If no assistance is available, a less potent but more affordable medication can be substituted.

PHARMACOLOGIC:

High Potency Statins and Therapeutic Doses = 50% or greater LDL-C reduction	Moderate Potency Statins and Therapeutic Doses = 30-49% LDL-C reduction	Low Potency Statins and Therapeutic Doses = less than 30% LDL-C reduction
Atorvastatin 40-80 mg/day	Atorvastatin 10-20 mg/day	Simvastatin 10 mg/day
Rosuvastatin 20-40 mg/day	Rosuvastatin 5-10 mg/day	Pravastatin 10-20 mg/day
	Simvastatin 20-40 mg/day	Lovastatin 20 mg/day
	Pravastatin 40-80 mg/day	
	Lovastatin 40 mg mg/day	
NOTE: Initial doses are listed below, then double doses as discussed below.		

1. When initiating statin medications, recommended starting doses are:
   a. Rosuvastatin 10 mg daily,
   b. Atorvastatin 20 mg daily,
   c. Simvastatin 20 mg daily,
   d. Pravastatin 20 mg daily,
   e. Lovastatin 20 mg daily.

      i. Doses can be doubled every 2-4 weeks until the target dose is achieved. If a patient has difficulty tolerating an agent, consult with the delegating physician.

NOTE: If known or suspected liver disease, a statin should not be initiated without physician consultation. If a patient on statins develops elevated liver enzymes or muscle pain, the drug should be stopped immediately and notify delegating physician immediately. Statins are not to be used in pregnant or lactating women; consult with delegating physician. Potentially significant drug interactions may exist with statins (HMG-CoA Reductase Inhibitors), requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information.

NOTE: **Pe**rsons of reproductive **age** should be counseled to avoid pregnancy during **statin** therapy. Side effects **of statins** may include constipation, nausea,

abdominal pain, headache, insomnia, vertigo, and upper respiratory infections. Advise patients to immediately report symptoms of myopathy or rhabdomyolysis, especially when accompanied by fever or malaise, or if symptoms persist after discontinuation of drug. Instruct patients to immediately report symptoms of liver injury. Instruct patients to avoid grapefruit juice while taking **simvastatin, atorvastatin, or lovastatin**.

PATIENT EDUCATION/COUNSELING

1. Lifestyle Modifications:

NOTE: **All patients with elevated blood pressure or hypertension should receive information and counseling on lifestyle interventions. Treatment of hypertension should involve nonpharmacologic therapy alone or in concert with antihypertensive drug therapy.**

a. Counsel regarding the Dietary Approaches to Stop Hypertension (DASH), Reduced Sodium Diet. **The DASH diet is high in vegetables, fruits, low-fat dairy products, whole grains, poultry, fish, and nuts and low in sweets, sugar-sweetened beverages, and red meats.** For specific recommendations: https://www.nhlbi.nih.gov/health-topics/dash-eating-plan.
b. Achieve/maintain desirable body weight or BMI of 18.5-24.9 kg/m^2.
c. Reduce daily sodium intake to less than 2,300 mg. Reduce intake less than 1,500 mg among persons who are 51 or older, African American or have hypertension, diabetes, or chronic kidney disease.
d. Reduction of dietary fats and cholesterol to meet DASH recommendations.
e. **Limit alcohol intake. Adult men and women with hypertension should consume, respectively, no more than two and one alcoholic drinks daily.**
f. Adequate dietary potassium intake (if renal function is normal and not taking drugs known to raise potassium, such as ACE Inhibitors) of 3500-5000 mg/day. Foods that are high in potassium include bananas, potatoes, beans and yogurt.
g. Adequate intake of calcium, 1000-1500 mg/day based on age.
h. Choose foods that provide more potassium for patients who are not hyperkalemic, dietary fiber, calcium, and vitamin D. These foods include vegetables, fruits, whole grains, and skim or low-fat milk and milk products.
i. Moderate intensity aerobic exercise (e.g., walking, jogging, cycling, yoga, or swimming) for at least 30 minutes on 5-7 days per week.
j. Smokers and tobacco users should receive cessation counseling and be referred to the Georgia Quit Line 1-877-270-STOP (7867).

2. Emphasize the importance of adherence with all aspects of the treatment regimen and plan of care including diet, lifestyle changes, medications, and keeping follow-up appointments.

   NOTE: Nonadherence to antihypertensive treatment affects 10-80% of hypertensive patients and is one of the key drivers of suboptimal blood pressure control.

   At each encounter:
   a. Establish BP goals and review readings during each visit.
   b. Keep a log of BPs and bring the log to all visits
   c. Describe actions since the last visit to control BP
   d. Discuss what they would like to work on to improve BP
   e. Describe how they've been taking medication(s): e.g., morning versus evening, with meals versus on an empty stomach
   f. **Review medication adherence** [any forgotten or missed doses of medication(s)]
   g. Discuss any side effects and/or concerns about side effects
   h. Advise when and how to contact the healthcare team with questions or problems
   i. Advise to bring BP machines to all appointments scheduled for BP checks
   j. Advise to bring **all** medications, **including vitamins or herbal supplements,** for a brown bag medication review to determine understanding of the recommended medication treatment and adherence.
   k. Advise to always bring medication bag for all encounters with any health care provider (physician, nurse, pharmacist, or dietician/nutritionist)

3. Nurses should provide counseling on DASH Eating Plan if no Registered Dietitian or Public Health Nutritionist is available and reinforce counseling on follow-up visits.

4. Counsel about the signs and symptoms of stroke and heart attack. Stress that both conditions are medical emergencies and to call 911 (or for an ambulance where 911 is not locally available) if experiencing any of the following:
   a. Signs and symptoms of stroke may include sudden numbness or weakness in the face, arm or leg, especially on one side of the body; sudden confusion or trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden severe headache with no known cause
   b. Signs and symptoms of heart attack may include uncomfortable pressure, fullness, squeezing or pain in the center of the chest lasting more than a few minutes; pain spreading to the shoulders, neck or arms; chest discomfort with lightheadedness, increased sweating, profound weakness, fainting, nausea or shortness of breath.

5. Assess and administer vaccines indicated by the current Advisory Committee on Immunization Practices (ACIP) adult immunization schedule including those recommended for persons with chronic medical conditions. Review the Georgia Immunization Program Manual and the GIP's Immunization Schedule for current ACIP schedules and administration guidelines for each vaccine.

FOLLOW-UP CARE:

5. Clinic Appointments:
    a. When beginning anti-hypertensive therapy, **patient** should be seen about every 2 to 4 weeks until BP goal is achieved.
    b. After BP goal is reached and maintained and adjusting to the treatment regimen for 3 to 4 visits is achieved, may move appointments to 4-to-6-week intervals.
    c. When BP goals have been reached and maintained, less frequent (3 to 6 month) appointment intervals may be sufficient.

NOTE: Some patients may need and/or want closer supervision. Keeping them on a 4-week appointment interval may be necessary.

REFERRAL/CONSULTATION:

1. Refer to **DHD or** delegating physician if:
    a. Goal BP cannot be reached using the drugs included in this protocol.
    b. Any contraindication to medications.
    c. The need to use more than 3 drugs to reach goal BP.
    d. If secondary hypertension is suspected because subjective and/or objective findings indicate target organ damage (heart, brain, renal disease, peripheral artery disease or retinopathy), coarctation, Cushing's syndrome, or pheochromocytoma, refer the patient to a physician for further evaluation. Symptoms and findings include:
        1) Bruits in the carotid, abdominal, or femoral areas
        2) Palpable kidneys
        3) Episodes of sweating, tachycardia, and headache
        4) Absence of femoral pulses
        5) Unequal blood pressure in right and left arms
        6) Palpitations and paroxysmal symptoms
        7) Cushingoid-like appearance (i.e., moon face, buffalo hump, truncal obesity, striae)
        8) Hypo/hyperkalemia
        9) Sleep apnea, such as excessive daytime sleepiness
    e. Complications/side effects of therapy occur
    f. Less than 18 years old
    g. **Six** PVCs or more per minute, couplets (bigeminy), multifocal PVCs, or irregular heart rate (other than premature atrial contractions)
    h. Bradycardia (heart rate 56 beats per minute or less and is not taking a beta-blocker) or tachycardia (heart rate 100 beats per minute or greater).

i. ECG is abnormal.

2. Consult with delegating physician if:
   a. Presents with SBP equal to or greater than 200 mm Hg and/or DBP is equal to or greater than 110 mm Hg.
   b. Currently on an anti-hypertension regimen that is not included in this protocol.
   c. Any abnormal lab results, such as**:**
      1) Serum creatinine is 1.4 mg/dL or higher for women, 1.5 mg/dL or higher for men
      2) Serum potassium is 3.5 mEq or less, 5.5 mEq or greater
      3) Microalbuminuria
   d. BP has been elevated long enough or the elevation has been high enough to cause damage or complications, physical examination findings may include:
      1) Optic Fundi: Narrowing, copper-wiring, or A.V. nicking; hemorrhages, exudates, or papilledema.
      2) Chest & Lungs: Rales or congestion.
      3) Heart: LVH, PVCs, a gallop, unequal BP in both arms, and/or a displaced point of maximal impulse.
      4) Arterial Pulses: Bruits auscultated over the carotid arteries or abdominal aorta; distended neck veins, femoral arteries and/or renal arteries.
      5) Extremities: Edema and/or venous pooling, abnormal peripheral arterial pulsations, intermittent claudication.
      6) Neurologic: One-sided weakness, cranial nerve weakness, or hyperactive reflexes on the side of an old stroke

3. Refer patients with confirmed or suspected diabetes (fasting plasma glucose is 126 mg/dL or higher and/or Hemoglobin A1C is 6.5% or higher) to the health district's diabetes management program **or** PCP for management.

4. Refer all patients to a Registered Dietitian or Public Health Nutritionist for a nutritional evaluation and development of an appropriate meal plan or DASH Eating Plan counseling, if available.

5. Refer **individuals who are** pregnant, planning to become pregnant, or breast-feeding to an obstetrician for management of hypertension.

6. Utilize AAR model to provide smoking/nicotine use cessation counseling. Refer to the Georgia Quit Line 1-8777-270-STOP (7867). Use the Quit Line Fax Back Form as appropriate.

7. Where available, refer to a pharmacist and/or health educator, as needed for education and counseling.

8. Call 911 if patient presents with complaints of chest pain, shortness of breath, severe headache, sudden numbness or weakness of face, arm, or leg on one side, visual disturbances, trouble speaking or understanding, dizziness, loss of balance or coordination.

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IMMUNIZATION

STANDARD NURSE PROTOCOL FOR CHILDHOOD AND ADULT IMMUNIZATION

All Public Health locations that provide vaccine services will utilize the current edition of the Georgia Department of Public Health Immunization Program (GIP) Manual, which is developed based on the Advisory Committee on Immunization Practices Recommendations and the Centers for Disease Control and Prevention's (CDC) Epidemiology and Prevention of Vaccine Preventable Diseases' (Pink Book), for administering vaccines to children and adults. The GIP Manual contains detailed standards for vaccine administration, mandatory use of Vaccine Information Statements (VIS), recommendations and forms specific to the childhood and adult immunization schedules, recommended screening questionnaires for identifying possible contraindications and precautions to vaccines, and requirements for entering all vaccines into the Georgia Registry for Immunization Transactions and Services (GRITS). Go to https://dph.georgia.gov/immunization-publications for the GIP Manual.

Registered Professional Nurses (RNs) and Advanced Practice Registered Nurses (APRNs) will administer vaccines in accordance with the current edition of the GIP Manual and in accordance with the Nurse Protocol statute (O.C.G.A. § 43-34-23). Licensed Practical Nurses (LPNs) will administer immunizations under the supervision of either an RN, APRN or physician, in accordance with the Georgia Practical Nurses Practice Act [O.C.G.A. § 43-26-32(7)].

Training: All LPNs, RNs, and APRNs must complete the required training for administration of vaccines, as delineated in the **Georgia Department of Public Health Immunization Program Manual and The Policy and Procedure Manual for Public Health Nurse Training**, which may be found on the **Public Health Information Library (PHIL) 2.0** before they may administer vaccines.

All RNs, APRNs, and LPNs who administer vaccines will hold current certification in Basic Cardiac Life Support (BCLS).

All RNs, APRNs and LPNs who administer vaccines should also follow the GIP Manual guidelines regarding asking the patient to wait at least 15 minutes in a designated area post-vaccination before they leave the clinic site.

All RNs, APRNs, and LPNs who administer vaccines will provide the patient with written confirmation of all vaccines administered. This may be in the form of a print-out of vaccines administered or an immunization card.

STANDARD NURSE PROTOCOL FOR IMMUNIZATIONS DURING PUBLIC HEALTH EMERGENCIES

All staff that provides vaccine services as part of a Public Health clinic, campaign or mass vaccination event will adhere to requirements of The Georgia Immunization Program (GIP) Manual that provides Public Health personnel with up-to-date information and guidance. The GIP Manual is based primarily on the Recommendations of the Advisory Committee on Immunization Practices (ACIP). The ACIP Recommendations are located at http://www.cdc.gov/vaccines/hcp/acip-recs/index.html

The GIP Manual and ACIP recommendations are the official Department of Public Health (DPH) policies, procedures, and standards for administering vaccines, providing and documenting immunization services, and evaluating quality assurance in Public Health Districts.

The signatures below indicate an agreement between the delegating physician(s) and the registered professional nurse(s) RN(s) who are authorized to administer the vaccines included in the Nurse Protocol Agreement for Administering Vaccines during Public Health Emergencies.

The RN or APRN whose signature appears below on this signature page:

1. Has successfully completed all required training on the provision of vaccines in accordance with requirements of the Georgia Immunization Program Manual **and The Policy and Procedure Manual for Public Health Nurse Training** for vaccines included in the Nurse Protocol Agreement for Administering Vaccines during Public Health Emergencies.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN or APRN Date

APPENDIX 1

PROTOCOL AGREEMENT FOR IMMUNIZATIONS DURING PUBLIC HEALTH EMERGENCIES

The signatures below indicate an agreement authorized through O.C.G.A. § 43-34-23 between the delegating physician(s) and the registered professional nurse(s) (RNs) and/or advanced practice registered nurses (APRNs) that the undersigned individuals are authorized to administer, order and dispense the specific vaccines listed below in accordance with the requirements of the Nurse Protocol for Administering Vaccines During Public Health Emergencies.

Vaccine Administration:

Vaccines can be administered for the following populations (all ages or specific age groups):

1. _____

The following vaccines can be administered:

1. _____
2. _____
3. _____
4. _____
5. _____

The signatures below indicate an agreement between the delegating physician(s) and the registered professional nurse(s) RN(s) who are authorized to administer the vaccines listed in this agreement.

_____ _____
Signature of Delegating Physician Date

_____ _____
Signature of RN or APRN Date

OTHER INFECTIOUS DISEASES

2023 STANDARD NURSE PROTOCOL FOR OTHER INFECTIOUS DISEASES CLINICAL REVIEW TEAM

Melissa Tobin D'Angelo, MD **Physician Consultant- Epidemiology** **DPH**	**Jessica Pavlick, DrPH, MPH** **Epidemiology Preparedness Director** **DPH**
Ashley Moore **Epidemiologist** **DPH**	**Vanessa Aden** **Environmental Health** **DPH**

2022 STANDARD NURSE PROTOCOL FOR OTHER INFECTIOUS DISEASES CLINICAL REVIEW TEAM

Melissa Tobin D'Angelo, MD Physician Consultant- Epidemiology DPH	Gregory S. Felzien, MD, AAHIVS Medical Advisor DPH
Tracy Dabbs, PharmD Emergency Preparedness Pharmacist DPH	Tonia Parrott, PhD, MT (ASCP) Clinical Microbiology Director GPHL DPH
Andrea Gaines, BSN, RN County Nurse Manager - Hall District 2	Sherry Gregory, BSN, RN Infectious Disease Director District 1-2
Melissa Hunter District Epidemiology Director District 1-1	Kristy Smith, RN District 7
Dyna Cross Infectious Disease Coordinator District 10	Stacey Upshaw, MSN, RN Assistant Nursing Director District 5-1

STANDARD NURSE PROTOCOL FOR AMEBIASIS, UNCOMPLICATED (Amebic Colitis)

DEFINITION

Infection of the intestinal tract by certain species of the genus *Entamoeba*. Extraintestinal disease occasionally occurs, with the liver as the most common site.

Symptoms are typically mild and include loose stools with stomach pain and/or cramping. More severe disease is associated with immunosuppression, malnutrition, young and old age, pregnancy, residence in institutions, men who have sex with men, and residence in or travel to tropical countries with poor sanitary conditions. Travel duration of greater than 6 months has a significantly higher risk of acquiring infection than travel of shorter duration (e.g., less than 1 month). Symptoms of severe disease include fever, severe abdominal pain, and bloody stools.

Complications may include toxic megacolon, colon or perianal ulceration, intestinal perforation, and (rare) invasion of the liver, lungs, and brain. Amebic liver abscess occurs more commonly in men than women. Progression to amebic dysentery may occur if other causes of colitis are suspected and infected persons are inappropriately treated with corticosteroids and/or antimotility drugs.

ETIOLOGY

Entamoeba histolytica causes invasive disease. Entameoba dispar, entamoeba *hartmanni* and *Entamoeba bangladeshi* are noninvasive parasites and do not cause disease and do not require treatment. Entamoeba moshkoviskii may cause mild disease. The organisms are excreted as cysts or trophozoites in persons. Transmission occurs when cysts are ingested. Transmission has occasionally been associated with contaminated surfaces, food or water, and may occur sexually by oral-anal contact. In addition, men who have sex with men are at increased risk for amebiasis. The incubation period is usually 2-4 weeks, though in some instances it can take longer. If untreated, an infected person can excrete cysts intermittently and transmit infection for years. Most cyst passers are asymptomatic, with approximately 10-20% of people who are infected with E. histolytica becoming sick from the infection.

SUBJECTIVE

1. May be asymptomatic.

2. If history of mild, chronic symptoms (abdominal discomfort with loose stools containing blood or mucus alternating with periods of constipation or no

symptoms for 3 months or longer), refer patient to the delegating physician or consult a GI specialist.

3. If history of acute symptoms that have progressively increased over 1-3 weeks (grossly bloody or mucoid stools accompanied by lower abdominal pain, tenesmus, fever, chills and weight loss), refer patient to a physician.

OBJECTIVE

1. Patient does not appear acutely ill, no extensive weight loss or fever.

ASSESSMENT Amebiasis, asymptomatic or symptomatic mild to moderate disease.

PLAN

DIAGNOSTIC STUDIES

1. Obtain a minimum of three stool samples on separate days for microscopic identification of trophozoites or cysts in feces, if necessary. Use a collection kit designed for detection of ova and parasites (e.g., Para-Pak)

NOTE: Trophozoites containing red blood cells are more likely to be *Entamoeba histolytica* than *E. dispar*, *Entamoeba moshkovskii*, and *E. hartmanni*.

2. Assess whether patient has a history of liver and/or kidney disease. Perform Comprehensive Metabolic Panel if one has not been performed within previous three months. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning treatment.

3. Assess last menstrual period if person is of childbearing potential (approximately 15-50 years of age) or with menstrual cycle and not using contraceptives. If pregnant or possibly pregnant, refer to delegating physician for care.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Consult an online drug information resource (e.g. https://www.drugs.com/drug_interactions.html or https://online.lexi.com/lco/action/login) to assess for drug-drug interactions.

NOTE: Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Stress the importance of

chemoprophylaxis even if the patient is asymptomatic to prevent transmission of the condition to others and/or progression to symptomatic disease. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

1. Asymptomatic (cyst-passing) patients who are not pregnant or breastfeeding, have no history of renal and/or liver disease, and do not have hypersensitivity to paromomycin or components:
   a. Adults (18 years and older): Paromomycin sulfate 25-35 mg/kg PO, divided into 3 equal doses; give single dose with each meal, for 7 days. See dosage chart below. ‘
   b. Children and adolescents (2 years old through 17 years old) referred regimen: Paromomycin sulfate 25-35mg/kg PO, divided into 3 equal doses; give single dose with each meal, for 7 days. See dosage chart below.

Weight (kg)	Paromomycin Dosage (mg)
≤ 21 kg	Consult with delegating physician for dosing requirements and referral compounding pharmacy
22 kg to 30 kg	250 mg three times daily for 7 days
31 kg to 42 kg	Consult with delegating physician for dosing requirements and referral compounding pharmacy
43 kg to 60 kg	500 mg three times daily for 7 days
61 kg to 64 kg	Consult with delegating physician for dosing requirements and referral to compounding pharmacy
65 kg to 88 kg	750 mg three times daily for 7 days
89 kg to 120 kg	1,000 mg three times daily for 7 days
121 kg to 150 kg	1,250 mg three times daily for 7 days
≥ 151 kg	Consult with delegating physician for dosing requirements and referral compounding pharmacy

NOTE: When paromomycin therapy is being considered, adverse reactions may include (1% to 10%): Gastrointestinal (abdominal cramps, diarrhea, heartburn, nausea, and vomiting). Post marketing, and/or case reports occurring in less than 1% include secondary enterocolitis, eosinophilia, headache, ototoxicity, pruritus, steatorrhea, vertigo. Consult with delegating physician regarding any abnormal results or concerns of hearing impairment.

NOTE: Long term use of paromomycin may cause secondary infection.

NOTE: If patient is allergic to paromomycin or cannot tolerate paromomycin, consult with delegating physician for alternative chemoprophylaxis regimens.

2. Symptomatic patients with mild to moderate disease (diarrhea, abdominal pain) require systemic treatment.

a. Adults should receive Metronidazole 750 mg po TID for 10 days followed by Paromomycin (see above dosing).

NOTE: The use of Paromomycin following 10 days of Metronidazole is necessary in clearing intestinal cysts.

NOTE: Do not administer metronidazole to patients who have taken disulfiram within the last two weeks

PATIENT EDUCATION/COUNSELING

1. Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Stress that asymptomatic patients infected with E. histolytica should receive chemoprophylaxis as they can infect others and 4%– 10% develop disease within a year if left untreated. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible. Immediately report if a rash occurs.

2. If taking paromomycin, promptly report any ringing in the ears, hearing loss or dizziness.

3. Careful handwashing with soap and water following defecation.

4. Sanitary disposal of feces.

5. Keep nails clean and trim weekly. Avoid nail biting.

6. Treatment of drinking water or use of sealed bottled water or carbonated drinks if traveling in areas without chlorination.

7. If traveling to an endemic area, avoidance of food or drinks sold by street vendors, fountain drinks or any drinks with ice cubes, unpasteurized milk, cheese, or dairy products, or fresh fruit or vegetables not peeled by the traveler.

8. Avoidance of oral-anal sexual practices or use of barrier protection during oral-anal sexual practices.

9. Advise patient to discuss any concerns regarding ability to return to work with their occupational health representative. Reference the GA DPH Employee Health Redbook: https://dph.georgia.gov/sites/dph.georgia.gov/files/EnvHealth/Food/Misc/EnvHealthFoodDPHEmployeeRedBook2016.pdf

10. Advise patient to report any signs/symptoms of foodborne illness (vomiting, diarrhea, jaundice, sore throat with fever and/or infected wounds).

FOLLOW-UP

1. Repeat stool microscopic exam x3, collected on separate days, starting three to four weeks following completion of medication regime**.**

2. Household and sexual contacts should have stool microscopic studies x3 performed within four weeks of index case being identified. If household contacts and/or sexual contacts present with symptoms of the disease, stool studies should be done immediately.

REFERRAL/CONSULTATION

1. If history of mild, chronic symptoms (abdominal discomfort with loose stools containing blood or mucus alternating with periods of constipation or no symptoms for 3 months or longer), refer patient to delegating physician or GI specialist.

2. If history of acute symptoms that have progressively increased over 1-3 weeks (grossly bloody or mucoid stools accompanied by lower abdominal pain, tenesmus, fever, chills and weight loss), refer patient to delegating physician or GI specialist.

3. Refer patients with contraindications to listed treatments or who are pregnant or breastfeeding to delegating physician or GI specialist.

4. Refer symptomatic pediatric patients or consult with delegating physician before treating.

5. Refer any patient who develops worsening abdominal symptoms on treatment to delegating physician or GI specialist.

6. Refer any patient whose follow-up stool exams show persistent infection to delegating physician or GI specialist.

7. Consult with delegating physician regarding any abnormal lab/hearing screen results prior to treatment initiation.

8. Consult with delegating physician prior to beginning treatment for patients with history of kidney/liver disease or abnormal lab results.

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STANDARD NURSE PROTOCOL FOR CHEMOPROPHYLAXIS OF *HAEMOPHILUS INFLUENZAE* TYPE b (Hib) DISEASE CONTACTS

REQUIREMENTS:

Public health nurses must work closely with local communicable or infectious disease staff responsible for monitoring and investigating reported Haemophilus influenzae and Haemophilus influenzae type b cases and contacts to ensure that complete vaccination and medical history is obtained for the index case, that household and childcare contacts have been identified, and eligible contacts have been treated when appropriate. Public health personnel should ensure that *H. influenzae* isolates are serotyped and forwarded to the Georgia Public Health Laboratory (GPHL) for confirmation promptly as emphasized in this protocol.

DEFINITION

Haemophilus influenzae type b (Hib) is a particularly virulent strain of the bacterium *H. influenzae*. *H. influenzae* can cause invasive infections including meningitis (an inflammation of the membranes and fluid that surround the brain and spinal cord), bacteremia, pneumonia, cellulitis, epiglottitis, septic arthritis and other invasive infections.

Although there are many strains of *H. influenzae*, including typeable and non-typeable strains, any strain may cause invasive disease. Guidelines for chemoprophylaxis are written only for infections caused by Hib. When an index case of Hib disease is identified, post-exposure chemoprophylaxis should be offered to close contacts (defined below) as soon as possible (preferably within 24 hours). Studies have shown that chemoprophylaxis with rifampin eradicates greater than 95% of Hib carriage in contacts of primary Hib cases. In Georgia, from 2000-2020, 46 Hib cases were confirmed; 14 occurred among children.

Empirical vs. Delayed chemoprophylaxis of *H. influenzae* cases not known to be Hib:

1. Widespread use of the Hib vaccine has made Hib a rare cause of disease and offering chemoprophylaxis to all patients with invasive *H. influenzae* could result in significant overtreatment. However, a delay in chemoprophylaxis while waiting for serotype information to determine if *H. influenzae* isolates are serotype b may result in unnecessary spread of disease.

2. A proposed approach to optimize early decision-making regarding chemoprophylaxis is based on epidemiologic findings below, and includes:

a. Promptly obtaining immunization records and medical history for any child with invasive *H. influenzae* disease.
b. Empirical, early chemoprophylaxis of contacts (without waiting for serotype information) if the child with invasive *H. influenzae* disease is unimmunized OR incompletely immunized against Hib (defined below in 1a), OR is immunologically compromised (e.g. HIV, asplenia) regardless of vaccination status.
c. Delaying chemoprophylaxis of contacts until after the isolate is serotyped as Hib is appropriate when the index case is a fully immunized, immunologically normal child or an adult.
d. Consultation is available at 404-657-2588 (Acute Disease Epidemiology Section, GA Department of Public Health) if needed: Acute Disease Epidemiology | Georgia Department of Public Health
e. Serotyping of *H. influenzae* isolates is available at the Georgia Public Health Laboratory and some hospital and reference laboratories. All invasive *H. influenzae* isolates should be promptly sent to the GPHL for confirmatory serotyping.

3. Chemoprophylaxis recommended for:

    a. All household contacts (except pregnant persons), irrespective of age, when at least 1 of the contacts is younger than 4 years old and unimmunized or incompletely immunized.

NOTE: Household contacts are persons residing with the index case, or persons who spent 4 hours or longer with the index case for at least 5 of the 7 days preceding the day of hospital admission.

NOTE: Complete immunization means having had at least 1 dose of conjugate vaccine at 15 months of age or older; 2 doses between 12 and 14 months of age; or a 2- or 3-dose primary series when younger than 12 months with a booster dose at 12 months of age or older. See the Georgia Immunization Program Manual, Recommended Schedules and Guidelines, for vaccine information and vaccine administration guidelines at http://dph.georgia.gov/immunization-schedules.

    b. All household contacts with a child younger than 12 months of age who has not completed the primary Hib series.
    c. All household contacts with an immuno-compromised child younger than 18 years of age, irrespective of the child's Hib immunization status.
    d. Nursery and childcare center contacts (all attendees and childcare providers), irrespective of age or immunization status, when 2 or more cases of invasive disease have occurred within 60 days.
    e. Index case, if treated with regimens other than cefotaxime or ceftriaxone. Chemoprophylaxis usually is provided just before hospital discharge.

4. Chemoprophylaxis not recommended for:

    a. Household contacts with no children younger than 4 years of age other than the index patient and no one who is immunocompromised.
    b. Household contacts when all household contacts younger than 48 months of age have completed their Hib immunization series. See the previous page for definition of complete immunization.
    c. Pregnant persons.

ETIOLOGY

The bacteria *Haemophilus influenzae*, type b (Hib).

SUBJECTIVE

1. History of household or day-care contact as defined above under Chemoprophylaxis recommended.

2. History of incomplete or no Hib immunization/vaccination.

3. Absence of prodromal meningitis symptoms, e.g., respiratory illness or sore throat. Absence of meningitis disease symptoms, e.g., fever, headache, stiff neck or vomiting.

4. No history of hypersensitivity to any of the rifamycins or of liver function impairment.

OBJECTIVE

1. No signs of respiratory illness or meningitis.

ASSESSMENT Candidate for Chemoprophylaxis for *H. influenzae* type b disease exposure.

PLAN

DIAGNOSTIC STUDIES

1. Assess whether patient has a history of liver and/or kidney disease. Perform a Comprehensive Metabolic Panel if one has not been performed within the previous three months. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning treatment.

2. Assess last menstrual period if person is of childbearing potential (approximately 15-50 years of age) or with menstrual cycle and not using

contraceptives. If pregnant or possibly pregnant, refer to delegating physician for care.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Consult an online drug information resource (e.g. https://www.drugs.com/drug_interactions.html or https://online.lexi.com/lco/action/login) to assess for drug-drug interactions

NOTE: Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

NOTE: Most people can take Rifampin without difficulty. However, any of the following signs or symptoms should be reported as soon as possible to the delegation physician: fever, nausea, vomiting, loss of appetite, dark coffee or tea-colored urine, white/gray/light tan bowel movement, tiredness, weakness, yellow skin or sclera, bruising easily, rash/itching, and/or painful menstruation.

1. Rifampin chemoprophylaxis:

Begin chemoprophylaxis as soon as possible. If more than 14 days have passed since the last contact with the index case, the benefit of chemoprophylaxis is likely to be decreased.

NOTE: See Rifampin Pediatric Drug Chart: Appendix A

a. Infants less than 1 month old: Rifampin 10mg/kg/day PO once a day for 4 days (max 600mg/24 hours).
b. Infants over 1 month old and children/adolescents younger than 18 years old: Rifampin 20mg/kg (max 600mg/24 hours) PO once a day for 4 days.
c. Nonpregnant adults: Rifampin 600mg PO once a day for 4 days.

NOTE: Rifampin as a dry powder may be mixed with applesauce. PHARMACIST INFORMATION FOR COMPOUNDING**:** Rifampin oral suspension, compounded 10 mg/mL with simple or wild cherry syrup, is stable for 4 weeks at room temperature, or in refrigerator, when stored in an amber glass prescription bottle. Rifampin interacts with many drugs. Check the Rifampin product package insert for a complete list of drug interactions.

2. Evaluate status of all vaccinations and update as needed through administration of currently recommended doses for each. Children who have had Hib disease still need vaccination against Hib. See the Georgia

Immunization Program Manual at **https://dph.georgia.gov/immunization-section/immunization-publications**.

PATIENT EDUCATION/COUNSELING

1. Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

2. Avoid drinking alcohol while taking Rifampin due to increased risk of hepatotoxicity.

3. Rifampin is present in breast milk. The Centers for Disease Control and Prevention and other professional organizations state that breastfeeding should not be discouraged in women taking rifampin. Breastmilk may be stained a yellow, orange, red or brown color.

4. Rifampin may cause the urine, feces, saliva, sputum, sweat, breast milk and tears to temporarily turn red-orange.

5. Do not use soft contact lenses when on Rifampin; permanent discoloration may occur.

6. Since Rifampin has been reported to cross the placental barrier and appear in cord blood and in maternal milk, neonates and newborns of rifampin-treated mothers should be carefully observed for any evidence of side effects.

7. Rifampin may decrease the effectiveness of oral contraceptives. Consideration should be given to using alternative contraceptive measures during, and immediately following, Rifampin therapy, until the next cycle. The rationale for using an alternative or back-up method of birth control (e.g., copper-bearing IUD such as ParaGard, condoms, diaphragm) is that when Rifampin is prescribed, it reduces effectiveness (degree depending on method) of combined oral contraceptives, progestin-only oral contraceptives, Levonorgestrel implants, Depo-Provera, patch and ring. Advise condom back-up.

8. It is important for all children to receive Hib vaccine, starting at 2 months of age.

REFERRAL/CONSULTATION

1. Patients with adverse reactions to chemoprophylaxis should be referred to a delegating physician.

2. Patients with signs/symptoms of meningitis should be referred immediately to the nearest emergency room.

3. Refer pregnant patients to OB health care provider.

4. Consult with delegating physician prior to beginning treatment for patients with history of kidney/liver disease or abnormal lab results.

5. If there is an absolute contraindication to use of rifampin,
consult delegating physician regarding use of an alternative chemoprophylaxis.

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APPENDIX A

Rifampin Dosage Chart

Infants 1 month and younger: Rifampin 5 mg/kg PO every 12 hours for 2 days:

Weight (kg)	Rifampin Dose (mg)
1kg	5 mg
2kg	10 mg
3kg	15 mg
4kg	20 mg
5kg	25 mg
6kg	30 mg
7kg	35 mg
8kg	40 mg
9kg	45 mg

Infants over 1 month old and children/adolescents (younger than 18 years old): Rifampin 10 mg/kg (maximum 600 mg/dose) PO every 12 hours for 2 days

Weight (kg)	Rifampin Dose (mg)
1kg	10 mg
2kg	20 mg
3kg	30 mg
4kg	40 mg
5kg	50 mg
6kg	60 mg
7kg	70 mg
8kg	80 mg
9kg	90 mg

Nonpregnant adults: Rifampin 600 mg PO every 12 hours for 2 days

Weight (kg)	Rifampin Dose (mg)
1kg	20 mg
2kg	40 mg
3kg	60 mg
4kg	80 mg
5kg	100 mg
6kg	120 mg
7kg	140 mg
8kg	160 mg
9kg	180 mg
10kg	200 mg
11kg	220 mg

12kg	240 mg
13kg	260 mg
14kg	280 mg
15kg	300 mg
16kg	320 mg
17kg	340 mg
18kg	360 mg
19kg	380 mg
20kg	400 mg
21kg	420 mg
22kg	440 mg
23kg	460 mg
24kg	480 mg
25kg	500 mg
26kg	520 mg
27kg	540 mg
28kg	560 mg
29kg	580 mg
30kg and above	600 mg

Source: Payam Nahid, Susan E. Dorman, et. al., *Executive Summary: Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis, Clinical Infectious Disease*s, Volume 63, Issue 7, 1 October 2016, Pages 853–867, https://doi.org/10.1093/cid/ciw566

STANDARD NURSE PROTOCOL FOR CHEMOPROPHYLAXIS OF INVASIVE MENINGOCOCCAL DISEASE CONTACTS, INCLUDING MENINGITIS

REQUIREMENT:

Public health nurses must work closely with the local communicable or infectious disease coordinator (or other designated official) who is monitoring reported meningococcal disease cases and contacts, to ensure that all eligible contacts have been identified and provided with chemoprophylaxis.

DEFINITION

Invasive meningococcal disease includes meningitis (an inflammation of the membranes and fluid that surround the brain and spinal cord), bloodstream infections, or sepsis (often associated with a petechial or purpuric rash or pneumonia). Rarely, other sterile sites (such as joint fluid) may be infected.

When an index case of invasive meningococcal disease is identified, chemoprophylaxis should be offered to high-risk household, daycare, and preschool contacts as soon as possible, preferably within 24 hours of exposure. Chemoprophylaxis may be given up to 14 days after exposure with notification to the delegating physician. Chemoprophylaxis administered more than 14 days after onset of illness in the index patient is probably of limited or no value. Persons in some institutional settings also may require chemoprophylaxis.

Indications and guidelines for Chemoprophylaxis of contacts are:

1. High risk - Chemoprophylaxis recommended (close contact)

    a. All household contacts: especially children less than 2 years old.
    b. Childcare or preschool contact(s) during the 7 days prior to index case’s onset of illness.
    c. Direct exposure to the index case's oral secretions through kissing (especially deep French kissing), mouth-to-mouth resuscitation, or unprotected contact during endotracheal intubation during the 7 days prior to index case’s onset of illness.
    d. Frequently slept or ate in the same dwelling as the index case during the 7 days prior to index case’s onset of illness.
    e. Passengers seated directly next to index case during flight lasting more than 8 hours.

2. Low risk - Chemoprophylaxis not recommended:

    a. Casual contact: no history of direct exposure to index case's oral secretions, e.g., schoolmate or workmate.

b. Indirect contact: only contact is with a high-risk contact, no direct contact with the index case.
c. Health care personnel without direct exposure to the case's oral secretions.

3. In outbreak or cluster:
   a. Chemoprophylaxis for persons other than those at high risk should be given only after consultation with local public health authorities.

4. Non-invasive (e.g., respiratory cultures positive for *N. meningitidis*):
   a. Chemoprophylaxis is NOT recommended for close contacts of patients with *N. meningitidis* cultured from non-sterile sites.

ETIOLOGY

Meningococcal disease is caused by *Neisseria meningitidis,* a Gram-negative diplococcus (bacteria) with 13 serogroups. Strains belonging to groups A, B, C, Y, and W-135 are implicated most frequently in systemic disease. Asymptomatic colonization of the upper respiratory tract provides the focus from which the organism is spread.

SUBJECTIVE

1. History of contact as defined above under High risk: Chemoprophylaxis recommended.
2. Absence of prodromal meningitis symptoms (respiratory illness or sore throat.) Absence of meningitis disease symptoms (fever, headache, stiff neck or vomiting).

OBJECTIVE

No signs of respiratory illness or meningitis.

ASSESSMENT Candidate for chemoprophylaxis for meningococcal meningitis.

PLAN

DIAGNOSTIC STUDIES

1. Assess whether patient has a history of liver and/or kidney disease. Also, attempt to review previous (within past 3 months) Comprehensive Metabolic Panel results. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning chemoprophylaxis.
2. Assess last menstrual period if person is of child-bearing potential (approximately 15-50 years of age) or with menstrual cycle and not using

contraceptives. If pregnant or possibly pregnant, refer to delegating physician for care.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Consult an online drug information resource to assess for drug-drug interactions.
(e.g. https://www.drugs.com/drug_interactions.html or https://online.lexi.com/lco/action/login)

NOTE: Discuss the importance of compliance with the medication regiment and of completing the full course of chemoprophylaxis. Assist the patient or caretaker to develop a plan for compliance with taking or administering the medication to ensure close to around the clock coverage is provided.

1. Chemoprophylaxis: Rifampin, Ciprofloxacin, and Ceftriaxone are 90-95% effective in reducing nasopharyngeal carriage of *N. meningitidis* and are all acceptable for Chemoprophylaxis.

NOTE: Rifampin interacts with many drugs. Check the Rifampin product package insert for a complete list of drugs interactions.

a. Rifampin: See Rifampin Dosage Chart – Appendix A
   1) Infants 1 month and younger: Rifampin 5 mg/kg PO every 12 hours for 2 days.
   2) Infants over 1 month old and children/adolescents (younger than 18 years old): Rifampin 10 mg/kg (maximum 600mg/dose) PO every 12 hours for 2 days.
   3) Nonpregnant adults: Rifampin 600 mg PO every 12 hours for 2 days.

OR

b. Ceftriaxone:

NOTE: Give only if the patient cannot take Rifampin due to previous history of liver impairment, elevated liver function tests, or adverse/allergic reaction to Rifampin AND consult with delegating physician prior to ordering.

   1) Children under 15 years old: Ceftriaxone 125 mg IM single dose.

   2) Non-pregnant Adolescents (15 years and older**)** and Adults (including those with liver disease and/or, abnormal liver function tests): Ceftriaxone 250 mg IM single dose.

OR

   3) Non-pregnant adults (18 years old and >): Ciprofloxacin 500 mg PO single dose.

NOTE: If the patient is diabetic while receiving Ceftriaxone Chemoprophylaxis, the ACCU-CHEK Compact Plus system may provide incorrect (low) glucose results. Therefore, patients should stop using the ACCU-CHEK Compact Plus system and begin using an alternate blood glucose monitoring system for the duration of Ceftriaxone therapy and two full days (48 hours) after the last Ceftriaxone injection.

NOTE: Ceftriaxone can cause a false-positive reaction for urine glucose with Benedict's solution, Fehling's solution or with Clinitest tablets, but not with enzyme-based tests such as Clinistix and Tes-Tape.

NOTE: Do not give Ciprofloxacin to children or pregnant persons. Ciprofloxacin has been associated with an increased rate of adverse reactions involving the joints and surrounding tissue structures (like tendons) in children/adolescents (younger than 18 years old). Ciprofloxacin can be given to adults with elevated liver function tests or history of chronic liver disease.

NOTE: Recent report from CDC describes a strain of penicillin-resistant and ciprofloxacin-resistant, *β*-lactamase–producing *N. meningitidis* in the United States, including Georgia. Consideration of emerging antimicrobial resistance patterns should be made while providing treatment and prophylaxis. (12)

2. Immunizations:
   a. Since secondary cases can occur several weeks or more after onset of disease, meningococcal vaccine is a possible adjunct to Chemoprophylaxis during an outbreak caused by a serogroup covered by the available vaccines.
   b. See the GA Immunization Program Manual, Recommended Schedule and Guidelines for vaccine information, schedule, and guidelines for administration. http://dph.georgia.gov/immunization-schedules and https://dph.georgia.gov/immunization-section/immunization-publications

PATIENT EDUCATION/COUNSELING

1. Meningococcal meningitis is not highly contagious. Even close family members of a patient with meningitis have only a 1 in 250 chance of developing disease from the infected person.

2. The bacteria that cause meningococcal meningitis is spread through intimate, prolonged contact, such as "deep" kissing with exchange of saliva, or exposure to oral secretions with mouth-to-mouth resuscitation or by day-care contacts. The bacteria cannot live outside the human body, and animals do not carry the bacteria.

3. Review Rifampin product package insert for complete listing of interactions. If taking Rifampin:

    a. Avoid drinking alcohol while taking rifampin due to increased risk of hepatotoxicity.
    b. Rifampin is present in breast milk. The Centers for Disease Control and Prevention and other professional organizations state that breastfeeding should not be discouraged in women taking rifampin.
    c. Rifampin may cause the urine, feces, saliva, sputum, sweat, breastmilk and tears to temporarily turn red-orange.
    d. Do not use soft contact lenses when taking Rifampin because permanent discoloration may occur.
    e. Rifampin may decrease the effectiveness of oral contraceptives. Consideration should be given to using alternative contraceptive measures during, and immediately following, rifampin therapy, until the next cycle. The rationale for using an alternative or back-up method of birth control (e.g., copper-bearing IUD such as ParaGard, condoms, diaphragm) is that when Rifampin is prescribed, it reduces effectiveness (degree depending on method) of combined oral contraceptives, progestin-only oral contraceptives, Levonorgestrel implants, Depo-Provera, patch and ring. Advise condom back-up.
    f. Most people can take Rifampin without difficulty. However, any of the following signs or symptoms should be reported as soon as possible: fever, nausea, vomiting, loss of appetite, dark coffee or tea-colored urine, white/gray/light tan bowel movement, tiredness, weakness, yellow skin or sclera, bruising easily, rash/itching, and/or painful menstruation.

4. The effect of Ciprofloxacin can be decreased by calcium-rich foods such as dairy products, antacids, or calcium supplements. Ciprofloxacin should be taken 2 hours before or 6 hours after eating calcium-rich foods unless they are part of a larger meal that contains other non-calcium rich foods.

5. The manufacturer does not recommend use of Ciprofloxacin in breastfeeding persons due to concerns of potential articular damage; however, this risk is considered low even in children in receiving high therapeutic doses.

6. If the patient is diabetic while receiving Ceftriaxone chemoprophylaxis, the ACCU-CHEK Compact Plus system may provide incorrect (low) glucose results. Therefore, patients should stop using the ACCU-CHEK Compact Plus system and begin using an alternate blood glucose monitoring system for the duration of Ceftriaxone therapy and two full days (48 hours) after the last Ceftriaxone injection.

7. In general, antibiotics that are present in breast milk may cause non-dose related modification of bowel flora. Infants should be monitored for gastrointestinal disturbances. Ceftriaxone is considered compatible with

breastfeeding when used in recommended doses. The manufacturer recommends that caution be exercised when administered Ceftriaxone to nursing persons.

8. Routine immunization of adolescents and persons at risk for meningococcal disease is recommended. Immunization of college students is recommended by the American College Health Association and is an actual requirement for admission to public schools. See the Georgia Immunization Program Manual, "Recommended Schedule and Guidelines," for vaccine information and administration guidelines at **https://dph.georgia.gov/immunization-section/immunization-publications.**

9. Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

REFERRAL/CONSULTATION

1. Patients with adverse reactions to treatment should be referred to the delegating physician.

2. Patients with signs/symptoms of meningitis should be referred immediately to the nearest emergency room.

3. Refer pregnant persons to OB health care provider.

4. Consult with delegating physician prior to beginning treatment for patients with history of kidney/liver disease or abnormal lab results.

5. If there is an absolute contraindication to use any of the above listed medications, such as allergy, warnings on the package insert, etc. consult the delegating physician for alternative recommendations.

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STANDARD NURSE PROTOCOL FOR PREVENTATIVE TREATMENT OF PERTUSSIS CONTACTS

NOTE: Public health nurses must work closely with the District Epidemiologists/ Communicable/Infectious Disease Coordinator (or other designated official) who is monitoring reported pertussis cases and contacts to ensure that all contacts have been identified and received prophylaxis.

DEFINITION

Pertussis is a highly contagious bacterial infection of the upper respiratory tract. The classic clinical manifestations of pertussis infection are paroxysmal cough, inspiratory whoop, and post-tussive emesis. The classic symptoms are often not seen in adolescents and adults whose infection may result in a protracted cough and is occasionally associated with substantial morbidity. Groups at highest risk of pertussis-related morbidity and mortality include infants (especially those younger than six months), young children who have not been fully immunized, and older adults. In children, and particularly infants, morbidity is more often substantial, and the disease may be fatal.

Transmission — The incubation period for *B. pertussis* ranges from 1 to 3 weeks but is most typically 7 to 10 days. Pertussis infection is spread via respiratory droplets, which are aerosolized by paroxysms of coughing. In one study, approximately one-third of exposed individuals within households developed pertussis. Asymptomatic infection appears to be common and may contribute to transmission of pertussis between household contacts.

ETIOLOGY

Pertussis is caused by the gram-negative coccobacillus *B. pertussis*, a strict human pathogen. Eight additional Bordetella species have been identified that can cause respiratory illness in humans.

SUBJECTIVE

1. Recent history of close contact (e.g., household, daycare):
   a. A probable case of pertussis e.g., a person with cough illness lasting 2 weeks or more, with at least one of the following symptoms: paroxysms of coughing, inspiratory “whoop”, post-tussive vomiting; AND absence of lab confirmation

   OR

   b. An infant less than 1 year old with a cough illness of any duration, with at least one of the following symptoms: paroxysms of coughing, inspiratory “whoop”, post-tussive vomiting, or apnea, with or without cyanosis; AND absence of lab confirmation.

   OR

2. A confirmed case of pertussis defined by a positive culture; or a positive PCR test in association with clinical symptoms as outlined in “a” above. May or may not have a history of adequate immunization against pertussis.

3. Denies upper respiratory symptoms.

4. Denies history of allergy or other contraindications to taking the medications.

OBJECTIVE

1. No signs of upper respiratory illness.

NOTE: For patient with upper respiratory signs**/**symptoms, care for patient using the Standard Nurse Protocol for Identification and Treatment of Probable Pertussis.

2. Denies having liver disease or hepatic dysfunction.

ASSESSMENT Candidate for Chemoprophylaxis of pertussis

PLAN

DIAGNOSTIC STUDIES

1. Assess for history of liver and/or kidney disease. Attempt to review previous (within past 3 months) Comprehensive Metabolic Panel results. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning Chemoprophylaxis.

2. Assess last menstrual period if person is of child-bearing potential (approximately 15-45 years of age). If pregnant or possibly pregnant, refer to delegating physician for care.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Consult an online drug information resource (e.g. https://www.drugs.com/drug_interactions.html or https://online.lexi.com/lco/action/login) to assess for drug-drug interactions

NOTE: Discuss the importance of compliance with the medication regimen and of completing the full course of chemoprophylaxis**.** Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

1. Chemoprophylaxis
   a. Azithromycin:
      1) Children less than 6 months of age: Azithromycin 10mg/kg PO once daily for 5 days.
      2) Children 6 months – 12 years old: Azithromycin 10mg/kg (maximum of 500mg) PO once on day 1, then 5 mg/kg (maximum 250mg/day) PO once on days 2 through 5.
      3) Adolescents (at least 13 years old) and Adults (including patients who are pregnant): Azithromycin 500mg PO once on day 1, then 250mg PO once on days 2 through 5.
   b. Erythromycin (preferably the estolate form):

NOTE: Do not give in hepatic dysfunction or pre-existing liver disease.

      1) Infants (at least 1 month old) and children (younger than 13 years old): Erythromycin estolate 40mg/kg divided in 4 equal doses; give 1 dose every 6 hours PO for 14 days (maximum of 2 grams total daily).

NOTE: Erythromycin estolate not preferred agent for infants less than 1 month due to increased risk of infantile hypertrophic pyloric stenosis).

      2) Adolescents (at least 13 years old) and Adults: Erythromycin 500mg PO every six hours for 14 days.

OR

   c. Sulfamethoxazole/trimethoprim (TMP-SMX):

NOTE: Give only if patient cannot take other medication listed. Do not give if pregnant, pre-existing liver disease, allergic to sulfa drugs, or infant less than 2 months old.

NOTE: Breastfeeding: TMP-SMX is excreted in the breast milk; however, mothers who are taking TMP-SMX can breastfeed healthy, full-term infants who are at least one month old. Breastfeeding while on TMP-SMX should be avoided in infants with glucose-6-phosphate dehydrogenase deficiency, and TMP-SMX should be used cautiously during breastfeeding if the infant is jaundiced, premature, or ill. All infants should be monitored for hemolysis and jaundice if they are breastfeeding while the mother is on TMP-SMX.

      1) Infants 2 months of age and older children (younger than 13 years old):
         a) SMZ/TMP (40 mg/8 mg)/kg, divided into 2 equal doses; give 1 dose every 12 hours for 14 days.
      2) Adolescents (at least 13 years old) and Adults: SMZ/TMP 800 mg/160 mg PO every 12 hours for 14 days.

2. Immunizations:
   a. Initiate or continue the pertussis immunization schedule for contacts. See the ACIP Recommended Immunization Schedules for vaccine information and vaccine administration guidelines: http://dph.georgia.gov/immunization-schedules

PATIENT EDUCATION/COUNSELING

1. All close contacts need to take the medication, regardless of age or immunization status, because pertussis immunity is not absolute and may not prevent infection.

2. Discuss the importance of compliance with the medication regimen and of completing the full course of chemoprophylaxis. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

3. Report as soon as possible if apparent side effects to the medication develop (e.g., if nausea, vomiting, diarrhea, severe abdominal pain, or symptoms of hepatitis occur during erythromycin therapy).

4. Seek medical care if the contact develops symptoms of respiratory illness within 21 days (maximum incubation period) of the last exposure to the infected person.

5. Assure that unimmunized or incompletely immunized children under age 7 complete the vaccine series. Review current recommendations for individuals over age 7 years. See ACIP Recommended Immunization Schedules for vaccine information and vaccine administration guidelines at https://dph.georgia.gov/immunization-schedules

6. Avoid aluminum or magnesium containing antacids 2 hours before and up to 2 hours after taking azithromycin.

7. Educate patients who receive Azithromycin about adverse effects (QT prolongation, torsades de pointes, etc.) and document patient's understanding. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-azithromycin-zithromax-or-zmax-and-risk-potentially-fatal-heart

8. Consult local school board concerning policy of returning to school. If no policy exists the recommendation is for children who develop symptoms consistent with pertussis to be excluded from school or day care until they have completed five days of effective antimicrobial therapy, or, if they are not treated, 21 days after the onset of symptoms.

REFERRAL/CONSULTATION

1. Refer all exposed infants less than 6 months of age to delegating physician or pediatrician**.**
2. Manage care of all contacts with respiratory signs/symptoms using the Standard Nurse Protocol for Identification and Treatment of Probable Pertussis Cases.
3. Ensure all pregnant persons have an OB providing prenatal care. Notify her OB that patient is receiving preventative treatment for pertussis.
4. Ensure all children have a Primary Care Provider. Notify the child's provider that patient is receiving preventative treatment for pertussis.
5. Consult with delegating physician (or refer to pediatrician) patients who are immunocompromised, unable to take any of the above medications, or who have experience serious adverse medication effects.
6. Consult with physician prior to beginning chemoprophylaxis for patients with history of kidney/liver disease or abnormal lab results.

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STANDARD NURSE PROTOCOL FOR IDENTIFICATION AND CHEMOPHYLAXIS OF PROBABLE PERTUSSIS CASES

NOTE: Public health nurses must work closely with the District Epidemiologists/ Communicable/ Infectious Disease Coordinator (or another designated official) who is monitoring reported pertussis cases and contacts to ensure that all contacts have been identified and provided chemophylaxis**.**

DEFINITION

Pertussis is a highly contagious bacterial infection of the upper respiratory tract. The classic clinical manifestations of pertussis infection are paroxysmal cough, inspiratory whoop, and post-tussive emesis. The classic symptoms are often not seen in adolescents and adults whose infection may result in a protracted cough and is occasionally associated with substantial morbidity. Groups at highest risk of pertussis-related morbidity and mortality include infants (especially those younger than six months), young children who have not been fully immunized, and older adults. In children, and particularly infants, morbidity is more often substantial, and the disease may be fatal.

Transmission — The incubation period for *B. pertussis* ranges from 1 to 3 weeks but is most typically 7 to 10 days. Pertussis infection is spread via respiratory droplets, which are aerosolized by paroxysms of coughing. In one study, approximately one-third of exposed individuals within households developed pertussis. Asymptomatic infection appears to be common and may contribute to transmission of pertussis between household contacts.

ETIOLOGY

Pertussis is caused by the gram-negative coccobacillus *B. pertussis*, a strict human pathogen. Eight additional Bordetella species have been identified that can cause respiratory illness in humans.

SUBJECTIVE

1. Cough illness of 2 weeks or more with one of the following: paroxysms of coughing, inspiratory “whoop,” or post-tussive vomiting, without other apparent cause. A high degree of suspicion should apply to infants (less than 1 year old) who may have atypical symptoms including gagging, difficulty feeding and/or apnea instead of or in addition to cough. Infant cough can be less than 2 weeks in duration.

2. Upper respiratory symptoms of coryza (runny nose)**,** sneezing, low-grade fever, and a mild, occasional cough that preceded the prolonged cough.

3. May or may not have a history of adequate immunization against pertussis.

4. No history of allergy or other contraindications to the medications recommended for treatment.

OBJECTIVE

1. A cough illness with at least one of the following:
   a. Coughing fits (paroxysms)
   b. Inspiratory whoop
   c. Post-tussive vomiting
   d. Apnea, with or without cyanosis (infants less than 1 year old)

LABORATORY FINDINGS

1. May or may not have positive culture results. Serology is not a valid test for the identification of pertussis. If the case meets the clinical definition, PCR can be used to confirm a diagnosis. Consult with the District Epidemiologist or State Vaccine-Preventable Disease Epidemiology Unit (404-657-2588) for questions about case confirmation, lab testing, and results.

ASSESSMENT Candidate for pertussis treatment.

PLAN

DIAGNOSTIC STUDIES

1. Assess whether patient has a history of liver and/or kidney disease. Perform Comprehensive Metabolic Panel if one has not been performed within previous three months. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning treatment.

2. Collect a nasopharyngeal swab specimen for polymerase chain reaction (PCR) testing and/or culture for B. pertussis. PCR testing has a more rapid turnaround time than culture. Both tests are available through the Georgia Public Health Laboratory. Contact the State Vaccine-Preventable Diseases Unit at (404-657-2588) for further information.

   NOTE: All suspect pertussis cases should be laboratory tested for confirmation. Consult with the District Epidemiologist or State Vaccine-Preventable Disease Unit (404-657-2588) to report a suspect case of pertussis and for further guidance. All specimens should be submitted to the Georgia Public Health Laboratory and approval is required through the epidemiologist. Information regarding the collection and transport of specimens can be found at: http://dph.georgia.gov/sites/dph.georgia.gov/files/related_files/site_page/ADES_Pertussis_Specimen_Collection_Submission-Guidelines.pdf

NOTE: To view how to collect a nasopharyngeal swab refer to https://www.youtube.com/watch?v=zqX56LGItgQ

NOTE: Culture media and nasopharyngeal swabs are available at the District Epidemiology Office. Specimen collection is of limited usefulness if done more than 3 weeks after symptom onset.

THERAPEUTIC

1. Do not wait for test results to initiate therapy when there is a high suspicion of disease. Patients should begin treatment for pertussis immediately after presumptive diagnosis. Studies have shown that treatment is most effective when administered in the early stages of disease.

PHARMACOLOGIC

NOTE: Consult an online drug information resource (e.g. https://www.drugs.com/drug_interactions.html https://online.lexi.com/lco/action/login) to assess for drug-drug interactions

NOTE**:** Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

1. Azithromycin:
   a. Infants less than 6 months old: Azithromycin 10 mg/kg PO daily for 5 days
   b. Children 6 months of age through 12 years old: Azithromycin 10 mg/kg (maximum of 500 mg) PO once on day 1, then 5mg/kg (maximum 250 mg/day) PO once days 2 through 5.
   c. Adolescents (at least 13 years old) and adults (including patients who are pregnant): Azithromycin 500 mg PO once on day 1, then 250 mg PO once on days 2 through 5.

OR

2. Erythromycin (preferably the estolate form):

NOTE: Do not give in hepatic dysfunction or pre-existing liver disease. Also, do not give to infants less than 1 month old due to infantile hypertrophic pyloric stenosis.
   a. Children 1 month of age through 12 years old: Erythromycin 40 mg/kg (maximum of 2 grams) PO divided into 4 equal doses; give 1 dose every six hours for 14 days.
   b. Adolescents (at least 13 years old) and adults: Erythromycin 500 mg PO every six hours for 14 days.

OR, if cannot take others listed:

3. Sulfamethoxazole/ Trimethoprim (SMZ/TMP)

NOTE: Give only if patient cannot take other medications listed. Do not give if patient is pregnant, has pre-existing liver disease, is allergic to sulfa drugs, or is younger than 2 months old.

NOTE: Breastfeeding: TMP-SMX is excreted in the breast milk; however, mothers who are taking TMP-SMX can breastfeed healthy, full-term infants who are at least one month old. Breastfeeding while on TMP-SMX should be avoided in infants with glucose-6-phosphate dehydrogenase deficiency, and TMP-SMX should be used cautiously during breastfeeding if the infant is jaundiced, premature, or ill. All infants should be monitored for hemolysis and jaundice if they are breastfeeding while the mother is on TMP-SMX.

   a. Children 2 months of age through 12 years of age: SMZ/TMP (40 mg/8 mg)/kg divided in 2 equal doses; give 1 dose PO every 12 hours for 14 days.
   b. Adolescents (at least 13 years old) and adults: SMZ/TMP (800 mg/160 mg) PO every 12 hours for 14 days.

4. Immunization:
   a. Initiate or continue the pertussis immunization schedule for cases. See the ACIP Recommended Immunization Schedules, for vaccine information and vaccine administration guidelines at http://dph.georgia.gov/immunization-schedules

PATIENT EDUCATION/COUNSELING

1. Identify all close contacts (household contacts and other contacts who are pregnant or caring for an infant, immunocompromised, or have an underlying medical condition that would be exacerbated by pertussis such as severe asthma or cystic fibrosis) and advise them to seek medical care for chemoprophylaxis regardless of age or immunization status, because pertussis immunity is not absolute and may not prevent infection.

2. Counsel patient about the importance of compliance with the medication regimen and completing the full course of treatment. A minimum of five days of treatment must be completed before returning to school or work.

3. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible. Report as soon as possible if side effects of the medication develop

(e.g., if nausea, vomiting, diarrhea, severe abdominal pain, or symptoms of hepatitis occur during erythromycin therapy).

4. Assure that unimmunized or incompletely immunized children under age 7 complete the vaccine series. Review current recommendations for individuals over age 7 years. See the Georgia Immunization Program Manual, Recommended Schedules and Guidelines, for vaccine information and vaccine administration guidelines: **https://dph.georgia.gov/immunization-section/immunization-publications**.

5. Avoid aluminum or magnesium containing antacids 2 hours before and up to 2 hours after taking Erythromycin.

6. Erythromycin enteric-coated tablets or an ester derivative (e.g., estolate, ethylsuccinate) may be taken with food to minimize gastrointestinal irritation.

7. If patient is presumptively diagnosed and treated in third trimester of pregnancy, instruct patient to inform obstetrical provider of presumptive diagnosis due to possible risk of transmission to newborn infant. Patient should be advised that family members and others who will be in close contact with the newborn should be vaccinated with Tdap as a protective measure. https://www.cdc.gov/vaccines/schedules/index.html.

8. All close contacts of newborns should be advised to update their pertussis immunization status with Tdap per CDC guidelines. The CDC recommends pregnant persons get the whooping cough vaccine between 27 and 36 weeks of each pregnancy, preferably during the earlier part of this time period. https://www.cdc.gov/features/tdap-in-pregnancy/index.html

9. Educate patients who receive Azithromycin about adverse effects (QT prolongation, torsades de pointes, etc.) and document patient's understanding. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM343347.pdf

REFERRAL/CONSULTATION

1. Refer all infants less than 6 months of age with respiratory signs/symptoms to delegating physician or pediatrician. If child has a Primary Care Provider, notify PCP that patient is receiving treatment for pertussis.

2. Ensure all pregnant persons have an OB providing prenatal care. Notify OB that patient is receiving treatment for pertussis. If patient is presumptively diagnosed and treated in third trimester of pregnancy, inform primary care provider and/or obstetrical provider of presumptive diagnosis due to possible risk of transmission to newborn infant.

3. Consult with delegating physician or refer to specialist any patients who are immunocompromised, unable to take any of the above medications or who experience adverse effects from medication.

4. Consult with delegating physician regarding any patient that may have a history of liver/kidney disease or abnormal lab results.

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STANDARD NURSE PROTOCOL FOR CHEMOPROPHYLAXIS OF RHEUMATIC FEVER

DEFINITION

Patients with history of acute rheumatic fever are at high risk for recurrence if they develop a streptococcal group A upper respiratory tract infection. Because both asymptomatic and symptomatic infections can trigger a recurrence, the most effective protection from recurrences is continuous antibiotic chemoprophylaxis, perhaps for life.

Acute Rheumatic Fever is an inflammatory, multisystem disease that occurs 1-5 weeks to 6 months after infection with group A hemolytic streptococci. It is characterized by focal inflammatory lesions of the connective tissue structures (especially of the heart, blood vessels, and joints) and by the presence of Aschoff bodies in the myocardium and skin. Typically, the onset is signaled by the sudden occurrence of fever and major manifestations such as joint pain (arthritis), possibly followed by heart and pericardial disease (carditis may be clinical or subclinical), skin changes (erythema marginatum, subcutaneous nodules), and/or chorea. Minor manifestations can include clinical findings (fever and arthralgias), laboratory findings (elevated erythrocyte sedimentation rate, abnormal C-reactive protein) and/or electrocardiographic (prolonged PR interval) alterations. Diagnosis requires 2 major criteria or 1 major and 2 minor criteria with supporting evidence of antecedent group A streptococcal infection.
See Appendix A for more information.

ETIOLOGY

Certain M Serotypes of Group A Beta hemolytic *Streptococcus pyogenes*

SUBJECTIVE

1. Documented history of acute rheumatic fever.

2. No history of allergic reaction to any chemoprophylaxis being considered.

OBJECTIVE

1. Displays signs and symptoms of acute rheumatic fever**:**
   a. Fever
   b. Painful and tender joints most often in the knees, ankles, elbows and wrists
   c. Pain in one joint that migrates to another joint
   d. Red, hot or swollen joints

e. Small, painless bumps (nodules) beneath the skin
f. Chest pain
g. Heart murmur
h. Fatigue
i. Flat or slightly raised, painless rash with a ragged edge (erythema marginatum)
j. Jerky, uncontrollable body movements (Sydenham chorea, or St. Vitus' dance) most often in the hands, feet and face
k. Outbursts of unusual behavior, such as crying or inappropriate laughing, that accompanies Sydenham chorea

ASSESSMENT Candidate for secondary chemoprophylaxis of acute rheumatic fever and no contraindication to medication selected.

PLAN **DIAGNOSTIC STUDIES**

1. Assess for a history of liver and/or kidney disease. Attempt to review previous (within past 3 months) Comprehensive Metabolic Panel results. If results are abnormal or patient reports history of liver/kidney disease, consult with delegating physician before beginning chemoprophylaxis.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Consult an online drug information resource (e.g. https://www.drugs.com/drug_interactions.html or https://online.lexi.com/lco/action/login) to assess for drug-drug interactions

NOTE: Discuss the importance of compliance with the medication regimen and of completing the full course of treatment. Assist the patient/caretaker to develop a written plan for taking, or administering, the medication so coverage is as close to around-the-clock as possible.

1. Penicillin G benzathine (Bicillin L-A)
   a. Adults and children (greater than 60 lbs [27 kg]): Bicillin L-A 1.2 million units IM every 3-4 weeks. Administration every 3 weeks is recommended in certain high-risk situations. High risk situations are listed at http://www.aafp.org/afp/2010/0201/p346.html
   b. Patients weighing 60 lbs (27 kg) or less: Bicillin L-A 600,000 units/kg IM every 3-4 weeks. Administration every 3 weeks is recommended in certain high-risk situations. High risk situations are listed at http://www.aafp.org/afp/2010/0201/p346.html

NOTE: IM injections are recommended until late adolescence or young adulthood AND free of rheumatic attacks for at least 5 years; if there is risk of

noncompliance with injections, then a change to oral chemoprophylaxis is recommended.

OR

2. Penicillin V tablets
   a. Children ≤ 27 kg: Penicillin V 250 mg PO every 12 hours for 10 days.
   b. Children 2-3 years old that have sickle cell disease or anatomically asplenic: Penicillin V 125 mg PO every 12 hours for 10 days
   c. Children **>** 27 kg and Adults: Penicillin V 500 mg PO every 12 hours for 10 days.

NOTE: There are alternative regiments for patients with penicillin allergy (listed below). Persons reporting a penicillin allergy should be assessed as per the Standard Nurse Protocol for Penicillin Allergy.

OR

3. If allergic to penicillin and sulfonamide drugs, give Erythromycin. Susceptibility testing should be pursued prior to use of this drug class (macrolides).
   a. Children > than 20 kg and adults: 250 mg PO every 6 hours for 10 days
   b. Children ≤ 20 kg: 40 mg/kg/day PO in 4 divided doses for 10 days.

OR

4. Azithromycin is more expensive than Erythromycin, but it has fewer adverse effects and permits once daily dosing. Susceptibility testing should be pursued prior to use of this drug class (macrolides).
   a. Adults: 500 mg PO once daily for 5 days
   b. Children: 12 mg/kg (maximum 500 mg) PO once daily for 5 days

NON-PHARMACOLOGIC

1. Patient is under medical supervision.

2. Monitoring of medication compliance is jointly managed by public health and primary care providers, including cardiologist. Efforts will be made to ensure access to care and medications.

PATIENT EDUCATION/COUNSELING

1. Review importance of preventing recurrences of Acute Rheumatic Fever.

2. Counsel patient on medications, directions for taking them, potential side effects and management.

REFERRAL/CONSULTATION

1. Consult with primary care provider and/or cardiologist or if patient is non-adherent with treatment or displays the following signs or symptoms of recurrence of Acute Rheumatic Fever:

a. Fever
b. Painful and tender joints, most often in the knees, ankles, elbows and wrists
c. Pain in one joint that migrates to another joint
d. Red, hot or swollen joints
e. Small, painless bumps (nodules) beneath the skin
f. Chest pain
g. Heart murmur
h. Fatigue
i. Flat or slightly raised, painless rash with a ragged edge (erythema marginatum)
j. Jerky, uncontrollable body movements (Sydenham chorea, or St. Vitus' dance) most often in the hands, feet and face
k. Outbursts of unusual behavior, such as crying or inappropriate laughing, that accompanies Sydenham chorea

2. Refer to the delegating provider or cardiologist for duration of therapy and discissions on discontinuation of chemoprophylaxis.

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Appendix A

Symptoms of febrile illness versus neurologic illness in patients with acute rheumatic fever.

Acute Febrile Illness	Neurologic Illness (25% to 30%)

• Onset two to four weeks after GAS infection
• Fever is common
• Acute joint symptoms and signs
• Carditis
  ○ Clinical and subclinical
• Skin manifestations and subcutaneous nodules (both are rare)
• Raised inflammatory markers
• Evidence of preceding GAS infection (elevated ASO and anti-DNase B titers)
• Dramatic symptomatic response to aspirin and NSAIDS
• Duration usually <6 weeks
• Followed by RHD in approximately 75%
	• Later onset
	  ○ Two to six months after GAS infection
	• No fever
	• Joint manifestations are not a feature
	• Behavioral disorder and distinctive chorea
	• Carditis >30%
	  ○ Often subclinical
	• Often normal inflammatory markers
	• ASO often unhelpful, anti-DNase B may be raised
	• Followed by RHD in approximately 50%

Graphic 111437 Version 1.0

Revised Jones Criteria

A. For all Patient Populations with Evidence of Preceding GAS Infection:	
Diagnosis: Initial ARF	
Diagnosis: Recurrent ARF	
B. Major Criteria:	
Low risk populations*	Moderate and high-risk populations:
Carditis	Carditis
• Clinical and /or subclinical ¶	• Clinical and /or subclinical ¶
Arthritis	Arthritis
• Polyarthritis only	• Monoarthritis or polyarthritis • Polyarthralgia Δ
Chorea	Chorea
Erythema marginatum	Erythema marginatum
Subcutaneous nodules	Subcutaneous nodules
C. Minor criteria	
Low risk populations*	Moderate and high-risk populations
Polyarthralgia	Monoarthralgia
Fever (>38.5 C)	Fever (>38.5 C)
ESB >60 mm in 1st hour &/or CRP>3.0 mg/dL◊	ESR >30 mm/h &/or CRP >3.0 mg/dL◊
Prolonged PR interval after accounting for age variability (unless carditis is a major criterion)	Prolonged PR interval after accounting for age variability (unless carditis is a major criterion)

Evidence of preceding GAS infection is required for both populations.
GAS: group A streptococcal infection; ARF: acute rheumatic fever; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

* Low-risk populations are those with ARF incidence ≤2 per 100,000 school-aged children or all-age rheumatic heart disease prevalence of ≤1 per 1000 population-year.
¶ Subclinical carditis indicates echocardiographic valvulitis.
Δ See section on polyarthralgia, which should only be considered as a major manifestation in moderate- to high-risk populations after exclusion of other causes. As in past versions of criterial, erythema marginatum and subcutaneous nodules are rarely "stand alone" major criteria. Additionally, joint manifestations can only be considered in either the major or minor categories but not both in the same patient.
◊ CRP value must be greater than upper limit of normal for laboratory. Also, because ESR may evolve during course of ARF, peak ESR values should be used.

2023 STANDARD NURSE PROTOCOL FOR SEASONAL INFLUENZA CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR SEASONAL INFLUENZA

Note: Parental or guardian consent for diagnostic studies and treatment under this protocol is required for individuals less than 18 years of age.

DEFINITION

Influenza is an acute viral respiratory disease that affects individuals of all ages worldwide. Seasonal influenza A and B virus epidemics are associated with significant morbidity and mortality each year in the United States and worldwide. Influenza activity typically occurs during September through April in the United States. Human influenza A and B viruses cause seasonal epidemics of disease nearly every winter in temperate climates. Influenza A viruses are divided into subtypes based on two proteins on the surface of the virus: hemagglutinin (HA or H) and neuraminidase (NA or N). There are 18 different H subtypes (H1 through H18) and 11 different N subtypes (N1 through N11). In humans, three major subtypes of hemagglutinins (H1, H2, and H3) and two subtypes of neuraminidases (N1 and N2) have been described. Influenza A virus subtypes that routinely circulate in humans include A(H1N1) and A(H3N2). More than 130 influenza A subtype combinations have been identified in nature, primarily from wild birds. Influenza A viruses are the only influenza viruses known to cause global influenza pandemics. A pandemic can occur when a new influenza A virus emerges that can spread efficiently among humans. Influenza A viruses are found in many different animals, including birds, pigs, and other animals. Influenza B — Influenza B viruses are classified into two lineages: B/Yamagata and B/Victoria. In general, the genetic and antigenic properties of influenza B viruses change more slowly than influenza A viruses. Influenza B viruses circulate widely only in humans.

ETIOLOGY

The pathogenesis of disease caused by influenza virus is not completely understood, particularly in molecular terms. Initial viral infection occurs in the upper respiratory columnar epithelium and then spreads distally in airways. Cell damage and death occurs through inhibition of host cell protein synthesis and induction of apoptotic changes in various cell types.

The typical incubation period is one to four days (average two days). The time between onset of illness among household contacts is three to four days.

Symptoms of influenza include:

- **Abrupt onset of fever**
- **Nonproductive cough**
- **Myalgia**
- **Malaise**
- **Sore throat**
- **Nausea**
- **Nasal congestion**
- **Headache**

NOTE: The clinical course of uncomplicated influenza in adults involves fever and respiratory symptoms for about three days, after which time most show signs of improvement; complete recovery may take 10 to 14 days (longer in adults ≥ 65 years of age).

NOTE: Among vaccinated individuals, clinical manifestations may be similar but less severe.

- **In children, gastrointestinal symptoms such as vomiting and diarrhea may also be present.**
- **Older adults (≥ 65 years) and immunosuppressed patients are more likely to have subtle signs and symptoms; they may present without fever, sore throat, and myalgias.**
    - **However, older adults are more likely to present with:**
        - **Altered mental status**
        - **Anorexia**
        - **Malaise**
        - **Weakness**
        - **Dizziness**

Most people recover from uncomplicated influenza without sequela after 3-7 days, but influenza can cause complications that result in severe illness and death in those at high risk.

Groups at high risk for influenza complications include:

- **Children < 5 years, but especially < 2 years of age**
- **Adults ≥ 65 years of age**
    - **Elderly persons have the highest mortality rates attributable to influenza.**
- **People who are pregnant or up to 2 weeks postpartum**
- **Non-Hispanic Black persons, Hispanic or Latino persons, and American Indian or Alaska Native persons**
- **People with medical conditions including:**
    - **Asthma**
    - **Neurologic and neurodevelopmental conditions (such as cerebral palsy, epilepsy, stroke, intellectual disability,**

moderate-to-severe developmental delay, muscular dystrophy, and spinal cord injury)
- **Chronic lung disease (e.g., chronic obstructive pulmonary disease, cystic fibrosis)**
- **Heart disease (e.g., congenital heart disease, congestive heart failure, coronary artery disease)**
- **Blood disorders (e.g., sickle cell disease)**
- **Endocrine disorders (e.g., diabetes mellitus)**
- **Kidney diseases**
- **Liver disorders**
- **Metabolic disorders (e.g., inherited metabolic disorders and mitochondrial disorders)**
- **Weakened immune system due to disease (e.g., HIV, AIDS, cancer) or medication (e.g., chemotherapy or radiation therapy, chronic glucocorticoids)**
- **Children < 19 years of age who are receiving long-term aspirin therapy**
- **People with Class III obesity (body mass index ≥ 40 kg/m²or ≥140% of the 95th percentile value)**

INELIGIBILITY

Infants less than 1 year of age are not eligible for influenza management and treatment under this nursing protocol. Referral to pediatrician is required.

SUBJECTIVE

1. **Patient, or parent/guardian, provides a focused health history to include review of symptoms, past and current medical history, current medications, hospitalizations, surgeries, injuries, vaccination status, and results from any recent medical assessments or at home tests (e.g., COVID-19).**
    a. **Because influenza vaccine effectiveness is widely variable, a history of current season influenza vaccination does not exclude a diagnosis of influenza.**
2. **Reports any of the following signs or symptoms of uncomplicated influenza:**
    a. **Abrupt onset of fever**
    b. **Nonproductive cough**
        i. **An abrupt onset of fever with cough is most predictive of uncomplicated influenza in adults during the influenza season.**
    c. **Myalgia**
    d. **Chills or sweats**
    e. **Malaise**
    f. **Sore throat/hoarseness**

g. **Rhinitis**
h. **Nausea**
i. **Nasal congestion**
j. **Headache**
k. **Young children may also present with diarrhea and vomiting.**
l. **Elderly persons may present without fever and with milder systemic symptoms, but with a higher frequency of:**
    i. **Altered mental status**
    ii. **Anorexia**
    iii. **Malaise**
    iv. **Weakness**
    v. **Dizziness**

OBJECTIVE

1. **Check and record vital signs: blood pressure; height, weight, and calculate BMI; and temperature.**
    a. **Fever usually ranges from 100 to 104°F but can be as high as 106°F.**

2. **Perform a focused physical exam to include evaluation of lymph nodes, heart, lungs, nasal passages, and pharynx.**
    a. **Physical findings are generally few.**
        i. **Patient may appear hot and flushed.**
        ii. **Oropharyngeal abnormalities other than hyperemia are uncommon.**
        iii. **Mild cervical lymphadenopathy may be present and is more common in younger patients.**
        iv. **Physical examination of the lungs is generally unremarkable.**

3. **During influenza activity, clinicians should test for influenza:**
    a. **In high-risk patients, including immunocompromised persons who present with influenza-like illness, pneumonia, or nonspecific respiratory illness (e.g., cough without fever).**
        - **High risk patients include children, older adults, pregnant women, people with certain medical conditions, and Black, Hispanic or Latino, and American Indian or Alaska Native persons. See comprehensive list of high-risk medical conditions in Etiology section.**
    b. **In patients who present with acute onset of respiratory symptoms with or without fever and exacerbation of chronic medical conditions (e.g., asthma, chronic obstructive pulmonary disease, heart failure).**
    c. **Clinicians may consider influenza testing for patients not at high risk for influenza complications who present with influenza-like illness or nonspecific respiratory illness (e.g., cough without fever) who can recover at home and results might reduce use of unnecessary antibiotics, further diagnostic testing, and time in the emergency**

department,

d. During low influenza activity without any link to an influenza outbreak:
- **Clinicians can consider influenza testing in patients with acute onset of respiratory symptoms with or without fever, especially for immunocompromised and high-risk patients.**

ASSESSMENT

Differential diagnosis list includes influenza, common cold, COVID-19, pneumonia, respiratory syncytial virus, and acute HIV infection.

PLAN

DIAGNOSTIC STUDIES

NOTE: Nurses should collect upper respiratory tract specimens for influenza testing as soon after illness onset as possible.

1. **Obtain specimen using a flocked swab for rapid influenza A and B diagnostic test.**
   a. **Nasopharyngeal specimens are preferred over other specimens to optimize virus detection.**
      i. **If nasopharyngeal specimens are not available, nasal and throat swab specimens should be collected and combined for testing. If it is possible to obtain only one specimen, nasal swab is preferred.**

   b. **Perform a rapid molecular assay, nucleic acid amplification test, for influenza A and B per package insert.**
      i. **Preferred diagnostic test due to high sensitivity and high specificity.**

      OR

   c. **Perform a rapid influenza A and B antigen test per package insert.**
      i. **Low to moderate sensitivity; high specificity.**

2. **Perform a rapid, fourth generation, HIV antigen and/or antibody blood test to determine HIV status, if indicated.**

3. **SARS-CoV-2 testing for COVID-19, if available. Otherwise, encourage the patient to take an at-home test for COVID-19 or refer the patient to a local specimen point of collection site.**

THERAPEUTIC

Treatment with antivirals reduces the duration of symptoms and risk of some complications (e.g., bronchitis, otitis media, and pneumonia) and hospitalization, and may decrease mortality among high-risk populations. Antiviral treatment is clinically most beneficial when started as close to illness onset as possible, ideally within 48 hours.

1. **Priority groups for antiviral treatment of influenza:**
    a. **Antiviral treatment is recommended as early as possible, even if 48 hours have elapsed since illness onset, for any patient with confirmed influenza, irrespective of vaccination history, who are at a higher risk for influenza complications (see Etiology section for list of high-risk individuals/conditions).**

2. **Antiviral treatment can be considered for any previously healthy, symptomatic patient not at high risk for influenza complications, who is diagnosed with confirmed influenza if treatment can be initiated within 48 hours of illness onset.**

PHARMACOLOGIC

DISCLAIMER: Drug shortages can occur for many reasons, including manufacturing and quality problems, delays, discontinuations, and supply chain interruptions. The FDA maintains a list of current drug shortages which may be found at https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm

1. **Oseltamivir (Tamiflu), available in capsules or oral suspension.**
    a. **Adults and children 13 years and older: 75 mg PO twice daily for 5 days. May be administered without regard to meals; take with food to improve tolerance.**
        i. **May be used during pregnancy; preferred drug for influenza treatment.**
        ii. **Dose adjustments of oseltamivir are recommended for patients with creatinine clearance between 10 and 60 mL/min:**
            1. **CrCl of 31 to 60 mL/min: 30 mg twice daily for 5 days**
            2. **CrCl of 11 to 30 mL/min: 30 mg once daily for 5 days**

    b. **Children:**

        i. **Patients 1 to 12 years of age based on weight:**
            1. **< 33 lb. (≤ 15 kg): 30 mg twice daily PO for 5 days**
            2. **33 to 50 lb. (> 15 to 23 kg): 45 mg twice daily PO for 5 days**
            3. **> 50 to 88 lb. (> 23 to 40 kg): 60 mg twice daily PO for 5 days**

4. **> 88 lb. (> 40 kg): 75 mg PO twice daily for 5 days**

ii. **For children, if oral suspension is not available, oral capsules may be ordered or dispensed. The capsules may be opened and mixed with a thick, sweetened liquid such as regular or sugar-free chocolate syrup. Provide parent or guardian with CDC's guidance for Mixing Oseltamivir Capsules for Children.**

c. Adverse Reactions may include nausea, vomiting, headache.

d. Warning and Precautions:

i. **Serious skin/hypersensitivity reactions such as Stevens-Johnson Syndrome, toxic epidermal necrolysis and erythema multiforme: Discontinue Tamiflu If allergic-like reactions occur or are suspected.**

ii. **Neuropsychiatric events: Patients with influenza, including those receiving Tamiflu, particularly pediatric patients, may be at increased risk of confusion or abnormal behavior early in their illness. Monitor for signs of abnormal behavior.**

iii. **Use with caution in patients with severe hepatic impairment.**

iv. **Use with caution in patients with renal impairment: dosage adjustment is required for patients with renal impairment.**

e. Contraindications: Do not dispense or order oseltamivir if patient has a history of hypersensitivity to oseltamivir or any component of the formulation. Consult Lexicomp for warnings, precautions, and drug interactions.

2. Over-the-counter oral acetaminophen or ibuprofen may be recommended as needed for fever and aches per package instructions.

a. For children, follow Standard Nurse Protocol for Fever.

PATIENT EDUCATION/COUNSELING

1. Provide information about the infection including prevention of transmission to others.

2. Annual influenza vaccination is recommended for all people 6 months and older. Annual vaccination is the best method for preventing or mitigating the impact of influenza.

3. Notify patients to stay home, rest, and drink plenty of fluids. Do not go to

work or school until your fever has been gone for at least 24 hours without taking medicine such as acetaminophen.

4. **Notify parents to not give aspirin or medicines that contain aspirin to children younger than 18. In children, aspirin can cause a serious problem called Reye's syndrome.**

5. **Most people with the flu get better on their own within 1 to 2 weeks.**
    a. **Patients should be advised to go to the hospital if they experience:**
        i. **Trouble breathing or are short of breath**
        ii. **Feel pain or pressure in chest or stomach**
        iii. **Signs of being dehydrated, such as dizziness when standing or not passing urine**
        iv. **Feel confused**
        v. **Have severe vomiting, cannot stop vomiting, or cannot drink enough fluids**

    b. **Patients should take their children to the hospital if they:**
        i. **Start breathing fast or have trouble breathing**
        ii. **Start to turn blue or purple**
        iii. **Are not drinking enough fluids**
        iv. **Do not have tears when crying (in infants)**
        v. **Will not wake up or will not interact with you**
        vi. **Are so unhappy that they do not want to be held**
        vii. **Get better from the flu but then get sick again with a fever or cough**
        viii. **Have a fever with a rash**

6. **If patient is given any oral medications, provide patient with directions for taking the medication, possible side effects, and what to do about the side effects. Seek medical care immediately if adverse reaction or systemic symptoms develop.**

FOLLOW-UP

1. **Contact patient in 3 days to assess for status after initiating treatment and to determine if referral to primary care provider or emergency department is indicated.**

CONSULTATION/REFERRAL

1. **Infants less than 1 year of age are not eligible for influenza management and treatment under this nursing protocol. Referral to pediatrician is required.**

2. **A negative result from a rapid influenza A and B test does not exclude**

influenza virus infection in patients with signs and symptoms suggestive of influenza. The patient should be advised to seek medical care if he/she continues to feel unwell or experiences worsening of symptoms.

3. **Consult delegating physician if further medical guidance is needed, or this Nurse Protocol is not applicable or sufficient for therapeutic evaluation and management of the patient.**

4. **Hospitalization is warranted for patients with significant dehydration and for severely ill patients, especially those with respiratory distress, hypoxemia, impaired cardiopulmonary function, or altered mental status.**

5. **Refer patient to a primary care provider or emergency department for the following:**
    a. **Patient who deteriorates after initial improvement for treatment of influenza.**
    b. **Patient who fails to improve after 3-5 days of antiviral treatment.**
    c. **Patients with influenza who remain febrile for more than three to five days, develop fever after defervescence, or demonstrate worsening symptoms to rule out concomitant infection.**
    d. **If diagnosis is questionable or pneumonia is suspected (e.g., tachypnea, rales, pleural friction rub, absent breath sounds, wheezing, and/or egophony).**
        i. **Contact 911 if patient exhibits signs of respiratory distress.**

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PERINATAL HEPATITIS EXPOSURE

PERINATAL HEPATITIS B EXPOSURE

Hepatitis B virus (HBV) can be transmitted from an infected mother to her infant at birth through contact with infected blood or body fluids that contain blood. HBV-exposed infants have a 90% risk of developing chronic infection if infected perinatally. Post-exposure prophylaxis with Hepatitis B Immune Globulin (HBIG) and Hepatitis B vaccine should be administered within 12 hours of birth to prevent infection. Additional Hepatitis B vaccine doses should be administered at 1-2 months of age and at 6 months of age.

All children born to HBV-infected women should be tested for HBV infection at 9 to 12 months of age. Testing must include the hepatitis B surface antigen (HBsAg) and the hepatitis B surface antibody (anti-HBs). The child must be at least 9 months of age and have not received a Hepatitis B vaccine in the previous 30 days.

Perinatal HBV testing referrals will be made to public health clinics by District Epidemiology staff or private medical providers.

Testing guidance for HBV-exposed infants:

1. **Collect the specimen as outlined in the Georgia Public Health Laboratory (GPHL) Manual. Complete GPHL form 3583 section Immunology – Hepatitis Testing and order the appropriate laboratory test for the infant/child:**

Infant/Child Current Age	HBV Test Code at GPHL
≥9 months of age	1410 Hep B (Routine Screen)

   a. **If testing cannot be performed in the public health clinic provide a laboratory requisition form to the family for specimen collection at a contracted private laboratory**

2. **Report laboratory results (positive and negative results) to District Epidemiology staff or the referring provider and the child's family.**

3. **Make referrals for infants/children that are infected or who are still susceptible:**
   a. **Refer HBV-infected infants/children (HBsAg: Positive and anti-HBs: Negative) to a pediatrician for linkage to a specialist for further evaluation.**
   b. **Administer additional Hepatitis B vaccine dose(s) to infants/children who did not develop adequate antibody levels (HBsAg: Negative and anti-HBs: Negative) and are still susceptible to infection.**

Note: Public Health staff will utilize the current edition of the Georgia Department of Public Health Immunization Program (GIP) Manual's Perinatal Hepatitis B

Prevention Program Guidelines as their policy to provide required management of infants born to hepatitis B surface antigen (HBsAg)-positive women.

Go to www.dph.ga.gov/perinatal-hepatitis-b for additional resources and for DPH's Perinatal Hepatitis B Prevention Program contact information.

PERINATAL HEPATITIS C EXPOSURE

Hepatitis C virus (HCV) can be transmitted from an infected mother to her infant at birth through contact with infected blood or body fluids that contain blood. HCV-exposed infants have a 5% risk of developing infection; the risk of infection increases if the mother is co-infected with HIV. There is no prophylaxis to prevent infection.

All children born to HCV-infected women should be tested for HCV infection. Testing is recommended using an antibody-based test after 18 months of age. Testing with an HCV RNA assay can be considered in the first year of life. Although the optimal timing of such a test is unknown, HCV RNA testing is not recommended before 2 months of age.

Perinatal HCV testing referrals will be made to public health clinics by District Epidemiology staff or private medical providers.

Testing guidance for HCV-exposed infants:

1. **Determine the appropriate laboratory test based on infant's/child's current age:**

Infant/Child Current Age	Recommended HCV Test
≥2 months of age	HCV RNA by PCR (HCV RNA)
≥18 months of age	HCV antibody (anti-HCV)

2. **Collect the specimen as outlined in the Georgia Public Health Laboratory (GPHL) Manual. Complete GPHL form 3583 section Immunology – Hepatitis Testing and order age-appropriate laboratory test for infant/child for:**

Infant/Child Current Age	HCV Test Code at GPHL
≥2 months of age	1490 HCV Viral Load
≥18 months of age	1480 Anti-HCV (Ab) with Reflex to HCV Viral Load

   a. **If testing cannot be performed in the public health clinic provide a laboratory requisition form to the family for specimen collection at a contracted private laboratory.**

3. **Report laboratory results (positive and negative results) to District Epidemiology staff or the referring provider and the child's family.**

4. **Refer HCV-infected infants/children to a pediatrician for linkage to a specialist for further evaluation.**

Go to www.dph.ga.gov/perinatal-hepatitis-c for additional resources and for DPH's Viral Hepatitis Program contact information.

SEXUALLY TRANSMITTED INFECTIONS

2023 STANDARD NURSE PROTOCOL FOR SEXUALLY TRANSMITTED INFECTIONS CLINICAL REVIEW TEAM

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GENERAL INFORMATION FOR SEXUALLY TRANSMITTED INFECTION (STI) EVALUATION & SCREENING

STI patients include persons who request sexual and reproductive healthcare services, those who are referred to a public health department by an epidemiologist (EPI), communicable disease specialist (CDS), disease investigative specialist (DIS), hospital, or medical provider, and contacts to an individual diagnosed with an STI. In public health departments, STI screening and assessment **are** only provided by appropriately trained licensed physicians, midlevel providers, and nurses.

STI patients should be provided information **about** their assessment, diagnosis, infectious process, implications for sexual partners, treatment options, medications, and recommended follow-up. Informational handouts and other educational materials should be provided to supplement the information as indicated.

Transgender persons have a gender identity that differs from the sex they were assigned at birth. Transgender women are women who were assigned male sex at birth (born with male anatomy). Transgender men are men who were assigned female sex at birth (born with female anatomy). Gender identity is independent of sexual orientation. Providers and clinicians who provide STI services for transgender persons should have knowledge of their patient's current anatomy and sexual behavior before counseling them about STI and HIV prevention. Document gender identity, sex assigned at birth, and current anatomy to improve sexual health care for transgender persons. Clinical assessment of transgender persons is based on anatomy at birth or post-gender-affirming surgery.

STI screening and visit components that must be completed and documented for all STI patients are listed below. If any components are not completed, documentation should include justification for why they weren't (e.g., not indicated).

1. Comprehensive sexual history
2. Health History
3. Physical assessment
4. Diagnostic tests:
    a. Gonorrhea (e.g., NAAT, culture for *Neisseria gonorrhoeae,* Gram-stain) and chlamydia testing (NAAT) according to the *Georgia STD Program Screening Criteria for Chlamydia and Gonorrhea*
    b. HIV testing is recommended annually or according to **the** risk for HIV infection
    c. Syphilis testing (nontreponemal and/or treponemal) completed based on health history and physical assessment findings
    d. Assessment for Vaginitis (wet mount/saline preparation, KOH)
    e. Pregnancy test if pregnancy status is not known
5. All health services must be documented before dispensing any STI 340 B medications.

STI causative organisms:

1. Bacterial: Chlamydia, Gonorrhea, and Syphilis
2. Viral: Human Papillomavirus (HPV), **Human immunodeficiency virus** (HIV), Genital Herpes (HSV), Hepatitis B and Hepatitis C
3. Parasitic: Scabies, Trichomoniasis, and pubic lice

STI clinical presentations:

1. Lesion: Primary Syphilis, Genital Herpes (HSV), Lymphogranuloma Venereum (LGV)
2. Discharge: Bacterial Vaginosis (BV), Vulvovaginal Candidiasis, Gonorrhea (GC), Chlamydia (CT), Pelvic Inflammatory Disease (PID), Epididymitis, Urethritis/Nongonococcal Urethritis (NGU), Cervicitis, Trichomoniasis
3. Rash: Secondary Syphilis, Scabies, Pediculosis Pubis, Gonorrhea (Disseminated Gonococcal Infection), Genital Herpes

NOTE: CDC recommends that everyone between the ages of 13 and 64 get tested for HIV at least once as part of routine health care. For those at risk for HIV infection, annual testing is recommended. Additionally, sexually active gay and bisexual men may benefit from getting an HIV test more often, possibly every 3 to 6 months.

REFERENCES:

1. Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men — United States, 2017 | MMWR (cdc.gov)

2. Centers for Disease Control an*d Prevention,* Sexually Transmitted Infections Treatment Guidelines, 2021 (cdc.gov) Volume 70, No. 4. Detection of STIs in Special Populations, Transgender and Gender Diverse Persons, Retrieved October 17, 2021.

STANDARD NURSE PROTOCOL FOR GONORRHEA

DEFINITION

Gonorrhea is a sexually transmitted infection caused by *Neisseria gonorrhoeae* bacterium. *Neisseria gonorrhoeae* can infect the reproductive, anorectal, ocular and pharyngeal mucous membranes. Such infections may be symptomatic or asymptomatic in all persons. Humans are the only known host. Occasionally, the periurethral or Bartholin glands may also show signs of being infected. Gonorrhea is the 2nd most common reported communicable disease. Georgia ranks 16th nationally for most reported cases.

Incubation of gonorrhea is between 1-14 days. Generally, symptoms develop in men within 2-5 days and in women within 10 days. However, infections in men and women may be asymptomatic.

ETIOLOGY

Neisseria gonorrhoeae is an intracellular Gram-negative diplococcus bacteria. Infections caused by antibiotic resistant strains are clinically indistinguishable from drug-sensitive infections. Sexual contact without a condom is a primary cause for acquisition of gonorrhea.

SUBJECTIVE

1. May be asymptomatic at the infected site.
2. Males frequently have purulent urethral discharge (generally within 24 hours of exposure) followed by dysuria.
3. Females may notice an increased vaginal discharge, intermenstrual bleeding, and dysuria.
4. Rectal discharge, pain, pruritis and/or scant bleeding may be present in those with a history of anal sex.
5. Sore throat may be present in those with a history of oral sex.
6. Exposure: oral, anal, or penile-vaginal sex, with a sex partner recently diagnosed with a ST**I**.
7. Other symptoms: lymphadenopathy, testicular pain or swelling, lower abdominal pain, swollen penis, or labia.

OBJECTIVE

1. Mucoid, mucopurulent, or purulent discharge from the infected site.
2. Erythema and edema of the cervix in females or urethral meatus in males.
3. Symptoms can include but are not limited to erythema, mucopurulent discharge, and/or scant bleeding.
4. Pharyngeal inflammation, Anorectal infections are commonly asymptomatic.

ASSESSMENT Gonorrhea specify exposed site(s) by clinical assessment.

PLAN

The desired outcomes of treatment are biological cure and prevention of transmission. Treatment of sex partners helps to prevent reinfection of the index patient and infection of other partners.

1. Any patient with a positive gonorrhea test should also be tested for chlamydia, syphilis, and HIV.

2. Subgroups of MSM are at high risk for gonorrhea infection and should be screened at exposure sites. Rectal gonorrhea infections, especially those that are recurrent, have been associated with an increased risk for HIV seroconversion among MSM.

3. If the criteria for gonorrhea are not present, treatment should be deferred pending the results of the diagnostic studies. Empiric treatment for gonorrhea should be given in the following cases:
   a. Documented or Contact to Gonorrhea
   b. Documented or contact to PID
   c. Documented or contact to Epididymitis
   d. Symptoms of discharge in males with visible discharge in males on examination (in cases where Gram stain is unavailable).
   e. Non-occupational post-exposure (nPEP)

4. Exposure by non-occupational post-exposure (nPEP) should be provided with prophylaxis for GC, CT, and Trichomoniasis. Testing should be conducted prior to treatment. Refer to nPEP Standard Nurse Protocol for follow-up.

DIAGNOSTIC STUDIES

1. Nonculture detection of N. gonorrhoeae (e.g., DNA probe, nucleic acid amplification test (NAAT)) at the anatomical site of exposure and/or symptoms (rectal, vaginal, urethra, oropharynx).
   NOTE: The Aptima Combo 2 Assay is FDA approved only for individuals ≥ 14 years of age.

   The performance characteristics of the Aptima Combo 2 Assay have not been evaluated in adolescents 13 years of age and younger.

   For adolescents 11-13 years of age, nurses can send Aptima Combo 2 Assay specimens to GPHL who will coordinate NAAT testing through other State Public Health Laboratories. Delays in results may be expected.

   To collect Aptima Combo 2 Assay specimens for NAAT testing in

adolescents 10 years of age and younger, consultation with the District Health Director or delegating physician is required. If approved, consult with a private laboratory prior to sending specimen. Do not send specimens to GPHL for this age population.

2. Culture for N. gonorrhoeae, with or without confirmatory tests when indicated:
   a. Antimicrobial susceptibility testing when suspected therapeutic failure after adequate gonorrhea treatment. GC culture media in transport container must be used for culture specimen collection. **See NOTE below.**
   b. As requested by a physician or supervisor.

3. (If available) Gram-negative intracellular diplococci seen on a smear of male urethral discharge. Gram stains are to be done in-house on symptomatic male patients to make a diagnosis and treat the patient on the same day.

4. NAAT can be used to collect urogenital, extragenital, and urine specimens.
   a. Either "1" or "2" must be performed in female patients. In male patients, "1" or "2" must be performed, and when available, "3". If NAAT is in short supply, "3" must be performed if available for male patients.
   b. If suspected therapeutic failure after GC treatment, GC culture media in a transport container must be used for specimen collection.

   NOTE: **Contact GPHL concerning** GC culture media in transport container supplies when a case of therapeutic failure after GC treatment is suspected.

THERAPEUTIC

PHARMACOLOGIC

Empiric treatment for gonorrhea should be given in the following cases:

- Documented **or** contact to Gonorrhea
- Documented or contact to PID
- Documented or contact to Epididymitis
- Symptoms of discharge in males with visible discharge on examination (in cases where Gram stain is not available).
- Non-occupational post-exposure (nPEP)

NOTE: Persons with HIV should receive the same treatment regimen as those without HIV.

NOTE: If self-reported allergy to cephalosporins or Penicillins, refer to Appendix A, PCN Allergy Assessment and Algorithm, to rule out allergy.

NOTE: **Patients should be treated according to the Standard Nurse Protocol for Chlamydia when coinfected with Chlamydia or when Chlamydia coinfection cannot be ruled out.**

1. **Uncomplicated urogenital, rectal, or pharyngeal infection in persons** weighing less than 150kg/330lbs or weighing at least 45kg/99lbs:

   Ceftriaxone 500mg IM, single dose.

2. **Uncomplicated urogenital, rectal, or pharyngeal infection in persons** weighing equal to or more than 150kg/330lbs:

   Ceftriaxone 1g IM, single dose

3. **Uncomplicated gonococcal urogenital, vulvovaginitis, cervicitis, or urethritis infection in persons weighing ≤45 kg, recommended regimen for:**

   Ceftriaxone 25–50 mg/kg body weight IV or IM in a single dose, not to exceed 250 mg IM.

NOTE: The Aptima Combo 2 Assay is FDA approved only for ≥ 14 years of age.

NOTE: The performance characteristics of the Aptima Combo 2 Assay have not been evaluated in adolescents 13 years of age and younger.

NOTE: For adolescents 11-13 years of age, nurse can send Aptima Combo 2 Assay specimens to GPHL who will coordinate NAAT testing through other State Public Health Laboratories. Delays in results may be expected.

NOTE: To collect Aptima Combo 2 Assay specimens for NAAT testing in adolescents 10 years of age and younger, consultation with the District Health Director or delegating physician is required. If approved, consult with a private laboratory prior to sending specimen. Do not send specimens to GPHL for this age population.

NOTE: Suspected or confirmed sexual abuse or sexual assault is to be reported immediately.

4. Alternative regimen for uncomplicated urogenital, rectal, or pharyngeal infection in adults, adolescents, or children weighing 45kg(99lbs) or greater:

   Cefixime 800 mg po single dose

OR
Gentamicin 240 mg IM, single dose

Plus
Azithromycin 2 g, PO, single dose

NOTE: Gentamicin should only be considered for treatment following an allergy assessment using Appendix A: Penicillin Allergy Assessment and Algorithm found in the Standard Nurse Protocol for Gonorrhea.

NOTE: Prior to using gentamicin, consultation with the delegating physician is required.

NOTE: Do not use gentamicin to treat pregnant persons.

NOTE Breastfeeding:

1. Azithromycin: Can be provided to lactating women. If infant is 2 weeks or younger, encourage patients to discuss with their pediatrician. Manufacturer guidance: the decision to breastfeed during therapy should include the risk of infant exposure, the benefits of breastfeeding to the infant (especially during the first 2 weeks of life), and benefits of treatment to the mother. The option to pump and discard during treatment and for two days after treatment is completed can be offered.

2. Ceftriaxone IM: Compatible with breastfeeding when used in usual recommended doses.

3. Cefixime: According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother.

4. Gentamicin: Compatible with breastfeeding when used in usual recommended doses. Infants should be monitored for thrush and diarrhea

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of untreated infection. **https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea.htm**

3. Directions for taking medication and management of potential side effects.
4. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known

sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for examination and treatment.

5. Annual screening is recommended for all MSM.

6. Counsel about high risk of reinfection if patient's partner(s) is/are not tested and treated. The use of protective barriers) (condoms, diaphragm, etc.) with any untreated partner(s) are not protective during sexual intercourse. Provide education and counseling on the correct usage of protective barriers if using or plan to use.

7. Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

8. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

9. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

10. Advise patient to return to clinic in 7 days or less if symptoms do not resolve.

11. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

12. Avoidance of breastfeeding has been and continues to be a standard, strong recommendation for HIV-infected persons in the United States, because maternal ART dramatically reduces but does not eliminate breastmilk transmission. Further, safe infant feeding alternatives are readily available in the United States. In addition, there are concerns about other potential risks, including toxicity for the neonate or increased risk of development of ARV drug resistance, should transmission occur, due to variable passage of drugs into breastmilk.

13. HIV antibody test to determine HIV status, if unknown.

14. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728,

http://www.ashasexualhealth.org/stdsstis/herpes/

Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

15. Refer to DPH Immunization Program Manual **https://dph.georgia.gov/immunization-section/immunization-publications** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

2. All identified sex partners, as defined above, should be examined, and promptly treated with one of the treatment regimens for chlamydia. If index patient is eligible, Expedited Partner Therapy could be utilized.

3. All identified sex partners, as defined above, should be examined, and promptly treated with one of the regimens for gonorrhea.

FOLLOW-UP

1. A test-of-cure is recommended 7-14 days after initial treatment, regardless of the treatment regimen, for patients positive for pharyngeal gonorrhea. If the NAAT is positive, effort should be made to perform a confirmatory culture before retreatment. All positive cultures for test-of-cure should undergo antimicrobial susceptibility testing.

2. A test-of-cure is unnecessary if patients with uncomplicated urogenital or rectal gonorrhea, are treated with any of the recommended or alternative regimens and symptoms have resolved.

3. If test of cure is positive for gonorrhea and reinfection is ruled out, consult with delegating physician and contact DPH STD Nurse Consultant.

4. A patient with symptoms that persist after treatment and reinfection is ruled out, should have a gonorrhea culture done with antimicrobial sensitivity testing on positive cultures. If gonorrhea culture is not available, a second

NAAT test can be performed 7 days after treatment. The Hologic APTIMA 2 test is a dual performance test but GC results should be the only results assessed if the test was done within two weeks of adequate treatment for positive Chlamydia. When a patient is adequately treated for chlamydia and a second test is conducted within four weeks of treatment, the NAAT chlamydia lab results may return positive.

5. *N. gonorrhoeae* infection is prevalent among patients who have been diagnosed with and treated for gonorrhea in the previous several months. Most infections result from reinfection rather than treatment failure, indicating a need for improved patient education and referral of sex partners. Clinicians should recommend patients with gonorrhea be retested 3 months after treatment. If patients do not seek medical care for retesting in 3 months, providers are encouraged to test these patients whenever they next seek medical care within the following 12 months, regardless of whether the patient(s) believe that their sex partner(s) were treated. Retesting is distinct from test-of-cure; the latter detects therapeutic failure, which is not recommended if the patient receives first line treatment.

6. If Azithromycin is given and patient vomits within 30 minutes of taking, the dose may be repeated.

CONSULTATION/REFERRAL

1. Consult with delegating physician if:
   a. Signs of Bartholin's gland, Skene's gland abscess or cyst are present.
   b. Patient cannot tolerate cephalosporins or penicillin.
   c. Further medical guidance is needed, and STI Nurse Protocol is not applicable for the therapeutic treatment of the patient.

2. If cephalosporin resistant gonorrhea is suspected, consult with delegating physician, and contact the DPH STD Nurse Consultant. Treatment failure due to cephalosporin resistant gonorrhea should be considered in:
   a. Persons whose symptoms do not resolve within 3-5 days after appropriate treatment and report no sexual contact during the post treatment follow-up period.
   b. Persons with a positive test-of-cure and no reported sexual contact during the post-treatment follow-up period.
   c. Persons with a positive *N. gonorrhoeae* culture greater than 72 hours after treatment for gonorrhea with no sexual contact reported during the post-treatment follow-up period.

3. Dual treatment with Gentamicin 240mg IM plus Azithromycin 2gm PO can be considered an alternative to ceftriaxone for non-pregnant persons with cephalosporin allergy. Consult with the delegating physician before

proceeding with this treatment regimen.

4. PCN Allergy Assessment and Algorithm (Appendix A) should be completed on all patients who report penicillin allergy.

5. Gram stains are inadequate to evaluate prepubertal minors for gonorrhea and should not be used to diagnose or exclude gonorrhea. Specimens from the vagina, urethra, pharynx, or rectum should be streaked onto selective media for isolation of *N. gonorrhoeae*.

6. Refer patient to a District Disease Intervention Specialists for prevention counseling and assistance with partner referral.

7. Patients with acute arthritis, skin pustules, meningitis or eye infection should be referred to ER immediately for emergency evaluation, treatment and follow up. Delegating physician should be notified of referral.

8. Hospitalization and consultation with an infectious disease specialist is recommended for initial therapy of patients diagnosed with disseminated gonococcal infection (DGI). DGI can manifest as rash, arthritis, or flu-like symptoms.

9. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel. https://gets.sharepoint.com/sites/DPHIntranet/PHIL/FormsAndPolicies/GeneralCounsel/GC-09014%20Mandatory%20Reporting%20of%20Suspected%20Child%20Abuse.pdf

10. Infants exposed to mothers infected with *N. gonorrhea* during vaginal delivery must be referred to pediatrician for evaluation and possible treatment.

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Appendix A: **Penicillin Allergy Assessment and Algorithm**

Background:

Penicillin (PCN) allergy is reported by approximately 10% of the United States population. Patients with unconfirmed PCN allergy often receive suboptimal treatment for infectious diseases with second-line, broad-spectrum antibiotics that tend to be less effective, costlier, and associated with an increased risk of pseudomembranous colitis and antibiotic-resistant infections. Penicillin allergy wanes over time where 50% of individuals after 5 years and 80% after 10 years will no longer be allergic.

Note: Over 90% of reported PCN allergies can be excluded by comprehensive patient history, record review, and antibiotic pharmacy fill history. The PCN allergy label can be removed in 92.8% following a direct Amoxicillin challenge

Studies have demonstrated that greater than 94% of patients who report a PCN allergy can tolerate the antibiotic. Recent studies have also found that direct oral challenges to Amoxicillin without preceding skin tests are safe in patients who report a low-risk history of PCN allergy, such as Amoxicillin-induced rashes. Among 100 million people exposed to oral Amoxicillin between 1972 and 2007 in the United Kingdom, only 1 death after anaphylaxis in association with oral Amoxicillin was identified.

Cross-reactivity between PCNs and Cephalosporins is less common than previously thought with an overall 1-2% of patients with a confirmed PCN allergy also having a Cephalosporin allergy.

Note: A reaction to Cefalexin or Cefaclor (both Cephalosporins) is more likely if the patient had a recent Amoxicillin or Ampicillin allergy because these drugs have a similar side-chain structure. In addition, nearly 40% of patients with anaphylaxis to PCN have a cross-reactivity with cephalosporins.

Potential B-Lactam antibiotic Side effects, Adverse Reactions, Allergic signs and symptoms and Anaphylaxis (see Beta-Lactam antibiotic examples, page 5 of this appendix):	
Side Effect / Adverse Reactions:	• Redness at site of IM administration • Itching at site of IM administration • Pain at site of IM administration • Diarrhea • Nausea • Vomiting • Erythema • Itching without rash
-vs-	

Allergic Signs and Symptoms:	• Skin rash • Hives • Itching with rash • Fever • Swelling • Shortness of breath • Wheezing • Runny nose • Itchy, watery eyes
Anaphylaxis:	• Hypotension • Angioedema • Tightening of the airways and throat causing trouble breathing • Nausea or abdominal cramps • Dizziness or lightheadedness • Weak, rapid pulse • Drop in blood pressure • Seizures • Loss of consciousness • Stevens-Johnson syndrome (SJS) • Toxic epidermal necrolysis (TEN) • Acute generalized exanthematous pustulosis • Maculopapular exanthema • Drug reaction with eosinophilia and systemic symptoms (DRESS)

Penicillin Allergy Assessment:

1. Appropriate antibiotic prescribing in a patient reporting a PCN allergy requires an understanding of allergy severity (severe vs. non-severe) and timing (immediate vs. delayed) and antibiotics tolerated since the reaction.

2. Questions for assessing Penicillin allergy:

Severity (severe vs. non-severe):	1. Do you remember any details of the reaction? 2. Did the reaction involve any symptoms other than a rash? 3. Did the reaction involve blistering, ulceration, sloughing of the skin or lining of the mouth, eyes, genitals (SJS, TEN, DRESS)? 4. Did the reaction involve any organ failure? (e.g., required dialysis?) 5. If a reaction occurred, how was the reaction managed? Did it require treatment or hospitalization?

	6. Was the reaction life threatening? (e.g., required emergency room visit, hospitalization, intensive care unit admission?)
Timing: Immediate onset within hours of first or second dose, Delayed onset after days, Occurrence recent or distant past:	1. Did the reaction occur within the past year? If not within the last year, how long ago? 2. How long after taking the antibiotic did the reaction occur? (e.g., minutes, hours, days)?
Antibiotics tolerated since reaction: • Self-report • Chart review • Pharmacy review	1. Do you recall the name of the antibiotic that caused the reaction? 2. Since the reaction, have you taken any antibiotics? • Do you recall the name of the antibiotic? • Did you have any reactions? • Were you able to complete the course of therapy?

NOTE: If the patient cannot recall the details of the reaction, use the time since reaction (childhood vs. recent) and treatment (outpatient or inpatient) to gauge the likely severity. Most people who report allergy to a PCN in childhood can tolerate the drug as an adult.

Risk Assessment: (Also see Algorithm Figure #1)

1. No Increased Risk: Proceed with preferred therapy per protocol and remove the individual's PCN allergy from the records:
   a. If individual reports taking and tolerating Penicillin
      OR
   b. Chart review (clinic and/or outside records) demonstrates the individual was prescribed a PCN and was able to tolerate treatment.
      OR
   c. Individual's pharmacy has documented that a PCN was picked up and the patient confirms the medication was taken without side effects or a reaction.

2. Low Risk: History of PCN use with reported side effect(s) not requiring treatment or hospitalization (i.e., any benign rash, GI symptoms, headache, or benign somatic symptoms or the previous side effect(s) occurs more than 10 years ago).
   a. If the delegating provider is present in the clinic, proceed with oral challenge otherwise, discuss information obtained in number one above and number two here with the delegating provider prior to proceeding with the oral challenge.

NOTE: In individuals with low-risk PCN allergy (benign rash, GI symptoms, headache, or benign somatic symptoms or the previous side effects occurred more than 10 years) recent research supports the safety and efficacy of a direct oral Amoxicillin challenge. Those with severe reactions or reactions within 12 months of evaluation were not challenged.

3. Moderate Risk: If the individual reports a history of shortness of breath or anaphylaxis.
   a. Proceed with skin testing (see nurse protocol)
   b. If skin testing is unavailable in the clinic or through a collaborative partner, then proceed with alternative therapy using a non-beta-lactam.

4. High Risk: If the individual reports blistering rash, hemolytic anemia, nephritis, hepatitis, hospitalization.
   a. Avoid all beta-lactams and proceed to alternative therapy that is a non-beta-lactam.
   b. Document allergy to all beta-lactams in the records.

Note: One exception is syphilis in pregnancy where the only approved therapy is PCN. Individuals would require referral for desensitization and treatment.

Amoxicillin Oral Challenge:

1. Medication Allergies that qualify patient for oral Amoxicillin challenge:
   - Penicillin
   - Amoxicillin
   - Ampicillin
   - Ampicillin-sulbactam
   - Amoxicillin Clavulanic Acid

2. Oral Amoxicillin Challenge:
   a. Contact the delegating physician prior to starting the oral challenge and again immediately if a reaction develops.
      - Obtain baseline vitals
      - Give oral Amoxicillin 250 mg and move patient to a monitored setting for 61 minutes
      - Obtain vitals every 15 minutes and as needed if the patient becomes symptomatic during the 61-minute monitoring

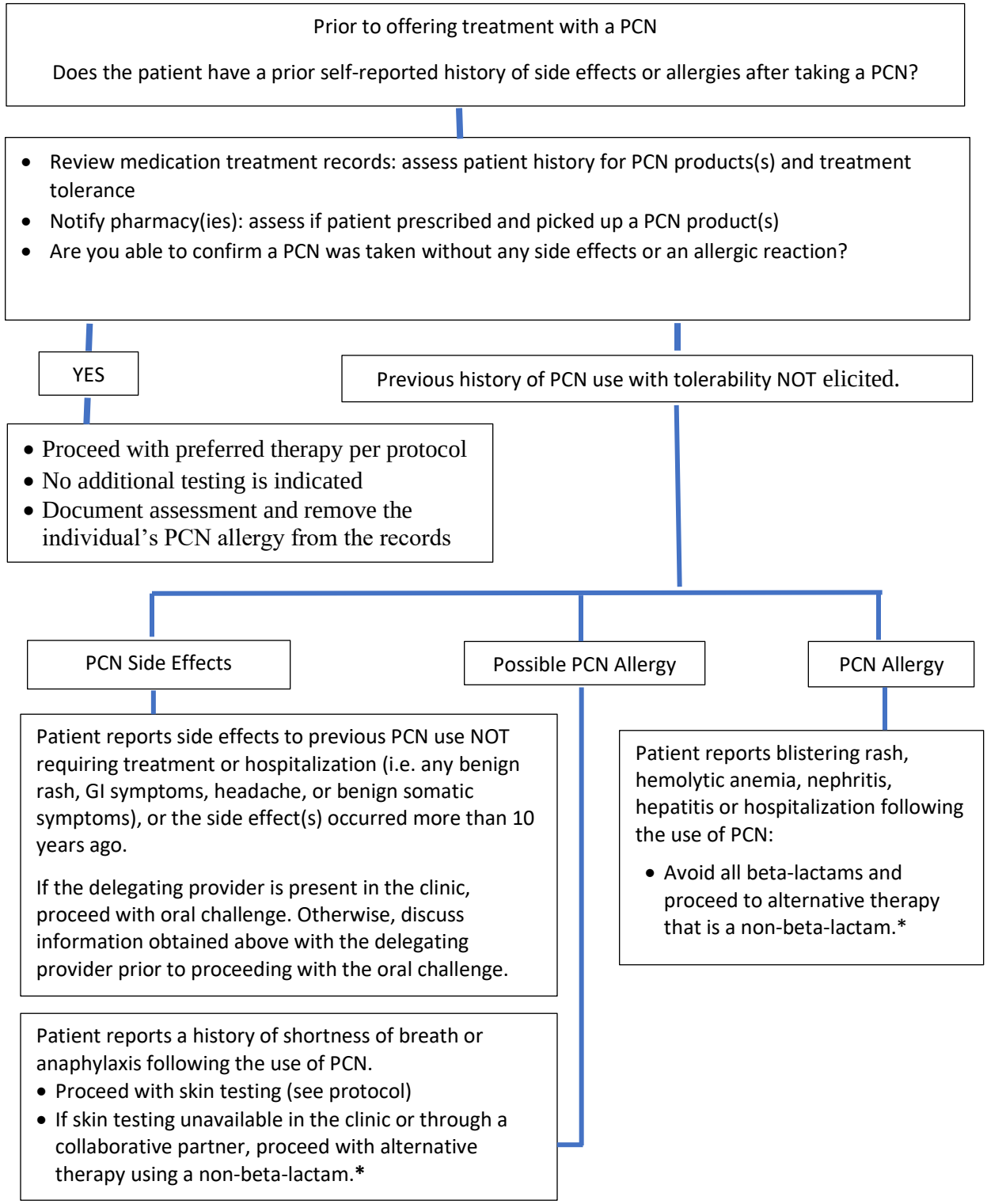
3. Items to have readily available during oral challenge are:
   - Code cart in the room throughout the monitoring
   - Blood pressure machine and stethoscope
   - Thermometer
   - Pulse Ox
   - Phone

4. Oral Penicillin Challenge billing: Use CPT code CPT95076 that requires documentation of at least 61 minutes of monitoring.

Beta-Lactam antibiotic examples (not all inclusive):

Penicillin		Cephalosporin	
Generic	Trade	Generic	Trade
Ampicillin		Ceftriaxone	Rocephin™
Amoxicillin	Amoxil™	Cefotaxime	Claforan™
Amoxicillin/Clavulanate	Augmentin™	Cefuroxime	Ceftin™
Amoxicillin/Sulbactam	Unasyn™	Cefepime	Maxipime™
Dicloxacillin	Dycill™ / Dynapen™	Ceftazidime	Tazicef™
Nafcillin	Nallpen™	Cefpodoxime	Vantin™
Oxacillin	Bactocill™	Cefaclor	Ceclor™
Penicillin G	Pfizerpen™	Cephalexin	Keflex™
Penicillin V	PC Pen VK™ / Pen-V™	Cefadroxil	Duricef™
Piperacillin	Pipracil™	Cefixime	Suprax™
Piperacillin/Tazobactam	Zosyn™	Ceftaroline	Teflaro™

Figure #1: Penicillin (PCN) Allergy Risk Assessment Algorithm



***** One exception is syphilis in pregnancy where the only approved therapy is PCN. Individuals would require referral for desensitization and treatment.

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STANDARD NURSE PROTOCOL FOR CHLAMYDIA

DEFINITION

Chlamydia is a common sexually transmitted disease caused by bacteria that is often asymptomatic in all persons. Chlamydia is the most common reported STI in the United States. Georgia ranks 6th nationally for the most reported cases.

ETIOLOGY

Chlamydia trachomatis is an obligate intracellular bacterial agent with at least 15 serologic variants (serovars), which includes Lymphogranuloma Venereum (LGV). Serovars A–C is the ocular pathotype which is responsible for trachoma. Ocular strains are rarely isolated from the genital tract. Serovars D–K is the genital pathotype, which causes sexually transmitted infections. Serovars L1–L3, more invasive, can attack local lymphatic nodes, leading to LGV. Chlamydia generally infects the columnar epithelial cells and often becomes chronic, lasting months to more than a year if untreated. Incubation is poorly defined but usually at least 1 week. The life cycle of chlamydia is 72 hours.

SUBJECTIVE

1. Females may report a history of:
   a. Abnormal discharge from vagina
   b. Bleeding after intercourse
   c. Dysuria, pyuria, urinary frequency

2. Males may report a history of:
   a. Mucoid or watery urethral discharge
   b. Itching of urethral meatus
   c. Dysuria
   d. Pain or swelling of testicles
   e. Pyuria or urinary frequency

3. Anal symptoms
   a. Rectal pain
   b. Discharge or bleeding

OBJECTIVE

1. Frequently asymptomatic in all persons, also known as the “silent infection”.

2. Females may present with:
   a. Mucoid to mucopurulent endocervical discharge
   b. Cervical ectopy/friability

3. Males may present with:
   a. Mucoid to mucopurulent urethral discharge
   b. Redness at urethral meatus

4. Anal symptoms
   a. Pain.
   b. Discharge or bleeding from rectum

5. Chlamydial conjunctivitis can occur through contact with infected genital secretions.

ASSESSMENT Chlamydia specify exposed site(s) by clinical assessment

PLAN

The desired outcomes of treatment of infected patients are: biologic cure, prevention of pelvic inflammatory disease (PID), ectopic pregnancy and infertility, prevention of transmission to sex partners, and prevention of transmission from infected females to infants during birth. Treatment of sex partners helps to prevent reinfection and sequelae of Chlamydia in the index patient as well as infection of other partners.

Annual screening of all sexually active women aged <25 years is recommended, as is screening of older women at increased risk for infection (e.g., women aged ≥25 years who have a new sex partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has an STI). The primary focus of screening is to detect the infection and prevent complications.

Empiric treatment for chlamydia should be given in the following cases:

- **Documented or contact to Chlamydia**
- **Documented or contact to PID**
- **Documented or contact to Epididymitis**
- **Non-occupational post-exposure (nPEP)**

DIAGNOSTIC STUDIES

NOTES: NAAT testing should be performed at the anatomical site of exposure and/or symptoms (rectal, vaginal, urethra, oropharynx).

Any **person with a positive chlamydia test should be tested for gonorrhea, syphilis, and HIV.**

The Aptima Combo 2 Assay is FDA approved only for ≥ 14 years

of age.
The performance characteristics of the Aptima Combo 2 Assay have not been evaluated in adolescents 13 years of age and younger.

For adolescents 11-13 years of age, nurse can send Aptima Combo 2 Assay specimens to GPHL who will coordinate NAAT testing through other State Public Health Laboratories. Delays in results may be expected.

To collect Aptima Combo 2 Assay specimens for NAAT testing in adolescents 10 years of age and younger, consultation with the District Health Director or delegating physician is required. If approved, consult with a private laboratory prior to sending specimen. Do not send specimens to GPHL for this age population.

Suspected or confirmed sexual abuse or sexual assault is to be reported immediately.

1. Chlamydia NAAT test.

2. FDA cleared positive Chlamydia trachomatis test.

THERAPEUTIC

PHARMACOLOGIC

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NOTE: Persons with HIV should receive the same treatment regimen as persons without HIV.

NOTE: Patients should be treated according to the Standard Nurse Protocol for Gonorrhea when coinfected with Gonorrhea or when Gonorrhea coinfection cannot be ruled out.

1. Recommended regimen for non-pregnant adults and adolescents:

   a. Doxycycline 100 mg PO, every 12 hours for 7 days.
   OR
   b. Doxycycline delayed - release 200 mg PO, daily for 7 days.

NOTE: Do not give Doxycycline to children under the age of 8.

1. Alternative regimen for non-pregnant adults and adolescents: Should be reserved for patients who are unlikely to complete the full Doxycycline course or cannot take Doxycycline:

a. Azithromycin 1g PO, single dose (see DOT note below)
OR
b. Levofloxacin 500 mg P.O. daily for 7 days

2. Alternative Regimen for Pregnant Persons:
   a. Azithromycin 1g PO, single dose (see DOT note below)
   OR
   b. Amoxicillin 500 mg P.O. 3 times a day for 7 days

3. For children weighing less than 45 kg/ 99lbs:
   a. Erythromycin base or ethylsuccinate 50 mg/kg orally, divided into 4 doses daily for 14 days

4. For children weighing 45 kg/99 lbs or greater but are less than 8 years of age:
   a. Azithromycin 1 gm PO as a single dose

5. For children weighing 45 kg/99 lbs or greater but are 8 years of age or older:
   a. Azithromycin 1 gm PO as a single dose
   OR
   b. Doxycycline 100 mg PO twice daily for 7 days

If Azithromycin is given, it should be given via DOT (direct observation therapy) to increase adherence to therapy.

For nonpregnant individuals, Azithromycin should be reserved for patients who are unlikely to complete the full doxycycline course or cannot take doxycycline.

NOTE: Breastfeeding:

1. Doxycycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Azithromycin: Can be utilized in lactating women. If infant is 2 weeks or younger, encourage patients to discuss with their pediatrician. Manufacturer guidance indicates the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant (especially during the first 2 weeks of life), and benefits of treatment to the mother. An option to pump and discard during treatment and for two days after treatment is completed, can be offered.

3. Amoxicillin: Although the manufacturer recommends that caution be exercised when administering amoxicillin for those breastfeeding, amoxicillin is considered compatible with breastfeeding when used in usual

recommended doses.

4. Levofloxacin: Not recommend in breastfeeding patients during therapy or for 2 days after the last dose due to concerns of potential serious adverse reactions. Lactating patients can pump and discard breast milk during therapy and for 2 days after the last levofloxacin dose.

PATIENT EDUCATION/COUNSELING

1. Reinforce information with handouts when indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of untreated infection. **https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm**

3. Directions for taking medication and management of potential side effects.

4. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

5. Abstain from sex with partner(s) until partner(s) has/have been treated.

6. Counsel about high risk of reinfection if patient's partner(s) is/are not tested and treated. The use of protective barriers) (condoms, diaphragm, etc.) with any untreated partner(s) are not protective during sexual intercourse. Provide education and counseling on the correct usage of protective barriers if using or plan to use.

7. Educate patients who receive Azithromycin about adverse effects (QT Prolongation, torsades de pointes, etc.) and document the patient's understanding. **http://www.fda.gov/downloads/Drugs/DrugSafety/UCM343347.pdf, https://www.nhs.uk/conditions/long-qt-syndrome/**

8. Abstain from intercourse until 7 days after taking azithromycin or until the 7 days Doxycycline regimen has been completed.

9. Advise to return to clinic for all lab results. Advise if lab results are positive additional treatment may be needed.

10. Education and counseling on the correct usage of protective barriers (condoms, dental dams, etc.).

11. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

12. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

13. Refer to DPH Immunization Program Manual **https://dph.georgia.gov/immunization-section/immunization-publications** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

14. HIV antibody test to determine HIV status, if unknown.

15. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357). Advise patient to return to clinic in 7 days if symptoms do not resolve.

16. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

MANAGEMENT OF SEX PARTNERS

1. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

2. All identified sex partners, as defined above, should be examined, and promptly treated with one of the treatment regimens for chlamydia. If the index patient is eligible, Expedited Partner Therapy could be utilized.

3. Provide written note(s) to give to partner(s) to refer them for exam and treatment.

FOLLOW-UP

1. Pregnant persons should be retested 4 weeks after completing therapy and rescreened near time of delivery.

2. Chlamydia infected persons are recommended to be retested approximately 3 months after treatment, regardless of whether they believe their sex partners were treated. If retesting at 3 months is not possible, clinicians should retest the next time the patient(s) presents for medical care in the 12 months following initial treatment.

3. If patient vomits within thirty minutes of taking Azithromycin, the dose may be repeated.

4. A NAAT test should not be used less than 4 weeks following completion of treatment due to possible false positive results.

CONSULTATION/REFERRAL

1. Consult with delegating physician if:
   a. Signs of Bartholin's gland or Skene's gland abscess or cyst are present.
   b. Signs and symptoms of prostatitis (blood in the urine, painful ejaculation or sexual dysfunction).
   c. Signs and symptoms of conjunctivitis (redness, itching, tearing of the eyes, discharge or crusting around the eyes, pink eye, irritation or inflammation of the conjunctiva).
   d. Signs and symptoms of reactive arthritis. Persons with chlamydia are at higher risk of developing reactive arthritis, formerly known as Reiter's syndrome. This condition typically affects the joints, eyes, and urethra.
   e. If further medical guidance is needed and the STI Nurse Protocol is not applicable for therapeutic treatment of the patient.

2. If pregnant and cannot tolerate medication, refer to OB/GYN or OB provider.

3. Refer the patient to a District Disease Intervention Specialist for prevention counseling and assistance with partner referral.

4. Infants exposed to mothers infected with Chlamydia during vaginal delivery must be referred to pediatrician for evaluation and possible treatment.

5. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting

of Suspected Child Abuse by Public Health Personnel.

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STANDARD NURSE PROTOCOL FOR EXPEDITED PARTNER THERAPY (EPT) FOR CHLAMYDIA AND GONORRHEA

DEFINITION

Expedited Partner Therapy (EPT) is the clinical practice of treating the sex partners of patients diagnosed with chlamydia and/or gonorrhea by providing medications to the patient to take to his/her partner without any medical evaluation intervention or professional prevention counseling.

ELIGIBILITY

1. EPT can be provided in the following cases:
   a. Partner(s) of index patients who are diagnosed through laboratory confirmation with chlamydia infection.
   b. Partner(s) of index patients who are diagnosed through laboratory confirmation with gonorrhea infection.
   c. Health care provider may identify sex partner(s) within past 60 days or may give EPT to most recent sex partner(s) if no partner(s) within the past 60 days.
   d. Partner(s) who are pregnant or may be pregnant.
   e. Partner(s) who are unable or unlikely to seek timely clinical services.

INELIGIBILITY

1. EPT should not be provided in the following cases:
   a. It is not recommended that partner(s) of index patients co-infected with syphilis, or HIV at the time of chlamydia and/or gonorrhea diagnosis receive EPT due to concerns regarding antibiotic resistance and the need for additional medical treatment. Partner(s) of index patients co-infected with both chlamydia and gonococcal infections should be encouraged to return to the clinic for additional evaluation.

2. Special populations NOT recommended to receive EPT:
   a. Male patients known to have sex with other men (MSM): Not recommended for EPT due to the lack of data to demonstrate the effectiveness of EPT in the MSM population and the risk of missing STI/HIV co-infections.
   b. Index patients 19 years of age and younger: The preferred approach to managing the treatment of sex partner(s) of adolescents is for partner notification to be carried out by health department staff where feasible. If health department partner notification is not available and providers choose to use EPT for individuals 19 years of age and younger, EPT should be offered as dispensed medication, not a prescription.
   c. Victims of sexual assault/abuse: Suspected or confirmed child abuse, sexual abuse/assault, or in cases where the patient's safety may be at risk,

EPT should not be offered.

SUBJECTIVE Patient meets eligibility criteria listed above to receive EPT.

OBJECTIVE

Index patient has positive chlamydia and/or gonorrhea test result(s) and received adequate information and counseling.

ASSESSMENT Patient eligible to receive EPT.

PLAN

The desired outcomes of treatment are biologic cure and prevention of transmission. Treatment of sex partners helps to prevent reinfection of the index patient and infection of other partners.

DIAGNOSTIC STUDIES

1. Index patient has chlamydia positive test.
2. Index patient has gonorrhea positive test.
3. Index patient have a negative HIV and syphilis test.

NOTE: Any index patient who tests positive for chlamydia and/or gonorrhea should be tested for chlamydia, gonorrhea, syphilis, and HIV.

THERAPEUTIC

NOTE: For treatment and care of index patient refer to the Standard Nurse Protocol for Chlamydia and/or the Standard Nurse Protocol for Gonorrhea as indicated.

NOTE: Sex partner(s) with allergies to Azithromycin, Doxycycline, or Cefixime should seek medical care for an alternative treatment.

NOTE: If adherence with multiday dosing is a considerable concern, azithromycin can be considered but has lower treatment efficacy.

PHARMACOLOGIC

1. Partners of person with positive Gonorrhea test and positive or unknown Chlamydia test results:
   a. Non-pregnant:
      1) Cefixime 800 mg PO, single dose plus Doxycycline 100 mg 2 times a day for 7 days

      OR
   b. Pregnant OR cannot take Doxycycline or concerns with completion of

multiday regimen:
1) Cefixime 800 mg PO, single dose plus Azithromycin 1 g PO, single dose (see note above)

2. Partners of person with positive Gonorrhea test and negative Chlamydia test results:
   a. Cefixime 800 mg PO, single dose

4. Partners of person with positive Chlamydia test and negative Gonorrhea test:
   a. Non-pregnant:
      1) Doxycycline 100 mg 2 times a day PO for 7 days
         OR
   b. Pregnant or cannot take Doxycycline or concerns with completion of multiday regimen:
      1) Azithromycin 1g PO, single dose

5. Partners of person with positive Chlamydia test and unknown Gonorrhea test:

NOTE: When Gonorrhea test is unknown, treatment should be offered for Chlamydia and Gonorrhea.

   a. Non-pregnant partners:
      1) Doxycycline 100 mg 2 times a day PO for 7 days
         PLUS
         Cefixime 800 mg PO, single dose

   b. Pregnant or cannot take Doxycycline or concerns with completion of multiday regimen:
      1) Azithromycin 1 g PO, single dose
         PLUS
         Cefixime 800 mg PO, single dose

NOTE: Breastfeeding:

1. Doxycycline: Breastfeeding partners should discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Azithromycin: Can be used during lactation. If infant is 2 weeks or younger, encourage patients to discuss with their pediatrician. According to the manufacturer the decision to breastfeed during therapy should include consideration of the risk of infant exposure, the benefits of breastfeeding to the infant (especially during the first 2 weeks of life), and benefits of treatment to the mother. If breastfeeding pumping and discarding breastmilk during treatment and for two days after treatment is completed can be an option.

3. Cefixime: According to the manufacturer, the decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and benefits of treatment to the mother.

NOTES: Doxycycline is contraindicated for pregnant partners of index case.

Azithromycin 1g can be provided if partner of index case is pregnant or adherence with multiday dosing is a considerable concern.

Azithromycin has lower treatment efficacy among persons with rectal chlamydia.

4. Dispensing requirements:
   a. Dispense doses separately for each of the index patient partners.
   b. The product may be given to the index patient but must be labeled separately for each partner. If the partner's name is unknown, dispensation can occur using the index patient's name.
   c. However, when either the patient or partner is unnamed, the dispenser may create a unique identifier and use that instead of a name for both labeling and record keeping purposes.
   d. All doses must be documented as part of therapy for index patient when using 340B medications.
   e. The EPT drug shall be dispensed with a written warning that contains, at a minimum, the following information contained in Appendix B):
      1) The drug should be taken as soon as possible and in accordance with the directions.
      2) The partner should consult a physician or the local health department before taking EPT drug if the partner is already taking any medications, is allergic to any drug, is pregnant, or has a serious health condition.
      3) The partner should seek testing after three months to ensure that the infection has been successfully treated.

NOTES: The patient should be given enough doses to treat each sex partner in the past 60 days whom the patient feels confident contacting. If the patient reports no sex partners in the past 60 days, provide one dose for the most recent sex partner.

If EPT order is called in to a Pharmacy, the Delegating Physician must be consulted. The order must contain the words, "Expedited Partner Therapy" or "EPT". It must include the wording "Do not fill after 30 days from the date written. Refills are not allowed.

PATIENT EDUCATION/COUNSELING TO PROVIDE TO PARTNER

1. Reinforce pertinent information with handouts as indicated.

2. Counsel patient regarding the basics of EPT.

3. Patient should be given an EPT information sheet (in an appropriate language) for each partner who will receive EPT (Appendix B).

4. Patients are encouraged to advise all partners who were exposed during the previous 60 days or last known partner to seek clinical evaluation.

5. Patients and partners should abstain from sex for at least seven days after treatment and until seven days after all partners have been treated, to decrease the risk of re-infecting the index patient.

6. Breastfeeding partners who are given Doxycycline should be advised to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

7. Side effects of medication that require immediate evaluation.

8. Allergy information advising patient not to take the medication if allergic.

9. Telephone numbers of providers to contact for answers to their questions.

10. Follow-up information.

FOLLOW-UP

1. Testing 3-4 weeks after completion of drug therapy to determine the effectiveness of treatment.
2. Chlamydia and/or gonorrhea infected persons (nonpregnant or pregnant) and men are recommended to be retested approximately 3 months after treatment, regardless of whether they believe their sex partners were treated. If retesting at 3 months is not possible, clinicians should retest the next time the patient(s) presents for medical care in the 12 months following initial treatment.
3. If Azithromycin is provided and the medication is vomited within thirty minutes of taking it, the dose may be repeated if medication is available. If medication not available, patient should seek medical attention evaluation.
4. A NAAT test should not be used less than 4 weeks following completion of treatment with Azithromycin due to possible false positive results.
5. Pregnant persons should be tested 3-4 weeks after completing therapy and rescreened near time of delivery.

CONSULTATION/REFERRAL

1. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

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Appendix A

Coaching Patients About Partner Notification

Patients may experience anger, embarrassment, fear, and discomfort when learning that they have an STI. This may be exacerbated when they realize they will need to disclose this information to partners so that their partners receive treatment. To help patients better understand the importance of partner notification and treatment, the following should be discussed:

- If the partner does not receive treatment, and they have sex again, there is a great likelihood that the patient will become re-infected.
- If people are not aware they have the infection and/or do not get treated, they can develop serious health complications.
- If a partner does not get treated, he/she can spread the infection to other partners, now or in the future.

Provide coaching on successful ways to initiate this difficult conversation. Whenever possible, offer patients the opportunity to talk through how to best approach their partners before leaving the exam room when the option of EPT has been decided.

There are additional key messages that should be conveyed to patients for their partner(s) when EPT is prescribed:

- Partners should read the informational material very carefully before taking the medication.
- Partners who have a known allergy to medications provided, have signs or symptoms of sexually transmitted infections (HIV, Syphilis, Gonorrhea, Chlamydia, etc.) or other contraindications (impaired hepatic function, severe renal disease (eGFR of less than 10mL/min), underlying myasthenia gravis, symptoms of more serious infection (see below)) should see their healthcare provider prior to taking the medication for additional assessment.
  Note: Adverse reaction to Azithromycin is rare.
- Partners should seek a complete STI evaluation as soon as possible, regardless of whether they take the medication.
- Partners who have symptoms of a more serious infection (e.g., pelvic pain in women, testicular pain in men, fever in women or men) should not take the EPT medications and should seek care as soon as possible.
- Partners who are or could be pregnant should seek care as soon as possible.
- Patients and partners should abstain from sex for at least seven days after treatment and until seven days after all partners have been treated, to decrease the risk of recurrent infection.
- Partners should be advised to seek clinical services for re-testing three months after treatment.

Appendix B Urgent and Private Important Information About Your Health

Directions For Sex Partners of Persons with Chlamydia
Please Read Very Carefully

Your sex partner has recently been treated for chlamydia. Chlamydia is a sexually transmitted infection (STI) that you can get from having any kind of sex (oral, vaginal, or anal) with a person who already has it. You may have been exposed but the good news is that it's easily treated. You are being given medication called azithromycin (also known as "Zithromax") or doxycycline to treat chlamydia.

The best way to take care of this infection is to see a health care provider or medical clinic provider right away. If it will not be possible to see a health care provider for several days, you should take the azithromycin provided. Even if you decide to take the medicine, it is very important to see a health care provider as soon as you can to get tested for other STIs. People can have more than one STI at the same time. The medication will not cure other sexually transmitted infections. Having STIs can increase your risk of getting HIV, so also get an HIV test.

SYMPTOMS

Some people with chlamydia have symptoms, but most do not. Symptoms may include pain in the testicles, pelvis, or lower part of your belly. You may also have pain when you urinate or when having sex. Many people with chlamydia do not know they are infected because they feel fine.

BEFORE TAKING THE MEDICINE

The medicine is very safe but DO NOT TAKE if any of the following are true:

- You are female have lower belly pain; pain during sex; vomiting; or fever.
- You are male and have pain or swelling in the testicles or fever.
- You have ever had a bad reaction, rash, breathing problems, or allergic reaction after taking azithromycin or other antibiotics. People who are allergic to some antibiotics may be allergic to other types. If you do have allergies to antibiotics, you should check with a health care provider or medical clinic before taking this medicine.
- You have a serious long-term illness, such as kidney, heart, or liver disease.
- If you are currently taking another prescription medication, including medicine for diabetes, consult your pharmacist before taking the medication to ask about drug interactions.
- If any of these circumstances exist, or if you are not sure, do not take the prescribed medication. Instead, you should talk to a health care provider or medical clinic as soon as possible so they can find the best treatment for you.

WARNINGS

- If you do not take medicine to cure chlamydia, you can get very sick. Women

who aren't treated might not be able to have children.

- If you are pregnant, seek medical evaluation before taking the medicines. Doxycycline should not be taken while pregnant.
- If you are breastfeeding please follow the guidance below:
  a. Azithromycin: Can be taken while breastfeeding but if infant is 2 weeks old or less, please consult infant's pediatrician before beginning medication.
  b. Doxycycline: If breastfeeding pump and discard breastmilk throughout treatment and for two days after treatment is completed. All breastmilk that is pumped should be discarded and not saved or provided to infant.

HOW TO TAKE THE MEDICINE

- Azithromycin can be taken without food but taking it with food decreases the chance of an upset stomach and increases the amount of medicine absorbed.
- Doxycycline can be taken with food or milk to reduce upset stomach. Drink at least 8 ounces of water with each dose and sit up for at least 30 minutes.
- You need to take all the pills according to the directions to be cured.
- If given Azithromycin do NOT take antacids that have magnesium or aluminum, such as Gaviscon, Milk of Magnesia, Mylanta, Rolaids, or Maalox, for one hour before or two hours after taking the azithromycin.
- Do NOT share or give this medication to anyone else.

SIDE EFFECTS

Possible side effects that are not serious include: slightly upset stomach, diarrhea, dizziness, and vaginal yeast infection.

ALLERGIC REACTIONS

Allergic reactions are rare. If you have ever had a bad reaction, rash, breathing problems or other allergic reactions with azithromycin or other antibiotics, consult a health care provider or pharmacy before taking.

Possible serious allergic reactions include:

- Difficulty breathing/tightness in the chest
- Closing of your throat
- Swelling of your lips or tongue
- Hives (bumps or welts on your skin that itch intensely)

NEXT STEPS

- After completing the medication, do not have sex (even with a condom) for the next seven days. It takes seven days for the medicine to cure chlamydia.
- If you have sex with or without a condom during those first seven days, if you are infected, you can still pass on the infection to your sex partners.
- If you have any other sex partners, tell them you are getting treated for chlamydia, so they can get tested and potentially treated too.
- People who are infected with chlamydia once are very likely to get it again.
- Get tested for chlamydia and other STIs 4 weeks from now and again in 3

months to be sure you did not get another infection.

Appendix C Urgent and Private Important Information About Your Health

Directions For Sex Partners of Persons with Gonorrhea
Please Read Very Carefully

Your sex partner has recently been treated for gonorrhea. Gonorrhea is a sexually transmitted infection (STI) that you can get from having any kind of sex (oral, vaginal, or anal) with a person who already has it. You may have been exposed but the good news is that it's easily treated. You are being given medications called Cefixime to treat gonorrhea.

The best way to take care of this infection is to see a health care provider or medical clinic provider right away. If it will not be possible to see a health care provider for several days, you should take the medications provided. Even if you decide to take the medicine, it is very important to see a health care provider as soon as you can to get tested for other STIs. People can have more than one STI at the same time. The provided medications will not cure other sexually transmitted infections. Having STIs can increase your risk of getting HIV, so also get an HIV test.

SYMPTOMS

Some people with gonorrhea have symptoms, but most do not. Symptoms may include a discharge from the infected site, sore throat, testicular pain or swelling, lower abdominal pain and/or swelling of the genital area. swollen penis, or labia. Many people with gonorrhea do not know they are infected because they feel fine.

BEFORE TAKING THE MEDICINE

The medicine is very safe but DO NOT TAKE if any of the following are true:

- You are female have lower belly pain; pain during sex; vomiting; or fever.
- You are male and have pain or swelling in the testicles or fever.
- You have ever had a bad reaction, rash, breathing problems, or allergic reaction after taking the prescribed medications or other antibiotics. People who are allergic to some antibiotics may be allergic to other types. If you do have allergies to antibiotics, you should check with a health care provider or medical clinic before taking this medicine.
- You have a serious long-term illness, such as kidney, heart, or liver disease.
- If you are currently taking another prescription medication, including medicine for diabetes, consult your pharmacist before taking the medication to ask about drug interactions.
- If any of these circumstances exist, or if you are not sure, do not take the prescribed medications. Instead, you should talk to a health care provider or medical clinic as soon as possible so they can find the best treatment for you.

WARNINGS

- If you do not take medicine to cure gonorrhea, you can get very sick. Women who aren't treated might not be able to have children.

- If you are pregnant, seek medical evaluation before taking the medicines.
- If you are breastfeeding and medication has been provided, please follow the guidance below:
  a. Cefixime: If breastfeeding, contact the health department for additional guidance or consult infant's pediatrician.

HOW TO TAKE THE MEDICINE

- You can take these pills without food but taking them with food decreases the likelihood of having an upset stomach and increases the medicine absorbed.
- You need to take all the pills you were given according to the directions to be cured.
- Do NOT share or give this medication to anyone else.

SIDE EFFECTS

Possible side effects that are not serious include: Dizziness, vaginal yeast infection, slightly upset stomach and diarrhea.

ALLERGIC REACTIONS

Allergic reactions are rare. If you have ever had a bad reaction, rash, breathing problems or other allergic reactions with the prescribed medications or other antibiotics, consult a health care provider or pharmacy before taking.

Possible serious allergic reactions include:

- Difficulty breathing/tightness in the chest
- Closing of your throat
- Swelling of your lips or tongue
- Hives (bumps or welts on your skin that itch intensely)

NEXT STEPS

- After taking the prescribed medications, do not have sex (even with a condom) for the next seven days. It takes seven days for the medicine to cure gonorrhea.
- If you have sex with or without a condom during those first seven days, if you are infected, you can still pass on the infection to your sex partners.
- If you have any other sex partners, tell them you are getting treated for chlamydia, so they can get tested and potentially treated too.
- People who are infected with gonorrhea once are very likely to get it again.
- Get tested for gonorrhea and other STIs 4 weeks from now and again in 3 months to be sure you did not get another infection.

STANDARD NURSE PROTOCOLS FOR BACTERIAL VAGINOSIS (BV)

DEFINITION

Bacterial vaginosis (BV) is an infection caused when too much of certain bacteria change the normal pH balance of bacteria in the vagina. The clinical result of replacement of the normal *Lactobacillus* species in the vagina with high concentrations of anaerobic bacteria. This polymicrobial clinical syndrome is the most prevalent cause of vaginal discharge or malodor. However, half of the women whose illnesses meet the clinical criteria for BV are asymptomatic. Though associated with having multiple sex partners (male or female), it is unclear whether BV results from acquisition of a sexually transmitted pathogen. In addition, BV is associated with having a new sex partner, douching, lack of condom use, and lack of vaginal lactobacilli; women who have never been sexually active are rarely affected. BV prevalence has been reported as increased in women with copper containing IUDs but not with hormonal contraception. Treatment of male sex partners has not been beneficial in preventing recurrences.

Women with BV are at an increased risk for the acquisition of some STIs (e.g., HIV, *N. gonorrhoeae*, C. trachomatis, and HSV- 2), complications after gynecologic surgery, and recurrence of BV. BV has been associated with adverse pregnancy outcomes including Chorioamnionitis, premature rupture of membranes, preterm labor, and preterm birth). Some specialists recommend screening pregnant persons at risk (e.g., those who have previously delivered a premature infant) for BV at the first prenatal visit.

ETIOLOGY

High concentrations of anaerobic bacteria (e.g., *Prevotella* species and *Mobiluncus* species), *Gardnerella vaginalis*, and *Mycoplasma hominis*, *Ureaplasma* species, and anaerobic bacteria and decrease in concentration of *Lactobacillus* species. Incubation period is unknown.

SUBJECTIVE

1. Frequently asymptomatic.
2. Off-white or gray vaginal discharge.
3. A strong, offensive, fish-like odor that is often most noticeable after intercourse and during menses.
4. Pain, itching, or burning in the vagina may occur.
5. Dysuria.

OBJECTIVE

1. Homogeneous, off-white, non-inflammatory discharge that smoothly coats the vaginal walls.
2. The pH of vaginal secretions is higher than 4.5.
3. A "fishy" odor from vaginal discharge, before or after mixing it with 10% KOH (positive "whiff" test).
4. "Clue cells" (epithelial cells with a granular appearance caused by adherent bacteria) on microscopic wet mount of vaginal discharge.

ASSESSMENT Bacterial Vaginosis

PLAN

The desired outcome of treatment includes relief of vaginal signs and symptoms of infection, reduction in the risk for acquiring CT, GC, Trichomoniasis, M. genitalium, HIV, HPV and HSV-2, reducing the risk for infectious complications after abortion or hysterectomy, and reducing the risk of acquiring a STI.

DIAGNOSTIC STUDIES

Amsel's Diagnostic Criteria (observation for classic discharge, clue cells, "whiff" test and vaginal pH). At least 3 of the following 4 are present (Amsel's Diagnostic Criteria):

a. Homogeneous, white, non-inflammatory discharge that smoothly coats the vaginal walls.
b. The pH of vaginal secretions is higher than 4.5 (collect from pooled vaginal secretions or against the lateral vaginal wall).
c. A "fishy" odor of vaginal discharge, before or after mixing it with 10% KOH (positive "whiff" test).
d. "Clue cells" (epithelial cells with a granular appearance caused by adherent bacteria) on microscopic wet mount of vaginal discharge.

NOTE: The Papanicolaou (Pap) smear is **not** reliable for diagnosis of BV. If BV is suggested, the patient should be asked about symptoms, and if symptomatic **recommend undergoing** standard diagnostic testing and treatment for BV.

NOTE: Any patients who test positive for recurrences of BV should be tested for gonorrhea, chlamydia, syphilis, and HIV.

THERAPEUTIC Treatment is only recommended for women with symptoms.

PHARMACOLOGIC

1. Recommended regimen for non-pregnant persons:
   a. Metronidazole 500 mg PO, every 12 hours for 7 days
      OR
   b. Metronidazole gel 0.75% one full applicator (5 g), intravaginally, once a day for 5 days

OR

c. Clindamycin cream 2% one full applicator (5 g) intravaginally at bedtime for 7 days,

OR

d. Clindamycin 300 mg PO every 12 hours for 7 days

OR

e. Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days

NOTE: Clindamycin cream is preferred in case of allergy or intolerance to metronidazole.

2. Alternative regimen for persons who are not pregnant:
   a. Secnidazole 2 g granules PO once

NOTE: Secnidazole oral granules should be sprinkled onto unsweetened applesauce, yogurt, or pudding before ingestion. A glass of water can be taken after administration to aid in swallowing. The mixture should be consumed within 30 minutes, and the granules should not be crunched or chewed.

3. Recommended regimen for pregnant persons in their 2nd or 3rd trimester of pregnancy only:
   a. Metronidazole 500 mg PO, every 12 hours for 7 days

   OR

   b. Clindamycin 300 mg PO twice daily for 7 days

   OR

   c. Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days

   OR

   d. Metronidazole gel 0.75% one full applicator (5 g) intravaginally, once a day for 5 days

   OR

   e. Clindamycin cream 2% one full applicator (5 g) intravaginally at bedtime for 7 days,

NOTE: Assess for possible pregnancy. Pregnant persons in their 1st trimester should be referred to their OB/GYN or OB provider for treatment for BV.

NOTE: Pregnant symptomatic persons in the 2nd and 3rd trimester of pregnancy can be treated with the same regimen as non-pregnant persons. While oral and vaginal treatments are options, some data indicate greater efficacy of oral metronidazole against upper tract infection compared with other options.

NOTE: Breastfeeding:

1. Metronidazole: Breastfeeding should be withheld and breastmilk should be pumped and discarded during treatment and for 24 hours after the last dose.

2. Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora. If Clindamycin is used while breastfeeding interruption of breastfeeding is recommended and pumping and discarding breastmilk during treatment.

3. Secnidazole: Breastfeeding should be withheld, and breastmilk should be pumped and discarded throughout treatment and 96 hours after completion of treatment.

NOTE: Persons with HIV should receive the same treatment regimen as those without HIV.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection https://www.cdc.gov/std/bv/stdfact-bacterial-vaginosis.htm).

3. Directions for taking medication and management of potential side effects.

4. The infection is generally not considered to be sexually transmitted, so sex partners should be referred for examination only if they are symptomatic of possible STI, otherwise no treatment is necessary for sex partners.

5. Immunity deficiencies may predispose patient to a higher risk of BV. Educate and counsel on healthy eating and nutrition intake (https://www.cdc.gov/nutrition/strategies-guidelines/nutrition-facts-label.html).

6. Educate and counsel of the correct usage of protective barriers (condoms, dental dams, etc.).

7. BV is associated with high recurrence placing women at higher risk of other STIs (e.g., *HIV, N. gonorrhoeae, C. trachomatis, and HSV- 2*).

8. Advise the patient to return to clinic for all lab results. Inform patient if lab results are positive additional treatment may be needed. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

9. Instruct patient to return for reevaluation if symptoms persist.

10. Assist patient in developing a personalized STI/HIV risk reduction plan

and document patient's plan. Abstain from sex until all the symptoms are resolved.

11. Abstain from sex for the duration of treatment and/or until all lab results are obtained.

12. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

13. Advise patient to return to clinic 7 days after completion of treatment if symptoms do not resolve.

14. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

15. HIV antibody test to determine HIV status, if unknown.

16. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

17. Refer to DPH Immunization Program Manual https://dph.georgia.gov/immunization-section/immunization-publications and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

FOLLOW-UP

Patient should return only if symptoms persist after treatment or recur. Use another treatment option regimen for recurrent disease.

CONSULTATION/REFERRAL

1. Consult delegating physician if:
   a. Patient would benefit from long term therapy for BV
   b. Further medical guidance is needed, and STI Standard Nurse Protocol is not applicable for therapeutic treatment of patient.

2. Refer to OB/GYN or OB provider if (three or more) recurrences within 6 months that do not respond to alternative treatment regimens. Suppressive therapy is recommended.

3. Refer pregnant persons in their 1st trimester to OB/GYN for treatment of BV.

4. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel. https://gets.sharepoint.com/sites/DPHIntranet/PHIL/FormsAndPolicies/GeneralCounselng%2

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STANDARD NURSE PROTOCOL FOR TRICHOMONIASIS

DEFINITION

Trichomoniasis is the most prevalent non-viral sexually transmitted infection in the United States. Trichomoniasis is a sexually transmitted infection of the urogenital tract, most commonly found in the urethra and vagina in women. Humans are the only natural host. Trichomoniasis is considered the most common curable STI.

Vaginal trichomonas has been associated with adverse pregnancy outcomes, particularly premature rupture of the membranes, preterm delivery, and low birthweight. High risk populations include those with multiple sex partners, those with a history of STIs, and those that exchange sex for payment and use injecting drugs**.** Douching is not recommended because it might increase the risk for vaginal trichomoniasis. Transmission through fomites among women who have sex with women is possible.

ETIOLOGY

Trichomonas vaginalis is a flagellated protozoan with an undulating membrane and flagella. The incubation period averages one week but ranges from 5 to 28 days.

SUBJECTIVE

1. Male symptoms may include:
   a. Itching and irritation inside the penis
   b. Dysuria or burning after ejaculation
   c. Penile discharge

2. Female symptoms may include:
   a. Itching, soreness and/or burning in vaginal area
   b. Dysuria
   c. Discharge with an offensive odor
   d. Discolored Discharge
   e. Vulvar irritation

OBJECTIVE

1. May be asymptomatic in both females and males. In males, may present as non-gonococcal urethritis (See Standard Nurse Protocol for non-gonococcal urethritis).

2. Females may present with:
   a. Profuse yellowish-green, malodorous, thin vaginal discharge.

b. Vulvar inflammation with edema or excoriations.
c. Cervix may have a granular appearance with punctate hemorrhages ("strawberry cervix").
d. Pruritus, dysuria, frequency, lower abdominal pain, or dyspareunia have been associated with discharge.

3. Males may present with:
   a. Clear or mucopurulent urethral discharge
   b. Dysuria
   c. Mild pruritus
   d. Urethritis, epididymitis, or prostatitis

ASSESSMENT Trichomoniasis

PLAN

The desired outcome of treatment is relief of symptoms, microbiologic cure, and reduction of transmission and potential infection with other STIs.

DIAGNOSTIC STUDIES (with or without objective findings)

1. Typical motile trichomonas seen on wet mount of vaginal discharge (Organisms remain motile for 10 to 20 minutes after collection of the sample. Read immediately due to sensitivity decreases quickly after collection.)
   OR
   Nucleic Acid Amplification Test (NAAT) (Cannot be collected on throat or rectal swabs). **The performance characteristics of the Aptima Trichomonas have not been evaluated in women 13 years of age and younger.**
   OR
2. Identification of *T. vaginalis* on culture
   OR
3. FDA cleared Point of Care (POC) rapid test (Osom)

NOTE: The pH of vaginal secretions is higher than 4.5 (collect from pooled vaginal secretions or against the lateral vaginal wall).

NOTE: The Papanicolaou (Pap) smear is **not** reliable for diagnosis of Trichomonas. If Trichomonas is suggested, the patient should be asked about symptoms, and if symptomatic recommend undergoing standard diagnostic testing and treatment for Trichomonas.

NOTE: Males who have been circumcised might have a somewhat reduced risk of trichomoniasis.

NOTE: When using a wet mount, slides should be evaluated immediately

because the sensitivity declines as evaluation is delayed.

THERAPEUTIC

NOTE: Any patients who test positive for trichomoniasis should be tested for gonorrhea, chlamydia, syphilis, and HIV.

NOTE: Untreated infections might last for months to years with associated two to threefold increased risk for HIV acquisition.

PHARMACOLOGIC

NOTE: Assess for possible pregnancy. Pregnant persons in their 1st trimester should be referred to their OB/GYN or OB provider for treatment for BV.

1. For 2nd and 3rd trimester pregnant and non-pregnant:
   a. Metronidazole 500 mg orally every 12 hours for 7 days.

2. For 2nd and 3rd trimester pregnant and non-pregnant persons if compliance with 7-day regimen is a concern:
   a. Metronidazole 2 g PO in a single dose.

3. Alternative regimen for non-pregnant:
   a. Tinidazole 2 g PO in a single dose.

4. Recommended treatment for persons with HIV:
   a. Metronidazole 500 mg PO every 12 hours for 7 days.

5. For male positive cases:
   a. Metronidazole 2 g orally in a single dose

NOTE: Sexual contacts who are in the first trimester of pregnancy should contact their prenatal care provider for treatment and follow-up.

Breastfeeding:
1. Metronidazole: Breastfeeding should be withheld, and breastmilk should be pumped and discarded during treatment and for 24 hours after the last dose.
2. Tinidazole: Breastfeeding should be withheld, and breastmilk should be pumped and discarded during treatment and for 3 days after the last dose.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection

(https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm).

3. Directions for taking medication and management of potential side effects.

4. Concurrent treatment of all sex partners is vital for preventing reinfections. Current partners should be referred for presumptive therapy. Partners also should be advised to abstain from intercourse until they and their sex partners have been treated and any symptoms have resolved. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

5. After single-dose therapy of sexual contacts, patients should abstain from intercourse until **all** partners have waited at least seven days since taking the last antibiotic dose.

6. Routine annual screening for Trichomoniasis in asymptomatic women with HIV is recommended.

7. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

8. Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

9. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

10. Counsel about high risk of reinfection if patient's partner(s) is/are not tested and treated. The use of protective barriers) (condoms, diaphragm, etc.) with any untreated partner(s) are not protective during sexual intercourse. Provide education and counseling on the correct usage of protective barriers if using or plan to use

11. If person of childbearing potential counsel on the use of contraceptives to reduce the risk of unintended pregnancy.

12. Advise patient to return to clinic 7 days after completion of treatment if symptoms do not resolve.

13. Inform patient if additional lab(s) is/are positive, partner(s) will need treatment.

14. HIV antibody test to determine HIV status, if unknown.

15. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

16. Refer to DPH Immunization Program Manual **https://dph.georgia.gov/immunization-section/immunization-publications** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. Current partners should be referred for presumptive therapy. Partners also should be advised to abstain from intercourse until they and their sex partners have been treated and any symptoms have resolved. Provide patient with written note(s) to give to partner(s) to refer them to HD for examination and treatment.
2. All identified sex partners should be examined and promptly treated in accordance with treatment guidance listed above.

FOLLOW-UP

1. Patient should return if symptoms persist after treatment or recur. If infection or reinfection is confirmed, re-treat with the 7-day regimen of metronidazole.
2. Because of the high rate of reinfection among women treated for trichomoniasis, retesting is recommended for all sexually active women 2 weeks to 3 months after initial treatment. If retesting at 3 months is not possible, retesting should be done whenever persons next seek medical care within 12 months after initial treatment. Data are insufficient to support retesting men after treatment.

CONSULTATION/REFERRAL

1. Consult with delegating physician if:
   a. Patient is allergic to nitroimidazoles for desensitization referral.
   b. Repeated treatment failure. Assure that partner(s) have been treated.
   c. Further medical guidance is needed, and STI Standard Nurse Protocol is not applicable to treat patient.

2. Refer pregnant persons in first trimester to their prenatal care provider.

3. Antimicrobial resistance occurs in 4%-10% of vaginal trichomoniasis cases. If resistance is suspected after adequate treatment with recommended regimen or alternative regimen and reinfection is excluded susceptibility testing should be done. Contact CDC at https://www.cdc.gov/laboratory/specimen-submission/detail.html?CDCTestCode=CDC-10239 for testing (if available).

4. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel. https://gets.sharepoint.com/sites/DPHIntranet/PHIL/FormsAndPolicies/GeneralCounsel/GC-09014%20Mandatory%20Reporting%20of%20Suspected%20Child%20Abuse.pdf

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STANDARD NURSE PROTOCOL FOR UNCOMPLICATED VULVOVAGINAL CANDIDIASIS (VVC) (Yeast infection)

DEFINITION

Uncomplicated vulvovaginal candidiasis (VVC) is a common infection (yeast infection) that may occasionally also cause cutaneous penile lesions in male sex partners (e.g. *Candidal* balanitis), but is not always considered to be an STI. An estimated 75% of women will experience at least one episode of VVC during their lifetime, and 40%-45% will have two or more episodes. In contrast to oropharyngeal candidiasis, it is generally not considered an opportunistic infection. It is seldom a cause of symptoms in postmenopausal women, unless taking hormone replacement therapy, or prepubertal girls. Vulvovaginal candidiasis is not considered a sexually transmitted disease.

ETIOLOGY

Most infections are caused by *Candida albicans* which grows as oval budding yeast cells**,** hyphae**,** and pseudohyphae and thrives best when the vaginal pH is 4.5 to 5. Other *Candida* species or yeasts may occasionally cause similar symptoms. The incubation period is unknown.

SUBJECTIVE

1. Vulvovaginal itching.
2. Thick, curdy vaginal discharge.
3. May have vaginal soreness, pain with intercourse, vulvar burning and external dysuria.
4. Redness and swelling of the vulva sometimes with splits or fissures**.**

OBJECTIVE

NOTE: Many women are asymptomatic. Symptoms are caused by overgrowth of normally occurring yeast forms. Contributing factors, which disrupt the normally protective vaginal flora include medications, diabetes, HIV, pregnancy, and other immuno-suppressive conditions.

1. Pruritis, vulvar edema, fissures, excoriations and erythema in the vulvovaginal area. A thick white, cottage cheese like vaginal discharge may be present.
2. Identification of typical budding yeast, hyphae, or pseudohyphae on microscopic exam of vaginal discharge, by saline or adding 10% KOH solution to wet mount.
3. Vaginal pH less than 4.5.

ASSESSMENT Vulvovaginal Candidiasis (VVC)

PLAN

The desired outcome of treatment is the relief of symptoms, microbiologic cure, and reduction of transmission and potential infection with STIs**.**

DIAGNOSTIC STUDIES

1. Wet preparation (10% KOH, saline)
   a. Pruritis and erythema in the vulvovaginal area. A thick white, cottage cheese like vaginal discharge may be present.
   And
   b. Identification of typical budding yeast, hyphae, or pseudohyphae on microscopic exam of vaginal discharge, by saline or adding 10% KOH solution to wet mount.
   And/or
   c. Vaginal pH less than 4.5

   NOTE: The Papanicolaou (Pap) smear is not reliable for diagnosis of vulvovaginal candidiasis. If vulvovaginal candidiasis is suggested, the patient should be asked about symptoms, and if symptomatic recommend undergoing standard diagnostic testing and treatment for vulvovaginal candidiasis.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Vulvovaginal candidiasis is an important concern for persons with HIV. The colonization rates of candida have shown to be higher than persons without HIV although the relationship of vulvovaginal candidiasis to HIV remains unclear. Therapy for uncomplicated and complicated VVC in persons with HIV infection should not differ from that for persons without HIV.

NOTE: Oral medications take a day or two longer than topical therapy to relieve symptoms.

1. Intravaginal agents (*Available without a prescription)
   a. Non-pregnant persons:

      1) Butoconazole 2% cream 5 g, one applicatorful intravaginally for 3 days,
      OR
      2) Clotrimazole* 1% cream 5 g, one applicatorful intravaginally for 7-14 days,
      OR
      3) Miconazole* 100 mg vaginal suppository, one suppository for 7 days,

OR

4) Miconazole 200 mg vaginal suppository, one suppository for 3 days,

OR

5) Miconazole* 2% cream 5 g, one applicatorful intravaginally for 7 days,

OR

6) Tioconazole* 6.5% ointment 5 g intravaginally in a single application,

OR

7) Terconazole 0.4% cream 5 g, one applicatorful intravaginally for 7 days,

OR

8) Terconazole 80 mg vaginal suppository, one suppository for 3 day,

OR

9) Terconazole 0.8% cream 5 g, one applicatorful, intravaginally for 3 days.

OR

2. Oral agent for non-pregnant persons:
   a. Fluconazole (Diflucan) 150 mg PO once.

NOTE: Persons with HIV should receive the same treatment regimen as persons without HIV.

NON-PHARMACOLOGIC

1. Keep irritated vulvovaginal area as clean and dry as possible. Patting the vulva dry with a soft towel, instead of rubbing.
2. "Sitz baths" as directed for vulva irritation. Do not add soap, bubble bath, or anything else to the water. Using only water and unscented non-soap cleanser to wash your vulva.
3. Wearing cotton underwear and avoiding underwear or pants that are too tight.
4. Do not use sprays or powders on the vulva.
5. Do not douche or put liquid inside the vagina to rinse it out.
6. Do not wipe with baby wipes or scented toilet paper after using the toilet.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of untreated infection: **http://www.cdc.gov/fungal/diseases/candidiasis/genital/index.html**

3. Directions for taking medication and management of potential side effects.

4. Although many preparations of intravaginal agents are available without a prescription, self-medication is advised only if persons previously diagnosed with VVC experience a recurrence of the same symptoms.

5. Butoconazole and clotrimazole cream, tioconazole ointment, and miconazole creams and suppositories are oil-based and may weaken latex condoms and diaphragms, therefore other methods of contraception should be used.

6. If taking fluconazole (Diflucan), noticeable improvement in symptoms may not occur for a few days. Even with a single dose, nausea, vomiting, diarrhea, abdominal pain and headache may occur.

7. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

8. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

9. Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan. Abstain from sex until all the symptoms are resolved.

10. Abstain from sex for the duration of treatment and/or until all lab results are obtained.

11. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit.

12. Inform patient if lab results are positive additional treatment may be needed.

13. HIV antibody test to determine HIV status, if unknown.

14. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728 http://www.ashasexualhealth.org/stdsstis/herpes

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

15. Refer to DPH Immunization Program Manual https://dph.georgia.gov/document/document/immunizationcompleteprogrammanualrev112719pdf/download and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. No routine exam and/or treatment is necessary but may be considered in females with recurrent infections. A minority of male sex partners who have balanitis, characterized by erythematous areas on the glans of the penis in conjunction with pruritus or irritation, can benefit from treatment with over-the-counter topical antifungal agents to relieve symptoms.

FOLLOW-UP

Only if symptoms persist or recur after treatment.

CONSULTATION/REFERRAL

1. Consult delegating physician for referral of patients with frequent recurrent episodes not responding to usual therapy. Women who experience **3** or more episodes of VVC within a year are described as having Recurrent Vulvovaginal Candidiasis (RVVC). Risk factors include uncontrolled diabetes mellitus, immunosuppression, and corticosteroid use most women who have RVVC have no apparent predisposing conditions. HIV status of the patient, if known needs to be provided to the consulting delegating physician.

2. If pregnant refer to OB/GYN or OB provider for treatment.

3. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel. https://gets.sharepoint.com/sites/DPHIntranet/PHIL/FormsAndPolicies/GeneralCounsel/GC-09014%20Mandatory%20Reporting%20of%20Suspected%20Child%20Abuse.pdf

4. Consult delegating physician when further medical guidance is needed, and STI Standard Nurse Protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR PELVIC INFLAMMATORY DISEASE (PID)

DEFINITION

Pelvic inflammatory disease (PID) is a polymicrobial infection of female reproductive organs and a complication caused by cervical microorganisms (including Chlamydia trachomatis and Neisseria gonorrhoeae, and potentially Mycoplasma genitalium), as well as the vaginal microflora, including anaerobic organisms, enteric gram-negative rods, streptococci, genital mycoplasmas, and Gardnerella vaginalis, which is associated with bacterial vaginosis. The clinical syndrome is due to the ascending spread of microorganisms from the vagina and endocervix to the endometrium, the fallopian tubes or to contiguous structures.

If untreated, acute infections may result in peritonitis caused by rupture of a tubo-ovarian abscess and acute or subclinical infections may result in chronic pain, pelvic adhesions, involuntary infertility, or ectopic pregnancy.

The intensity of symptoms may vary widely from mild to acute. Many episodes of PID go unrecognized. Although some women may have asymptomatic PID, many have mild or non-specific symptoms or signs such as abnormal bleeding, dyspareunia or vaginal discharge. Experts recommend that providers maintain a low threshold of diagnosis for PID and recognize when PID should be suspected.

ETIOLOGY

Sexually transmitted organisms, especially *Neisseria gonorrhoeae* and *Chlamydia trachomatis* are implicated in cases of PID. However, organisms not usually associated with sexual transmission, such as anaerobes G. vaginalis, Haemophilus influenzae, enteric Gram-negative rods, and Streptococcus agalactiae, U. urealyticum, and M. genitalium might be associated with some PID cases. The incubation period for PID is undefined.

SUBJECTIVE

1. Mild to moderate lower abdominal pain or tenderness.
2. Vaginal discharge with or without a bad odor.
3. Dyspareunia and/or bleeding after sex.
4. Fever and chills.
5. Anorexia.
6. Nausea.
7. Bleeding between periods**.**
8. May have a history of previous PID, recent insertion of an IUD, or onset of symptoms during the first 5-10 days of the menstrual cycle.

OBJECTIVE

The following criteria are used to diagnose pelvic inflammatory disease:

1. A high index of suspicion must be kept in sexually active females. Minimum criteria to institute empiric treatment is cervical motion tenderness and/or uterine/adnexal tenderness.

2. Additional criteria that support a diagnosis of PID include:
   a. Abnormal cervical or vaginal mucopurulent discharge.
   b. Presence of white blood cells (WBCs) on saline microscopy of vaginal secretions.
   c. Laboratory documentation of cervical infection with *N. gonorrhoeae* or *C. trachomatis.*
   d. Oral temperature may be 101° F (38.3° C) or higher.
   e. Wet prep of vaginal fluid to detect presence of concomitant infection (e.g., BV and Trichomonas).

   NOTE: If the cervical discharge appears normal and no white blood cells are found on the wet prep, the diagnosis of PID is unlikely and an alternative diagnosis needs to be considered.

ASSESSMENT Pelvic Inflammatory Disease

PLAN

The desired outcome of treatment is to demonstrate substantial clinical improvement within 3 days after initiation of therapy, with subsequent resolution of all signs and symptoms, prevention of formation of scar tissue both outside and inside the fallopian tubes that can lead to tubal blockage, ectopic pregnancy, infertility and long-term pelvic/abdominal pain.

DIAGNOSTIC STUDIES

1. Tests for gonorrhea and chlamydia.
2. Pelvic examination for cervical motion tenderness (chandelier sign), uterine tenderness, or adnexal tenderness; also, evaluate for cervical exudates or cervical friability.
3. Wet Preparation (saline, 10% KOH).
4. Pregnancy test if there is a possibility that patient may be pregnant (see Consultation/Referral section for more information).

NOTE: Any patients who test positive for gonorrhea or chlamydia should be tested for syphilis and HIV.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Persons with HIV infection responded equally well to recommended parenteral and IM/oral antibiotic regimens as women without HIV infection.

NOTE : Unstable persons need immediate attention and should be transported via EMS to the nearest emergency department for assessment and possible admission for parenteral treatment.

1. Recommended treatment for non-pregnant persons:
   a. If weighing less than 150 kg/330 lbs OR children weighing greater than or at least 45 kg/ 99lbs: Ceftriaxone 500 mg IM in a single dose

      If weighing more than or equal to 150 kg/ 330lbs: Ceftriaxone 1 g IM single dose is recommended

      PLUS

      Doxycycline 100 mg PO every 12 hours for 14 days (8 years of age and older)

      PLUS

      Metronidazole 500 mg PO every 12 hours for 14 days

      OR

   b. Cefoxitin 2 g IM in a single dose

      PLUS

      Probenecid 1 g PO in a single dose

      PLUS

      Doxycycline 100 mg PO every 12 hours for 14 days

      PLUS

      Metronidazole 500 mg PO every 12 hours for 14 days

2. Alternative treatment for non-pregnant persons:
   1) If weighing less than 150 kg/ 330 lbs OR children weighing greater than or at least 45 kg/ 99 lbs: Ceftriaxone 500 mg IM in a single dose

      If weighing more than or equal to 150 kg/ 330 lbs Ceftriaxone 1g IM single dose is recommended

      PLUS

      Doxycycline 100 mg PO every 12 hours for 14 days

      PLUS

      Metronidazole 500 mg PO every 12 hours for 14 days

      OR

   If cephalosporin or doxycycline allergy AND community prevalence and risk for gonorrhea are low, alternative treatment for non-pregnant persons:
   a. Levofloxacin 500 mg PO daily for 14 days

PLUS

b. Metronidazole 500 mg PO every 12 hours for 14 days.

NOTE: Breastfeeding:

1. Doxycycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Metronidazole: Breastfeeding should be withheld and breastmilk should be pumped and discarded during treatment and for 24 hours after the last dose.

3. Levofloxacin: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

NOTE: Pregnant persons suspected of having PID are at high risk for maternal morbidity and preterm delivery. These persons should be hospitalized and treated with IV antimicrobials in consultation with an infectious disease specialist.

NOTE: Doxycycline should not be given to less than 8 years of age.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection (**https://www.cdc.gov/std/pid/stdfact-pid.htm**).

3. Directions for taking medication and what to do about potential side effects.

4. Return appointment for evaluation in 2-3 days.

5. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

6. Counsel to avoid sex with untreated partners.

7. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

8. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

9. If patient is of childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

10. Instruct patient to go to Emergency Room/Urgent Care if symptoms worsen.

11. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

12. HIV antibody test to determine HIV status, if unknown.

13. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

14. Refer to DPH Immunization Program Manual https://dph.georgia.gov/document/document/immunizationcompleteprogrammanualrev112719pdf/download and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

All sex partners from 60 days prior to the onset of symptoms or diagnosis should be examined for STIs and promptly treated with a regimen effective against both gonorrhea and chlamydia, regardless of symptoms or Gram stain or other test results. Male sex partners of females with PID caused by chlamydia or gonorrhea often are asymptomatic. Avoid sex with partner(s) until partner(s) has/have been

treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

FOLLOW-UP

1. Evaluation, by bimanual examination, within 48-72 hours after initiation of therapy for symptomatic improvement. Also, discuss medication compliance and stress importance of completing therapy.
2. Provide additional rescreening and repeat examination for patients diagnosed with gonorrhea and chlamydia at 3-12 months after completing PID therapy.

CONSULTATION/REFERRAL

1. Treatment must be initiated as soon as possible. If a referral is made to an APRN or physician to confirm the diagnosis, begin treatment before the referral is made, unless the APRN or physician is on-site and can see the patient immediately**.**

2. Consult with delegating physician immediately, for possible hospitalization and/or parenteral treatment when:

    a. Surgical emergencies such as appendicitis cannot be excluded.
    b. Tubo-ovarian abscess.
    c. The patient is pregnant.
    d. The patient has failed to respond clinically to oral therapy.
    e. The patient is unable to follow or tolerate an outpatient oral regimen.
    f. The patient has signs of a severe illness, nausea and vomiting, or a high fever.

3. If a patient with an IUD does not respond to treatment with clinical improvement within 48-72 hours of initiating treatment consult with delegating physician for possible IUD removal and contraceptive counseling.

4. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel. https://gets.sharepoint.com/sites/DPHIntranet/PHIL/FormsAndPolicies/GeneralCounsel/GC-09014%20Mandatory%20Reporting%20of%20Suspected%20Child%20Abuse.pdf

5. Chlamydia and/or gonorrhea infected women (nonpregnant or pregnant) and

men are recommended to be retested approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated. If retesting at 3 months is not possible, clinicians should retest the next time the patient(s) presents for medical care in the 12 months following initial treatment.

6. Consult delegating physician when further medical guidance is needed, and STI nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR EPIDIDYMITIS, SEXUALLY TRANSMITTED

DEFINITION

Epididymitis is a clinical syndrome characterized by inflammation of the epididymis causing pain and tenderness that lasts less than 6 weeks, associated with urethritis that may be asymptomatic, usually occurring in younger men. Epididymitis occurring in older men is usually nonsexual and may be associated with urinary tract infections, systemic disease and immunosuppression. In addition, in older men, non-sexually transmitted acute epididymitis is also associated with prostate biopsy, urinary tract instrumentation or surgery, systemic disease, and/or immunosuppression.

ETIOLOGY

Common causes are *Chlamydia trachomatis* or *Neisseria gonorrhoeae*, *Escherichia coli* and *Pseudomonas spp.* Mycobacterium tuberculosis (TB) can cause epididymitis. Other bacteria (such as Ureaplasma) may also cause the condition. Medication induced or autoimmune disease epididymitis is possible. Infection can occur in males who are the insertive partners during anal intercourse. Sexually transmitted acute epididymitis usually is accompanied by urethritis, which frequently is asymptomatic.

SUBJECTIVE

1. Scrotal pain, tenderness and swelling, usually unilateral.
2. May have dysuria and/or urethral discharge.
3. No history of trauma to the area.

OBJECTIVE

1. Scrotal tenderness and swelling observed during assessment. Inability to differentiate epididymis from testicle during palpation (see consultation and referral section).
2. Gram-stain smear is positive for urethritis (e.g., smear contains 2 or more polymorphonuclear leukocytes per oil immersion field). The smear may or may not be positive for *Neisseria gonorrhoeae.*
3. Microscope examination of first-void urine sediment demonstrating 10 or more polymorphonuclear leukocytes per high power field,
4. Positive leukocyte esterase test on first-void urine.

ASSESSMENT Epididymitis

PLAN

The desired outcomes of treatment are microbiologic cure, alleviation of signs and symptoms, prevention of transmission of infection to others, and prevention of potential complications (e.g., infertility or chronic pain).

DIAGNOSTIC STUDIES

1. Scrotal tenderness and swelling observed during assessment. Inability to differentiate epididymis from testicle during palpation (see referral).

And

2. Gram-stain smear is positive for urethritis (e.g., smear contains 2 or more polymorphonuclear leukocytes per oil immersion field). The smear may or may not be positive for Neisseria gonorrhoeae.

OR

3. Microscope examination of first-void urine sediment demonstrating 10 or more polymorphonuclear leukocytes per high power field,

OR

4. Positive leukocyte esterase test on first-void urine.

5. Laboratory tests for gonorrhea and chlamydia, Nucleic Acid hybridization tests and/or gonorrhea culture.

6. Cremasteric reflex (lightly stroking the superior and medial part of the thigh to make the cremaster muscle contract and pull up the ipsilateral testis) should be assessed. A positive cremasteric reflex most likely indicative of a diagnosis of epididymitis.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Any persons who test positive for gonorrhea or chlamydia should be tested for syphilis and HIV.

NOTE: Persons with HIV who have uncomplicated acute epididymitis should receive the same treatment regimen as those without HIV. Other causes have also been identified in persons with HIV including salmonella, toxoplasmosis, U. *urealyticum*, Corynebacterium sp., Mycoplasma sp., and Mima *polymorpha.*

1. Recommended treatment if epididymitis is most likely due to gonococcal or chlamydial infection:

For persons weighing less than 150 kg/ 330 lbs:

a. Ceftriaxone 500 mg IM, single

PLUS

b. Doxycycline 100 mg PO every 12 hours for 10 days.

OR

For persons weighing more than or equal to 150 kg/ 330 lbs:

a. Ceftriaxone 1g IM, single dose

PLUS

b. Doxycycline 100 mg PO every 12 hours for 10 days, (if patient is 8 years of age or older).

NOTE: PCN allergy algorithm should be completed on all patients who self-report penicillin allergy. If a true PCN allergy is identified refer to allergist for desensitization with subsequent treatment.
NOTE: Do not give Doxycycline to minors under the age of 8.

2. Recommended treatment if epididymitis is if most likely due to gonococcal, or chlamydial infection or/and enteric organisms (men who practice insertive anal sex):

For persons weighing less than 150 kg/ 330 lbs:

a. Ceftriaxone 500 mg IM, single

PLUS

b. Levofloxacin 500 mg PO once daily for 10 days, if patient is aged 18 years and over

OR

For persons weighing more than or equal to 150 kg/ 330 lbs:

a. Ceftriaxone 1g IM, single dose

PLUS

b. Levofloxacin 500 mg PO once daily for 10 days, if patient is aged 18 years and over

3. If most likely due to enteric organisms (men who practice insertive anal sex) or with negative gonococcal culture or nucleic acid amplification test:
   a. Levofloxacin 500 mg PO once daily for 10 days, if patient is aged 18 years and over

NON-PHARMACOLOGIC MEASURES

1. Recommend bed rest, scrotal elevation, and underwear support to relieve swelling and pain.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for

sequelae and complications of the untreated infection **https://www.mayoclinic.org/diseases-conditions/epididymitis/symptoms-causes/syc-20363853**.

3. Directions for taking medication and potential side effects and what to do about them.

4. Counsel patient about comfort measures (e.g. over-the-counter oral analgesics for pain, bed rest, scrotal elevation and support to relieve swelling and pain).

5. Advise patient to seek emergency medical care promptly if symptoms do not improve or worsen. Patient's symptoms should start improving within 48 hours of the initiation of treatment.

6. If infection with gonorrhea and/or chlamydia is known or suspected, refer sex partners for examination and treatment. Avoid sex until treatment is completed, and patient and partner(s) no longer have symptoms.

7. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

8. If suspect that epididymitis is medication induced or possible mycobacterium tuberculosis consult with delegating physician.

9. Education and counseling on the correct usage of protective barriers (condoms, dental dams, etc.).

10. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

11. Emphasize patient follow up in 3 days for re-evaluation (if date of follow up falls on a weekend, have patient return for re-evaluation the next open clinic day).

12. Emphasize the importance for patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive and additional treatment will be needed.

13. If additional laboratory tests are positive for STI (e.g., gonorrhea), partners also need treatment.

14. HIV antibody test to determine HIV status, if unknown.

15. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

16. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

If gonorrhea and/or chlamydial infection is known, or suspected, in the index patient, all sex partners from 60 days prior to the onset of symptoms or diagnosis should be examined and receive appropriate treatment for gonorrhea and chlamydia.

FOLLOW-UP

Re-evaluate patient for improvement of symptoms in 2-3 days. Failure to improve means the diagnosis and therapy should be reevaluated and hospitalization may be necessary.

CONSULTATION/REFERRAL

1. Immediately consult the delegating physician if unable to perform the necessary diagnostic testing or patient cannot be treated with recommended drugs.

2. Refer immediately for emergency evaluation if testicular torsion or scrotal trauma is suspected.

3. If the diagnosis is questionable refer to a urologist. If the patient has intense pain, refer immediately for emergency evaluation even when urethritis is documented by gram stain.

4. If patient shows no improvement of signs/symptoms in 3 days refer to a urologist or primary care physician.

5. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report

suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the **Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.**

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STANDARD NURSE PROTOCOL FOR CERVICITIS

DEFINITION

Cervicitis is a clinical syndrome characterized by yellow or green mucopurulent exudate visible in the endocervical canal or an endocervical swab specimen and/or easily induced endocervical bleeding.

ETIOLOGY

Chlamydia trachomatis and *Neisseria gonorrhoeae* may cause cervicitis, but can also be due to trichomoniasis, genital herpes, *M. genitalium* or Bacterial Vaginitis. In most cases, neither organism can be isolated. In some cases, the condition persists despite repeated courses of antimicrobial therapy; therefore, alternative diagnoses should be considered.

SUBJECTIVE

1. Frequently asymptomatic.
2. Discharge from the vagina.
3. Abnormal vaginal bleeding (e.g., after intercourse).
4. Dysuria, urinary frequency
5. Dyspareunia
6. Vulvovaginal irritation

OBJECTIVE

1. Presence of a purulent or mucopurulent exudate visible in the endocervical canal or in an endocervical swab specimen (positive swab test).
   AND/OR
2. Easily induced bleeding occurs with insertion of the first endocervical swab (cervical friability).

ASSESSMENT Cervicitis

PLAN

The desired outcomes of treatment are microbiologic cure, alleviation of signs and symptoms, prevention of transmission of infection to others, and treatment of sex partners.

DIAGNOSTIC STUDIES

1. Gonorrhea, chlamydia, and trichomoniasis tests.
   OR
   Gonorrhea and chlamydia tests

2. Presence of a purulent or mucopurulent exudate visible in the endocervical canal or an endocervical swab specimen (positive swab test).

   AND/OR

   Easily induced bleeding occurs with insertion of the first endocervical swab (cervical friability).

3. Wet Preparation (saline, 10%KOH).

THERAPEUTIC

NOTE: Any patients who test positive for gonorrhea or chlamydia should be tested for syphilis and HIV.

NOTE: Persons with HIV that have cervicitis should receive the same treatment regimen as persons without HIV. Cervicitis increases cervical HIV shedding and treatment in persons with HIV reduces HIV shedding from the cervix and might reduce HIV transmission to susceptible sex partners.

1. The results of the chlamydia and gonorrhea tests should be used to determine the need for treatment unless the patient is unlikely to be located for treatment when test results are available.
2. If the patient is unlikely to be located for treatment when the test results are available, empiric treatment to cover gonorrhea and/or chlamydia may be given. See gonorrhea and chlamydia protocols for treatment choices.
3. BV, candidiasis, or trichomoniasis should be treated if diagnosed.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection **(https://medlineplus.gov/ency/article/001495.htm).**

3. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

4. Directions for taking medication and what to do about potential side effects.

5. Encourage self-referral of recent sex partner(s) for examination and possible treatment. Avoid sex until partner(s) has been treated.

6. Abstain from sex for 7 days after therapy is started and/or until all lab results are obtained.

7. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved and partner(s) are tested and treated.

8. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

9. If patient is of childbearing potential counsel on the use of contraceptives to reduce the risk of unintended pregnancy. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

10. HIV antibody test to determine HIV status, if unknown.

11. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

12. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

13. Advise patient to return to clinic in 7 days or less if symptoms do not resolve.

14. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

15. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

MANAGEMENT OF SEX PARTNERS

1. Self-referred sex partner(s) should be screened, examined, and treated based on their results or the test results of the index patient.
2. Partners of females who are treated for cervicitis before test results are available should be screened, examined, and receive treatment for the same suspected infection(s) as the female partner.
3. Provide patient with written note(s) to give to partner(s) to refer them to health department for examination and treatment.

FOLLOW-UP

1. If symptoms persist, patients should return for re-evaluation. However, after the possibilities of relapse and reinfection have been excluded, management of persistent cervicitis is unclear.
2. If the chlamydia or gonorrhea test is positive, it is recommended to retest patient approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated. If retesting at 3 months is not possible, clinicians should retest whenever patient next present for medical care in the 12 months following initial treatment.

CONSULTATION/REFERRAL

1. Consult with or refer to primary care provider for additional evaluation if symptoms persist after relapse and reinfection have been excluded.

2. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

3. Consult delegating physician when further medical guidance is needed, and STI Standard Nurse Protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR URETHRITIS/NONGONOCOCCAL URETHRITIS (NGU)

DEFINITION

Urethritis, as characterized by urethral inflammation, can result from infectious and noninfectious conditions. Non-gonococcal urethritis (NGU) is a sexually transmitted clinical syndrome in men, usually characterized by a mucoid-to-purulent urethral discharge and often accompanied by dysuria or urethral itching. NGU is diagnosed if urethritis is present and Gram-negative intracellular organisms cannot be identified on Gram stains. May progress to epididymitis, prostatitis or reactive arthritis if untreated.

ETIOLOGY

Chlamydia trachomatis causes 15%- 40% of cases, with lower prevalence occurring in older men. The etiology of many cases of nonchlamydial NGU is unknown. *Ureaplasma urealyticum* and possibly *Mycoplasma genitalium* are implicated in as many as 15%-25% of NGU cases. Trichomonas vaginalis and *herpes simplex virus* occasionally cause NGU. NGU can be acquired by fellatio, sometimes because of specific pathogens such as HSV, Epstein Barr Virus, and adenovirus. Incubation is variable due to the underlying cause.

SUBJECTIVE

1. Urethral discharge, especially in the morning.
2. Itching or burning of the urethra.

OBJECTIVE

1. Mucopurulent or purulent discharge.
2. Gram stain of urethral secretions demonstrating 2 or more WBC per oil immersion field.
3. Positive leukocyte esterase (dipstick) test in a first morning void urine or sediment demonstrating 10 or greater WBC per high power field.
4. When available a Gram stain that is negative for Gram-negative intracellular diplococci.

ASSESSMENT Urethritis/Nongonococcal Urethritis (NGU)

PLAN

The desired outcome of treatment is alleviation of symptoms and microbiologic cure of infection.

DIAGNOSTIC STUDIES

1. Gonorrhea and Chlamydia tests.

2. Documentation of urethritis by:
   a. Mucopurulent or purulent discharge,
      OR
   b. Gram stain of urethral secretions demonstrating 2 or more WBCs per oil immersion field.
      OR
   c. Positive leukocyte esterase test in a first morning void urine sediment demonstrating 10 or more WBCs per high power field.
      And/OR
   d. Gram stain for Gram-negative intracellular diplococci, when available

NOTE: If gram stain urethral secretion specimens have less than 5 WBCs per HPF and patient urinated within 2 hours prior to specimen collection, collect another sample 2 hours after void and/or prior to next void.

NOTE: If the criteria for urethritis are not present, treatment should be deferred pending the results of the diagnostic studies. Empiric treatment of symptoms without documentation of urethritis is recommended only for patients at high risk for infection who are unlikely to return for a follow-up evaluation (e.g. minors who have multiple partners, non-compliance for follow up of previous positive results, etc.).

THERAPEUTIC

NOTE: Any patients that have positive tests for gonorrhea or chlamydia should be tested for syphilis and HIV.

NOTE: Persons with HIV that have NGU can receive the same treatment regimen as persons without HIV. In addition, NGU might facilitate HIV transmission.

PHARMACOLOGIC

1. Recommended regimens for patients that meet criteria for NGU:
   a. Doxycycline 100 mg PO every 12 hours for 7 days if patient is at least 8 years old,

2. Alternative regimens:
   a. Azithromycin 1 g PO in a single dose
      OR
   b. Azithromycin 500 mg PO single dose, then 250 mg PO daily for 4 days.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of untreated infection **(http://www.ashasexualhealth.org/stdsstis/ngu/).**

3. Directions for taking medication and what to do about potential side effects.

4. All sex partners from 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide written note(s) to give to partner(s) to refer them in for exam and treatment.

5. Abstain from sex with partner(s) until partner(s) has/have been treated.

6. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

7. Counsel about high risk of reinfection if patient's partner(s) is/are not tested and treated. The use of protective barriers) (condoms, diaphragm, etc.) with any untreated partner(s) are not protective during sexual intercourse. Provide education and counseling on the correct usage of protective barriers if using or plan to use.

8. Educate patients who receive Azithromycin about adverse effects (QT Prolongation, torsades de pointes, etc.) and document the patient's understanding. **http://www.fda.gov/downloads/Drugs/DrugSafety/UCM343347.pdf or https://www.nhs.uk/conditions/long-qt-syndrome/**

9. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

10. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

11. Instruct patient to abstain from sexual intercourse until at least 7 days after therapy has started and/or until all lab results are obtained. The partner(s) must be adequately treated, and the treated patient's symptoms completely resolved, and sex partners have been adequately treated.

12. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

13. HIV antibody test to determine HIV status, if unknown.

14. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

15. Advise patient to return to clinic in 7 days if symptoms do not resolve.

MANAGEMENT OF SEX PARTNERS

1. All identified sex partners should be examined and treated according to the management of the diagnostic findings.

2. Provide written note(s) to give to partner(s) to refer them in for exam and treatment.

3. All sex partners from the 60 days prior to the onset of symptoms or diagnosis should be examined and promptly treated with one of the recommended regimens.

FOLLOW-UP

1. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment will be needed.
2. Inform patient if additional lab(s) is/are positive, partner(s) will need additional treatment also.
3. The patient should return if symptoms persist or return within three months of treatment. Patient(s) with persistent or recurrent urethritis should be retreated with the initial regimen if they have failed to comply with the regimen, or if they have been re-exposed to an untreated sex partner. Otherwise, refer to delegating physician.
4. If the chlamydia or gonorrhea test is positive, recommended to retest patient approximately 3 months after treatment, regardless of whether they believe that their sex partners were treated. If retesting at 3 months is not possible, clinicians should retest whenever patient next present for medical care in the

12 months following initial treatment.

5. If provided Azithromycin and vomits within thirty minutes of taking, the dose may be repeated.

CONSULTATION/REFERRAL

1. Refer to urologist or primary care physician for evaluation and treatment if persistent or recurrent NGU is suspected. Patient may need additional testing for M. genitalium or T. vaginalis.

2. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

3. Consult delegating physician when further medical guidance is needed, and STI Standard Nurse Protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR LYMPHOGRANULOMA VENEREUM (LGV)

DEFINITION

Lymphogranuloma Venereum (LGV) is a systemic, sexually transmitted disease (STI) or infection caused by a type of Chlamydia trachomatis (serovars L1, L2, L3). It is rarely diagnosed in the United States or other industrialized countries. LGV is more common in men who have sex with men than women or heterosexual men. Men who have sex with men who have signs and symptoms of proctocolitis should receive testing for LGV. Incubation period ranges between 3-12 days. LGV has three clinical stages:

1. First stage: Often unrecognized due to rapid healing. A painless papule at the site of infection, which ulcerates and then heals rapidly. Mild urethritis may also occur. The patient rarely presents for examination at this stage.

2. Secondary Stage: Usually occurring 14-45 days after the first stage, it is characterized by painful increasing inguinal lymphadenopathy or, in patients exposed by receptive anal intercourse, acute hemorrhagic proctitis. The lymphadenopathy is usually unilateral; less than 20% have the “groove sign” showing involvement of the femoral nodes. Diagnosis and treatment during this stage can have the desired outcome of curing infection and prevention of ongoing tissue destruction.

3. Third stage: This stage can occur years after denoted by chronic inflammation of the lymph nodes, ulceration and fistula formation, genital elephantiasis, or infertility. Patients, especially those who have engaged in unprotected anal sex, may present with an atypical presentation. Symptoms could include proctitis or proctocolitis with rectal discharge, bleeding, pain on defecation or tenesmus.

ETIOLOGY

Chlamydia trachomatis is an obligate intracellular bacterial agent with at least 18 serologic variants divided between biologic variants. LGV is serologic variant (serovars) L1, L2, and/or L3.

SUBJECTIVE

1. With or without tender, (typically) unilateral, swollen glands (lymph nodes/bubo) in the groin.
2. May have history of briefly occurring painless papule/ulcer in the genital area.
3. Proctitis or proctocolitis with mucoid or hemorrhagic rectal discharge, tenderness and bleeding, with history of ana sex. May complain of constipation, pain on defecation and tenesmus.

OBJECTIVE

Diagnosis of LGV can be complicated. Diagnosis should be made considering a thorough sexual history, travel history, clinical findings and several laboratory tests including Chlamydia serology and Chlamydia serotyping of specimens.

1. Patient history and clinical findings consistent with LGV. One or more tender, progressively enlarging, fluctuant inguinal lymph nodes,

OR

2. Characteristic signs of hemorrhagic proctitis in a patient with history of rectal sex. May be accompanied by fever, malaise and myalgias.

ASSESSMENT Lymphogranuloma Venereum (LGV)

PLAN

The desired outcomes of treatment are biologic cure, prevention of transmission and prevent ongoing tissue damage. Treatment of sex partners helps to prevent reinfection of the index patient and infection of other partners.

DIAGNOSTIC STUDIES

NOTE: Patient presents with history and signs/symptoms that are suggestive of LGV consult with the delegating physician. Notify DPH STI Nurse Consultant of suspected or confirmed LGV case.

NOTE: Chlamydia serology by microimmunofluoroscence (MIF) or complement fixation serologic test for a lymphogranuloma venereum strain of *Chlamydia trachomatis* (serum) is not used routinely because the utility of these serologic methods has not been established, interpretation has not been standardized, and validation for clinical proctitis presentation has not been done. MIF and LGV serotype are to be submitted to a private laboratory for processing. Georgia Public Health Laboratory does not conduct testing to diagnose LGV. Chlamydia trachomatis LGV Molecular Detection specimens can be submitted to the CDC Infectious Diseases Laboratory (when available) https://www.cdc.gov/laboratory/specimen-submission/detail.html?CDCTestCode=CDC-10523.

1. Gonorrhea and chlamydia testing.

2. C. trachomatis NAAT at the symptomatic anatomic site (i.e, rectal swab)

   NOTE: NAAT would detect both LGV strains and non-LGV C. trachomatis strains. Therefore, all persons presenting with proctocolitis (e.g., bloody discharge, tenesmus, and rectal ulcers) should be tested for chlamydia with a NAAT performed on rectal specimens.

3. Serology for HIV and for syphilis (RPR)

4. Herpes serology and/or herpes culture.

5. If available, a rectal Gram stain with >10 white blood cells have been associated with rectal LGV.

6. If available, isolation/culture of *Chlamydia trachomatis* from clinical specimen (genital lesions, rectal specimens, and lymph node specimens.)

THERAPEUTIC

PHARMACOLOGIC

NOTE: LGV should be presumptively treated when signs are symptoms are indicated.

NOTE: Any patients with a positive test for LGV should be tested for syphilis and HIV.

NOTE: Persons with HIV should receive the same regimens as persons without HIV. Prolonged therapy might be required, and delay in resolution of symptoms might occur.

1. If patient is not pregnant and 8 years of age or older:
   a. Doxycycline 100 mg PO every 12 hours a day for 21 days.

NOTE: Do not give to minors under the age of 8.

2. If patient is pregnant or cannot take Doxycycline:
   a. Azithromycin 1 gm orally once weekly for 3 weeks*

NOTE: A C. trachomatis NAAT test of cure should be considered 4 weeks after completion of Azithromycin treatment.

OR

   b. Erythromycin base 500 mg PO, every 6 hours for 21 days.

NOTE: Breastfeeding:

1. Doxycycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Azithromycin: Can be given while breastfeeding. If infant is 2 weeks or

younger, encourage to discuss with infant's pediatrician. According to manufacturer guidance the decision to breastfeed during therapy should include consideration of the risk of infant exposure, the benefits of breastfeeding to the infant (especially during the first 2 weeks of life), and benefits of treatment to the mother. A suggestion to pump and discard during treatment and for two days after treatment is completed, can be offered.

3. Erythromycin: Compatible with breastfeeding for doses recommended above.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection: **(https://medlineplus.gov/ency/article/000634.htm)**

3. Give directions for taking the medication and potential side effects and what to do about them. Stress the importance of finishing medications. Advise to abstain from sexual contact until treatment is completed and until partners have finished all their medication.

4. All sex partners from 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide written note(s) to give to partner(s) to refer them in for exam and treatment.

5. Abstain from sex for 7 days after therapy is begun and/or until all lab results are obtained.

6. Advise patient to return to clinic in 7 days or less if symptoms do not resolve.

7. Stress safe sex practices among men who have sex with men (MSM) and bisexual men. Emphasize the importance of using condoms and avoiding penetrating sex. Limiting the number of sex partners and regular use of protective barriers can also reduce risk.

8. Counsel patient on individualized STI/HIV risk reductions and incorporate reduction plan.

   NOTE: LGV can facilitate the spread of other STIs including HIV because of the disease's ulcers. Keep acute HIV infection and syphilis in mind as well as LGV when patients present with symptoms. HIV and syphilis are

more prevalent than LGV in Georgia and patients should be screened for all STIs.

9. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

10. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

11. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

12. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

13. HIV antibody test to determine HIV status, if unknown.

14. Emphasize the importance of regular health screenings among high-risk populations.

15. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

16. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. All identified sex partners, as defined above, should be examined and promptly treated with one of the above regimens for Lymphogranuloma Venereum.
2. Provide written note(s) to give to partner(s) to refer them in for exam and treatment.
3. All sex partners from 60 days prior to the onset of symptoms or positive test

should be referred for examination (tested at the anatomic site of exposure) and treatment. Avoid sex with partner(s) until partner(s) has been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide written note(s) to give to partner(s) to refer them in for exam and treatment.

FOLLOW UP

1. Assess patient every 1-2 weeks until all lesions are healed, or signs and symptoms have resolved. Clinical response is the best gauge of therapy effectiveness.
2. All persons who have been treated for LGV should be retested for chlamydia 3 months after treatment. If retesting at 3 months is not possible, clinicians should retest whenever patient presents next for medical care in the 12 months following initial treatment.
3. Pregnant persons treated for LGV should have a test of cure performed 4 weeks after the initial C. trachomatis NAAT-positive test.

CONSULTATION/REFERRAL

1. Consult with delegating physician if:
   a. Inadequate response to treatment (continued signs and symptoms of LGV in the absence of possible reinfection).
   b. Lymph node enlargement continues to the point where rupture seems possible (blue color of overlying skin shows that rupture is imminent); refer for aspiration or incision and drainage.
   c. Consult when further medical guidance is needed and STI nursing protocol is not applicable for therapeutic treatment of patient.
   d. Surgical consultation may be needed for tertiary or late-stage disease if complications like fistulas or strictures cause damage to the anorectal area.

2. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the **Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel**.

3. Refer to a District Communicable Disease Specialist for prevention counseling and assistance with partner referral.

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STANDARD NURSE PROTOCOL FOR GENITAL/PERIANAL WARTS

DEFINITION

Infection of the genital and/or anal areas with the *human papillomavirus* (HPV) which results in genital/perianal warts. It is usually sexually transmitted and the viral strains causing anogenital warts are not usually found on other areas of the body. Asymptomatic genital HPV infection is common and usually self-limited. While intra-anal warts are seen predominately in patients who have receptive anal intercourse, perianal warts can occur in males and females who do not give a history of anal sex. Most HPV infections, including those with carcinogenic HPV genotypes, typically resolve within 12 months. HPV infections that persist beyond 12 months increase the likelihood of precancerous or cancerous lesions, although not all persistent infections progress.

ETIOLOGY

Genital/perianal warts are members of the Papillomavirus family and are DNA virus. There are more than 150 types identified. More than 40 HPV types can infect the genital tract. The larger, fleshy warts are usually caused by HPV types 6 or 11 (90%), they have been associated with conjunctival, nasal, oral, and laryngeal warts. HPV types 16, 18, 31, 33 and 35 are usually flat, papular, or pedunculated growths on the genital mucosa. HPV 16 and 18 are the cause of penile, vaginal, vulvar, anal, oropharyngeal and cervical cancers. The higher-numbered types are the ones associated with cervical and other anogenital cancers. Regardless of type, most HPV infections are subclinical. However, depending on the size and anatomic location, genital warts can be painful, friable and pruritic. Incubation period is unknown but is estimated to range from 3 months to several years.

SUBJECTIVE

1. May have no noticeable symptoms.
2. Bumps/growths in the genital or anal areas.
3. Bumps/growths may be painful or pruritic.
4. Dyspareunia and burning discomfort.

OBJECTIVE

1. The following criteria are used to diagnose genital/perianal warts:
   a. Single or multiple typical soft, fleshy growths on the skin or mucous membranes around the vulvovaginal area, anal area, penis, urethra, or perineum. They may be like cauliflower, with a stalk-like base, or have a broad base.
   b. Atypical cytologic changes on a Pap smear is suggestive of subclinical HPV infection. HPV is associated with high grade intraepithelial neoplasia.

ASSESSMENT Genital and/or Perianal Warts (specify site)

PLAN

The desired outcome of treatment is the removal of symptomatic warts. Treatment can induce wart-free periods in most patients.

DIAGNOSTIC STUDIES

1. Visual inspection.
2. Syphilis testing with initial diagnosis of HPV.
3. HIV antibody test to determine HIV status, if unknown.
4. A biopsy referral may be indicated if the wart(s) does not respond to therapy or gets worse during treatment.

THERAPEUTIC

Recommended regimens are for external anogenital warts (i.e., penis, groin, scrotum, vulva, perineum, external anus, and perianus*).

NOTE: Treatment of genital warts is optional, and the warts may spontaneously regress, remain unchanged or resolve spontaneously. Many patients will require a course of therapy rather than a single treatment. Treatment is not indicated in the absence of lesions. Selection of specific therapies is based on lesion location, provider experience, availability, and patient preference.

PHARMACOLOGIC

NOTE: Any patient who tests positive for HPV should be tested for gonorrhea, chlamydia, syphilis and HIV.

NOTE: Persons with HIV can receive the same treatment regimen as persons without HIV. Persons who are otherwise immunosuppressed are more likely to develop anogenital warts than persons without HIV. Such persons can have larger or more numerous lesions, might not respond to therapy as well as those who are immunocompetent, and might have more frequent recurrences after treatment.

NOTE: For patient-applied therapy, clinicians must educate and demonstrate, to the patient, proper application technique of the initial treatment before dispensing medication to the patient.

NOTE: For genital warts only. Patient must be able to identify and reach warts to be treated; the first application is to be applied by the clinician in order to demonstrate the proper application technique and identify which warts should be

treated.

1. Patient-Applied treatment:
   a. Podofilox 0.5% solution or gel. Apply solution with a cotton swab, or gel with a finger or swab, twice a day for 3 days, followed by 4 days of no therapy. After the application of treatment, the solution or gel should be allowed to dry. Wash hands before and after applying medication.

      This cycle may be repeated, as necessary, for a total of 4 cycles. The total area treated should not exceed 10 cm^2, and no more than 0.5 mL of podofilox used per day. Clinician should apply the initial treatment to demonstrate to patient proper application technique.

      OR

   b. Imiquimod 5% cream (e.g., Aldara) if 12 years of age or older. Apply cream with a finger or cotton swab at bedtime, three times a week until warts are cleared, for up to 16 weeks. Wash hands before and after applying the medication. Wash the treatment area with mild soap and water 6-10 hours after the application. Educate patient about local inflammatory reaction.

NOTE: Podofilox or Imiquimod should not be used if pregnant or breastfeeding.

OR

   c. Sinecatechins 15% ointment (e.g., Veregen). Apply three times daily (0.5-cm strand of ointment to each wart) with finger to ensure coverage until complete clearance of warts is achieved, for up to 16 weeks. The medication should not be washed off after use. All sexual contact should be avoided while medication is on skin. Educate patient on local inflammatory reaction.

NOTE: Do not use in persons with HIV infection, other immunocompromised conditions, genital herpes or is pregnant. This medication may weaken condoms and vaginal diaphragms.

2. Provider or Clinician Administered treatment:

NOTE: Trichloroacetic acid should not be used in pregnant or nursing patients. Treatment outlined is not for individuals with lesions in the urethra, vagina, anal, or cervical areas.

NOTE: Refer to the product package insertion prior to administration.

   a. Trichloroacetic acid (TCA) 80-90% solution applied sparingly to warts and allowed to dry to a white "frosting" before the patient sits or stands. If an excess amount is applied, powder the treated area with liquid soap preparation, talc, or sodium bicarbonate (e.g., baking soda) to remove unreacted acid. May repeat weekly as necessary.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection: https://www.cdc.gov/std/hpv/stdfact-hpv.htm, https://www.cdc.gov/std/hpv/stdfact-hpv-and-men.htm and https://www.cdc.gov/std/hpv/stdfact-hpv-vaccine-young-women.htm

3. For the fleshy warts, stress that these are not usually caused by the same strains that are associated with cancer, but it is possible that other strains are also present. Treatment of external warts is not likely to influence the development of cervical cancer.

4. Directions of how to apply the medication and care of the treated area.

5. No treatment, even laser or liquid nitrogen (cryotherapy), is known to eradicate the virus, and recurrences are common. Recurrences occur most frequently during the first 3 months and are usually due to reactivation of latent virus rather than reinfection by a sex partner.

6. If warts are left untreated, they may resolve on their own, stay the same or increase in size and number.

7. Infected females should undergo regular cervical Pap screening as recommended for females without genital warts.

8. Partners may be infected with HPV even if they have no visible warts. The use of condoms may reduce transmission to new partners. Correct and consistent condoms use may lower transmission and contact of HPV but may not provide full protection based upon location(s) of HPV not covered by condom.

9. HPV infection may persist lifelong in a dormant state and become infectious intermittently.

10. Vaccination should be administered to eligible patients or refer patients to another facility equipped to provide the vaccine.

11. Time of HPV acquisition cannot be definitively determined. Genital warts can develop months or years after acquiring HPV.

12. For patient-applied treatment:
    a. Do not use more often than directed or on any other area of the body. Wash hands before and immediately after applying medication.
    b. Report problems with application or side-effects, such as bleeding or

severe swelling of tissue. Mild to moderate pain or local irritation is common with podofilox.

c. Mild to moderate local inflammatory reactions (e.g. irritation, ulceration/erosions, vesicles, edema, rash, hypopigmentation) are common with imiquimod and Sinecatechins.
d. Do not share the medication with anyone else.
e. Do not have intercourse during the days when warts are being treated with podofilox or when imiquimod cream/Sinecatechins ointment on the skin.
f. Persons should avoid getting pregnant. Advise provider if she may be or intends to become pregnant.

13. Abstain from sex until treatment is completed or until obvious warts are no longer present to reduce transmission risk to partner(s).

14. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

15. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

16. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

17. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

18. If patient is of childbearing potential counsel on the use of contraceptives to reduce the risk of unintended pregnancy. 9. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired

19. If pregnant should be educated and counseled concerning the low risk for warts on the larynx of their infants or minors (http://www.nidcd.nih.gov/health/voice/pages/laryngeal.aspx/#3 or http://www.rrpf.org/whatisRRP.html).

20. HIV antibody test to determine HIV status, if unknown.

21. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily; HIV/AIDS Information Line In Georgia: (404) 876-9944; AID Atlanta In Atlanta: (404) 870-7700. Outside of Georgia: (800) 551-2728;

http://www.ashasexualhealth.org/stdsstis/herpes/; Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

22. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. Recommend a pap smear for female partners **if indicated.**
2. All identified sex partners should be examined and promptly treated according to findings.
3. Provide written note(s) to give to partner(s) for exam and treatment referral.

FOLLOW-UP

1. If desired, patients using self-administered treatment may return in a few weeks for assessment of treatment response.
2. For provider-administered topical treatment, apply weekly as needed. If no significant improvement in four weeks, or if warts have not completely cleared after six weeks, alternative therapy should be used**.**

CONSULTATION/REFERRAL

1. Refer patient(s) to a dermatologist or primary care provider if requests are made for treatment of lesions not located in the vulvovaginal area, anal area, penis, urethra or perineum. In addition, refer patient(s) who may require or request cryotherapy or surgical removal.

2. For Pap smear recommendations follow Georgia Breast and Cervical Cancer Program Cervical Screening Guidelines.

3. If patient is pregnant, consult with delegating physician for possible referral to OB provider.

4. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

5. Consult delegating physician if warts do not respond to treatment or when further medical guidance is needed, and STI nursing protocol is not applicable for therapeutic treatment of patient.

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STANDARD NURSE PROTOCOL FOR GENITAL/ANOGENITAL HERPES

DEFINITION

Genital/anogenital herpes (HSV) is a chronic, lifelong sexually transmissible viral infection characterized by recurring vesicular blisters resulting in ulcerative lesions on the genitals or adjacent areas that heal spontaneously without scarring. However, typical lesions are absent in many infected patients.

Some severe cases of first episode infection last an average of 12 days and aseptic meningitis or generalized symptoms due to viremia may occur. Subsequent milder recurrent infections do not last as long. During latency between clinical episodes, viral shedding occurs intermittently, and individuals may transmit the virus to partners with asymptomatic viral shedding.

Most people with HSV-II (genital herpes infection) do not know they have it. Most infected patients never recognize signs suggestive of genital herpes; some will have symptoms shortly after infection and then never again. Many cases are acquired from patients who do not know that they are infected.

Persistent infection (lesions more than 4 weeks) or extensive anogenital ulceration and proctitis occur in immunocompromised patients. Lesions caused by HSV are common among persons with HIV. These individuals may experience increased viral shedding, have more prolonged episodes, and may experience more severe and atypical symptoms. HSV with chronic ulcers (greater than1 month's duration) or bronchitis, pneumonitis, or esophagitis (onset at age greater than 1 month) is an AIDS defining illness.

ETIOLOGY

HSV is an enveloped, double-stranded, DNA virus. Herpes simplex virus (HSV), type 1 or type 2. HSV-I usually involve the face and skin above the waist and HSV-II usually involves the skin below the waist. However at least 20% of genital herpes are caused by HSV-I. Most genital infections are with HSV-II, which is most apt to cause recurrences and shedding. Presence of HSV II antibodies implies anogenital infection. Incubation period is, on average, 4 days but ranges from 2 days to 2 weeks.

SUBJECTIVE

1. Single or multiple blisters and/or shallow ulcers, usually painful, anywhere on the genitals.
2. May have swollen tender lymph nodes in the groin.
3. Fever, headache, or malaise or myalgias.
4. Pruritic lesions.
5. Dysuria.

6. Vaginal or urethral discharge**.**

OBJECTIVE

1. Typical vesicular lesions and/or shallow ulcers.
2. May have atypical papular lesions and no ulcers**.**
3. May have enlarged, tender inguinal lymph nodes.
4. Suspicious genital/anogenital papules, vesicles or ulcers, with a history of episode(s) of similar symptoms or sexual exposure to a patient with HSV are suggestive.
5. In the setting of persons with HIV, a large non-healing genital/anogenital ulceration may be HSV.

ASSESSMENT Genital/Anogenital Herpes

PLAN

The desired outcome of treatment with systemic antiviral drugs are to treat or prevent symptomatic genital herpes recurrences and improve quality of life and suppress the virus to prevent transmission to sexual partners.

Counseling regarding the natural history of genital herpes, risks for sexual and perinatal transmission, and methods for reducing transmission is also integral to clinical management.

NOTE: Screening for HSV-I and HSV-II in the general population is not indicated.

DIAGNOSTIC STUDIES

NOTE: Any patients with a positive HSV test should be tested for gonorrhea, chlamydia, syphilis and HIV. HSV-2 genital herpes infection has a two-to-threefold increased risk of acquiring HIV – all persons with genital/anogenital herpes should be tested for HIV.

NOTE: Sensitivity of viral culture is low and as healing begins culture sensitivity declines rapidly. Sensitivity of PCR is high with less likely false positives. Positive culture and PCR gives a definitive diagnosis. However, absence of a positive culture or PCR does not mean the patient does not have herpes. The virus may not always be cultured from the lesion if it is not present in adequate amounts.

NOTE: Herpes culture or PCR should be performed first when noticeable symptoms are present.

1. A clinical diagnosis is made based on the presence of characteristic single or multiple blisters and/or shallow painful ulcers that are typical for herpes.

AND

2. Herpes culture or PCR to confirm diagnosis of typical lesions if lesion(s) are present.

   OR

   In cases of a self reported history of chronic or episodic outbreaks with a lack of laboratory confirmation and no lesions present on exam, may order a type-specfic antibody test or encourage client to present for exam when lesions are present for a herpes culture or PCR.

   Type-specific antibody test may not be ordered with an initial or acute outbreak or with a presumed time of acquisition of infection less than 12 weeks.

   NOTE: Type-specific HSV serologic assays in conjunction with herpes culture, might be useful in the following scenarios:
   - If patient has a history of recurring genital/anogenital or atypical lesions but, if obtaining an adequate specimen for a culture is not possible, order type-specific serologic antibody tests for HSV 1 and 2.
   - A clinical diagnosis of genital/anogenital herpes without laboratory confirmation.
   - A partner with genital/anogenital herpes.
   - A patient with a history of multiple sex partners.
   - Persons with HIV
   - MSM at increased risk for HIV acquisition.

   NOTE: Primary (acute) infection may be diagnosed in patients who are HSV antibody-negative but have positive viral cultures with evidence of acute infection. Pending serology testing or repeat serology 12 weeks after primary infection may result in more accurate HSV antibody positive result.

3. Syphilis testing and/or if available, darkfield exam of lesion fluid to rule out syphilis.

4. **Screen for mpox and collect specimens for testing, if indicated, based on client's subjective history in accordance with the Standard Nurse Protocol for Mpox.**

5. Recommendation: Identification of HSV I and/or HSV II in lesion scrapings by cell culture.

THERAPEUTIC

PHARMACOLOGIC

Systemic antiviral drugs partially control the signs/symptoms of herpes episodes when used to treat first clinical episodes, recurrent episodes or daily suppressive therapy. However, these drugs neither eradicate latent virus nor affect subsequent risk, frequency, or severity of recurrences after the drug is discontinued.

NOTE: Empiric treatment for genital/anogenital herpes can be provided if clinical manifestations (e.g., painful blister(s), shallow ulcer(s)) of herpes are identified and the patient is unlikely to be located for treatment when test results are available. If empiric treatment is provided, see patient education section for required education.

NOTE: Pregnant persons with first or episodic Herpes should be referred to an OB provider for treatment and evaluation.

3. First genital/anogenital episode

NOTE: Treatment may be extended if healing is incomplete after 10 days of therapy.

a. Acyclovir 400 mg PO every 8 hours for 7-10 days,
OR
b. Famciclovir 250 mg PO q 8 hours for 7-10 days,
OR
c. Valacyclovir 1 g PO every 12 hours for 7-10 days.

NOTE: Valacyclovir has enhanced absorption after oral administration.

4. Episodic recurrent episodes:
a. Acyclovir 800 mg PO every 12 hours for 5 days,
OR
b. Acyclovir 800 mg PO every 8 hours for 2 days,
OR
c. Famciclovir 125 mg PO every 12 hours for 5 days,
OR
d. Famciclovir 500 mg PO once followed by 250 mg PO every 12 hours for 2 days
OR
e. Famciclovir 1 g PO every 12 hours for 1 day
OR
f. Valacyclovir 500 mg PO every 12 hours for 3 days
OR
g. Valacyclovir 1 g PO once a day for 5 days

NOTE: Effective episodic treatment of recurrent herpes requires initiation of therapy within 1 day of lesion onset, or during the prodrome that precedes some outbreaks, if not on daily suppressive therapy. The patient should be provided with 1 cycle worth of medication with instructions to self-initiate treatment immediately when symptoms begin. If a cycle worth of medication is not provided to the patient for prodromal stage when patient present with a recurrent episode the patient should be screened for STIs.

5. Daily suppressive therapy for non-pregnant persons:

NOTE: It is a patient/clinician decision to determine whether a patient should receive daily suppressive therapy or episodic therapy.

a. Acyclovir 400 mg PO every 12 hours a day
OR
b. Famciclovir 250 mg PO every 12 hours a day
OR
c. Valacyclovir 500 mg PO once a day, use only if 9 or fewer recurrences per year
OR
d. Valacyclovir 1 g PO once a day.

NOTE: The use of Valacyclovir may be less effective than other dosing regimens in patients who have more than 9 episodes per year. The use of Famciclovir may be less effective for suppression of viral shedding.

NOTE: Baseline kidney (BUN, Albumin, GFR, Potassium, Creatinine Clearance, etc.) and liver (ALP, ALT, AST, Bilirubin, Lipase, Protein, etc.) function test recommended prior to the start of daily suppressive therapy and then annually or as needed based on symptoms, drug-drug interactions, etc. Consult with and report abnormal findings to delegating physician for guidance of patient care.

NOTE: If daily suppressive therapy has been initiated, at the completion of annual therapy the patient can:

1) Continue daily suppressive therapy.
2) Discontinue daily suppressive therapy. If or when the patient has an outbreak, after reassessment, daily suppressive therapy can be restarted, if indicated versus a trial of episodic treatment.

6. Persons with HIV:

a. Episodic treatment:
1) Acyclovir 400 mg PO every 8 hours a day, for 5-10 days
OR
2) Famciclovir 500 mg PO every 12 hours a day for 5-10 days

OR

3) Valacyclovir 1 g PO every 12 hours a day for 5-10 days

b. Daily suppressive therapy:
   1) Acyclovir 400 – 800 mg PO 2-3 times a day
   OR
   2) Famciclovir 500 mg PO every 12 hours a day
   OR
   3) Valacyclovir 500 mg PO every 12 hours a day

NOTE: Suppressive therapy with oral acyclovir, valacyclovir, or famciclovir is effective in preventing recurrences and is preferred for patients who have severe or frequent HSV recurrences or who want to minimize the frequency of recurrences. Suppressive therapy for HSV may be continued indefinitely, without regard for improved CD4 cell count, although need for continuation should be addressed on an annual basis, particularly if immune reconstitution has occurred.

7. Over-the-counter oral analgesic of patient's choice (e.g., acetaminophen or ibuprofen) as needed for pain related to outbreak and prodrome syndrome.

NON-PHARMACOLOGIC MEASURES

1. Keep affected areas as clean and dry as possible. Pat lesions dry; avoid rubbing the area. (The use of ointments will retain moisture and may delay healing.)
2. Encourage increased intake of fluids (e.g., water) to dilute urine if it burns the affected area.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide the name and information about the infection. Educate for sequelae and complications of the untreated infection. **https://www.cdc.gov/std/herpes/stdfact-herpes.htm**

3. Counseling of infected patients and their sex partners is critical to help the patient cope with the infection and to prevent sexual and perinatal transmission.

4. Although initial counseling is important, many patients benefit more from counseling about the chronic aspects of the disease after the acute illness subsides.

5. Educate about the natural history of the disease, the potential for recurrent episodes, and the risks of asymptomatic viral shedding between episodes.

6. Give clear directions for taking medication and management of potential side effects.

7. Advise patients experiencing a first episode that suppressive and episodic antiviral therapy is available to prevent or shorten the duration of recurrent episodes.

8. Provide information on comfort and pain-relieving measures.

9. Encourage patients to inform their current sex partner(s) about the infection and inform future partner(s) before initiating a sexual relationship. Encourage patients to inform sex partner(s) of infected patients that they might be infected even if they have no symptoms.

10. Sexual transmission can occur during asymptomatic periods. Prodrome occurs before recurring episodes. A day or two before an outbreak occurs; the genital/anogenital skin gets sensations such as itching, tingling or pain. This period is called prodrome phase. The skin also sheds virus during this phase. Therefore, it is important to have no sexual relation during this period. If your partner has herpes, ask them to keep you informed about their prodrome phase.

11. Avoid sexual activity with uninfected partners when lesions or prodromal symptoms are present. At other times, correctly used latex condoms may reduce the risk of transmission when the infected areas are covered.

12. Explain the risk for neonatal infection to all patients, including men. Advise infected persons of childbearing potential to inform health-care providers who care for them during pregnancy and those who will care for their newborn infant.

13. Patients should refer all symptomatic sex partner(s) for evaluation. Asymptomatic sex partners may be referred for evaluation and counseling. Sex partners of infected person should be advised that they may be infected even if they have no symptoms.

14. Discuss resources available for more information and support.

15. Provide information about the availability of latex condoms.

16. Risk of neonatal HSV should be discussed with all sexes.

17. Refer all pregnant persons who are infected or exposed to herpes to obstetrician.

18. Episodic treatment does not reduce risk of transmission.

19. Recurrence of lesions does not mean that the patient has been re-exposed.

20. Recurrences and subclinical shedding are much more frequent for genital HSV-II then for genital HSV-I infection.

21. When exposed to HIV, HSV-II seropositive persons are at increased risk for HIV acquisition.

22. Pregnant persons who conceive while taking daily suppressive should consult with their OB/GYN or OB provider for treatment regimen guidance.

23. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

24. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired

25. Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

26. All sex partners 60 days prior to the onset of symptoms or positive test should be referred for examination and treatment. Avoid sex with partner(s) until partner(s) has/have been treated. Refer the last known sex partner if the last sexual contact was greater than 60 days before onset of symptoms or diagnosis. Provide patient with written note(s) to give to partner(s) to refer them to HD for exam and treatment.

27. For additional information and psychological support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

28. Persons without symptoms or signs of genital/anogenital herpes or prodrome can deliver vaginally. Women with recurrent genital/anogenital herpetic lesions near or at the onset of delivery should deliver by C-section to prevent transmission to infant during vaginal delivery.

29. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

30. HIV antibody test to determine HIV status, if unknown.

31. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. Symptomatic sex partners should be managed the same as any patient with genital/anogenital lesions. Educate to understand the natural history of HSV including possibility of asymptomatic shedding of virus and lesions reappearing without sexual re-exposure.

2. Ask asymptomatic partners about a history of typical or atypical genital/anogenital lesions and encourage examining themselves for lesions in the future. Counsel about the possibility of being infected even if they have never been symptomatic. Order type-specific serologic antibody testing to determine whether the risk for HSV acquisition exists.

FOLLOW-UP

1. Schedule an appointment with the patient when culture results are available. Individualize counseling according to clinical progress and apparent emotional impact where further education and counseling for patient and sex partners may be indicated. Assist patient to develop a personalized STI/HIV risk reduction plan.

2. If the patient did not have a positive herpes culture, order type-specific serologic antibody testing to confirm the clinical diagnosis of genital/anogenital herpes and determine the type of antibodies present. This has important counseling implications, since HSV-I genital infection is less likely to cause asymptomatic shedding or to recur than HSV-II.

3. For patients on continuous daily suppressive therapy, discuss therapy after one year, to assess the patient's psychological adjustment to genital/anogenital herpes, rate of recurrent episodes, and the need to continue or discontinue therapy.

CONSULTATION/REFERRAL

1. Consult with delegating physician for referral of the following:

a. If pregnant provide records including copy of labs to the OB/GYN or OB provider for adequate treatment
b. History of renal impairment
c. Persistent lesions

2. Consult delegating physician when further medical guidance is needed, and STI nursing protocol is not applicable for therapeutic treatment of patient.

3. If signs or symptoms of meningitis present refer immediately for emergency evaluation. Consult delegating physician If symptoms of meningitis (e.g., headache, nausea, vomiting, stiff neck) during first or with recurrent episode(s).

4. Refer all pregnant patients who are infected or exposed to herpes to OB/GYN for treatment.

5. Persons who conceive while taking daily suppressive should consult with their OB/GYN or OB provider for treatment regimen guidance.

6. For additional information and psychological support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

   HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

   Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

7. In persons with HIV who are receiving antiviral treatment and lesions persist or recur refer to Infectious Disease specialist and/or HIV specialist for evaluation of possible resistance.

8. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

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STANDARD NURSE PROTOCOL FOR SYPHILIS, EARLY SYMPTOMATIC (PRIMARY and SECONDARY)

DEFINITION

Early symptomatic syphilis is the symptomatic stages occurring during the first year of untreated syphilis infection.

The primary stage is characterized by a painless, indurated ulcer (chancre) that appears at the site(s) of sexual exposure in about 21 days (range of 10-90 days) and lasts from 1 to 5 weeks before spontaneously healing.

The secondary stage, which usually appears 1 to 5 weeks after the primary chancre is healed, is characterized by a variety of skin or mucous membrane rashes or other type lesions. They will disappear spontaneously within 2 to 6 weeks but may recur within the year.

ETIOLOGY

Treponema pallidum is a spirochete which causes syphilis. The primary chancre and certain moist lesions (condyloma lata or mucous patches) of secondary syphilis are very contagious, and sexual contact when such lesions are present is the usual mode of transmission.

SUBJECTIVE

NOTE: Symptomatic neurosyphilis (abnormal walk (gait), numbness in toes, feet, or legs, confusion or poor concentration, headaches, seizures, visual problems, weakness, or stiff neck) can rarely occur in the secondary stage and should be considered if signs and/or symptoms of meningitis are present. Any patient with signs or symptoms of meningitis should be referred to the nearest emergency room immediately.

1. Possible Primary Syphilis
   a. Painless open sore in the genital area.
   b. May have non-tender, swollen glands in the groin.
   c. No definitive history of contact to a known case of early syphilis, though patient may have noticed a suspicious lesion or rash on a sex partner.

2. Primary Syphilis:
   a. Painless open sore, at a site of sexual exposure.
   b. Localized, non-tender swollen glands.

3. Secondary Syphilis: Has one or more of the following:
   a. Rough, red, or reddish-brown rash on the body and/or extremities. Rash usually does not itch.

b. Growths/lesions in the anogenital region.
c. Hair falling out.
d. Swollen glands.
e. Sores in the mouth, vagina, or anus.
f. Fever, malaise.

OBJECTIVE

1. Primary Syphilis:
   a. Firm, round, painless ulcer (chancre) with an indurated border and relatively smooth base, at a site of sexual exposure, e.g., genitals, anus, mouth.
   b. Localized firm, non-tender, enlarged lymph nodes.

2. Secondary Syphilis (one or more of the following is present):
   a. Bilaterally symmetrical macular or popular, nonpruritic rash on body and/or extremities. May be only on the palms and soles (palmar/plantar).
   b. Condyloma lata (large, raised, gray or white lesions, usually in the genital and/or anal region or mouth).
   c. Patchy hair loss on scalp, eyebrows or eyelashes.
   d. Generalized enlarged lymph nodes.
   e. Mucous patches in the mouth or on the cervix.

PHYSICAL EXAM / LAB FINDINGS

1. Primary Syphilis
   a. Identification of *T. pallidum* on darkfield microscopic exam of serum from a chancre is definitive.
      OR
   b. Typical ulcer (chancre),
      AND
      A newly reactive nontreponemal, confirmed by a reactive treponemal,
      OR
      A four-fold or greater increase over the last known nontreponemal titer in a patient with a previous history of syphilis is presumptive.

   c. A typical ulcer and exposure to a known case of early syphilis in the previous 10-90 days is suggestive of primary syphilis.

NOTE**:** Patients with a typical ulcer, a newly reactive nontreponemal or STAT Positive nontreponemal card test and no history of previous syphilis may be treated for primary syphilis prior to the results of the treponemal test.

2. Secondary Syphilis
   a. Identification of *T. pallidum* on darkfield microscopic exam of lesion material is definitive.

OR

b. Typical signs (e.g., rash, mucous patches)
AND
Newly reactive nontreponemal test confirmed by a treponemal test,
OR
A four-fold increase over the last known titer in a patient with a previous history of syphilis is presumptive.

NOTE: Patients with secondary typical signs, a newly reactive nontreponemal or STAT positive nontreponemal and no history of previous syphilis may be treated for secondary syphilis prior to the results of the treponemal test being available.

Typical dermatologic signs and exposure to a known case of early syphilis in the past six months is suggestive of secondary syphilis.

3. Persons with HIV:
When clinical findings are suggestive of syphilis, but serologic tests are nonreactive, or their interpretation is unclear, alternative tests may need to be considered. Neurosyphilis should be considered in persons with HIV with neurologic symptoms.

ASSESSMENT Primary Syphilis OR Secondary Syphilis

PLAN

The desired outcome of treatment and case management is to ensure infection cure in the patient, prevention of infection in sexual partners exposed within the preceding 90 days, and congenital infection.

DIAGNOSTIC STUDIES

1. Nontreponemal titer, if not already done. False-positive nontreponemal test results can be associated with various medical conditions and factors unrelated to syphilis, including other infections (e.g., HIV), autoimmune conditions (e.g., Lupus), immunizations, pregnancy, IV drug use and older age. VDRL and RPR cannot be compared.

2. Repeat nontreponemal test if lab results are equivocal or indeterminate in 2-4 weeks.

3. Confirmatory test by a reactive treponemal. Interpretation of Syphilis EIA, A-TRP or TPPA results.
   a. Reactive means a diagnosis of syphilis is confirmed.
   b. Minimal reactive or equivocal means the test could not be called either reactive or non-reactive and a second specimen should be submitted for repeat testing in two to four weeks.

c. Non-reactive means a diagnosis of syphilis is not confirmed.

4. If confirmatory test is reactive and the nontreponemal is non-reactive, redraw the nontreponemal within two to four weeks.

5. If RPR is negative, a different treponemal test should be done. If second treponemal is negative and infection risks are low, treatment may not be indicated.

6. **Herpes culture or PCR for acute/initial clinical manifestations.**

   a. In cases of a self reported history of chronic or episodic outbreaks with a lack of laboratory confirmation and no lesions present on exam, may order a type-specfic antibody test or encourage client to present for exam when lesions are present for a herpes culture or PCR.

   Type-specific antibody test may not be ordered with an initial or acute outbreak or with a presumed time of acquisition of infection less than 12 weeks.

7. HIV antibody test to determine HIV status, if unknown.

8. Recommendation: RPR STAT Card, if available. Must be able to titer out results if RPR STAT card report indicates positive findings, confirmed by a reactive treponemal EIA, A-TRP, or TPPA. If RPR card test is negative, titer out results to rule out prozone phenomenon (false negative test).

9. Recommendation: Darkfield microscopic exam if resources are available.

10. **If a patient is at risk or has symptoms of syphilis and the nontreponemal results are negative, prozone effect may cause a false-negative reaction. If clinical suspicion of prozone effect, request the lab to titer the sample or dilute the serum to a 1/16 dilution to rule out the prozone effect.**

DIAGNOSTIC TEST	RESULTS
RPR	Non-confirmatory -Nontreponemal
VDRL	Non-confirmatory- Nontreponemal
A-TRP	Confirmatory- Treponemal
EIA	Confirmatory- Treponemal
FTA-ABS	Confirmatory- Treponemal
TPPA	Confirmatory- Treponemal

NOTE: Patients with a positive treponemal screening test should receive a nontreponemal test to confirm the screening test. If the nontreponemal test is

negative, another type of treponemal test, different from the initial treponemal test (A-TRP, FTA-ABS, TPPA, or EIA), should be done.

THERAPEUTIC

NOTE: Empiric treatment for primary or secondary syphilis can be provided if clinical manifestations (e.g., chancre, skin rash, lymphadenopathy) of primary or secondary are identified and the patient is unlikely to be located for treatment when test results are available. If empiric treatment is provided see patient education section for required education.

NOTE: Presumptive treatment of pregnant persons may be imperative to prevent risk or reduce the possibility of congenital spread of syphilis during confirmation of diagnosis.

Recommendation: At the time of treatment, collect non-treponemal test to be compared with follow up serologic response.

PHARMACOLOGIC

REMINDER: If Benzathine Penicillin G is in short supply, reserve existing penicillin for pregnant patients or with HIV.

NOTE: Any patients who test positive for syphilis should be tested for gonorrhea, chlamydia and HIV.

NOTE**:** Combinations of benzathine penicillin, procaine penicillin, and oral penicillin preparations are not considered appropriate for the treatment of syphilis.

NOTE: If self-reported allergy to Penicillins refer to Standard Nurse Protocol for Gonorrhea Appendix A, PCN Allergy Assessment and Algorithm to rule out allergy. Persons with a true penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with benzathine penicillin.

1. Recommended regimen if patient is not pregnant and without HIV:
   a. Benzathine Penicillin G, 2.4 million units (mu) IM, once.
      OR
   b. If allergy to penicillin (see note above): Doxycycline 100 mg PO every 12 hours for 14 days (if patient is 8 years of age or older).

2. Alternative regimen if patient is not pregnant and without HIV:
   a. Tetracycline 500 mg PO every 6 hours for 14 days if patient is at least 8 years of age

NOTE: Persons with HIV who have primary or secondary syphilis should be treated as persons without HIV.

3. Persons with HIV:
   a. Benzathine Penicillin G, 2.4 million units IM, once.
   OR
   b. If self-reported allergy to Penicillins refer to Standard Nurse Protocol for Gonorrhea Appendix A, PCN Allergy Assessment and Algorithm to rule out allergy. Persons with a true penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with benzathine penicillin.

4. Alternative Regimen if allergic to penicillin, non-pregnant and desensitization is unavailable:
   a. Doxycycline 100 mg PO every 12 hours for 14 days, with careful monitoring for compliance, (if patient is 8 years of age or older).

NOTE: The efficacy of the alternative regimen in persons with HIV has not been well studied. Close serologic and clinical follow-up should be performed with alternative therapy.

5. If patient is pregnant:
   a. Benzathine Penicillin G, 2.4 million units IM, once.
   OR
   b. If self-reported allergy to Penicillins refer to Standard Nurse Protocol for Gonorrhea Appendix A, PCN Allergy Assessment and Algorithm to rule out allergy. If true allergy identified refer patient for skin testing and possible desensitization, then subsequent treatment with penicillin.

NOTE: Breastfeeding:

1. Doxycycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Penicillin G benzathine: Compatible with breastfeeding when used in usual recommended doses.

3. Tetracycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment until completion of treatment. All breastmilk that is pumped during treatment, should be discarded, and not saved or provided to infant.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequela and complications of the untreated infection https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm

3. If patient is given oral medication provide patient with directions for taking the medication, possible side effects, and what to do about the side effects.

4. Inform patient(s) about the possibility of having a Jarisch-Herxheimer reaction (e.g., fever, chills, headache, myalgia, and exacerbation of cutaneous lesions). Educate as follows:
   a. If pregnant, seek medical care immediately if notice a change in fetal movement or uterine contractions. Pregnant persons may have more severe reactions and should contact their prenatal care provider at the first sign or symptoms.
   b. Jarisch-Herxheimer reaction may occur within 12 hours after treatment of early syphilis. Local reaction may consist of intensification of lesions (e.g., a chancre may become edematous or a faint secondary rash may become prominent).
   c. Systemic reaction may consist of a rise in temperature to 101-102 degrees Fahrenheit. The self-limiting reaction usually lasts a few hours but may be up to 24 hours. Antipyretic may be taken as needed. (If pregnant, seek medical care immediately if notice a change in fetal movement or uterine contractions.)

5. Signs and symptoms of neurosyphilis. See Appendix A Appointment Card Signs/Symptoms of Neurosyphilis. If neurologic or ophthalmic disease is suspected patient should be referred for CSF analysis, otologic and ophthalmologic examination.

6. The need for, and schedule of, follow-up blood tests 6, and 12 months after treatment. Resolution of signs and symptoms should occur within 3 to 6 months and seroversion or a fold four decline in nontreponemal titers within 12 to 24 months.

7. Patients treated during the primary stage of syphilis may revert to being serologically nonreactive after 1-3 years.

8. Patients who receive positive treponemal screening test should have a standard nontreponemal test with titer preformed to guide patient management decisions.

9. Counseling regarding abstinence until therapy is completed.

10. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.
11. The need for examination and treatment of sex partner(s) and avoidance of sex with untreated partner(s). Introduce the patient to the Communicable Disease Specialist who will assist them with notifying partner(s) of need for examination and treatment.

12. Inform patient if additional lab(s) is/are positive, partner(s) will also need additional treatment.

13. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

14. If empiric treatment is provided, patient education must include:

    a. Information of presumptive therapy with pending lab results.

    b. Patient option to consent to treatment or refusal of treatment prior to lab results due to the high suspicion of syphilis.

    c. Patient must return for lab results.

    d. Patients should be referred to a Communicable Disease Specialist for further counseling.
    e. Updated demographics (current locating information, phone number, emergency contact, etc.) collected on patient and provided to CDS.

15. Refer all pregnant patients to OB/GYN or OB provider to seek prenatal care and/or fetal evaluation.

16. If pregnant should be tested for syphilis during 1st and 3rd trimester (Title 31. Health Chapter 17. Control Of Venereal Disease § 31-17-4.2. HIV and Syphilis Pregnancy Screening).

17. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

18. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

19. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

20. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

1. Provide written note(s) to patient to give to partner(s) to refer them to the HD for exam and treatment.

2. Contacts to Primary Syphilis:
   a. If index patient test results are available, examine and treat, with one of the regimens listed above, all referred partners exposed within 3 months (90 days) of patient reported onset of symptoms or diagnosis, whichever is longer.
   b. Examine and treat partners exposed longer than 3 months (>90 days) before diagnosis should be treated presumptively if index patient test results are not immediately available. Treatment presumptively.

3. Contacts to Secondary Syphilis:
   a. If index patient test results are available, examine and treat, with one of the regimens listed above, all referred partners exposed within 6 months (180 days) of patient reported onset of symptoms or diagnosis, whichever is longer.
   b. Examine and treat partners exposed longer than 3 months (>90 days) before diagnosis should be treated presumptively if index patient test results are not immediately available and follow up is uncertain. Treat presumptively.

FOLLOW-UP

1. Monitor compliance if taking alternative regimen from Benzathine penicillin G.

2. Schedule a routine appointment for a clinical evaluation and repeat RPR at 6 and 12 months after receiving treatment. Serologic response should be compared with the titer at the time of treatment.

3. Seropositive pregnant women should be considered infected unless adequate treatment history is clearly documented, and sequential serologic antibody

titers have decreased as recommended for the syphilis stage.

4. If pregnant, clinical evaluation and non-treponemal tests should be done at least once during the third trimester and again at time of delivery. Monthly non-treponemal titers may be indicated for persons at risk for reinfection.

5. Persons with HIV should be managed in the same manner as HIV-negative patients. However, persons with HIV should have their RPR titers monitored at 3-month intervals for a year, and then at 24 months after therapy (3, 6,9,12, and 24 months).

6. In persons with HIV, if at 24-month follow-up there is less than a fourfold decrease in titers additional clinical and serologic (e.g., CSF, neurosyphilis rule out, etc.) follow-up is recommended. If additional follow-up cannot be ensured or a fourfold titer is not obtained retreatment with Benzathine Penicillin G, 2.4 million units IM, once for 3 doses (7.2 million units total).

7. For patients who sustain an increased nontreponemal titer, clinical and serologic monitoring should be done annually. Serologic titers might not decrease despite negative CSF findings and retreatment.

8. Clinical presentation and non-treponemal test titer response should be appropriate for the stage of disease. Non-treponemal test titers may decline more slowly if previously had syphilis. Serologic response to treatment includes but is not limited to syphilis stage, initial nontreponemal antibody titers, and age.

CONSULTATION/REFERRAL

1. Seek medical consultation from delegating physician if:
   a. Signs/symptoms persist or recur.
   b. A sustained four-fold increase in non-treponemal test titer compared to the baseline or maximum titer occurs. (The patient probably failed treatment or was re-infected. The patient should be re-treated and reevaluated for HIV infection and/or re-exposure. A cerebral spinal fluid exam should also be performed).
   c. Titers have not declined fourfold within 12 months. The patient should be reevaluated for HIV. If further clinical and serologic follow up cannot be assured, re-treatment should be given.
   d. In either instance above, re-treatment should consist of three weekly doses of benzathine penicillin 2.4 million units IM, unless CSF exam indicates that neurosyphilis is present.
   e. Consult delegating physician when further medical guidance is needed, and STI nursing protocol is not applicable for therapeutic treatment of patient.
   f. Probable or suspected cases of syphilis with clinical magnifications or

reactive non-treponemal test titer consult with delegating physician immediately to initiate possible presumptive treatment while pending confirmation.

g. Patient(s) with true penicillin-allergy that need skin testing and desensitization, as necessary.

2. If patient displays signs/symptoms of neurologic or ophthalmic disease immediately refer patient to ophthalmologist or neurologist for emergency evaluation. Inform delegating physician of need for referral.

3. All primary and secondary syphilis cases should be referred to a Communicable Disease Specialist for further counseling and sex partner referral.

4. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.

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STANDARD NURSE PROTOCOL FOR LATENT SYPHILIS (EARLY AND LATE)

DEFINITION

The intervals during untreated syphilis infection, after the primary stage, are characterized by seroreactivity without other evidence of disease. Diagnosis is dependent upon proper interpretation of serologic test results, history of contact to syphilis and/or history of previous signs and symptoms.

Patients who have latent syphilis acquired within the preceding year are classified as having early latent (EL) syphilis.

Late latent (LL) syphilis is defined as having latent syphilis for more than 1 year.

Neurosyphilis can occur at any stage of syphilis. Neurosyphilis is an infection of the brain or spinal cord. Neurosyphilis can apply to all stages of syphilis: primary syphilis, secondary syphilis, early latent syphilis, late latent syphilis, and late syphilis with clinical manifestations. Clinical description of symptomatic neurosyphilis can consist of abnormal walk (gait), numbness in toes, feet, or legs, confusion or poor concentration, headaches, seizures, visual problems, weakness, or stiff neck.

ETIOLOGY

Treponema pallidum, a spirochete is responsible for causing syphilis. Unless there are hidden lesions present during the early latent periods, the infection can only be spread through contact with infected blood, such as trans placentally from mother to unborn child.

SUBJECTIVE

1. No current symptoms.
2. May have a history of symptoms (lesions, rashes, etc.) suggestive of primary or secondary syphilis.
3. May have a history of sexual contact with a known case of syphilis.

OBJECTIVE

The following criteria are used to diagnose latent syphilis:

1. Early Latent Syphilis:
   a. No clinical signs/symptoms

AND

b. Reactive non-treponemal and confirmatory tests

AND

c. Patient has had the following within the past year:
   1) A nonreactive serologic test or a four-fold titer increase on serial non-treponemal test(s)

   OR

   2) Symptoms consistent with primary or secondary syphilis

   OR

   3) Sexual exposure to a known case of primary, secondary or early latent syphilis.

2. Late Latent Syphilis:
   a. No clinical signs/symptoms

   AND

   b. Non-treponemal test and confirmatory tests

   AND

   c. The criteria for having acquired the infection within the preceding 12 months (see early latent syphilis above) are not met.

ASSESSMENT Early Latent Syphilis OR Late Latent Syphilis

PLAN

The desired outcome of case management of early latent syphilis is to cure the infection in the patient and prevent development of infection in sexual partner(s) exposed within the preceding 90 days and to prevent congenital syphilis in a fetus. The desired outcome of treatment of late latent syphilis is to prevent the occurrence of or thwart the progression of late complications.

DIAGNOSTIC STUDIES

1. Careful re-examination of all accessible mucosal surfaces (e.g., the oral cavity, the female perineum, and underneath the foreskin in uncircumcised males) to evaluate for internal mucosal lesions.

2. Non-treponemal test if not already performed.

3. Confirmatory test by a reactive treponemal EIA, A-TRP, or TPPA.
   a. Interpretation of Syphilis EIA, TPPA or A-TRP results
      1) Reactive means a diagnosis of syphilis is confirmed.
      2) Minimal reactive or equivocal means the test could not be called either reactive or non-reactive and a second specimen should be submitted for repeat testing in 2-4 weeks.
      3) Non-reactive means a diagnosis of syphilis is not confirmed.

4. **For nonpregnant women, if confirmatory test is reactive and the nontreponeal test is non-reactive, redraw the nontrponemal test within two to four weeks. If the non-treponemal test is still negative a treponemal test should be done, preferably TPPA.**

5. **For pregnant women, if confirmatory test is reactive and the nontreponemal test is non-reactive, redraw both the nontrponemal and treponemal, preferably TPPA, within two weeks**.

6. Review Appendix A Appointment Card Signs/Symptoms of Neurosyphilis with patient. If any are identified refer immediately for emergency evaluation and notify delegating physician.

THERAPEUTIC

NOTE: After the completion of neurosyphilis treatment, benzathine penicillin 2.4 million units IM X 3 can be considered to provide total duration of therapy.

NOTE: If self-reported allergy to Penicillins refer to Standard Nurse Protocol for Gonorrhea Appendix A, PCN Allergy Assessment and Algorithm to rule out allergy. Persons with a true penicillin allergy whose compliance with therapy or follow-up cannot be ensured should be desensitized and treated with benzathine penicillin.

NOTE: Presumptive treatment of pregnant persons may be imperative to prevent risk or reduce the possibility of congenital spread of syphilis during confirmation of diagnosis.

NOTE: for pregnant women, if initial confirmatory test is reactive and the nontreponemal test is non-reactive, redraw both the nontrponemal and treponemal, preferably TPPA, within two weeks. If the second nontrponemal is negative, treponemal is reactive, the patient is asymptomatic, and there is no documentation of adequate treatment, presumptive treatment is recommended according to the stage of diagnosis.

PHARMACOLOGIC

Penicillin Shortages: If Benzathine Penicillin G is in short supply, reserve existing penicillin for pregnant and persons with HIV.

NOTE: PCN allergy algorithm found in the Standard Nurse Protocol for Gonorrhea, Appendix A, should be completed on all patients who report penicillin allergy.

1. Early Latent Syphilis
   a. The preferred regimen for patients who are not pregnant, not allergic to penicillin, are without HIV,and neurosyphilis is ruled out See Appendix A Appointment Card Signs/Symptoms of Neurosyphilis
      1) Benzathine Penicillin G, 2.4 million units IM, once.

OR

   b. Alternative regimen:
      1) Doxycycline 100 mg PO every 12 hours for 14 days, with careful monitoring for compliance, (if 8 years of age or older).

NOTE: Do not give Doxycycline to minors under the age of 8.

   c. If patient is pregnant and neurosyphilis is ruled out (See Appendix A Appointment Card Signs/Symptoms of Neurosyphilis):
      1) Benzathine Penicillin G, 2.4 million units IM, once.

NOTE: If patient is pregnant and a true PCN allergy is identified, refer to allergist for desensitization with subsequent treatment with penicillin.

   d. If person with HIV and neurosyphilis is ruled out (See Appendix A Appointment Card Signs/Symptoms of Neurosyphilis):
      1) Benzathine Penicillin G, 2.4 million units IM, once.

NOTE: If person with HIV and a true PCN allergy is identified, refer to allergy specialist for desensitization with subsequent treatment with penicillin.

OR

   e. Alternative regimen if allergic to penicillin and desensitization is unavailable:
      1) Doxycycline 100 mg PO, 2 times a day for 14 days, with careful monitoring for compliance, (if patient is 8 years of age or older).

NOTE: The efficacy of the Doxycycline regimen in persons with HIV has not been well studied. Close serologic and clinical follow-up should be performed with Doxycycline therapy.

NOTE: If pregnant, and/or a person with HIV, or has signs and symptoms of neurosyphilis, refer immediately for emergency evaluation. Delegating physician, Allergist and Infectious Disease specialist should be consulted.

2. Late Latent Syphilis
   a. If not pregnant, not allergic to penicillin, is without HIV, and does not have neuropsychiatric signs/ symptoms the preferred regimen is:
      1) Benzathine Penicillin G, 2.4 million units IM, once **weekly** for 3 doses (7.2 million units total).

NOTE: An interval of up to 10-14 days between doses may occur without re-

starting the sequence of injections

OR

2) PCN Allergic Reaction and Allergy Algorithm should be completed on all patients who report penicillin allergy. If true PCN allergy identified refer to allergist for desensitization with subsequent treatment with penicillin.

OR

3) If allergic to penicillin, and neurosyphilis has been ruled out, Doxycycline 100 mg PO every 12 hours for 28 days (if 8 years of age or older), with careful monitoring for compliance.

OR

4) Tetracycline 500mg PO every 6 hours for 28 days, (if patient is 8 years of age or older) with careful monitoring for compliance.

b. If patient is pregnant and does not have neuropsychiatric signs/symptoms:
   1) Benzathine Penicillin G, 2.4 million units IM, once weekly for 3 doses (7.2 million units total).

NOTE: Pregnant patients who miss any dose of therapy, scheduled at 7- 9 day intervals, must restart the sequence of injections.

OR

2) PCN Allergic Reaction and Allergy Algorithm should be completed on all patients who report penicillin allergy. If pregnant and a true PCN allergy is identified refer to allergy specialist for desensitization followed by subsequent treatment with: Benzathine Penicillin G, 2.4 million units IM, weekly for 3 doses (7.2 million units total).

NOTE: Breastfeeding:

1. Doxycycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment and for two days after completion of treatment. All breastmilk that is pumped during treatment and for two days after treatment is completed, should be discarded, and not saved or provided to infant.

2. Penicillin G benzathine: Compatible with breastfeeding when used in usual recommended doses.

3. Tetracycline: Instruct breastfeeding patients to discontinue breastfeeding throughout treatment until completion of treatment. All breastmilk that is pumped during treatment, should be discarded, and not saved or provided to infant.

NOTE: Do not give Doxycycline or Tetracycline to minors under the age of 8.

c. For persons with HIV that do not have neuropsychiatric signs/symptoms:

1) Benzathine Penicillin G, 2.4 million units IM, once **weekly** for 3 doses (7.2 million units total).

NOTE: Patient(s) who miss any dose of therapy, scheduled at 7- 9 day intervals, must restart the sequence of injections.

OR

2) PCN Allergic Reaction and Allergy Algorithm should be completed on all patients who report penicillin allergy. If true PCN allergy identified refer to allergist for desensitization with subsequent treatment with Benzathine Penicillin G, 2.4 million units IM once weekly for 3 doses (7.2 million units total).

OR

3) Alternative regimen if allergic to penicillin and desensitization is unavailable: Doxycycline 100 mg PO every 12 hours a day for 28 days, with careful monitoring for compliance, (if patient is 8 years of age or older).

NOTE: The efficacy of the Doxycycline regimen in persons with HIV has not been well studied. Close serologic monitoring and clinical follow-up should be performed with Doxycycline therapy.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide the name and significance of the infection. Educate for sequela and complications of the untreated syphilis infection https://www.cdc.gov/std/syphilis/stdfact-syphilis.htm.

3. If given oral medication, directions for administration and management of possible side effects.

4. Inform patients about the possibility of having a Jarisch-Herxheimer reaction (e.g., fever, chills, headache, myalgia, and exacerbation of cutaneous lesions). Educate patients as follows:
   a. If patient is pregnant, instruct patient to seek medical care immediately if she notices a change in fetal movement or uterine contractions. Pregnant persons may have more severe reactions and should contact their prenatal care provider at the first sign of symptoms.
   b. Jarisch-Herxheimer reaction may occur within 12 hours after treatment of early syphilis. Local reaction may consist of intensification of lesions (e.g., a chancre may become edematous or a faint secondary rash may become prominent).
   c. Systemic reaction may consist of a rise in temperature to 101-102 degrees Fahrenheit. The self-limiting reaction usually lasts a few hours but may be up to 24 hours. Antipyretic may be taken as needed.

d. Pregnant persons may have more severe reactions and should contact their prenatal care provider at the first sign or symptoms. (If pregnant, seek medical care immediately if notice a change in fetal movement or uterine contractions).

5. The need for and frequency of follow-up blood tests.

6. For early latent syphilis, provide information about the need for examination of sex partners and avoidance of sex with untreated partners. Introduce patients to the communicable disease specialist who will assist them with partner notification.

7. For late syphilis without neuropsychiatric signs/symptoms, give patient appointment card containing signs and symptoms of neurosyphilis with instructions on when to return.

8. Seropositive pregnant persons should be considered infected unless adequate documentation of treatment history in medical records and titers has declined.

9. All pregnant persons should be tested for syphilis during 1st and 3rd trimester (Title 31. Health Chapter 17. Control Of Venereal Disease § 31-17-4.2. HIV and Syphilis Pregnancy Screening).

10. If diagnosed for syphilis in the 2nd trimester of pregnancy, refer to OB/GYN or OB provider for sonographic fetal evaluation for congenital syphilis.

11. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved, and partner(s) are tested and treated.

12. Education and counseling of the correct usage of protective barriers (condoms, etc.).

13. Do not give Doxycycline if under 8 years old.

14. If patient is of childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

15. Review Appointment Card Signs/Symptoms of Neurosyphilis Attachment A, with patient. Refer all patients who have neuropsychiatric signs/symptoms immediately to ER for emergency evaluation. If no symptoms, review instructions on when to return for follow-up.

16. HIV antibody test to determine HIV status, if unknown.

17. For additional information and psychological support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)

18. Refer pregnant patients to OBGYN or OB provider for prenatal care.

19. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF SEX PARTNERS

Provide written note(s) to patient to give to sex partner(s) to come into health department for examination and treatment.

1. Contacts to Early Latent Syphilis:
   a. Examine all referred partners from the previous year.
   b. Treat all contacts exposed within the past 12 months, regardless of examination and serologic test results (with one of the above single-dose or 14-day regimens).

2. Contacts to Late Latent Syphilis (sex partners >12 months):
   a. Evaluate long-term or steady (e.g., marital) sex partners. No treatment is needed unless the partner is found to be infected.
   b. Minors born to an infected individual within the past few years should also be evaluated.

3. Examine and treat partners exposed longer than 3 months (>90 days) before diagnosis should be treated presumptively if index patient test results are not immediately available and follow up is uncertain. Treatment presumptively.

FOLLOW-UP (All latent syphilis)

1. Repeat syphilis testing at 6, 12, and 24 months after treatment for persons without HIV. Follow up non-treponemal test should be compared with the titer at the time of treatment.

2. Evaluate for possible neurosyphilis and re-treat appropriately with Benzathine Penicillin G, 2.4 million units IM, once for 3 doses (7.2 million units total) if:

a. Titers increase fourfold or more after 24 months.
b. If initial high titer (at least 1:32) fails to decline at least fourfold within 24 months.
c. If the patient develops signs or symptoms attributable to primary or secondary syphilis.

3. For persons with HIV repeat test for syphilis at 6, 12, 18 and 24 months after treatment. Refer patient for CSF (cerebrospinal fluid) exam and re-treat accordingly if:
   a. Signs or symptoms of syphilis that recur, persist, or sustain.
   b. If signs or symptoms of neurosyphilis develop.
   c. A fourfold or greater rise in titer.

4. Persons who have syphilis and symptoms or signs suggesting neurologic disease (e.g., cranial nerve dysfunction, meningitis, stroke, and hearing loss) or ophthalmic disease (e.g., uveitis, iritis, neuroretinitis, and optic neuritis) should be referred to infectious disease specialist and/or ophthalmologist for evaluation that includes CSF analysis, ocular slit-lamp ophthalmologic examination, and otologic examination. Treatment should be guided by the results of this evaluation.

5. A CSF examination should be performed if:
   a. A sustained (longer than 2 weeks) fourfold increase or greater in titer.
   b. An initially high titer (1:32 or greater) fails to decline at least fourfold within 24 months of therapy.
   c. Signs or symptoms attributable to syphilis develop.
   d. In such circumstances, patients with CSF abnormalities should be treated for neurosyphilis. If the CSF examination is negative, retreatment for latent syphilis should be administered. Serologic titers might fail to decline despite a negative CSF examination and a repeated course of therapy, especially if the initial nontreponemal titer is low (less than 1:8); in these circumstances, the need for additional therapy or repeated CSF examinations is unclear but is generally not recommended. Serologic and clinical monitoring should be offered along with a reevaluation for HIV.

6. If pregnant, clinical evaluation and evaluation for syphilis should be performed at least once during the third trimester and again at delivery.

CONSULTATION/REFERRAL

1. Consult delegating physician if further medical guidance is needed and STI nursing protocol is not applicable for therapeutic treatment of patient.

2. Refer all patients who have neuropsychiatric signs/symptoms immediately to ER for emergency evaluation; consult with delegating physician, allergy specialist, and infectious disease specialist.

3. PCN allergy algorithm should be completed on all patients who report penicillin allergy.

4. Diagnosis with syphilis during the 2nd trimester of pregnancy, should be referred to OB/GYN or OB provider for sonographic fetal evaluation for congenital syphilis.

5. If a true allergy is identified, refer to a primary care physician or dermatologist for skin testing for penicillin allergy and possible desensitization.

6. All latent syphilis cases should be referred to a Communicable Disease Specialist for further counseling and sex partner referral.

7. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the **Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.**

8. Refer pregnant patients to OB provider for prenatal care.

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Attachment A: Appointment Card Signs/Symptoms of Neurosyphilis

NOTE: The following appointment card depicts some of the symptoms and signs of Neurosyphilis.

It is very important that you return for treatment/follow up as discussed.

It is important that you repeat blood work every:

- ☐ Person with HIV 3, 6, 9, 12 and 24 months (after initial treatment)
- ☐ Person with HIV 6, 12, 18 and 24 months (after initial treatment)
- ☐ Person without HIV 6, 12 and 24 months (after initial treatment)
- ☐ Person without HIV 6 and 12 months (after initial treatment)

Return to:

PLACE HEALTH CLINIC LABEL HERE

On the following Dates:

Date	Treatment

If you are having complications, have been re-exposed to this infection or feel you are having signs and symptoms, please return as soon as possible.

If you or someone else notices you are having any of these signs and/or symptoms, you should return to the clinic or report to your primary care provider right away.

- ☐ Memory Loss
- ☐ Problems with Mental Function
- ☐ Unsteady Walking
- ☐ Balance Problems (Dizziness or Faint)
- ☐ Urinary Problems (Can't Hold Pee)
- ☐ Bowel Problems (Can't hold bowel movements)
- ☐ Vision Problems (Blurred vision, loss of vision)
- ☐ Eye Pain
- ☐ Problems Having Sex
- ☐ Numbness or Loss of Feeling in Legs
- ☐ Stiff Neck
- ☐ Headache
- ☐ Fever
- ☐ Loss of Hearing
- ☐ Persistent Nausea and Vomiting (Always throwing up)
- ☐ Seizures
- ☐ Stroke
- ☐ Unexplained Episodes of Severe Pain

STANDARD NURSE PROTOCOL FOR MPOX (formerly MONKEYPOX)

NOTE: The mpox outbreak is rapidly evolving, and this protocol is subject to change based on CDC and/or DPH guidance and recommendations. Mpox is not a sexually transmitted disease (STD), but it is transmitted through close, sustained physical contact which can include sexual contact. The differential diagnosis list for mpox includes STDs such as syphilis, Lymphogranuloma Venereum, and herpes simplex virus. During the current global outbreak of mpox, a rash or lesions can occur anywhere on the body but are often occurring in the genital and anorectal areas or in the mouth.

DEFINITION

Mpox is a rare disease caused by infection with the monkeypox virus. Monkeypox virus belongs to the *Orthopoxvirus* genus in the family *Poxviridae.* The *Orthopoxvirus* genus also includes variola virus which causes smallpox, vaccinia virus used in the smallpox vaccine, and cowpox virus. Mpox is not related to chickenpox.

ETIOLOGY

Mpox is a zoonotic infection endemic to several Central and West African countries. Before May 2022, cases outside of Africa were reported either among people with recent travel to Nigeria or contact with a person with a confirmed monkeypox virus infection. Since May 2022, mpox cases have been reported in multiple countries that don't normally have cases and the virus is spreading mostly through close, intimate contact with someone who is infected with monkeypox virus.

Mpox can spread from person-to-person through:

- Direct contact with the infectious rash, scabs, or body fluids
- Respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
- Touching items (such as clothing or linens) that have been in contact with infectious rash or body fluids
- Through the placenta to the fetus during pregnancy

Mpox infection can also occur from contact with infected animals including being scratched or bitten by the animal, preparing or eating the meat, or using products from the animal. This is not currently a primary transmission route in this outbreak. There is not currently information available that indicates risk to humans related to common domestic animals (e.g., dogs and cats) in the United States. Risk associated with animals, although still not high, is primarily related to documented susceptible species such as rodents and non-human primates in limited settings in countries where mpox typically circulates.

Mpox can spread from the time symptoms start until the rash has fully healed and a fresh layer of skin has formed. The illness typically lasts 2-4 weeks. People who do not

have mpox symptoms cannot spread the virus to others. It is not known if mpox is spread through semen or vaginal fluids.

Mpox symptoms almost always involve a characteristic rash, that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body including hands, feet, chest, genitals, or anus. Historically, the rash has been preceded by a prodrome including fever, lymphadenopathy, and often other non-specific symptoms such as malaise, headache, and muscle aches. In the most recent reported cases, prodromal symptoms have not always occurred but instead began with characteristic mpox-like lesions in the genital and perianal region in the absence of prodromal symptoms. For this reason, cases may be confused with more commonly seen infections including syphilis, chancroid, herpes, and varicella zoster. The average incubation period before symptom onset is 5–13 days.

SUBJECTIVE

3. Patient provides a focused health history (includes personal, family, social, or close contact with a person known or suspected to have mpox) that may indicate increased risk factors for development of mpox.
4. Patient is referred to the clinic by the Epidemiology Unit as being identified as a close contact to a patient known to have mpox and the patient reports symptoms of a rash or lesions.
5. Suspicion for mpox should be heightened if within 21 days prior to illness onset the person:
    a. Reports having contact with a person or people who have a similar appearing rash or who have received a diagnosis of confirmed or probable case of mpox, or
    b. Reports close or intimate contact with someone in a social network experiencing mpox outbreak such as men who have sex with men, or
6. Reports any of the following symptoms:
        a. Fever
        b. Chills
        c. Headache
        d. Muscle aches and backache
        e. Swollen lymph nodes
        f. Chills
        g. Exhaustion
        h. Respiratory symptoms (e.g., sore throat, nasal congestion, or cough)
        i. A rash that may look like pimples or blisters on the face, inside the mouth, and on other parts of the body including hands, feet, chest, genitals, or anus. The rash goes through different stages before healing completely. Sometimes, people get a rash first, followed by other symptoms. Others only experience a rash.

NOTE: The above list includes symptoms reported by CDC, but other symptoms that may be observed include proctitis (rectal inflammation), hematochezia (bleeding from rectum), and tenesmus (painful defecation).

OBJECTIVE

1. Characteristic rash, deep-seated and well-circumscribed lesions, often with central umbilication and lesion progression through specific sequential stages, macules, papules, vesicles, pustules, and scabs. Link to mpox rash photos**.**

2. Lesions may be disseminated or located in the genital or perianal area.

3. May have fever and/or swollen lymph nodes.

ASSESSMENT

Differential diagnosis includes Syphilis, Herpes Simplex, Mpox, and Lymphogranuloma Venereum.

PLAN

DIAGNOSTIC STUDIES

NOTE: Testing for mpox is done using real-time PCR testing on lesion material. Specimens are collected by vigorously swabbing or brushing an infected lesion with a sterile dry swab. The CDC advises collecting multiple specimens for preliminary and confirmatory testing.

NOTE: Prior to collection of specimens, nurses must review CDC's guidance on Infection Prevention and Control of Mpox in Healthcare Settings and utilize CDC recommended PPE [gown, NIOSH-approved N-95 mask, goggles or face shield, and gloves] during assessment and collection of specimens.

1. Utilize CDC recommended PPE [gown, NIOSH-approved N-95 mask, goggles or face shield, and gloves] during assessment and collection of specimens.

2. Contact District Epidemiologist to determine eligibility to send specimen to Georgia Public Health Laboratory (GPHL) then proceed with recommendations.

3. Collect specimens for mpox molecular testing to send to GPHL. The sample may include vesicle fluid, skin, crust, or lesion "roof".
   a. More than one lesion should be sampled, preferably from different locations on the body and/or from lesions with differing appearances.
   b. Swab at least two lesions, with two separate swabs per lesion. A total of 4 specimens will be collected and each swab must be placed in a separate plastic, sterile, leak-proof container, or collection tube for transport to GPHL. GPHL will send the extra specimen from each lesion to the CDC for confirmatory testing if indicated.
      i. Use a separate sterile nylon, polyester, or Dacron swab with a plastic, wood, or thin aluminum shaft for each collection. Do not use cotton swabs.
      ii. Swab the lesion vigorously to collect adequate DNA. It is not necessary to de-roof the lesion before swabbing.
      iii. Place each swab in an individual collection tube or sterile container without media. Do not use universal or other viral transport media. If a specimen was collected and placed in viral transport media in error, testing may be possible

iv. Re-swab the same lesion using a new sterile swab. This will result in two separate swabs per lesion.
v. Store and package swabs separately, one swab per container. When possible, use a plastic, sterile, leakproof container.
vi. Write the site of collection on each container and indicate swab 1 or swab 2 (ex. “right forearm swab 1” and “right forearm swab 2”).
vii. Label each collection tube or sterile container with at least two patient identifiers (e.g., name, date of birth, address, etc.) along with collection site
viii. Refrigerate (2-8°C) or freeze (-20°C or lower) specimens within an hour after collection.
    a) Specimens should only be frozen if shipment will be delayed more than 24-48 hours.

4. Chlamydia and gonorrhea NAAT testing at the anatomical sites of exposure and/or symptoms including rectal, vaginal, urethra, oropharynx.

5. HIV antigen and/or antibody test to determine HIV status, if unknown.

6. Herpes culture in accordance with the Standard Nurse Protocol for Herpes Simplex if characteristic single or multiple blisters and/or shallow painful ulcers that are typical for herpes are present.

7. Nontreponemal and treponemal tests for syphilis.

THERAPEUTIC

NOTE: Empiric treatment can be recommended or ordered if clinical manifestations (e.g., rash, itching, fever, or pain) are identified.

NON-PHARMACOLOGIC MEASURES

1. Skin lesions should be kept clean and dry when not showering or bathing to prevent bacterial superinfection.

2. Inert, anti-irritant topical agents such as calamine lotion or petroleum jelly can be used to manage itching.

3. For painful genital and anorectal lesions and proctitis, warm sitz baths (available in retail pharmacies) for at least 10 minutes several times a day may be helpful.

PHARMACOLOGIC

NOTE: Currently there is no treatment approved specifically for mpox infections. Antivirals developed for use in patients with smallpox may prove beneficial against mpox and some of these medical countermeasures are available from the Strategic National Stockpile (SNS).

1. Over-the-counter oral analgesic of patient's choice (e.g., acetaminophen or ibuprofen) may be recommended as needed for pain related to outbreak and prodrome syndrome.
2. Over-the-counter antihistamines (e.g., diphenhydramine) of patient's choice may be recommended as needed for itching.

3. For oral lesions:
   a. A saltwater rinse or gargle and/or over-the-counter oral antiseptic rinses or gels (e.g., OTC Orajel Antiseptic Rinse, Gly-Oxide Oral Antiseptic Cleanser) can be used to keep lesions clean.
   b. A prescription for Magic Mouth Wash may be called into a pharmacy. Parental consent is required in the event Magic Mouth Wash is prescribed to a minor. Provide to the pharmacist:
      1) Name of Product: Magic Mouth Wash
      2) Provide/state each of the following ingredients which should be mixed in equal amounts:
         - Diphenhydramine 12.5 mg/5 ML
         - Viscous lidocaine 2%
         - Mylanta® OR Maloxx® containing: Aluminum hydroxide 200 mg/magnesium hydroxide 200 mg/simethicone 20mg per 5 mL
      3) Swish, gargle, and spit 1 or 2 teaspoonfuls every 4 to 6 hours as need for oral pain/discomfort.
      4) Qty: 4 OZ (120ML)

4. For painful genital and anorectal lesions, topical benzocaine/lidocaine gels or products OTC anal/rectal products 20% benzocaine (e.g., Americaine hemorrhoidal ointment), lidocaine 5% (e.g., RectaSmoothe hemorrhoidal cream) may be recommended for temporary relief.

5. Stool softeners (e.g., docusate), sitz baths, and over-the-counter pain medications may be recommended for patients with symptoms of proctitis. Sometimes, the proctitis can become severe to include rectal bleeding and may require referral.

PATIENT EDUCATION/COUNSELING

7. Provide information about the infection including prevention of transmission to others. A person is infectious and can transmit mpox to others from the time a rash develops or at the onset of prodromal symptoms (e.g., fever, lymphadenopathy, chills, fatigue), whichever comes first, and remains infectious until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed.

8. Provide required information on DPH MpoxHome Isolation Guidance**.**

9. Close contacts should be referred for evaluation and vaccination, if indicated. JYNNEOS is a two-dose vaccine administered intradermally, 4 weeks (28 days) apart, that is indicated for adults 18 years of age and older without history of keloid scars

who are determined to be at high-risk for mpox infection. The vaccine should be administered subcutaneously for those 17 years of age and younger and for people of any age with a history of keloid scars. CDC recommends JYNNEOS vaccination for people who have had a high-risk exposure to mpox, some intermediate risk persons, and people who are at higher risk of being exposed to mpox.

a. Persons identified by public health officials as a contact of someone with mpox (vaccine indication: post exposure prophylaxis (PEP))
b. Persons with certain risk factors who are more likely to have been exposed to mpox (vaccine indication: expanded PEP)
c. Persons who are or may be at higher risk for exposure to mpox without a known or likely exposure to mpox (vaccine indication: PrEP)

10. Education and counseling regarding the correct usage of protective barriers during sex (condoms, dental dams, etc.) for general STI prevention.

11. Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan. Abstain from sex until all STI symptoms are resolved, and partner(s) are tested and treated.

12. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

13. Counsel patient on individualized STI/HIV risk reductions and incorporate reduction plan including determining PrEP eligibility.

14. Refer to the District's Epidemiologist for reporting and assistance with partner notification.

15. If patient is given any oral medications, provide patient with directions for taking the medication, possible side effects, and what to do about the side effects. Seek medical care immediately if adverse reaction or systemic symptoms develop.

FOLLOW-UP

2. Ensure that negative and positive results are reported to the individual tested.

3. Orthopoxvirus and mpox have been added to the **GA DPH Notifiable Disease List** and are required to be reported immediately.

CONSULTATION/REFERRAL

6. Consult delegating physician if further medical guidance is needed, or this Nurse Protocol is not applicable or sufficient for therapeutic evaluation and management of the patient.

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STANDARD NURSE PROTOCOL FOR PEDICULOSIS PUBIS (Crabs/Pubic Lice)

DEFINITION

Pediculosis pubis is an infestation of pubic hair with pubic louse, pubic louse may also infest facial hair or eyelashes. Lice deposit eggs (nits) on the hair shaft; nits hatch in one week. Keep a high index of suspicion of sexual molestation in minors with pubic lice.

ETIOLOGY

Crab louse, Phthirus pubis, typically spread by sexual contact or sleeping in the same bed. Nymphs and adult lice feed on human blood; only the body louse is known to spread disease. The female louse can survive for up to one month on the scalp and lay up to eight to 10 eggs per day at the skin-hair junction. The eggs hatch and mature into adults in 20 days. Incubation period is approximately 6-10 days.

SUBJECTIVE

1. Itching in the pubic area.
2. "Bugs" or "crabs in pubic area."

OBJECTIVE

1. Identification of lice, larvae, or nits attached to genital hair.
   OR
2. History of exposure to pubic lice and pruritic, reddened macules or papules or secondary excoriations are observed in the genital area.

ASSESSMENT Pediculosis Pubis (Crab or Pubic Lice)

PLAN

The desired outcome of treatment is to eliminate lice and nits from patients and their clothing and bedding.

DIAGNOSTIC STUDIES

1. Identification of lice, larvae, or nits attached to genital hairs.

2. History of exposure to pubic lice and pruritic, reddened macules or papules or secondary excoriations are observed in the genital area.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Any patients who are diagnosed with pubic lice/crabs should be tested for gonorrhea, chlamydia, syphilis and HIV.
NOTE: Persons with HIV infection should receive the same treatment regimen as persons without HIV.

NOTE: Prior to treatment of minors, consult with or refer to primary care provider. Keep a high index of suspicion of sexual molestation in minors with pubic lice.

1. Patients at least 2 months of age may use:
   a. Permethrin 1% cream rinse (e.g., NIX) applied to the affected area and washed off after 10 minutes. May repeat in 1 week if live lice are still found.

   OR

   b. Pyrethrins with Piperonyl Butoxide (e.g., RID) applied to the affected area and washed off after 10 minutes.

NOTE: Pregnant and breastfeeding patients may be treated with pyrethrins and piperonyl butoxide..

NOTE: Do not give to ragweed or chrysanthemums sensitized patients.

2. Mild topical antipruritic/anti-inflammatory cream or ointment may be obtained OTC for itching.

3. Alternative Regimens may be ordered, administered and dispensed after consulting with delegating physician.
   a. If patient is at least 2 years of age weighs at least 15 kg and is not pregnant give Ivermectin 250 mcg/kg PO once. Repeat in 7 to 14 days.

NOTE: Ivermectin is present in breastmilk so other regimens should be considered for breastfeeding persons when possible. If Ivermectin is provided during breastfeeding patients should be advised to pump and discard breastmilk during treatment.

OR

   b. If treatment failure is suspected due to resistance AND patient is 6 years of age or more, give Malathion 0.5% lotion applied for 8-12 hours and then washed off. May reapply in 7-9 days if needed.

NOTE: Malathion lotion is flammable; patients must avoid heat sources (fire, hair, dryers, curling irons, etc.

NON-PHARMACOLOGIC MEASURES

Bedding and clothing should be decontaminated (e.g., either machine-washed with hot water, or machine-dried using the heat cycle or dry-cleaned) or removed from body contact for at least 72 hours (clean clothing should be worn after treatment).

MANAGEMENT OF SEX PARTNERS

Inform all sex and bed/sleeping partners from within the preceding month to obtain over the counter medication and complete treatment as soon as possible. Avoid sex or sleeping with untreated partners.

PATIENTS EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for sequelae and complications of the untreated infection (http://www.ashasexualhealth.org/stdsstis/crabs/).

3. How to apply prescribed medication and decontaminate clothing and bedding. Fumigation of living areas is not necessary.

4. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

5. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

6. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

7. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved.

8. HIV antibody test to determine HIV status, if unknown.

9. For additional information and support, refer to: National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

   HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

   Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357).

10. Refer to the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html) and the **Georgia Department of Public Health Immunization Program Manual**.

FOLLOW-UP

1. Reevaluate in 1 week if symptoms persist.
2. Re-treatment may be necessary if lice or eggs are found. If no response to initial treatment, re-treatment with a different regimen is recommended.

CONSULTATION/REFERRAL

1. Consult with delegating physician:
   a. Consult with delegating physician for treatment of patients related to pediculosis pubis outbreak (e.g. nursing homes, jails, schools, and other communities).
   b. Consult delegating physician for referral of pediculosis pubis of the eyelashes/eyebrows.
   c. Consult delegating physician when further medical guidance is needed and/or STI nursing protocol is not applicable for therapeutic treatment of patient.

2. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the **Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.**

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STANDARD NURSE PROTOCOL FOR SCABIES RELATED TO SEXUAL TRANSMISSION

NOTE: Refer to Child Health Scabies Protocol when sexual transmission of infection can be ruled out.

DEFINITION

Scabies due to sexual transmission is the infestation with the "itch mite" which penetrates the skin, creating visible papules, vesicles, or small, linear burrows, which contain the mites and their eggs. Common sites in adults include the flexor surface of the wrists, webbing between fingers, anterior axillary folds, the external genitalia, and the inner aspects of the upper thigh. In infants, other skin areas including the neck, face and scalp may be affected. The early identification of patients with scabies and treatment of their contacts reduces community transmission.

The predominant symptom is pruritus due to sensitization. It begins two to six weeks after the first infestation, sooner after subsequent infestations. Complications include excoriations and secondary infections due to scratching.

ETIOLOGY

Scabies is caused by *Sarcoptes scabiei*, the itch mite, which travels from body to body through close physical contact, sleeping in the same bed or sharing clothing. It takes approximately 15–20 minutes for the mite to transfer between people. When the mite is dislodged from its host, it can survive for 24–36 hours at room temperature and may be transmitted from objects such as shared bedding, towels, clothing or other fomites. Lesions may be seen only in the genital and adjacent areas when spread sexually. The incubation period in people with no previous exposure is 4-6 weeks. People who have been previously infested are sensitized and can develop symptoms 1-4 days after exposure.

SUBJECTIVE

1. Severe itching, usually worse at night, associated with a "breaking out" or rash. Sweating and hot water may increase the intensity of itch.

2. May have history of similar symptoms in other family members, playmates, or sexual partners.

OBJECTIVE

1. Burrows in the skin, appearing as finely raised wavy lines from a few millimeters to a few centimeters in length.

2. Papules or vesicles.

3. Excoriations and possible signs of secondary infection from scratching.

ASSESSMENT Scabies due to sexual transmission

PLAN

The desired outcome of treatment is to eliminate the mites and relieve symptoms.

DIAGNOSTIC STUDIES

NOTE: If the patient is symptomatic for scabies and denies sexual (vaginal, penile, oral or anal) intercourse in the past 60 days, Scabies can be treated as outlined per protocol without STI screening (CT, GC, RPR, HIV). Documentation of assessment must be completed. Patient should be educated regarding the missed opportunity of screening for other STIs and possibility of asymptomatic infections.

1. Gross or microscopic identification of mites, larva or eggs on scraping from papules or burrows.

2. Burrows in the skin or characteristic pruritic, erythematous, papular eruptions, and other causes of dermatitis are excluded.

3. Diagnosis is suggestive in a patient who has had sexual or other close physical contact to a patient infested with scabies and has compatible skin lesions.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Any patients who test positive for scabies related to sexual transmission should be tested for gonorrhea, chlamydia, syphilis and HIV.

NOTE: Persons with HIV infection who have uncomplicated scabies should receive the same treatment regimens as those who are without HIV. Persons with HIV infection and others who are immunosuppressed are at increased risk for crusted scabies. Such persons should be managed in consultation with a specialist.

1. Recommended regimen for nonpregnant, nonlactating patient at least 2 months of age:
   a. Permethrin 5% Cream (e.g., Elimite), single application. Thoroughly massage into all skin from the neck down to the soles of the feet, avoiding contact with mucous membranes, eyes and mouth. Remove by washing after 8-14 hours.

2. If age is equal or greater than 2 years of age and weigh at least 15 kg:
   a. Ivermectin 200 mcg/kg orally, single dose, with food. Repeat in 2 weeks.

NOTE: Oral ivermectin has limited ovicidal activity; a second dose is required for

eradication

OR

b. Ivermectin 1% lotion, single application. Thoroughly massage into all skin from the neck down to the soles of the feet, avoiding contact with mucus membranes, eyes, and mouth. Remove by washing after 8-14 hours. May repeat treatment in 1 week if symptoms persist.

NOTE: Educate patient to take Ivermectin with food to increase bioavailability.

3. Alternative regimen for nonpregnant, nonlactating patients ten years of age or older:
   a. Lindane 1% lotion (1 oz.) or cream (30 g), single application to all skin areas from neck down and thoroughly wash off in 8 hours.

NOTE: Lindane is not recommended as first-line therapy because of toxicity. Use only as an alternative due to inability to tolerate other therapies or if other therapies have failed. All patients must be provided a medication guide.

Do not use Lindane:

1) Immediately after bath or shower.
2) Extensive dermatitis.
3) Pregnant or breastfeeding
4) If less than 10 years of age
5) Weights less than 110 pounds.
6) Uncontrolled seizures

4. Pregnant or breastfeeding:
   a. Permethrin 5% Cream, as above

NOTE: Pregnant and breastfeeding patients may be treated with pyrethrin.

OR

b. Ivermectin 1% Cream, as above

5. For relief of itching, suggest an OTC oral or topical antihistamine.

6. Bacitracin ointment (OTC) for mild secondary infection.

NON-PHARMACOLOGIC

1. Bedding and clothing should be decontaminated (**i.e.,** either dry cleaned or machine-washed and dried using the hot cycle) or removed from body contact for at least 72 hours. Fumigation of living areas is unnecessary.

2. Keep fingernails clean and well-trimmed to minimize secondary infection from scratching.

3. Bathe in cool water using a mild soap.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts as indicated.

2. Provide information about the infection and its significance. Educate for possible sequelae and complications of the untreated infection (http://www.ashasexualhealth.org/stdsstis/scabies/).

3. Directions for use of medication and management of possible side effects.

4. Post-scabetic itch and psychosocial stigma are typical sequelae of the scabies mite infestation. The rash and Itching may persist for up to two weeks even after successful treatment. Over the counter, Hydrocortisone cream (only use after diagnosis has been made) or Benadryl cream may relieve persistent itching.

5. Ideally, clothes, towels and bed linens should be machine washed at 60°C (140°F) and machine dried the day after the first treatment to reduce infestation and subsequent fomite transmission. Clothing or difficult-to-exterminate items such as child toys may also be kept in a sealed plastic bag for at least 48–72 hours.

6. Education and counseling of the correct usage of protective barriers (condoms, dental dams, etc.).

7. If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.

8. Advise the patient to return to clinic for all lab results even if presumptively treated at initial visit. Inform patient if lab results are positive additional treatment may be needed.

9. Assist patient in developing a personalized STI/HIV risk reduction plan and document patients plan. Abstain from sex until all the symptoms are resolved.

10. HIV antibody test to determine HIV status, if unknown.

11. For additional information and support refer to the National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily

    HIV/AIDS Information Line In Georgia: (404) 876-9944 AID Atlanta In Atlanta: (404) 870-7700 Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/

    Substance Abuse and Mental Health Service Administration 1-800-662-HELP

(4357)

12. Refer to **DPH Immunization Program Manual** and the Advisory Committee on Immunization Practices for immunization recommendations for Hepatitis A, B and HPV (https://www.cdc.gov/vaccines/acip/index.html)

MANAGEMENT OF PARTNERS

Those that have had close personal, household contacts, or sexual partners within the past month need examination and treatment (See THERAPEUTIC section for treatment recommendation).

FOLLOW-UP

Reexamine in 2 weeks. Retreatment 2 weeks after the initial treatment regimen can be considered for those persons who are still symptomatic or when live mites are observed. Use of an alternative regimen is recommended for those persons who do not respond initially to the recommended treatment. If alternative regimen is contraindicated refer patient to primary care physician or dermatologist.

CONSULTATION/REFERRAL

1. Refer to Child Health Scabies Protocol when infection can be ruled out as being acquired through sexual transmission.

2. Consult with delegating physician:
   a. For repeated treatment failure or failure to respond to treatment.
   b. For severe secondary infection.
   c. For treatment of patients related to scabies outbreak (nursing homes, jails, schools, and other communities).
   d. Prior to use of Lindane on any patient.

3. When further medical guidance is needed, and STI nursing protocol is not applicable for therapeutic treatment of patient.

4. Refer infants younger than 2 months of age to primary care physician or pediatrician for evaluation and treatment may also refer to the Child Health Standard Nurse Protocol for Scabies.

5. Public Health Employees are mandated reporters of suspected child abuse under the Georgia Child Abuse Reporting Law O.C.G.A. §19-7-5. As mandated reporters, public health employees are required to report suspected child abuse which includes sexual abuse or sexual exploitation. Public health employees report suspected child abuse according to the **Georgia Department of Public Health Policy #GC-09014 Mandatory Reporting of Suspected Child Abuse by Public Health Personnel.**

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STANDARD NURSE PROTOCOL FOR EXPRESS STI SERVICES

PURPOSE:

Express STI services, also known as fast-track, are for asymptomatic patients and require less intensive comprehensive clinical services. Patients are screened for the best STI care according to symptoms and risk. Express STI services have been shown to increase clinic capacity, reduce time to treatment, reduce visit time, and decrease visit cost, and therefore have the potential to increase access to testing while maximizing available resources.

Patients may opt to refuse Express STI services.

Any client who presents symptomatic, < 18 years of age, or a victim of abuse/assault/rape are ineligible for the Express STI Services and are to be seen by a clinician for comprehensive care.

PROCEDURE:

Express STI services are one of several less-intensive visit types, along with treatment-only visits. The method in which Express STI services are administered is based upon available trained staff and clinic flow. Express STI services are to include screening, testing, and education.

The patient will complete an Express STI Assessment (Apprendix A) to determine eligibility. A nurse, communicable disease investigation staff, or other trained staff will review the assessment to determine eligibility. If the patient has symptoms of a STI or is a contact to a known STI case, they are not eligible for Express STI Services and should be provided comprehensive STI services.

The following screenings will be completed as part of an Express STI service:

- **Gonorrhea and Chlamydia**
- **Syphilis**
- **HIV testing**

SUBJECTIVE

1. **No known contact to a STI**
2. **Asymptomatic**
3. **Deny comprehensive STI care**

OBJECTIVE

1. **Completion of Express STI Assessment (Apprendix A) determines qualification for Express STI service.**

DIAGNOSTIC STUDIES

a. **Gonorrhea and Chlamydia: See note below.**
    i. **Hologic NAAT Aptima Urine**
    ii. **Hologic NAAT Aptima Multitest for patient collected vaginal swab**
b. **HIV**
c. **Syphilis**

NOTE: The Aptima Combo 2 Assay is FDA approved only for ≥ 14 years of age.

The performance characteristics of the Aptima Combo 2 Assay have not been evaluated in adolescents 13 years of age and younger.

For adolescents 11-13 years of age, nurse can send Aptima Combo 2 Assay specimens to GPHL who will coordinate NAAT testing through other State Public Health Laboratories. Delays in results may be expected.

To collect Aptima Combo 2 Assay specimens for NAAT testing in adolescents 10 years of age and younger, consultation with the District Health Director or delegating physician is required. If approved, consult with a private laboratory prior to sending specimen. Do not send specimens to GPHL for this age population.

Suspected or confirmed sexual abuse or sexual assault is to be reported immediately.

PATIENT EDUCATION/COUNSELING

1. **Provide STI education (i.e., pamphlets, videos, handouts, etc.).**
2. **Reinforce pertinent information with STI handouts as indicated.**
3. **Assist patient(s) in developing a personalized STI/HIV risk reduction plan and document patient(s) plan.**
4. **Education and counseling on the correct usage of protective barriers (condoms, dental dams, etc.).**
5. **If person with childbearing potential, counsel on the use of contraceptives to reduce the risk of unintended pregnancy. Link to public health family planning services if desired.**
6. **Advise the patient to return to the clinic for lab results.**
7. **For additional information and support, refer to National CDC AIDS Hotline: 1-800-CDC-INFO (232-4636), 24 hours daily; HIV/AIDS Information Line In Georgia: (404) 876-9944; AID Atlanta In Atlanta: (404) 870-7700; Outside of Georgia: (800) 551-2728, http://www.ashasexualhealth.org/stdsstis/herpes/**
   Substance Abuse and Mental Health Service Administration 1-800-662-HELP (4357)
8. **Hepatitis A, Hepatitis B and/or HPV vaccine, if patient is unvaccinated and meets**

eligibility criteria for state supplied vaccines. To access most current version of the Eligibility Criteria for Vaccines Supplied by the GA Immunization Program for Children, Adolescents, and Adults go to the Georgia Department of Public Health Immunization Program Manual website.

FOLLOW-UP

1. **Patient to follow up for lab results.**

CONSULTATION/REFERRAL

1. **Patient does not qualify for Express STI service and comprehensive care is recommended.**

REFERENCES

1. **Centers for Disease Control an*d Prevention,* Sexually Transmitted Infections Treatment Guidelines, 2021 (cdc.gov) Volume 70, No. 4. Retrieved August 10, 2021.**

2. **Stoner, B., Reno, H., Brethauer, C., Spear, D. & Knaup, R. (2012). "Fast-track" STD services in an urban STD clinic: Increased clinical capacity, but reduced opportunities for same-day treatment. Sexually Transmitted Infections 88(Suppl 1)**

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Appendix A Express STI Assessment

Why did you come to the clinic today? (Mark all that apply)

□ My partner was treated for an infection

□ I have a problem
- _ Discharge (vagina, penis, rectum)
- _ Itching
- _ Odor
- _ Sores / Rash / Bumps
- _ Pain/ Abnormal Bleeding
- _ Other: _____

□ I have no symptoms. I am here for STI testing only.

Do you have sex with males, females, transgender, or all? (Mark all that apply)

□ Males **□ Females** **□ Transgender** **□ All**

How many partners have you had in the last 60 days? _____

When was your last sexual encounter (oral, anal, vaginal, penial)? _____

Date of last normal period_____

Birth Control? □ NO □ YES If yes, type _____

Are you pregnant? □ NO □ YES

How often do you use condoms or other barriers? □ Always □ Sometimes □ Never

In the past 90 days, have you:

Been told that one of your sex partners has syphilis or HIV?	□ NO	□ YES
Received anal sex?	□ NO	□ YES
Had oral sex?	□ NO	□ YES
Provided?	□ NO	□ YES
Received?	□ NO	□ YES
Used drugs like crack, crystal meth, or other IV drugs?	□ NO	□ YES

Are you allergic to any medicines or foods? □ NO □ YES
If yes, please list allergy and reaction _____

Have you taken any medicines in the past 2 weeks? □ NO □ YES
If yes, please list medications _____

Have you used the bathroom (urinated) in the last hour? □ NO □ YES

To the best of my knowledge, all the preceding answers and information provided are true and correct. If I ever have any change in my health, I will inform the clinic staff at the next appointment without fail.

PROCEDURE FOR
PENICILLIN ALLERGY TESTING (PRE-PEN)

Patient Eligibility and Criteria:

Who to test:

- Patients who report a penicillin allergy that may be IgE mediated but cannot remember their reaction and there is no objective data confirming the allergy.
- Penicillin is clinically indicated and is considered by the prescriber to be the preferred agent.
- Penicillin or beta-lactam antibiotics are withheld due to concern for allergy.

Who NOT to test:

- Patients known to be extremely hypersensitive to penicillin, e.g. anaphylactic reaction within the last 5 years.
- Patients with clear history of severe skin reaction such as Stevens-Johnson syndrome or toxic epidermal necrolysis.
- Patients who have received antihistamines within the last 48-72 hours.

Procedure

Step 1. Prick Test

e. Clean the volar surface of either forearm with an alcohol swab.
f. Using an ink pen, draw 3 vertical lines approximately 1 inch apart on the designated testing site of the arm labeling testing sites as follows: PRP, PG, +, ─
g. In quick sequence, apply skin prick tests with PRE-PEN (PRP), penicillin G (PG), histamine (+) and saline (─).
    - Tests are conducted by applying a small drop of solution from the corresponding prefilled syringe and then making a single, shallow puncture of the epidermis using a twisting motion with a Duotip Test-II pricking device. Use a new pricking device per site.

h. Read the test in 15-20 minutes: (document test results below)
    - The positive control (histamine skin test) should be positive (> 3 mm wheal) to ensure the test is working properly. Flare and itching at positive control site are common.
    - Test is negative: change in diameter of PRE-PEN and PenG wheal is less than 3 mm than that observed with the negative control. Proceed to intradermal test.
    - Test is positive: change in diameter of PRE-PEN or PenG wheal is greater than 3 mm than that observed with the negative control. As soon as a positive response is observed, the solution should be wiped off the skin. Do not proceed to intradermal test.

Step 2. Intradermal Test

a. Only conduct this test if patient produced a negative result with the prick test in step 1. Select 5 sites on the volar surface on the forearm. These sites should be on the opposite arm from the prick test if possible. Clean area with alcohol swab and label testing sites as PRP, PRP, PG, PG, C.
b. Using prefilled PRE-PEN syringe, intradermally inject 0.02 ml of PRE-PEN solution in duplicate (separate at least 2 cm apart). Mark the perimeter of each initial bleb with an ink pen.
c. Using prefilled PenG syringe, intradermally inject 0.02 ml of Pen G in duplicate (separate at least 2 cm apart). Mark the perimeter of each initial bleb with an ink pen.
d. Using prefilled saline syringe, intradermally inject 0.02 ml of saline. Mark the perimeter of initial bleb with an ink pen.
e. Read the test in 15-20 minutes: (document test results below)
    - Test is <u>negative</u>: there is no increase in the original bleb and no greater reaction than the negative control site.
    - Test is <u>positive</u>: bleb or wheal increases >3 mm from its original size. <u>Patient is NOT to receive penicillin.</u>

Step 3. (Optional) Oral Penicillin Challenge

a. Give patient oral penicillin (e.g., amoxicillin 250mg) challenge and move patient to in a monitored setting for 61 minutes.

APPENDIX A Penicillin Allergy Assessment (PrePen)

Results: _____

Patient: _____ DOB: _____

Nurse Performing Test: _____

Test Date	Product	Prick Width (mm)	Intradermal #1 Width (mm)	Intradermal #2 Width (mm)	Results (Pos/Neg/Ambiguous)
	PrePen (undiluted)				
	Penicillin G (10,000 U/ml)				
	Diluent Control				
	Histamine (1.0mg/ml)				

Interpretation:

- ☐ NEGATIVE for penicillin allergy
- ☐ POSITIVE for penicillin allergy

Physician Signature: _____

Date: _____ Time: _____

STANDARD NURSE PROTOCOLS FOR TUBERCULOSIS

2023 STANDARD NURSE PROTOCOLS FOR TUBERCULOSIS CLINICAL REVIEW TEAM

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Titilola Rush, RN, BSN **Tuberculosis Nurse Consultant** **DPH**	**Marjorie McDermott, RN, BSN** **Tuberculosis Nurse Consultant** **DPH, State TB Office**
Carolyn Martin, RN **Tuberculosis Nurse Consultant** **DPH**	**Olivia Echols, MSN, MPH, RN** **Infectious Disease Coordinator and TB Coordinator, District 10**

2022 STANDARD NURSE PROTOCOLS FOR TUBERCULOSIS CLINICAL REVIEW TEAM

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STANDARD NURSE PROTOCOL FOR ACTIVE TUBERCULOSIS (TB) DISEASE AGE 15 AND OVER

DEFINITION

Tuberculosis (TB) is an infectious disease transmitted through the air in droplet nuclei that are produced when a person with active TB disease of the lung or larynx sneezes, coughs, speaks, or sings. Persons breathing air contaminated with these droplet nuclei may become infected with TB.

Generally, a positive culture or positive Nucleic Acid Amplification test (NAAT) for *Mycobacterium tuberculosis* is necessary to confirm the diagnosis of TB disease. However, people being evaluated for TB may be diagnosed based on: a positive sputum/specimen smear for acid-fast bacilli (AFB); lung histology showing necrotizing granulomas with or without AFB; or clinical syndrome, even when a culture or pathologic specimen has not been, or cannot be obtained.

ETIOLOGY

Causative agent of TB is the *Mycobacterium tuberculosis* (*M.tb*) complex (*M. tuberculosis, M. bovis, M. africanum, M. microti, M. canetii, M. caprae, M.mungi and M. pinnipedii)*.

SUBJECTIVE

1. May have history of exposure to a known person with TB disease

2. May have history of active TB disease or latent TB infection

3. May have one or more of the following symptoms related to TB:
   a. Productive, prolonged cough (usually more than two- or three-weeks' duration)
   b. Fever
   c. Chest pain or pleuritic pain
   d. Chills
   e. Night sweats
   f. Easily fatigued
   g. Loss of appetite
   h. Weight loss without dieting
   i. Hemoptysis (coughing up blood)
   j. Headache
   k. Muscle/bone/joint pain

NOTE: A complete medical history and review of current medications is required to determine if there are any diseases/illnesses present that would require consultation the delegating physician.

OBJECTIVE

1. Physical examination performed per guidelines may reveal the following criteria that are useful in identifying a person with TB disease:
   a. Coughing or shortness of breath
   b. Fever/sweating
   c. Appears ill or fragile
   d. Vital signs (height, weight, BMI, blood pressure, respiratory rate)
   e. Jaundice of sclera or skin
   f. Abdominal tenderness
   g. Joint swelling or redness
   h. Difficulty walking, tremors
   i. Dizziness, syncope, memory loss

ASSESSMENT

1. Pulmonary tuberculosis
   OR
2. Extra-pulmonary tuberculosis
   OR
3. Person being evaluated for pulmonary tuberculosis
   OR
4. Person being evaluated for extra-pulmonary tuberculosis

NOTE: Patients with the following low and/or high-risk conditions are at risk for complications with TB treatment. Consultation with the delegating physician is required for a patient with any of the risk conditions listed below before they can be treated under this nurse protocol. Consultation with the delegating physician must be documented in the patient's record. Medications not included in the standard nurse TB protocols, must be ordered by a physician, and dispensed by a licensed pharmacist or physician. The nurse may continue to provide all other patient care under the Standard Nurse Protocol for Active TB.

Low Risk Conditions:

a. BMI greater than 30 (obese)
b. BMI lower than 17 (underweight)
c. Age greater than 75 years old
d. Diabetes mellitus
e. Liver disease
f. Extra-pulmonary TB not requiring 2nd line TB drugs or use of corticosteroid therapy (Excludes: Central Nervous System (CNS) TB, TB pericarditis: these cases must be referred for physician management.)
g. Allergic reactions not requiring 2nd line TB drugs
h. Review of current medications reveal potential for drug-drug interactions with TB medications
i. Treatment interruptions:
   1) During the initial phase of treatment if the lapse is 14 days or more in

duration.

2) During the continuation phase of treatment:
   a) If patient is smear positive initially and received less than 80% of the planned total doses for continuation phase.
   b) Any patient whose lapse is 3 months or more in duration combined or a lapse of 2 consecutive months.

High Risk Conditions:

a. TB treatment for children from birth up to 15 years of age (i.e., age 0 – 14 years)
b. Any known drug resistance to anti-TB medications
c. Known HIV infection
d. **Known or Suspected Central Nervous System (CNS) TB including TB Meningitis**.
e. TB pericarditis
f. TB patient requiring adjunctive use of corticosteroid therapy
g. Use of once-weekly Isoniazid and Rifapentine in continuation phase for active TB disease
h. Renal insufficiency **(**estimated creatinine clearance less than 70 mL/ min**)**
i. End-stage renal disease on hemodialysis
j. Any TB patient requiring 2nd line TB drugs
k. Treatment failure (positive culture of *M. tuberculosis* after 4 months of treatment)
l. Pregnant/Breastfeeding

PLAN

The desired outcomes of treatment of active TB disease are biologic cure, prevention of drug resistant TB and prevention of transmission of TB to individuals exposed to persons with active TB.

NOTE: Any hospital admissions or deaths of persons with TB disease are to be reported immediately to the District TB Coordinator who in turn will report to the State TB Office.

INITIAL DIAGNOSTIC STUDIES

1. If positive results for either an IGRA or a TST cannot be verified (including millimeters [mm] of induration), perform a TST or IGRA. An IGRA is the preferred method of testing in individuals 2 years of age and older who are foreign born and/or have a history of BCG vaccination. TB skin testing should be performed on children less than 2 years of age.

NOTE: **Some specific vaccinations may interfere with either of these tests for latent TB. For persons scheduled to receive a TST or IGRA, testing relative to vaccine administration should be done as follows:**

a. For live virus vaccines, LTBI testing (TST or IGRA) either on the same day or prior to the vaccine or 4-6 weeks after the administration of the vaccine.
b. **For JYNNEOS Mpox vaccine the effect of the vaccination on a TST or IGRA is unknown. Therefore, if a delay in TB testing for 4 weeks would cause a substantial burden (for example, preventing a person from working because of pre-employment screening policies), then TB testing should not be delayed. If a delay will not cause a substantial burden, then a delay of at least 4 weeks after JYNNEOS vaccine is preferred. TB testing can be done at the same time as JYNNEOS vaccination, as with other vaccines, and any sequence of vaccination and TB testing may be used at that time. If a JYNNEOS vaccine and TST are administered at the same time, they should be administered on opposite arms with the sites of administration documented. If the same arm must be used, then the injection sites should be separated by 8-10 cm (3-4 inches) along the length of the arm, reducing the chance of overlapping reactions. If an IGRA is done on the same visit as a JYNNEOS vaccination, either arm can be used for blood collection.**
c. For COVID-19 vaccines, no restrictions, testing with TST and IGRA can be done before, after, or during the same encounter as COVID-19 vaccination.
d. Consider relative risks and benefits of a decision to delay LTBI testing over the administration of a vaccine.
e. Check most recent CDC guidance for any updates relating to LTBI testing and COVID-19 vaccination: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#laboratory-testing

2. Collect three sputum specimens on consecutive days for culture per procedure for spontaneous sputum collection for TB. Identify patients with dry, non-productive cough for nebulized sputum induction. Follow guidelines for both spontaneous and nebulized sputum in the **TB Policy & Procedure Manual, current version**. Send specimen collected to the Georgia Public Health Laboratory (GPHL) in Decatur.

   Order testing for sputum specimens by either completing a paper lab slip found on the GPHL website at http://dph.ga.gov/lab or via your electronic laboratory ordering system. Order smear, culture, and sensitivity testing on all three specimens, then order NAAT on the first two specimens only. Do not mark "smear only" unless the patient has had a recent positive culture report.

   The public health nurse (PHN) or designee will obtain the first sputum specimen and provide the patient with two additional containers for collection. Instructions should be given to both patient and family on how to properly produce sputum for examinations. At least one of the specimens collected MUST be an early morning specimen as they provide the highest yield for detecting *M.tb*. Ideally the initial specimens should be collected over a three-day period, however multiple samples may be collected in the same day if eight hours has elapsed between collections and at least one is an early morning specimen.

Specimens not picked up the day of collection should be refrigerated. If necessary, the PHN or designee should collect, transport or mail the specimens. Optimum sputum specimens contain an 8-10 ml sample; however, any amount collected will be tested at the state lab. Specimens received by the lab that contain less than a 0.5 ml sample may have an insufficient quantity of material for all lab testing to be performed.

3. Perform the following baseline blood chemistry labs:
    a. Liver function test including aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase.
    b. CBC with platelet count.
    c. Serum Creatinine
    d. HgbA1C

NOTE: If HgbA1C is elevated between the **5.7%** and 6.4% (Pre-Diabetes), refer to nutritionist or Primary Care Physician for prediabetes education and counseling. If HgbA1C is 6.5% or greater (Diabetes), refer patient to PCP for evaluation and treatment.

    e. Hepatitis C antibody for all adults.

NOTE: If Hepatitis C Ab is positive, refer patient to PCP for evaluation and follow-up.

    f. Hepatitis B profile (HBsAg, HBsAb, HBcAb) should be obtained for all adults (regardless of birth country) and anyone less than 18 years old who is foreign-born.

NOTE: If HBsAg is positive, refer to PCP for evaluation and consideration for treatment. If all HB serology results are negative (i.e., the patient is susceptible to Hepatitis B infection), consider Hepatitis B immunization as per ACIP guidelines.

    g. All individuals will be tested for HIV using the opt-out approach. Consent is inferred unless patient declines testing. If HIV positive, collaborate with HIV Program to obtain CD4 T-cell count, then refer to consulting physician.

4. Obtain baseline visual acuity testing and red/green color discrimination for patients being placed on Ethambutol.

5. **Perform a urine pregnancy test, if of childbearing potential. If positive refer to the delegating physician.**

6. Refer patient to have chest x-ray performed to detect abnormalities compatible with TB disease.

DIAGNOSTIC STUDY FINDINGS

1. A positive interferon gamma release assay (IGRA) or a positive tuberculin skin test (TST). The absence of a positive IGRA/TST does not rule out the diagnosis of TB

disease or latent TB infection, particularly in immune compromised patients. Online link: **https://clinicalinfo.hiv.gov/en/guidelines-search?search=Tuberculosis**

2. Positive staining of AFB in sputum, bronchial brush, bronchial wash or lung tissue biopsy. However, a person with TB disease can be smear negative.

3. Chest x-ray showing abnormalities compatible with TB disease. (Radiographic findings of healed, inactive TB and reactivating TB sometimes cannot be distinguished). See opportunistic infections: **https://clinicalinfo.hiv.gov/en/guidelines-search?search=Tuberculosis**

4. The following criteria (one or more) are required for a confirmed diagnosis of TB:
   a. Pathology findings compatible with the diagnosis of TB.
   b. Specimens with positive culture or positive NAAT for *M.tb.*

THERAPEUTIC

PHARMACOLOGIC

1. Order medication for directly observed therapy (DOT) treatment.

a. For patients that do not require consultation with delegating physician, refer to tables 1 and 2 for options and dosages.

b. For patients that require consultation with delegating physician for possible second line medications not included in the protocol:

1) A PHN may only dispense first line TB medications (INH, RIF, EMB, and PZA) included in Standard Nurse Protocols.

2) If second line medications that are not included the Standard Nurse Protocol for Active TB are recommended, the medications must be ordered by a physician and dispensed by a licensed pharmacist or physician.

3) The PHN may continue to provide all other patient care under the nurse protocol. Follow guidelines for completing the second line therapy authorization form that is available on PHIL 2.0.

Note: Delegating physician's orders/prescriptions for second line medications may not be dispensed by an RN. The following is a list of options for dispensing medications prescribed by a physician that meets the Dispensing Practitioner Requirements of the Georgia Composite Medical Board:

- **The physician may dispense the medication from the district pharmacy.**
- **The physician may call or e-scribe the prescription to the district pharmacist or a local pharmacy.**
- **The physician may delegate to a PHN to send or call-in prescription for 2nd line medications.**

2. Video direct observed therapy (VDOT)
    a. Carefully selected patients meeting established minimum criteria may be eligible to receive their medications via VDOT. During VDOT the healthcare worker observes the patient take their medication via smartphone, laptop, or desktop. See **Tuberculosis Policy and Procedure Manual for additional information, located on PHIL 2.0.**

Table 1: Regimen Options - Treatment of Patients with Drug-Susceptible TB

Option	Total Duration (Months)	Initial Phase		Continuation Phase[8]		Comments
		Drugs	**Interval & Dose # (minimal duration)**	**Drug Regimen**	**Interval & Dose # (minimal duration)**	
1	6	Isoniazid Rifampin Pyrazinamide Ethambutol	Daily DOT for 40 doses (8 wks.)	**1a: INH/RIF** **OR**	**DOT - 7 days each week for 126 doses (18 weeks)** **OR**	Regimen must be directly observed. Continue Ethambutol until susceptibility to Isoniazid and Rifampin is obtained via drug susceptibility results.
				1b. INH/RIF **OR**	***DOT- 5 days per week for 90 doses (18 weeks)** **OR**	
				1c: INH/RIF	**Thrice-weekly DOT for 54 doses (18 weeks) is preferred treatment**	
Pyridoxine (Vitamin B6) 25 - 50 mg PO daily to prevent the development of Isoniazid-induced peripheral neuropathy.						

INH=Isoniazid RIF=Rifampin PZA=Pyrazinamide EMB=Ethambutol Vitamin B6=Pyridoxine

NOTE:

a. ***Daily DOT = 5 days/week (Monday through Friday). Self-administered doses (including those on weekends) will not be counted toward the total doses. 5 daily doses of DOT equal 3 thrice-weekly doses of DOT. Intermittent therapy is not recommended for HIV (+) individuals.
b. Split dosing should be avoided.
c. Refer to current drug reference or drug package insert for a complete list of adverse drug reactions and drug interaction.

[8] TB treatment may be extended beyond 6 months minimal duration as determined by consultation with and documentation from delegating physician.

Table 2: First-Line TB Drugs Dosages

Drugs	Adult Dose based on body weight in kilograms (kg)[9]		Adverse Reactions
	Daily	Thrice Weekly (preferred over twice weekly)	
Isoniazid	**300 mg**	900 mg (15 mg/kg Max.dose: 900 mg)	• Gastrointestinal (GI) upset • Liver enzyme elevation • Acute hepatitis • Peripheral neuropathy • Mild effects on central nervous system • Drug interactions
Rifampin	600 mg	600 mg	• Orange discoloration of body fluids and secretions • Drug interactions • GI upset • Hepatitis • Easy bruising/ bleeding • Influenza-like symptoms • Rash
Pyrazinamide [10]	40-55 kg: 1000 mg 56-75 kg: 1500 mg 76+ kg: 2000 mg	40-55 kg: 1500 mg 56-75 kg: 2500 mg 76+ kg: 3000 mg	• GI upset • Joint aches • Hepatitis • Rash • Hyperuricemia • Gout (rare)
Ethambutol	40-55 kg: 800 mg 56-75 kg: 1200 mg 76+ kg: 1600 mg	40-55 kg: 1200 mg 56-75 kg: 2000 mg 76+ kg: 2400 mg	• Optic neuritis

NOTE: Ethambutol and Pyrazinamide dosage adjustment may be needed if there is renal impairment. Patients with estimated creatinine clearance less than 70 mL/min or those with end-stage renal disease on dialysis are considered to be persons with complicated TB disease and dosing should be referred to the district contract TB physician or delegating physician for care; a patient with these conditions cannot be managed using this protocol.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts. Education/communication should use methods adapted to patient's cultural and linguistic background. Provide

9 Formula used to convert pounds to kilograms: Divide pounds by 2.2 to get kilograms. *Example: Patient weighs 154 pounds ÷ 2.2 = 70 kilograms.*

10 Calculate Pyrazinamide and Ethambutol doses using actual body weight. NOTE: Round up fractions of a dose to the nearest whole number. Obese patients' (BMI over 30), underweight patients' (BMI under 17) and adults over 75 years dosing should be determined in collaboration with the district delegating/contract TB physician.

education to the patient and his/her family, when family is available and document in the patient record.

2. The *"12 Points of Tuberculosis (TB) Patient Education"* and the *"Patient Tuberculosis Education Record"* are located on **PHIL 2.0 under Medical and Clinical Services**.

    a. Transmission of Tuberculosis
    b. Differences between latent TB infection (LTBI) and active TB disease
    c. Progression of LTBI to active TB disease
    d. Signs and symptoms of TB disease
    e. Importance of HIV testing and greater risk of progression to active TB if HIV infected
    f. Respiratory isolation and use of masks
    g. Infectious period
    h. Importance of chemotherapy as prescribed
    i. Side effects and adverse medication reactions
    j. Directly observed therapy
    k. Importance of regular medical assessments
    l. Importance of contact identification

3. For women on Rifamycin (Rifampin, Rifabutin, Rifapentine), review the importance of using an alternative or back-up method of birth control such as condoms, a copper-bearing IUD or diaphragm. Advise patients that Rifamycin use can reduce the effectiveness of combined oral contraceptives, progestin-only oral contraceptives, Levonorgestrel implants, Depo-Provera, the patch and ring.

4. The patient's immunization status. Assess and refer or administer vaccines indicated according to the current Advisory Committee on Immunization Practices (ACIP) childhood and adult immunization schedule.

    For persons scheduled to receive a TST or IGRA, testing should be done either on the same day as vaccination with live-virus vaccine OR 4-6 weeks after the administration of the live-virus vaccine and at least one month after smallpox vaccination**.**

    See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current ACIP schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at **https://dph.georgia.gov/immunization-section/immunization-publications**

5. Mental health assessment: If mental health problems are known, suspected, or patient answers "yes" to two or more related screening questions on F-3121R, send referral to the appropriate mental health agency or follow district policy**.**

6. Pre-diabetes education and counseling recommended for Hgb A1C 5.7% or

greater. Refer patient to a **diabetes protocoled public health nurse**, nutritionist, primary care physician, or provide additional counseling which may be assessed online at **http://dph.Georgia.gov/diabetes**

FOLLOW-UP

NOTE: Any hospital admissions or deaths of persons with TB disease are to be reported immediately to the District TB Coordinator who will then report to the State TB Program**.**

1. Continued patient management/follow-up by a case management team comprising the patient, PHN, physician and others determined by an individual needs assessment. Refer to the *TB Program Policy and Procedure Manual, current edition* and *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, 2nd Edition* located in each county health department and *"*Scaled Goal Matrix Tool: Uniform Clinical Performance Measures for TB Nurse Case Managers, 2006" located at **https://dph.georgia.gov/health-topics/tuberculosis-tb-prevention-and-control/tb-public-health-clinic-forms**

2. After the nursing assessment, the PHN will use the *"Case Management Timeline – A Tracking Form for TB Medical Records"* located on **https://dph.georgia.gov/health-topics/tuberculosis-tb-prevention-and-control/tb-public-health-clinic-forms** to determine documents to forward for review by the district TB coordinator, the district's contract physician and the state office.

3. Review the respiratory isolation status for the patient**.** All 3 of the following criteria must be met before isolation can be discontinued: patient has three consecutive negative AFB sputum smear results; patient has received standard anti-tuberculosis treatment for a minimum of two weeks; and patient has demonstrated clinical improvement.

   After the baseline 3 consecutive sputum specimens, collect follow-up sputum samples as follows:
   a. You may collect up to three sputum samples in a week until three consecutive negative AFB smears are obtained to determine when to discontinue respiratory isolation. Only one sputum sample that week should be marked on the lab form for smear/culture/sensitivity. Any additional sputum samples of the same week should be examined for AFB smear only.
   b. After three consecutively negative sputum smears are obtained, collect only one sputum specimen for smear/culture/sensitivity weekly until culture converts to negative.
   c. After sputum culture converts to negative, collect one sputum specimen monthly thereafter for smear/culture/sensitivity.
   d. Collect one sputum specimen at 60 days after medication treatment initiation for smear/culture/sensitivity test. A positive culture at this point identifies patients

at increased risk for relapse. If the culture is still positive, refer patient for treatment to the contract physician.

e. If the patient is unable to produce sputum spontaneously, attempt to collect using nebulized sputum induction guidelines per procedure in the **TB Policy & Procedure Manual, current version.** Document the collection attempt.

4. Monitor patient monthly for adverse drug reactions, drug-drug interactions, drug-food interactions, drug-lab interactions, infectious status, and clinical and bacteriologic response to therapy.

5. Provide HIV test results with post-test counseling to patient and, if positive, appropriate referrals to HIV care. Seek confirmation that patient kept referral appointment for HIV care. If assistance is needed in linking patients to HIV care, please see the following website: **https://capus.dph.ga.gov/ehe/ending-the-epedemic/**; A Georgia Ryan White HIV Clinic list can also be found at **https://capus.dph.ga.gov/ehe/get-treated/**

6. Conduct contact identification following the *Tuberculosis Policy and Procedure Manual,* the *Tuberculosis Nursing: A Comprehensive Guide to Patient Care, 2nd Edition,* and the *CDC Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis* (current edition).

7. Perform the following blood chemistry tests monthly to monitor reactions to TB drugs:
   a. AST and ALT
   b. Bilirubin
   c. Alkaline phosphatase
   d. CBC with platelets
   e. Serum creatinine monthly only if there are abnormalities at baseline or there are clinical reasons to obtain the measurements (e.g., hepatitis B or C virus infection, alcohol abuse, and abnormal kidney function)

8. Discontinue Isoniazid and/or Rifampin and report immediately to the consulting physician if any of the following occur:
   a. AST/ALT levels equal to or greater than 3 times the upper limit of normal with symptoms of adverse reactions.
   b. AST/ALT levels equal to or greater than 5 times the upper limit of normal in an asymptomatic patient.
   c. Patient reporting symptoms of adverse reactions.

9. Monitor the vision of patients taking Ethambutol by providing vision checks monthly, including visual acuity and red/green color discrimination.

10. At a minimum, adherence should be methodically assessed monthly.

11. Observe the patient for Isoniazid-induced peripheral neuropathy (e.g., tingling, numbness, pain) during therapy. If present, report to the delegating physician

immediately**.**

NOTE: Consult delegating physician when further medical guidance is needed and/or the TB nurse protocol is not applicable for therapeutic treatment of patient.

12. For patients with the following conditions**,** referral to the delegating physician is required and patients cannot be treated under this protocol.
    a. TB treatment for children from birth up to under 15 years of age (i.e., age 0 – 14 years)
    b. Any known drug resistance to anti-TB medications
    c. Known HIV infection
    d. Known or Suspected Central Nervous System (CNS) TB including TB Meningitis
    e. TB pericarditis
    f. TB patient requiring adjunctive use of corticosteroid therapy
    g. Use of once-weekly Isoniazid and Rifapentine in continuation phase for active TB disease
    h. Renal insufficiency with estimated creatinine clearance less than 70 ml/min
    i. End-stage renal disease on hemodialysis
    j. Any TB patient requiring 2nd line TB drugs
    k. Treatment failure (positive culture of *M. tb* after 4 months of treatment)
    l. Pregnant/Breastfeeding

NOTE: Consult delegating physician when further medical guidance is needed and/or the TB nursing protocol is not applicable for therapeutic treatment of patient.

13. Refer patient to a licensed dietitian if indicated. This will be especially important if the patient has a history of drug or alcohol abuse, is pregnant or breastfeeding, is HIV positive, has gastrointestinal side effects from TB drugs or other medications**,** has history of eating disorder or if BMI is greater than 30 or less than 17**.**

14. If patient needs housing, food or other frontline services, consult with the Georgia TB Program's Social Worker.

15. If smoker or tobacco user, refer to a local cessation program and/or the Georgia Tobacco Quit Line, 1-877-270-STOP (7867).

16. If substance abuse is known or suspected, refer for appropriate counseling**.** If mental health problems are known or suspected, refer to appropriate agency for counseling and intervention**.**

Table 3: TREATMENT OF TB - DRUG INTERACTIONS

Obtain and record a complete list of current prescription medications (including dose and frequency) from each LTBI and TB patient. Check for interactions between each of their medications and the planned LTBI/TB medications using a current drug reference. We recommend using Lexicomp, as all public health staff has access to this resource: **https://online.lexi.com/lco/action/home;jsessionid=de081f2350de3dbc91e.** The examples listed below are not exhaustive and do not substitute for the steps outlined above.

MEDICATION INTERACTIONS – RIFAMPIN and other Rifamycins (Rifapentine, Rifabutin)

Some Common Drugs/Drug Classes	**Effect on the co-administered drug**
Anticoagulants (Warfarin, Coumadin)	↓ serum concentration
Sulfonylureas (Glipizide, Glyburide, Glimepiride)	↓ serum concentration
Thiazolidinediones (Rosiglitazone, Pioglitazone)	↓ serum concentration
Contraceptives (oral, implants, patch, ring, injections)	↓ serum concentration
Fluconazole, Voriconazole, Itraconazole	↓ serum concentration
Corticosteroids	↓ serum concentration
Narcotics/analgesics (Methadone)	↓ serum concentration
Atovaquone (Mepron)	↓ serum concentration
Dapsone	↓ serum concentration
Cyclosporine	↓ serum concentration
Quinidine	↓ serum concentration
Lamotrigine (Lamictal)	↓ serum concentration
Phenytoin (Dilantin)	↓ serum concentration
Valproic acid and derivatives (Depakene, Depakote)	↓ serum concentration
Buspirone (Buspar)	↓ serum concentration
Thyroid hormone replacement	↓ serum concentration

DRUG INTERACTIONS – ISONIAZID

Name/type	**Effect on the co-administered drug**
Diazepam (Valium)	↓ serum concentration ↑ half-life
Phenytoin (Dilantin)	↑ serum concentration ↑ toxicity
Carbamazepine (Tegretol)	↑ serum concentration ↑ toxicity
Citalopram (Celexa)	↑ serum concentration ↑ toxicity
Alcohol	↑ risk of Isoniazid-induced hepatitis
Antacids	should be taken two hours apart, otherwise Isoniazid will have no effect

HIV: Antiretroviral therapy and TB medications

The information on interactions with Rifampin and HIV antiretroviral therapy (ART) is constantly changing; all people living with HIV (PLWH) should be referred to the contract physician for care. In general, only certain HIV medications can be used and Rifampin may be replaced by Rifabutin if appropriate to accommodate choice of ART. Rifabutin is on the formulary at the state pharmacy.

Recommended resource for HIV treatment guidelines and medication interactions: **https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new**.

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STANDARD NURSE PROTOCOL FOR LATENT TUBERCULOSIS INFECTION (LTBI) AND PRESUMPTIVE LTBI

DEFINITION

LTBI means that a person has been infected with M.tuberculosis (M.tb) but has no clinical or radiographic evidence of active TB disease. Individuals who are infected but do not have active disease are not infectious but, if not adequately treated, are at risk for developing disease and becoming infectious in the future.

Presumptive LTBI treatment is the practice of providing window period prophylaxis treatment to high-risk persons exposed to infectious people with TB disease. This means, when these exposed persons have an initial negative tuberculin skin test (TST) reaction (less than 5mm induration) or negative interferon gamma release assay (IGRA) test result and the test was performed less than eight weeks from the person's last exposure to a person with TB disease, treatment for LTBI is started until a follow-up TST/IGRA is negative. The window period is the time span between the date of a negative initial TST or IGRA and the date of the follow-up TST or IGRA.

Exposed persons at particularly high-risk of developing TB disease once infected with *M.tb* include: children less than 5 years of age and persons with compromised immune systems; compromised by HIV infection, medications (Prednisone, cancer chemotherapy, anti-rejection drugs for cancer therapy, tumor necrosis factor alpha agents antagonists) and certain medical conditions (diabetes mellitus, silicosis, end stage renal disease, cancer of the head and neck, reticuloendothelial diseases [e.g., lymphoma, leukemia], gastric or jejunoileal bypass surgery). These persons would benefit from presumptive LTBI therapy.

ETIOLOGY

Causative agent of TB is the *Mycobacterium tuberculosis* (*M.tb*) complex (*M. tuberculosis, M. bovis, M. africanum, M. microti, M.canetii, M. caprae, M.mungi and M. pinnipedii)*.

SUBJECTIVE

1. Patient may have a history of known exposure to a person with TB.

2. Patient has no symptoms of TB disease.

NOTE: A complete medical history and review of current medications is required to determine if there are any diseases/illnesses present that would require consultation or referral to delegating physician.

OBJECTIVE

1. Physical examination performed per programmatic guidelines shows no signs of

active TB disease present.

NOTE: If signs and symptoms of TB disease are evident, patient should have 3 consecutive negative sputum smears and negative cultures with evaluation by a clinician***/***delegating physician before starting treatment for LTBI.

ASSESSMENT

1. Latent tuberculosis infection

2. Presumptive latent tuberculosis infection during the window period

PLAN

The desired outcome of treatment is to decrease high-risk persons' chance of developing active TB disease once diagnosed with latent TB infection.

NOTE: Any hospital admissions or deaths of persons with TB disease are to be reported immediately to the District TB Coordinator who will then report to the State TB Program**.**

DIAGNOSTIC STUDIES

1. If positive results for either an IGRA or a TST cannot be verified (including millimeters [mm] of induration), perform a TST or IGRA. An IGRA is the preferred method of testing in individuals greater than or equal to 2 years of age who are foreign born and/or have a history of BCG vaccination. TB skin testing should be performed on children less than 2 years of age.

NOTE: Some specific vaccinations may interfere with either of these tests for latent TB. For persons scheduled to receive a TST or IGRA, testing relative to vaccine administration should be done as follows:

   a. For live virus vaccines, LTBI testing (TST or IGRA) either on the same day or prior to the vaccine or 4-6 weeks after the administration of the vaccine.
   b. **For JYNNEOS Mpox vaccine the effect of the vaccination on a TST or IGRA is unknown. Therefore, if a delay in TB testing for 4 weeks would cause a substantial burden (for example, preventing a person from working because of pre-employment screening policies), then TB testing should not be delayed. If a delay will not cause a substantial burden, then a delay of at least 4 weeks after JYNNEOS vaccine is preferred. TB testing can be done at the same time as JYNNEOS vaccination, as with other vaccines, and any sequence of vaccination and TB testing may be used at that time. If a JYNNEOS vaccine and TST are administered at the same time, they should be administered on opposite arms with the sites of administration documented. If the same arm must be used, then the injection sites should be separated by 8-10 cm (3-4 inches) along the**

length of the arm, reducing the chance of overlapping reactions. If an IGRA is done on the same visit as a JYNNEOS vaccination, either arm can be used for blood collection.

c. **For COVID-19 vaccines, no restrictions. Testing with TST and IGRA can be done before, after, or during the same encounter as COVID-19 vaccination.**
d. Consider relative risks and benefits of a decision to delay LTBI testing over the administration of a vaccine.
e. Check most recent CDC guidance for any updates relating to LTBI testing and COVID-19 vaccination: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#laboratory-testing

2. Perform the following baseline blood chemistry labs:
   a. Liver function test including aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, alkaline phosphatase
   b. CBC with platelet count
   c. Serum Creatinine
   d. HgbA1C
      NOTE: If HgbA1C is elevated between 5.7% and 6.4% (Pre-Diabetes), refer to nutritionist or Primary Care Physician for prediabetes education and counseling. If HgbA1C is 6.5% or greater (Diabetes), refer patient to PCP for evaluation and treatment.
   e. Hepatitis C antibody for all adults.
      NOTE: If Hepatitis C Ab is positive, refer patient to PCP for evaluation and follow-up.
   f. Hepatitis B profile (HBsAb, HBcAb) should be obtained for all adults (regardless of birth country) and anyone less than 18 years old who is foreign-born.
      NOTE: If HBsAg is positive, refer to PCP for evaluation and consideration for treatment. If all HB serology results are negative (i.e., the patient is susceptible to Hepatitis B infection), consider Hepatitis B immunization as per ACIP guidelines.

3. All individuals 13 years and older will be tested for HIV using the opt-out approach. Consent is inferred unless patient declines testing. Individuals younger than 13 years old should also be tested for HIV using the opt-out approach if the individual is sexually active or abuses drugs. If HIV positive, collaborate with HIV Program to obtain CD4 T-cell count, then refer to consulting physician.

4. Urine pregnancy test if woman is of childbearing age and sexually active. **Refer to delegating physician if pregnancy test is positive.**

5. Baseline complete blood count with platelets for patients on the Isoniazid-Rifapentine regimen and Rifampin regimen.

6. Chest x-ray performed to detect abnormalities compatible with TB disease. (Radiographic findings of healed, inactive TB and reactivating TB sometimes cannot be distinguished).

7. If any lab results are abnormal, consult with delegating physician.

NOTE: With the exception of HIV testing, the baseline lab measurements are not mandatory for children less than 15 years of age, unless a complicating medical condition (e.g., HIV, liver disease, renal disease, cardiac disease), foreign born requiring Hepatitis B testing, or high-risk lifestyle is known or suspected.

LABORATORY FINDINGS

1. Chest x-ray negative for evidence of tuberculosis disease.

2. Absence of clinical signs of TB disease, both pulmonary and extra-pulmonary.

3. Patients with the following conditions/illnesses should be treated for LTBI if they have a positive TST (5 mm or greater) and/or positive IGRA:
   a. HIV-positive
   b. Recently exposed to a person with TB disease
   c. Fibrotic changes on chest x-ray consistent with old TB
   d. Organ transplants recipients
   e. Candidates being considered for treatment with tumor necrosis factor (TNF) antagonists such as injectable Remicade [Infliximab] for rheumatologic conditions or ulcerative colitis prior to initiation of therapy)
   f. Persons receiving the equivalent of equal to or greater than 15mg daily of prednisone for 1 month or longer

4. Patients with the following conditions/illnesses should be treated for LTBI if they have a positive TST (10 mm or greater) and/or positive IGRA:
   a. People who have lived or spent time in high prevalence countries.
   b. Injection drug users.
   c. Residents and employees of high-risk congregate settings (e.g., correctional facilities, nursing homes and other long-term care facilities, homeless shelters, hospitals and other health care facilities).
   d. Mycobacteriology laboratory personnel.
   e. Persons with clinical conditions that place them at high risk of progression to TB disease (e.g., substance abuse, infection with *M.tb* within the past two years, diabetes, hematologic or reticuloendothelial malignancies, chronic renal failure, post-gastrectomy, silicosis, immunosuppressive therapy, chronic malabsorption syndromes)
   f. Children less than 5 years of age, or children and adolescents exposed to adults in high-risk groups.

5. Patients with no risk factors should be treated for LTBI if they have a positive TST (15mm or greater) and/or positive IGRA.

6. Persons exposed to a person with TB disease may be treated for presumptive LTBI. Exposed persons with suppressed immune systems due to HIV infection, prolonged corticosteroid therapy, organ transplant and/or use of tumor necrosis factor alpha inhibitors should be treated for presumptive LTBI with a full course of LTBI treatment, regardless if follow-up TST/IGRA is negative.

7. There is also a group of people that can be treated for presumptive LTBI but do not have to complete a full course of LTBI treatment (as discussed above). The following exposed persons being treated for presumptive LTBI treatment can stop treatment if the follow-up TST/IGRA is negative:
   a. Child less than 5 years of age.
   b. Person diagnosed with diabetes mellitus, silicosis, end stage renal disease, gastrectomy, jejunoileal bypass, leukemia, lymphoma, and/or cancer of the head or neck.

NOTE: Treatment of LTBI or presumptive LTBI might NOT be indicated for persons likely to be infected with drug-resistant *M.tb*. These persons should be referred to the delegating physician.

NOTE: Treatment of LTBI might NOT be completed on persons who have been exposed to a person later found not to have TB. The Public Health Nurse (PHN) should consult with the delegating physician for care.

THERAPEUTIC

PHARMACOLOGIC

1. Order medications for treatment from drug stock and send a copy of the drug order(s) to the District Pharmacist or District Drug Coordinator. Refer to Tables 1 and 2 for options and dosages.
   a. If a patient is referred to the delegating physician, the PHN may not dispense ANY of the prescribed medications. The Prescribing Physician that meets the Dispensing Practitioner requirements of the GA Composite Medical Board can dispense the TB drugs, send the prescription to the District Pharmacist or a pharmacy by phone call or E-Scribe or may delegate a PHN to send or call-in prescription orders. A physician cannot dispense another practitioner's orders.
   b. PHN may dispense Rifapentine when given in conjunction with Isoniazid for LTBI treatment. PHN may not dispense 2nd line TB medications. If 2nd line medications are ordered, a pharmacist or dispensing practitioner can dispense the 2nd line TB medications, or the prescription may be called in or E-scribed to a pharmacy by the prescribing physician.

2. **VIDEO DIRECTLY OBSERVED THERAPY (VDOT)**
   a. Carefully selected patients meeting established minimum criteria may be eligible to receive their medications via VDOT. In order to perform VDOT the healthcare worker observes the patient take their medication via smartphone, laptop, or desktop. See **Tuberculosis Policy and Procedure Manual on PHIL**

2.0 for additional information.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts. Education/communication should use methods adapted to patient's cultural and linguistic background. Provide education to the patient and his/her family, when family is available, and document in the patient record.

2. The *"12 Points of Tuberculosis (TB) Patient Education"* and the *"Patient Tuberculosis Education Record"* are located on **PHIL 2.0 under Medical and Clinical Services at https://gets.sharepoint.com/sites/PHIL#/Division/14/0TB web**
   a. Transmission of Tuberculosis
   b. Differences between latent TB infection (LTBI) and active TB disease
   c. Progression of LTBI to active TB disease
   d. Signs and symptoms of TB disease
   e. Importance of HIV testing and greater risk of progression to active TB if HIV infected
   f. Importance of chemotherapy as prescribed
   g. Side effects and adverse medication reactions
   h. Directly observed therapy (if necessary)
   i. Importance of regular medical assessments

3. For women on Rifamycin (Rifampin, Rifabutin, Rifapentine), review the importance of using an alternative or back-up method of birth control such as condoms, a copper-bearing IUD or diaphragm. Advise patients that Rifamycin use can reduce the effectiveness of combined oral contraceptives, progestin-only oral contraceptives, Levonorgestrel implants, Depo-Provera, the patch and ring.

4. The patient's immunization status. Assess and refer or administer vaccines indicated per the current Advisory Committee on Immunization Practices (ACIP) childhood and adult immunization schedule.

5. For persons scheduled to receive a TST, testing should be done either on the same day as vaccination with live-virus vaccine OR 4-6 weeks after the administration of the live-virus vaccine and at least one month after smallpox vaccination.

6. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current ACIP schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at **https://dph.georgia.gov/immunization-section/immunization-publications**

FOLLOW-UP

NOTE: Children (under age 15 years) are not required to have routine follow-up labs regardless of treatment regimen.

NOTE: Any hospital admissions or deaths of persons with TB disease are to be reported immediately to District TB Coordinator who will then report to the State TB Program.

1. At eight to ten weeks after initial TST/IGRA, a follow-up TST/IGRA is to be performed on exposed persons on window period prophylaxis. If the follow-up TST/IGRA is positive, treatment is to continue until a full course of LTBI treatment is completed.

   If the follow-up TST/IGRA is negative in an exposed person who is immunosuppressed, (due to HIV infection, prolonged corticosteroid therapy, organ transplant and/or use of tumor necrosis factor alpha inhibitors) a full course of LTBI treatment is required.

   If the follow-up TST/IGRA is negative in any other exposed person, then the window period treatment may be discontinued.

2. Monitor patients receiving LTBI therapy at least monthly for adverse drug reactions (such as hepatitis, peripheral neuropathy), drug-drug interactions, drug-food interactions, drug-lab interactions, adherence**.**
   a. Observe the patient for Isoniazid-induced peripheral neuropathy (e.g., tingling, numbness, pain) during therapy. If present, refer to the delegating physician immediately**.**
   b. Symptoms of hepatitis (nausea, loss of appetite, vomiting, persistently dark urine, yellowish skin, malaise, unexplained elevated temperature for more than three days, abdominal tenderness and/or right upper quadrant tenderness). If present, put all LTBI medications on hold, obtain AST/ALT levels and refer to the delegating physician immediately.

3. Provide HIV test results with post-test counseling to patient and, if positive, appropriate referrals to HIV care. Seek confirmation that patient kept referral appointment for HIV care. If assistance is needed in linking patients to HIV care, please see the following website: **https://capus.dph.ga.gov/ehe/ending-the-epedemic/**. A Georgia Ryan White HIV Clinic list can also be found at **https://capus.dph.ga.gov/ehe/get-treated/.**

4. Obtain monthly AST/ALT for patients considered at risk of developing hepatotoxicity. These patients include those with:
   a. baseline liver test abnormalities
   b. Continued regular alcohol use
   c. Known liver disorders
   d. Postpartum[11] women

11 Period of time immediately after the birth of an infant through 6 weeks. Pregnant women, particularly African-

5. Hold all TB medications and refer to the delegating physician immediately if:
   a. AST/ALT levels equal to or greater than 3 times the upper limit of normal with symptoms of adverse reactions.
   b. AST/ALT levels equal to or greater than 5 times the upper limit of normal in an asymptomatic patient.
   c. Patient reporting symptoms of adverse reactions.

NOTE: Any hospital admissions or deaths due to adverse reactions are to be reported immediately to the District TB Coordinator who will report to the State TB Program**.**

6. Obtain monthly complete blood count (with platelets) for patients receiving the Isoniazid-Rifapentine or Rifampin regimen. Hold all TB medications and refer to delegating physician if any results are abnormal.

7. If patient is a woman of child-bearing age, assess date of last menstrual period monthly. Perform pregnancy test as needed. If pregnancy test ever positive, hold all TB medications and refer to delegating physician immediately.

8. A clinical symptom screen is required for all patients who have a lapse in treatment. A repeat chest x-ray/evaluation is required for patients who are symptomatic or who have had a lapse in LTBI therapy for two months or more.

9. Identify those patients who are eligible for VDOT per the VDOT policy in the **TB Policy & Procedure Manual, current version on PHIL 2.0.**

CONSULTATION/REFERRAL

1. For patients with the following conditions, CONSULTATION with the delegating physician is required for patients to be treated under this protocol. Consultation must be documented in the patient's record.
   a. Diabetes mellitus
   b. Liver disease
   c. Allergic reactions not requiring 2nd line TB drugs
   d. Review of current medications reveal potential for drug-drug interactions with TB medications.
   e. Treatment interruptions of two months or more
   f. HIV positive or refuses HIV testing
   g. Any abnormal lab results

NOTE: Consult delegating physician when further medical guidance is needed and/or the LTBI nursing protocol is not applicable for therapeutic treatment of patient.

American and Hispanic women, may be at increased risk for fatal hepatitis associated with Isoniazid, per some reports. This risk may be increased during the postpartum period. These patients should be closely monitored for adverse reactions throughout the course of treatment. The risk of hepatitis from Isoniazid in pregnant/postpartum women does NOT preclude treatment of LTBI if these women are at extremely high risk for developing active TB (e.g., in close contact of person with TB disease, HIV positive, or with documented recent infection or conversion).

2. For patients with the following conditions, REFERRAL to the delegating physician is required. These patients would no longer be able to be treated under this protocol.
   a. Pregnant, breastfeeding or postpartum women
   b. Patients experiencing adverse reactions
   c. Patients with known exposure to a person with drug resistant TB disease
   d. Children 2 years of age and older who are close contacts for whom the Isoniazid and Rifapentine regimen may be considered because it offers practical advantages or because the child is unlikely to complete 9 months of daily Isoniazid.

NOTE: Consult delegating physician when further medical guidance is needed and LTBI nursing protocol is not applicable for therapeutic treatment of patient.

3. If smoker or tobacco user, refer to a local cessation program and/or the Georgia Tobacco Quit Line, 1-877-270-STOP (7867).

4. If mental health or substance abuse is known or suspected, refer for appropriate counseling for intervention and follow up.

5. If patient needs housing, food or other frontline services, consult with the Georgia TB Program's Social Worker.

TABLE A: LTBI MEDICATIONS IN PREFERRED PRIORITY RANKINGS

Priority rank*	Regimen	Recommendation Grade**
Preferred	**3 months isoniazid plus Rifapentine given once weekly**	**Strong**
Preferred	**4 months Rifampin given daily**	**Strong**
Preferred	**3 months Isoniazid plus Rifampin given daily**	**Conditional**
		Conditional
Alternative	**6 months Isoniazid given daily**	**Strong[§]**
		Conditional
Alternative	**9 months Isoniazid given daily**	**Conditional**

Modified from Table 3 in "Guidelines for the Treatment of LTBI: Recommendations of the NTCA and CDC, 2020. MMWR Recomm Rep 2020; 69(no, RR-1).
* *Preferred:* excellent tolerability and efficacy, shorter treatment duration, higher completion rates than longer regimens and therefore higher effectiveness; *alternative:* excellent efficacy but concerns regarding longer treatment duration, lower completion rates, and therefore lower effectiveness.
** *Strong:* strong GRADE recommendation for a regimen was made if the panel concluded that the desirable consequences of the intervention outweighed the undesirable consequences, the majority of well-informed patients would choose the regimen, and the evidence was at least moderate quality; *conditional:* conditional GRADE

recommendation was made for a regimen when uncertainty existed regarding whether the desirable consequences outweighed the undesirable consequences (e.g., low-quality evidence for a critical outcome such that additional evidence could change key findings, hence the recommendation). A conditional recommendation indicates that well-informed patients might make different choices regarding whether to choose the regimen.
§ Strong recommendation for those persons unable to take a preferred regimen (e.g., due to drug intolerability or drug-drug interactions).

Table B: Treatment of LTBI – Recommended Drug Regimens [and Dosages for Adults and Children] (Select ONE Option)

Drug	Interval and Duration	Adult Dosage	Criteria for Completion	Comments
Option A Isoniazid and Rifapentine	Once weekly for 12 doses. Duration: 3 months	Adults and Children >= 12 years: Isoniazid:15 mg/kg PO (round up to the nearest 50 or 100 mg); 900 mg PO max Children ages 2 -11 years: Isoniazid 25 mg/kg PO (round up to nearest 50 or 100 mg); 900 mg PO max dose Adults and Children: Rifapentine: 10-14 kg, 300 mg PO; 14.1-25 kg 450 mg PO; 25.1-32 kg 600 mg PO; 32.1-49.9 kg 750 mg PO; Equal to or greater than 50 kg, 900 mg (max dose) PO	11 doses within 16 weeks (doses may be given no more frequently than every 72 hours) In ages 2-5 years old, all 12 doses may be given by DOT. In ages 5 years and older, all 12 doses may be given by DOT or self-administered therapy.	Isoniazid and Rifapentine is recommended and the preferred regimen for treating LTBI in otherwise healthy patients aged 2 years and older at high risk for developing active TB. These patients include persons in close contact with person with TB disease, recent converters, HIV positive persons (NOT on antiretrovirals) and those with old, healed TB on chest x-ray. Isoniazid and Rifapentine should also be used in situations where it offers practical advantages over other preferred regimens. Isoniazid and Rifapentine is NOT recommended for the following patients: children less than 2 years of age, pregnant women or women expecting to become pregnant during treatment, patients who have LTBI with presumed Isoniazid or Rifampin resistance, and persons taking medications with clinically significant or unknown drug interactions with rifapentine. Refer to the contract physician children aged 2 and older who are close contacts for whom the Isoniazid and Rifapentine regimen should be considered because it offers practical advantages.
Option B Rifampin	Daily self-admininstered (7 days/ week) for 4 months (18 weeks) OR Daily DOT (Mon-Fri) for 4 months (18 weeks)	Adults: 10 mg/kg, max dose 600 mg PO. Children: 15-20 mg/kg, max dose 600 mg PO (see table D) OR 600 mg PO for all adults (15-20 mg/kg for children - max dose 600 mg) (see table D)	120 doses within 6 months OR 90 doses within 6 months	Daily Rifampin is a preferred regimen for treatment of LTBI with a strong recommendation. Rifampin therapy is the only preferred regimen for persons who acquired LTBI from a TB patient with Isoniazid-resistant, Rifampin susceptible TB disease; Rifampin is not recommended for persons who are: Taking medications with clinically significant or unknown drug interactions with rifampin, presumed infected with Rif-resistant M.TB, and women who are pregnant or expect to become pregnant within the 4 month regimen.

Option C Isoniazid and Rifampin	Daily- self-administered (7 days/week for 3 months (18 weeks)	Isoniazid: Adults and children age 15 and over: 300 mg PO Children up to age 14: 10-20 mg/kg PO– max dose 300 mg (see table C) Rifampin: Adults and children age 15 and over: 600 mg PO for all adults Children up to age 14: (15-20 mg/kg)- max dose 600 mg (see table D)	90 doses within 6 months	A regimen of 3 months of daily Isoniazid plus Rifampin is a preferred treatment that is conditionally recommended for adults of all ages, children and for HIV –positive persons as drug interactions allow. Among children aged < 15 years specifically, a 3-month course of daily Isoniazid plus Rifampin appeared as effective as a 6 month or longer course of Isoniazid. Isoniazid and Rifampin is not recommended for the following adults: Persons taking medications with clinically significant or unknown drug interactions with rifampin, presumed infected with RIF-resistant M.TB, and women who are pregnant or expect to become pregnant within the 3 month regimen. Refer to the contract physician children aged 2 and older who are close contacts for whom the Isoniazid and Rifampin regimen may be considered because it offers practical advantages over the other preferred regimens.
Option D Isoniazid 6 Months **OR**	Daily: self-administered (7 days/week) for 6 months OR Twice-weekly DOT for 6 months	Adults and children: Age 15 and over: Isoniazid 300 mg PO Children up to age 14: Isoniazid 10-20 mg/kg PO– max dose 300 mg (see table C) OR Adults and children: Age 15 and over: 900 mg max dose PO Children up to age 14: 20-40 mg/kg PO– max dose 900 mg (see table C)	180 doses within 9 months OR 52 doses within 9 months	Isoniazid therapy for 6 months is strongly recommended as an alternative for those unable to take a shorter preferred regimen, e.g., due to drug-drug intolerability or drug-drug interactions particularly in HIV negative persons. In HIV positive patients, Isoniazid may be taken concurrently taken with nucleoside reverse transcriptase inhibitors (NRTIs), protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs). NOTE: Twice weekly regimen not recommended for HIV positive patients. LTBI patients (including HIV infected) on daily INH LTBI regimen will no longer require DOT. Consider adding pyridoxine (Vitamin B6) 25-50mg to be given with each dose of isoniazid as a preventive measure against Isoniazid –induced peripheral neuropathy.

Option D Isoniazid 9 Months	Daily self-admin (7 days/ week) for 9 months OR Twice-weekly* DOT for 9 months	Adults and children age 15 and over: Isoniazid 300 mg PO Children up to age 14: Isoniazid 10-20 mg/kg PO– max dose 300 mg (see table C) OR Adults and children age 15 and over: 900 mg max dose PO Children up to age 14: 20-40 mg/kg PO– max dose 900 mg PO (see table C)	270 doses within 12 months OR 76 doses within 12 months	In HIV-positive patients, Isoniazid may be taken concurrently with nucleoside reverse transcriptase inhibitors (NRTIs), protease inhibitors, or non-nucleoside reverse transcriptase inhibitors (NNRTIs). NOTE: Twice-weekly regimen not recommended for HIV positive patients. LTBI patients (including HIV-infected) on daily INH LTBI regimen will no longer require DOT. Consider adding pyridoxine (Vitamin B6) 25 – 50 mg to be given with each dose of isoniazid as a preventive measure against Isoniazid-induced peripheral neuropathy.

*Twice-weekly doses should optimally be given at least two days apart, unless given to "catch up" on a missed dose. A dose given two consecutive days is discouraged. NOTE: Isoniazid is available in 100 and 300 mg tablets (both are scored for dividing in half (½). Rifapentine is available in 150 mg tablets only. Rifampin (rifampicin) is available as 150-mg and 300-mg capsules. Rifampin and Rifapentine cannot be substituted for each other. NOTE: DOT is RECOMMENDED for all patients less than 5 years of age and patients on ANY biweekly INH (which is usually prescribed for children). The INH/Rifapentine regimen may be self-administered or DOT – this is up to the discretion of the TB nurse.

Table C: PEDIATRIC DOSAGE - ISONIAZID IN CHILDREN (birth to 15 years)

Child's Weight (lbs)	Child's Weight (kg)	Daily Dose (mg) 10 – 15 mg/kg PO	Twice-weekly Dose (mg) 20 – 30 mg/kg PO
6 – 10	3 – 4.5	50	100 mg PO
11 – 14	5.0 – 6.0	50	150 mg PO
14.5 – 18	6.5 – 8.0	100	200 mg PO
18.5 – 21.5	8.5 – 9.5	100	250 mg PO
22 – 24	10.0 – 11	150	300 mg PO
25 – 29	11.5 – 13	150	350 mg PO
29.5 – 32	13.5 – 14.5	200	400 mg PO
33 – 35	15 – 16	200	450 mg PO
36 – 40	16.5 – 18.	250	500 mg PO
40.5 – 43	18.5 – 19.5	250	550 mg PO
44 – 48	20 – 21.5	300	600 mg PO
48.5 – 51	22 – 23	300	650 mg PO
52 – 54.5	23.5 – 24.5	300	700 mg PO
55 – 57.5	25 – 26	300	750 mg PO
58 – 62	26.5 – 28	300	800 mg PO
62.5 – 65	28.5 – 29.5	300	850 mg PO
66 +	30 +	300	900 mg PO

NOTE: Isoniazid tablets come in 50 mg, 100mg, 300 mg sizes and can be crushed for oral administration. Isoniazid tablets are also scored.

Isoniazid Syrup (50mg/5ml) should not be refrigerated. It contains sorbitol and will cause diarrhea. It should be used only when crushed tablets cannot accommodate the situation. (keep at room temperature).

TABLE D

PEDIATRIC DOSAGE: RIFAMPIN IN CHILDREN

(Birth to 15 years)

DOSE for Daily Therapy

Child's Weight (lbs)	Child's Weight (kg)	Dose mg(10-20 mg/kg)
15 - 32	7 - 14.5	150 mg
33 - 48.5	15 - 22	300 mg
49 - 65	22.5 - 29.5	450 mg
66+	30+	600 mg

Table E: Treatment of LTBI – Drug Adverse Reactions and Monitoring

NOTE: The baseline lab measurements are not mandatory for children less than 15 years of age, unless a complicating medical condition (e.g., HIV, liver disease, renal disease, cardiac disease), foreign born requiring Hepatitis B testing, or high-risk lifestyle is known or suspected.

Drug	Adverse Reactions	Monitoring NOTE: Report abnormal labs to delegating physician.	Comments
Isoniazid	Gastrointestinal (GI) upset, hepatic enzyme elevations, hepatitis, peripheral neuropathy, mild effects on central nervous system, drug interactions	Obtain aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, HgbA1C, and Hepatitis C antibody for all adults. Hepatitis B profile should be obtained for all adults (regardless of birth country) and anyone less than 18 years old who is foreign-born. All individuals will be tested for HIV using the opt-out approach. Consent is inferred unless patient declines testing. If HIV positive, collaborate with HIV Program to obtain CD4 T-cell count. Consult with delegating physician. Baseline CBC with platelets on Isoniazid-Rifapentine or Rifampin regimen**.**	Hepatitis risk increases with age and alcohol consumption, but these are not contraindications to prescribing INH. Pyridoxine can prevent isoniazid-induced peripheral neuropathy.
Rifampin and Rifapentine	Orange discoloration of body fluids (secretions, tears, urine), GI upset, drug interactions, hepatitis, thrombocytopenia, rash, fever, Influenza-like symptoms, hypersensitivity reaction[12]	Obtain aspartate aminotransferase (AST), alanine aminotransferase (ALT), bilirubin, HgbA1C, and Hepatitis C antibody for all adults**.** Hepatitis B profile should be obtained for all adults (regardless of birth country) and anyone less than 18 years old who is foreign-born. All individuals will be tested for HIV using the opt-out approach. Consent is inferred unless patient declines testing. If HIV positive, collaborate with HIV Program to obtain CD4 T-cell count. Consult with delegating physician. Baseline CBC with platelets on the Isoniazid-Rifapentine or Rifampin regimen**.**	Hepatitis risk increases with age and alcohol consumption, but these are not contraindications to prescribing Rifamycins.

[12] Hypersensitivity reactions may include a flu like syndrome (e.g. fever, chills, headaches, dizziness, and musculoskeletal pain), thrombocytopenia, shortness of breath or other signs and symptoms including wheezing, acute bronchospasm, urticaria, petechiae, purpura, pruritus, conjunctivitis, angioedema, hypotension or shock. If moderate to severe reaction (e.g., thrombocytopenia, hypotension), hospitalization or life-threatening event: discontinue treatment. If mild reaction (e.g., rash, dizziness, fever): Continue to monitor patient closely with a low threshold for discontinuing treatment.

Table F: Treatment of LTBI – Drug Interactions

NOTE: Obtain and record a complete list of current prescription medications (including dose and frequency) from each LTBI and TB patient. Check for interactions between each of their medications and the planned LTBI/TB medications using a current drug reference. **Lexicomp** is recommended and is an available public health resourcee. The examples listed below are not exhaustive and do not substitute for the steps outlined above.

MEDICATION INTERACTIONS – RIFAMPIN

Name/type	**Effect**
Anticoagulants (Warfarin, Coumadin)	↓ serum concentration
Sulfonylureas (Glipizide, Glyburide, Glimepiride)	↓ serum concentration
Thiazolidinediones (Rosiglitazone, Pioglitazone)	↓ serum concentration
Contraceptives (oral, implants, patch, ring, injections)	↓ serum concentration
Fluconazole, Voriconazole, Itraconazole	↓ serum concentration
Corticosteroids	↓ serum concentration
Narcotics/analgesics (Methadone)	↓ serum concentration
Atovaquone (Mepron)	↓ serum concentration
Dapsone	↓ serum concentration
Cyclosporine	↓ serum concentration
Quinidine	↓ serum concentration
Lamotrigine (Lamictal)	↓ serum concentration
Phenytoin (Dilantin)	↓ serum concentration
Valproic acid and derivatives (Depakene, Depakote)	↓ serum concentration
Buspirone (Buspar)	↓ serum concentration
Thyroid hormone replacement	↓ serum concentration

DRUG INTERACTIONS – ISONIAZID

Name/type	**Effect**
Diazepam (Valium)	↓ serum concentration ↑ half-life
Phenytoin (Dilantin)	↑ serum concentration ↑ toxicity
Carbamazepine (Tegretol)	↑ serum concentration ↑ toxicity
Citalopram (Celexa)	↑ serum concentration ↑ toxicity
Alcohol	↑ risk of Isoniazid-induced hepatitis
Antacids (Should be taken two hours apart, or Isoniazid will have no effect)	
Cycloserine	↑ risk of CNS toxicity

HIV: Antiretroviral therapy and medications for LTBI

The information on interactions with Rifamycins and HIV antiretroviral therapy (ART) is constantly changing; all people living with HIV (PLWH) should be referred to the contract Physician for care. In general, only certain HIV medications can be used in combination with Rifamycins**.** Recommended resource for HIV treatment guidelines and medication interactions: **https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new**

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WOMEN'S HEALTH

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2022 STANDARD NURSE PROTOCOLS FOR WOMEN'S HEALTH CLINICAL REVIEW TEAM

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) US MEDICAL ELIGIBILITY CRITERIA (MEC), SELECTED PRACTICE RECOMMENDATIONS (SPR) FOR CONTRACEPTIVE USE AND QUALITY FAMILY PLANNING (QFP)

The CDC US Medical Eligibility Criteria (MEC) and Selected Practice Recommendations (SPR) for Contraception Use reflect adaptations of the WHO Medical Eligibility Criteria and SPR to ensure appropriateness for use in the United States. Most of the U.S. guidance does not differ from the WHO guidance. However, several changes have been made, including adaptations of selected WHO recommendations, addition of recommendations for new medical conditions, and removal of recommendations for contraceptive methods not currently available in the United States.

In 2014, the CDC released Providing Quality Family Planning Services (QFP). Created in collaboration with the Office of Population Affairs and the Department of Health and Human Services, this document provides recommendations about how to provide high quality evidence-based family planning services. Used together, the MEC, SPR and QFP should guide clinicians in providing evidence-based contraceptive care in the United States.

The MEC contains recommendations for health-care providers for the safe use of contraceptive methods by women and men with various characteristics and medical conditions. It is intended to assist health-care providers when they counsel women, men, and couples about contraceptive method choice. These recommendations are meant to be a source of clinical guidance; health-care providers should always consider the individual clinical circumstances of each person seeking family planning services.

The SPR contains recommendations which are intended to help health-care providers address issues related to use of contraceptives, such as how to help a woman initiate use of a contraceptive method, which examinations and tests are needed before initiating use of a contraceptive method, what regular follow-up is needed, and how to address problems that often arise during use, including missed pills and side effects such as unscheduled bleeding.

CDC US Medical Eligibility Criteria for Contraceptive Use was updated in 2016.
http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf
This full report provides vital information, not only about what the recommendation is, but also why. Providers should be aware that this guidance is continually updated in response to emerging evidence. For updates, refer to the CDC's website:
https://www.cdc.gov/reproductivehealth/contraception/contraception_guidance.htm

Additional resources including android/iPhone/iPad apps, wall charts, wheels and guidance in Spanish can be accessed at that site. Local clinics should make copies of the CDC Medical Eligibility Criteria available to all clinic staff and should encourage its use with each contraceptive clinical encounter.

TYPE OF CONTRACEPTIVE		
CONDITION	**CATEGORY** • I=Initiation • C=Continuation	**CLARIFICATIONS / EVIDENCE**
Condition	• Condition classified from 1 to 4 • The categories for fertility awareness-based methods and surgical sterilization are described at the beginning of the relevant section.	• Clarifications and evidence regarding the classification

NA denotes a condition for which a ranking was not given by the Working Group but for which clarifications have been provided.

I=Initiation: This provides guidance for initiating a contraceptive method given the presence of a particular medical condition at the time of initiation.
C=Continuation: This provides guidance about whether to continue a contraceptive method if a particular medical condition has been diagnosed since starting that method of contraception. To illustrate this with an example: Stroke (history of a cerebrovascular accident). Initiating a contraceptive implant in someone with this situation is Medical Eligibility Criteria Category 2. This should be interpreted that it is acceptable to start using a contraceptive implant with this condition. However, for someone who had not had a stroke before using the implant, but who has a stroke while using the contraceptive implant, continuing the method is Medical Eligibility Criteria Category 3, and requires consultation with delegating physician.

Classification of categories:

Each condition was defined as representing either an individual's characteristics (e.g., age, history of pregnancy, use of certain medications) or a known pre-existing medical/pathological condition (e.g., diabetes, hypertension). It is expected that national and institutional health and service delivery environments will decide the most suitable means for screening for conditions according to their public health importance. Patient history will often be the most appropriate approach.

The conditions affecting eligibility for the use of each contraceptive method were classified under one of the following four categories:

1. A condition for which there is no restriction for the use of the contraceptive method.

2. A condition where the advantages of using the method generally outweigh the theoretical or proven risks.

3. A condition where the theoretical or proven risks usually outweigh the advantages of using the method.

4. A condition which represents an unacceptable health risk if the contraceptive method is used.

Abbreviations used by the CDC Medical Eligibility Criteria:

COC: Combined oral contraceptive
CHC: Combined hormonal contraceptive
POP: Progestin-only pill
POC: Progestin-only contraceptive
DMPA: Depot medroxyprogesterone acetate
Implants: Implanon & Nexplanon
Cu IUD: Copper IUD (ParaGard)
LNG IUD: Levonorgestrel IUD (e.g., Liletta, Kyleena, Mirena, Skyla)
UPA: Ulipristal Acetate

Using the categories in practice:

Categories 1 and 4 are self-explanatory. Classification of a method/condition as category 2 indicates the method can generally be used, but careful follow-up may be required. However, provision of a method to a woman with a condition classified as category 3 requires careful clinical judgment and access to clinical services; for such a woman, the severity of the condition and the availability, practicality, and acceptability of alternative methods should be taken into account. For a method/condition classified as category 3, use of that method is not usually recommended unless other more appropriate methods are not available or acceptable. Careful follow-up will be required.

Where resources for clinical judgment are limited, such as in community-based services, the four-category classification framework can be simplified into two categories. With this simplification, a classification of Category 3 indicates that a woman is not medically eligible to use the method. District level conditions are often consistent with community-based services and thus the two-tier approach listed in the following table is recommended. Provision of a contraceptive to a woman with a condition that falls into category 3 (for initiation or continuation) should be done only after consultation with the delegating MD.

CATEGORY	WITH CLINICAL JUDGMENT	WITH LIMITED CLINICAL JUDGMENT
1	Use method in any circumstances	Yes (Use the method)
2	Generally use the method	
3	Use of method not usually recommended unless other more appropriate methods are not available or not acceptable	No (Do not use the method)
4	Method not to be used	

NOTE: Age And When To Stop Using Contraception: A woman who has had menopause confirmed by the absence of menses for 12 months while not on hormones that may suppress menstruation no longer needs contraception. Age by itself is not a contraindication

to any method of contraception. Use of hormonal methods can mask the diagnosis of menopause. The average age of menopause in the U.S. is 51, and a clinician can be certain about menopause by age 55. A woman with no medical problems can continue her desired contraception as long as desired or until age 55. Medical co-morbidities increase with age and the combination of these (e.g., hypertension, diabetes, obesity) plus age may increase the risk, particularly with estrogen containing contraceptives. For all women, continuous reassessment of health, co-morbidities and reproductive goals and needs is essential and working with individual women to determine what is best as they near menopause.

The CDC US Medical Eligibility Criteria also highlights the importance of selecting contraceptive methods that have higher efficacy at preventing pregnancy. The following Table 1 lists the perfect and typical use failure rates of common contraceptives, as well as the continuation rates at one year. Providers should become familiar with the typical use failure rates, as those are the rates that are experienced by most patients. The CDC US Medical Eligibility Criteria also created a list of conditions that are associated with an increased risk of adverse events in the event of unintended pregnancy. See Box #1 below.

For women with conditions that may make unintended pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods may be the best choice. Women with these conditions should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception may not be the most appropriate choice because of their relatively higher typical-use rates of failure. Table 1 that follows shows the percentages of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year in the United States.

TABLE 1. Percentage of women experiencing an unintended pregnancy during the first year of typical use and the first year of perfect use of contraception and the percentage continuing use at the end of the first year — United States

Method	Women experiencing an unintended pregnancy within the first year of use		Women continuing use at 1 year[§]
	Typical use[*]	Perfect use[†]	
No method[¶]	85%	85%	
Spermicides[**]	29%	18%	42%
Withdrawal	27%	4%	43%
Fertility awareness–based methods	25%		51%
Standard Days method[††]		5%	
TwoDay method™[††]		4%	
Ovulation method[††]		3%	
Sponge			
Parous women	32%	20%	46%
Nulliparous women	16%	9%	57%
Diaphragm[§§]	16%	6%	57%
Condom[¶¶]			
Female (Reality®)	21%	5%	49%
Male	15%	2%	53%
Combined pill and progestin-only pill	8%	0.3%	68%
Evra patch®	8%	0.3%	68%
NuvaRing®	8%	0.3%	68%
Depo-Provera®	3%	0.3%	56%
Intrauterine device			
ParaGard® (copper T)	0.8%	0.6%	78%
Mirena® (LNG-IUS)	0.2%	0.2%	80%
Implanon®	0.05%	0.05%	84%
Female sterilization	0.5%	0.5%	100%
Male sterilization	0.15%	0.10%	100%
Emergency contraceptive pills[***]	Not applicable	Not applicable	Not applicable
Lactational amenorrhea methods[†††]	Not applicable	Not applicable	Not applicable

Adapted from Trussell J. Contraceptive efficacy. In Hatcher RA, Trussell J, Nelson AL, Cates W, Stewart FH, Kowal D. Contraceptive technology. 19th revised ed. New York, NY: Ardent Media; 2007.

* Among typical couples who initiate use of a method (not necessarily for the first time), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason. Estimates of the probability of pregnancy during the first year of typical use for spermicides, withdrawal, fertility awareness-based methods, the diaphragm, the male condom, the pill, and Depo-Provera are taken from the 1995 National Survey of Family Growth corrected for underreporting of abortion; see the text for the derivation of estimates for the other methods.

† Among couples who initiate use of a method (not necessarily for the first time) and who use it *perfectly* (both consistently and correctly), the percentage who experience an unintended pregnancy during the first year if they do not stop use for any other reason. See the text for the derivation of the estimate for each method.

§ Among couples attempting to avoid pregnancy, the percentage who continue to use a method for 1 year.

¶ The percentages becoming pregnant in the typical use and perfect use columns are based on data from populations where contraception is not used and from women who cease using contraception to become pregnant. Of these, approximately 89% become pregnant within 1 year. This estimate was lowered slightly (to 85%) to represent the percentage who would become pregnant within 1 year among women now relying on reversible methods of contraception if they abandoned contraception altogether.

** Foams, creams, gels, vaginal suppositories, and vaginal film.

†† The TwoDay and Ovulation methods are based on evaluation of cervical mucus. The Standard Days method avoids intercourse on cycle days 8–19.

§§ With spermicidal cream or jelly.

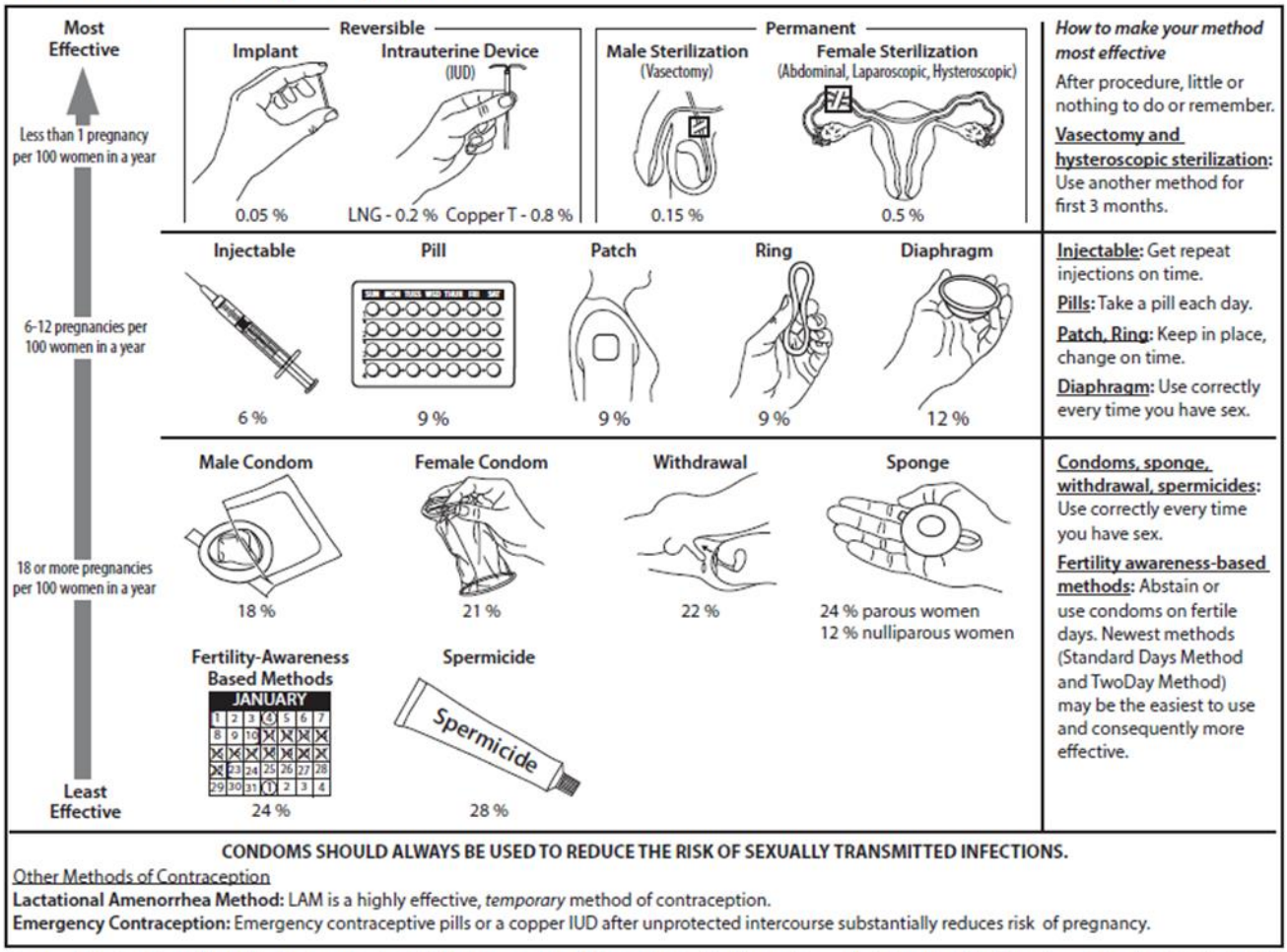
¶¶ Without spermicides.

*** Treatment initiated within 72 hours after unprotected intercourse reduces the risk for pregnancy by at least 75%. The treatment schedule is 1 dose within 120 hours after unprotected intercourse and a second dose 12 hours after the first dose. Both doses of Plan B can be taken at the same time. Plan B (1 dose is 1 white pill) is the only dedicated product specifically marketed for emergency contraception. The Food and Drug Administration has in addition declared the following 22 brands of oral contraceptives to be safe and effective for emergency contraception: Ogestrel or Ovral (1 dose is 2 white pills); Levlen or Nordette (1 dose is 4 light-orange pills); Cryselle, Levora, Low-Ogestrel, Lo/Ovral, or Quasence (1 dose is 4 white pills); Tri-Levlen or Triphasil (1 dose is 4 yellow pills); Jolessa, Portia, Seasonale, or Trivora (1 dose is 4 pink pills); Seasonique (1 dose is 4 light blue-green pills); Empresse (1 dose is 4 orange pills); Alesse, Lessina, or Levlite (1 dose is 5 pink pills); Aviane (1 dose is 5 orange pills); and Lutera (1 dose is 5 white pills).

††† Lactational amenorrhea method is a highly effective *temporary* method of contraception. However, to maintain effective protection against pregnancy, another method of contraception must be used as soon as menstruation resumes, the frequency or duration of breastfeeding is reduced, bottle feeds are introduced, or the baby reaches 6 months of age.

The following graphic may be useful in interpreting the above efficacy data and when counseling patients. In general, provider counseling can follow a hierarchical approach if the patient prioritizes method efficacy. For patients who prioritize other method characteristics (e.g., bleeding profile, presence or absence of hormones, etc.), this may still be a useful tool to provide a visual for the patient.

FIGURE. Effectiveness of family planning methods*



CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, *temporary* method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/ Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

Box #1: Conditions associated with increased risk for adverse health events as a result of pregnancy*:

- Breast cancer
- Complicated valvular heart disease
- Cystic fibrosis
- Diabetes: insulin dependent with nephropathy, retinopathy, or neuropathy, or other vascular disease; or of > 20 years duration
- Endometrial or ovarian cancer
- Epilepsy
- Hypertension (systolic ≥ 160 mm Hg or diastolic ≥ 100 mm Hg)
- History of bariatric surgery within the past 2 years
- HIV: not clinically well or not receiving antiretroviral therapy
- Ischemic heart disease
- Gestational trophoblastic disease
- Hepatocellular adenoma and malignant liver tumors (hepatoma)
- Peripartum cardiomyopathy
- Schistosomiasis with fibrosis of the liver
- Severe (decompensated) cirrhosis
- Sickle cell disease
- Solid organ transplantation within the past 2 years
- Stroke
- Systemic lupus erythematosus
- Thombogenic mutations
- Tuberculosis

***Long-acting, highly effective contraceptive methods might be the best choice for women with conditions that are associated with increased risk for adverse health events as a result of pregnancy. These women should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure.

Recreated from http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf. Box 2

The CDC's Selected Practice Recommendations for Contraceptive Use (SPR) were updated in 2016: SPR can be found: http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf
Like the Medical Eligibility Criteria, the SPR represents an extensive and ongoing review of the literature regarding how to use contraception. Specifically, the SPR provides recommendations on when to initiate contraceptives, which studies are necessary prior to initiation, and makes some suggestions on clinical management scenarios.

Clinicians are encouraged to read the document in its entirety, including the detailed review on the utility of a urine pregnancy test. This set of protocols (in particular, the Initiation of

Contraceptives protocol) reflects that using a checklist to be "reasonably certain that a woman is not pregnant" has a very high probability that the woman is not pregnant. See Box #2 below. The SPR supports immediate initiation for all methods of contraception if you can be reasonably certain that the woman is not pregnant.

Box #2: How to be reasonably certain that a woman is not pregnant:

A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- Is ≤7 days after the start of normal menses
- Has not had sexual intercourse since the start of last normal menses
- Has been correctly and consistently using a reliable method of contraception
- Is ≤ 7 days after spontaneous or induced abortion
- Is within 4 weeks postpartum
- Is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority (≥85%) of feeds are breastfeeds), amenorrheic, and <6 months postpartum

Recreated from http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf Box 2

When To Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back-up) needed	Examinations or tests needed before initiation*
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection†
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection†
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; HIV = human immunodeficiency virus; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use.*

* Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 1). However, measuring weight and calculating BMI (weight [kg] / height [m]^2) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

† Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's *STD Treatment Guidelines* (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Other key recommendations from the SPR include a detailed discussion of the tests and/or examinations that are needed before initiation of contraceptive methods. For this classification:

- Class A: essential and mandatory in all circumstances for safe and effective use of the

contraceptive method.

- Class B: contributes substantially to safe and effective use, but implementation may be considered within the public health and/or service context; risk of not performing an examination or test should be balanced against the benefits of making the contraceptive method available.
- Class C: does not contribute substantially to safe and effective use of the contraceptive method.

The SPR discusses follow-up suggestions after contraceptive initiation (table below). Adolescents and women with complex medical histories may require additional or tailored follow-up. The SPR also makes recommendations about management of abnormal bleeding during contraceptive use and what to do with a woman who develops PID with an IUD in situ. These are reflected in those specific protocols.

TABLE. Examinations and tests needed before initiation of contraceptive methods

	Contraceptive method and class							
Examination or test	**Cu-IUD and LNG-IUD**	**Implant**	**Injectable**	**CHC**	**POP**	**Condom**	**Diaphragm or cervical cap**	**Spermicide**
Examination								
Blood pressure	C	C	C	A*	C	C	C	C
Weight (BMI) (weight [kg]/ height [m]^2)	—†	—†	—†	—†	—†	C	C	C
Clinical breast examination	C	C	C	C	C	C	C	C
Bimanual examination and cervical inspection	A	C	C	C	C	C	A§	C
Laboratory test								
Glucose	C	C	C	C	C	C	C	C
Lipids	C	C	C	C	C	C	C	C
Liver enzymes	C	C	C	C	C	C	C	C
Hemoglobin	C	C	C	C	C	C	C	C
Thrombogenic mutations	C	C	C	C	C	C	C	C
Cervical cytology (Papanicolaou smear)	C	C	C	C	C	C	C	C
STD screening with laboratory tests	—¶	C	C	C	C	C	C	C
HIV screening with laboratory tests	C	C	C	C	C	C	C	C

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; HIV = human immunodeficiency virus; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pill; STD = sexually transmitted disease; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use, 2010*.

* In cases in which access to health care might be limited, the blood pressure measurement can be obtained by the woman in a nonclinical setting (e.g., pharmacy or fire station) and self-reported to the provider.

† Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women (Box 2). However, measuring weight and calculating BMI at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

§ A bimanual examination (not cervical inspection) is needed for diaphragm fitting.

¶ Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to CDC's *STD Treatment Guidelines* (available at http://www.cdc.gov/std/treatment). If a woman has not been screened according to guidelines, screening can be performed at the time of IUD insertion and insertion should not be delayed. Women with purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. MEC 4). Women who have a very high individual likelihood of STD exposure (e.g., those with a currently infected partner) generally should not undergo IUD insertion (U.S. MEC 3). For these women, IUD insertion should be delayed until appropriate testing and treatment occurs.

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

NOTE (regarding length of contraceptive use): The long-acting methods of contraception are often effective for longer than the FDA approved time. The Copper T380A is approved for use for 10 years, however clinical data demonstrates its effectiveness for 12 years, and probably longer. The contraceptive implant is approved for use for 3 years however, clinical data demonstrates its effectiveness for 5 years, and probably longer. This information can be used when counseling women at the time of initiation as well as at the end of the FDA approval window. If the patient is satisfied with the method at the end of the FDA approval window and would like to continue using it, evidence indicates that it still provides contraception as noted above. If the patient would like to have it removed, this should be honored.

NOTE: Long-acting methods of contraception (Paraguard IUD, Levonorgestrel IUDs, and Nexplanon) must be inserted by the expiration date listed on the package. When inserted prior to the expiration date, the product will be effective for the length of recommended use.

PROVIDING QUALITY FAMILY PLANNING

Providing Quality Family Planning is an essential service for the health of families. These recommendations help "put everything together," and suggest how to intertwine the MEC and SPR into clinical settings. Figure 1 in QFP (below) shows how providing family planning services is embedded within a larger framework of preventive care. Clinicians providing family planning should be equipped to provide all Family Planning Services as well as Related Preventive Health Services, with referral as needed. Provision of Other preventive health services should be available on-site or by referral.

FIGURE 1. Family planning and related and other preventive health services

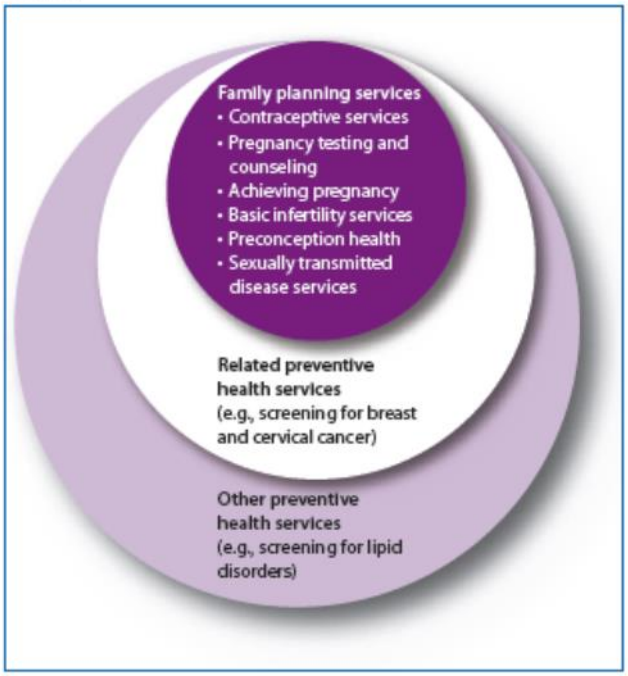
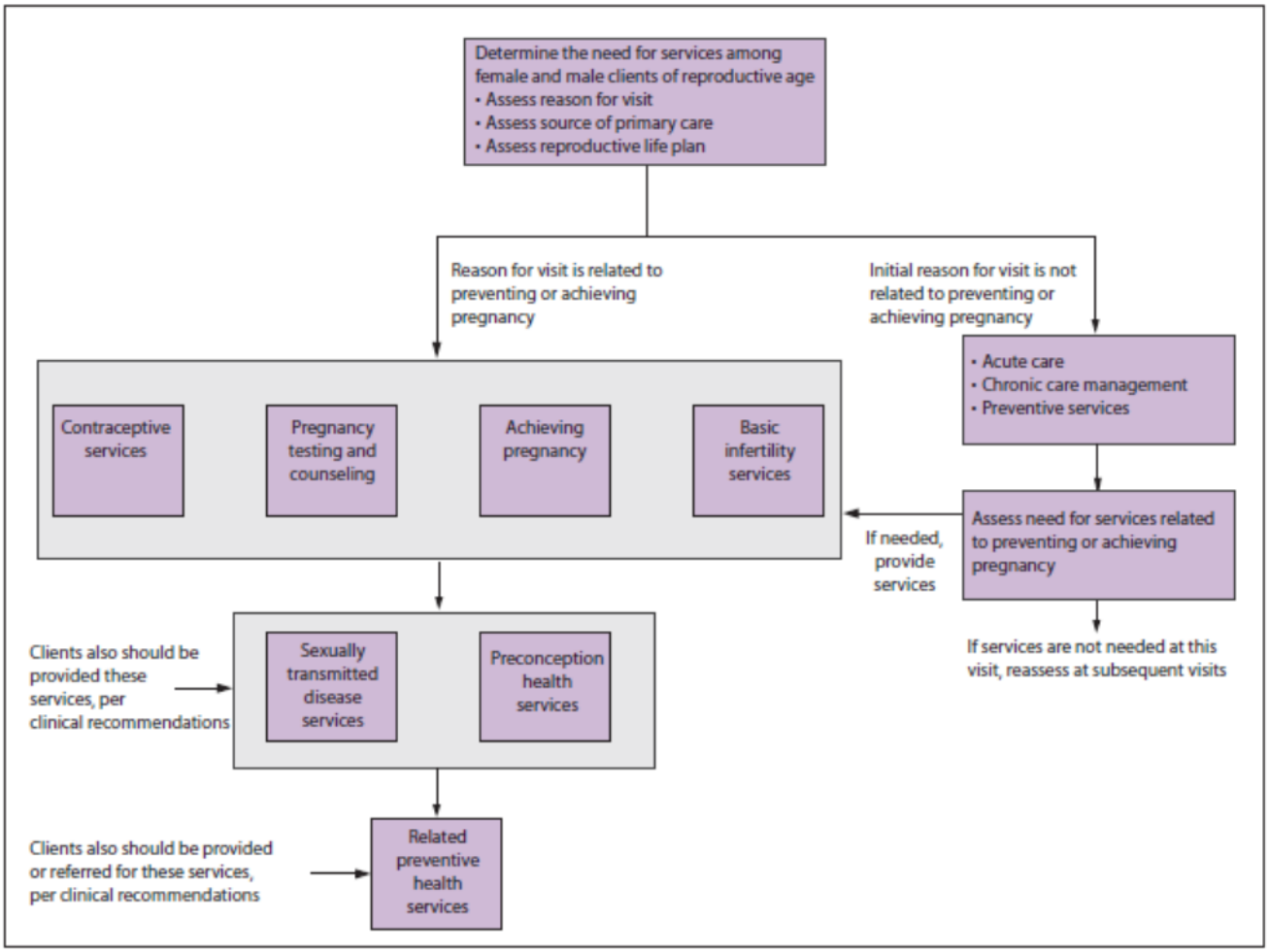


FIGURE 2. Clinical pathway of family planning services for women and men of reproductive age



A suggested clinical pathway is depicted in Figure 2. Determining the reason for the visit, other sources of care and reproductive life plan are the first steps. A reproductive life plan can be a simple assessment to understand the fertility goals of the patient. See questions listed in Box 3 that follows. As Figure 2 indicates, clinicians should ask a woman about her source of primary care. If she is receiving primary care services elsewhere, a clinician need not repeat these in conjunction with providing Family Planning services.

Box #3: Recommended questions to ask when assessing a client's reproductive life plan:

Providers should discuss a reproductive life plan with clients receiving contraceptive, pregnancy testing and counseling, basic infertility, sexually transmitted disease, and preconception health services in accordance with CDC's recommendation that all persons capable of having a child should have a reproductive life plan. *****

1. Providers should assess the client's reproductive life plan by asking the client questions such as:
    - Do you have any children now?
    - Do you want to have (more) children?
    - How many (more) children would you like to have and when?

* Source: CDC Recommendations to improve preconception health and health care. United States: a report of the CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care. MMWR 2006:55(No. RR-6).

The QFP makes the following recommendations for steps to providing contraceptive services. Clinicians should follow these steps:

1. Establish and maintain rapport:
    a. Use open ended questions, listen, encourage sharing, demonstrate empathy and acceptance
    b. Maintain privacy and confidentiality, explain how personal information will be used
    c. Encourage questions

2. Obtain clinical and social information:
    a. Medical history, including menstrual, obstetric history, conditions that may affect contraceptive eligibility (see MEC). A complete medication history including herbal medications should be obtained and reviewed for potential interactions with contraceptives. Certain prescription medications, over the counter medications and herbal medications may decrease the effectiveness of contraceptives. Review patient's current medication history and consult online drug database, for example, Lexicomp, for more detailed information.
    b. Reproductive life plan (as above). It is important to acknowledge that each patient may not fit into categories of completely wanting or wishing to avoid pregnancy. Providers should work collaboratively and incorporate shared decision-making in all family planning counseling interactions.
    c. Contraceptive history and preferences
    d. Sexual health assessment (using the 5 P's)
        1) Practices (what types of sexual activity are they engaging in, e.g., vaginal, oral, anal)
        2) Pregnancy prevention method
        3) Partner (number, gender, concurrency)
        4) Protection from STDs (what are they doing for STD prevention, e.g.,

condoms, abstinence, monogamy)
5) Past STD history (self and partner(s), those with history of STDs are at higher risk of STDs)

3. Work interactively to select the most effective and appropriate contraceptive method incorporating the following:
   a. Method effectiveness
   b. Correct use
   c. Non-contraceptive benefits
   d. Side effects
   e. Protection from STDs/HIV
   f. Providers should also incorporate additional concerns identified from social history into this discussion (e.g., socio-behavioral concerns, intimate partner violence, mental health, and substance use) that may impact method use

4. Conduct a physical assessment related to contraceptive use, when warranted (see SPR Table-Examination and tests needed before initiation of contraceptive methods also see Preventive Care and Health Screening Protocol for screening that may be valuable for overall health).

5. Provide contraceptive method along with instructions, help patient develop a plan for use, confirm understanding, arrange follow-up.
   a. Start the method the day of visit when possible (see Initiation of Contraceptives protocol).
   b. Provide multiple cycles (ideally a full year) of pill, patch, or ring when possible.

REFERENCES:

1. CDC, U.S. Medical Eligibility Criteria for Contraceptive Use, 2016, MMWR 2016; 65: 3 http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf

2. CDC, U.S. Selected Practice Recommendations for Contraceptive Use, 2016. MMWR 2016; 65:4 http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf

3. Centers for Disease Control and Prevention, Providing Quality Family Planning MMWR 2014 http://www.cdc.gov/mmwr/pdf/rr/rr6304.pdf

STANDARD NURSE PROTOCOL FOR PREVENTIVE CARE AND HEALTH SCREENING

DEFINITION

Preventive care and health screening is an important part of providing health care to women, and it focuses on promoting and maintaining health over a woman's lifetime. Screening, by its definition, is performed before the onset of symptoms of disease to prevent disease or to identify it in its early stages. Recommendations for preventive care and health screening are generally grouped by age and are determined after identifying major causes of morbidity and mortality for that age group. Attention is directed towards those conditions for which early identification can impact the trajectory of the disease and intervention is possible.

ETIOLOGY

A well-woman visit provides an excellent opportunity to counsel patients about maintaining a healthy lifestyle and minimizing health risks. A visit focused on preventive care and wellness is encouraged at least once per year, and this care may be accomplished over more than one visit. A comprehensive history is one of the most important aspects of a well-woman visit. This protocol discusses the examination, counseling and testing that should be offered as a part of preventive care in a family planning setting. Please note that offering preventive care and health screening is valuable for overall health, but there is no screening that is necessary for the safe provision of contraception. Preventive care and screening, like all aspects of clinical care, change over time. Providers must make efforts to be up-to-date on recommendations. Provider resources include the US Preventive Services Task Force **https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics/uspstf-a-and-b-recommendations** and American College of Obstetricians and Gynecologists www.acog.org.

Cervical cancer screening and breast cancer screening should be consistent with current Georgia Breast and Cervical Cancer Program Screening Guidelines.

SUBJECTIVE

1. Patient's general well-being **(**including complete medical, surgical, social, and obstetric/gynecologic history, reproductive goals, and medication use (including herbal and over the counter) and allergies) and health habits (including exercise, nutrition, sexuality, substance use, mental health, experiences of intimate partner violence and immunization history).

2. A family history to include cancer, heart disease, hypertension, high cholesterol, diabetes, autoimmune diseases, mental health disorders, bleeding and clotting disorders and other concerns.

OBJECTIVE

EXAM

The following exam components can be performed and documented at the preventive and screening visit, if needed, and periodically thereafter. If a woman indicates that she has a primary care physician and has had appropriate screening based on Tables 1-3 below, this can be documented per patient history, and these services do not need to be repeated. Note: Performance of a pelvic exam in an asymptomatic woman should be done after discussing the potential risks and benefits of performing the exam and should be based on shared decision-making between the patient and provider. Exam components listed in the table below are for screening exams for a well person. Additional components of the physical exam should be completed as clinically appropriate.

TABLE 1: Exam components

	Menarche-18 years	19-39 years	40-64 years
Height	X	X	X
Weight	X	X	X
BMI	X	X	X
Blood pressure	X	X	X
Tanner staging of secondary sexual characteristics	X		
Neck (thyroid and lymph nodes)		X	X
Heart and Lung	X	X	X
Breast exam		X	X
Abdomen	X	X	X
Pelvic exam*****	As indicated	X (Cervical cancer screening begins at age 21)	X
Rectal exam			X (Begin age 50; may begin at 45 for high-risk populations)
General Health and wellness (ex. skin, oral cavity), as indicated	X	X	X

*Pelvic exams should be performed for cervical cancer screening and for women who are having symptoms. Evidence suggests that this exam may be performed or deferred based on shared decision-making with the patient.

ASSESSMENT Preventive care and health screening

PLAN

DIAGNOSTIC STUDIES (Please see chart below)

The following table outlines the diagnostic studies (lab and other) that should be performed or recommended, if needed, by age category. Depending upon the setting, some may require referral. Clinicians should follow BCCP guidelines for screening in special populations and for follow-up of abnormal screening.

TABLE 2: Screening and Diagnostic Studies

	Menarche-18 years	19-39 years	40-64 years
Urine pregnancy test	As indicated	As indicated	As indicated
Cervical cancer screening	None	▪ Ages 21-29: Cytology alone every 3 years ▪ Age 30 and over: Co-testing (cytology plus High-Risk HPV testing) every 5 years OR ▪ High-Risk HPV testing alone every 5 years OR ▪ Acceptable for cytology alone every 3 years	▪ Co-testing (cytology plus High-Risk HPV testing) every 5 years OR ▪ High-Risk HPV testing alone every 5 years OR ▪ Acceptable for cytology alone every 3 years
Urinalysis	As indicated	As indicated	As indicated
Hemoglobin	As indicated	As indicated	As indicated
Wet prep	As indicated	As indicated	As indicated
Lipids[13]			Begin at age 40 and every 3-5 years thereafter)
Fasting glucose[14]			Begin at age 40 and every 3-5 years thereafter)
Mammography			Every 1-2 years ages 40-49, annually thereafter)
Colon cancer screening			Begin at age 50 (several organizations support initiating screening at age 45. Clinicians are encouraged to discuss these recommendations with patients and initiate screening accordingly). Preference for colonoscopy every 10 years or annual Fecal Immunochemical Test (FIT). Multitarget stool DNA test every 3 years, Flexible sigmoidoscopy every 5–10 years, CT Colonography every 5 years or Colon Capsule every 5 years are acceptable.

1. For those who are at increased risk for cardiovascular disease, lipid screening may occur after age 20 and every five years thereafter. Increased risk can occur with the following:
   a. BMI greater than 30
   b. Hypertension
   c. Personal history of coronary heart disease
   d. Diabetes

e. Family history of early onset heart disease (less than 50 years for males and less than 60 years for females)
f. Tobacco use

2. For those with hypertension or a history of gestational diabetes, screening for type 2 diabetes with a fasting glucose is appropriate. In some settings, screening with stat HGB A1c may be appropriate.

TABLE 3: STD Screening

The following table outlines a risk-based strategy for STD screening. Providers are reminded that screening is to be applied to asymptomatic patients and that additional testing may be appropriate for symptomatic patients. Providers are also encouraged to be aware of their local epidemiology of STDs and any epidemic-level prevalence of disease in the state. STD screening, as with other preventive health studies, can be recommended but not required.

	Females
Chlamydia	• Annually all women less than 25 years old. • Women 25 years old and over, screen annually if new partners, multiple partners, or partners with other partners. • Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.
Gonorrhea	• Annually all women less than 25 years old. • Women 25 years old and over, screen annually if new partners, multiple partners, previous STD or gonorrhea, inconsistent condom use if at risk, commercial sex work, and drug use. • Those who have previously tested positive should be screened for reinfection 3 months after treatment or whenever the person presents for care in the 12 months following initial treatment.
HIV	• Everyone aged 13-64 should be routinely screened for HIV**.** HIV screening should be offered at initial visit and reassessed annually for additional screening needs. • Individuals at high-risk should be screened at least annually. High-risk includes injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test. • In addition to screening, those at high risk should be assessed for and provided information about PrEP (Pre-exposure Prophylaxis) for HIV. • All women who seek evaluation and treatment for STDs should be offered screening for HIV.
Hepatitis C	• Hepatitis C screening at least once in a lifetime for all adults aged 18 years and older, except in settings where the prevalence of HCV

	infection (HCV RNA-positivity) is less than 0.1%.
Syphilis	• Populations at risk include MSM, commercial sex workers, persons who exchange sex for drugs, those in adult correction facilities and those living in communities with high prevalence of syphilis.

PATIENT EDUCATION AND COUNSELING

1. Obesity: For those with BMI greater than 30, intensive, multicomponent behavioral interventions for obese adults include the following components:
   a. Behavioral management activities, such as setting weight-loss goals.
   b. Improving diet or nutrition and increasing physical activity
      1) Regular aerobic physical activity at least 30 minutes per day, most days of the week.
      2) Refer for diet and nutrition counseling, if available.
   c. Addressing barriers to change.
   d. Self-monitoring.
   e. Strategizing how to maintain lifestyle changes.

2. Nutrition
   a. Counsel or refer to nutritionist or dietician (if available) if patient has poor dietary intake, is overweight or underweight, is anemic or has any chronic disease related to poor nutrition.
   b. Recommend that all women who are seeking pregnancy or are capable of pregnancy are consuming 400 mcg of folic acid daily for prevention of neural tube defects.

3. Smoking: For women reporting any amount of smoking,
   a. Refer patient to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user. Patient must be 13 years or older to receive services.
   b. Providers may utilize the 5 A framework to tobacco cessation
      1) Ask about tobacco use.
      2) Advise to quit through clear personalized messages.
      3) Assess willingness to quit.
      4) Assist to quit.
      5) Arrange follow-up and support

4. Alcohol use
   a. May screen using AUDIT, AUDIT-C, CAGE, T-ACE or single question tool.
      1) Single question tool is “How many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 years) or more drinks in a day?”
      2) A positive screen is more than 1 time.
   b. Women identified to have a positive screen should have additional conversation to assess for alcohol abuse or dependence. She may need to be counseled

that her level of drinking may be negatively impacting her health and safety and referred to local resources, including Alcoholics Anonymous.

5. Immunizations
   a. Emphasize importance of keeping immunizations current; assess patient's immunization status and administer vaccines indicated according to the current Advisory Committee on Immunization Practices childhood or adult immunization schedule. If patient declines vaccination, document refusal.
   b. See the Georgia Immunization Program Manual, Recommended Schedule and Guidelines, for current immunization schedules and administration guidelines for each vaccine. The Georgia Immunization Manual may be accessed online at https://dph.georgia.gov/immunization-section/immunization-publications
   c. The CDC guidance on Providing Quality Family Planning Services recommends the following immunizations related to reproductive health:
      1) Human Papillomavirus (HPV)
      2) Hepatitis B: Routine hepatitis B vaccination should be offered to all unvaccinated children and adolescents aged 18 years and younger and all unvaccinated adults who do not have a document history of hepatitis B infection.

6. Intimate Partner Violence:
   a. Women should be asked about safety within their relationship including physical, emotional and sexual violence and coercion.
   b. Those who are experiencing partner violence should be referred to local resources. If the patient is under 18 years of age, then consult legal counsel for possible reporting as child abuse **and follow mandatory reporting guidelines**.

7. Depression
   a. Depression screening should occur at least annually for those thirteen years and older, and for all pregnant and postpartum people.
   b. Use of a validated screener (and the published score for a positive screen) is recommended, for example the PHQ-9, PHQ-2, or Edinburgh Postpartum Depression Screen.
   c. Anxiety frequently co-occurs with depression, but optimal screening intervals are not clear and **nurses should use their best clinical judgement or consult with their delegating physician.**
   d. Those who have a positive screen should be provided the Georgia Crisis and Access Line (GCAL 1-800-715-4225) and/or encouraged to visit ReferralConnect via https://www.georgiacollaborative.com/providers/georgia-crisis-and-access-line-gcal/
   e. Endorsement of active thoughts of harm to self or others is a medical emergency and **clinicians** should consult with **District Health Director or delegating physician** and plan for emergency care.

FOLLOW-UP

1. As indicated by exam, patient education and counseling.

CONSULTATION/REFERRAL

1. Women with abnormal screening labs (those that fall outside the lab report's reference range) or findings which are not covered by a separate nurse protocol - such as Iron Deficiency Anemia in Non-Pregnant Women or Bacterial Cystitis - should be referred to MD for appropriate follow-up (i.e. to a primary care provider for management of laboratory abnormalities), as indicated.

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STANDARD NURSE PROTOCOL FOR EMERGENCY CONTRACEPTIVE PILLS (ECPs)

DEFINITION

Emergency Contraception (EC) is a contraceptive method used to prevent pregnancy. ECPs are ineffective if a woman is already pregnant. Progestin-only ECPs are increased doses of levonorgestrel taken after sexual intercourse to prevent pregnancy by inhibiting ovulation.

Ulipristal acetate is the newest branded ECP. It is a selective progestin receptor modulator. It also works to delay ovulation. It is only available by prescription but has superior efficacy in preventing pregnancy compared to progestin-only ECP between 72-120 hours after sex and also in women who are obese.

The copper IUD is the most effective method of EC and should be offered to women who need EC as well as desire contraception going forward. It can be placed up to 5 days after unprotected sex and left in place up to at least 10 years, with studies suggesting up to 12 years efficacy. See Copper IUD protocol for details on placement.

As of April 2013, a court ruling indicated levonorgestrel based ECP must be made available over-the-counter, with no age or gender restrictions. However, some individuals only have insurance coverage for levonorgestrel ECP when the medication is prescribed by a clinician. Ulipristal acetate and the Copper IUD are available only by prescription.

ETIOLOGY

ECP work by delaying or preventing ovulation. ECP are most effective if given within 72 hours of unprotected intercourse but are effective up to 120 hours. The sooner ECP are initiated, the more effective the treatment. ECP will not disrupt a pregnancy once implantation has occurred. The effectiveness of treatment depends on when in the woman's menstrual cycle the emergency contraception is used and how soon after sex it is taken.

There are no medical contraindications to the use of ECP except known pregnancy and allergy to the medicine. The duration of use of ECP is less than that of regular use of combined oral contraceptives and progestin only pills and thus would be expected to have less clinical impact.

SUBJECTIVE

1. Patient provides history of unprotected sexual intercourse within the last 120 hours (5 days) and requests post-coital contraception as an emergency measure only (not as ongoing routine contraception). For women who are interested in ongoing contraception, the copper IUD provides the most effective EC and highly effective long-acting reversible contraception. It should be discussed with all women requesting emergency contraception (See Copper IUD Protocol).

NOTE: Progestin only EC is most effective if given within 72 hours of unprotected intercourse. The sooner ECP are initiated, the more effective the treatment. If the patient is more than 72 hours from unprotected intercourse, educate the woman that the copper IUD and ulipristal acetate are superior to levonorgestrel for pregnancy prevention in this window.

2. Due to the time-sensitive nature of use of ECPs, patients may request and/or providers can recommend or provide EC in advance for use as needed. This may be particularly valuable for women who elect short term or coitally-dependent contraception (contraceptive pills, condoms, contraceptive patch, contraceptive rings, etc.) or for any woman who has a medical condition that puts her at increased risk if she experiences an unintended pregnancy (See Box 2 CDC Medical Eligibility Criteria). **For a woman who presents for an ECP and elects to not initiate or use an ongoing contraceptive method, an additional ECP may be dispensed in advance for use as needed.**

3. Precautions: When providing oral levonorgestrel (e.g., Plan B® One-Step, Next Choice, etc.) or ulipristal acetate, Ella®:
    a. History of hypersensitivity to any component of ECPs.
    b. Known or suspected pregnancy.

OBJECTIVE

1. A pregnancy test is not needed before providing ECP but may be performed if the patient reports more than one act of unprotected intercourse since last menstrual period (LMP).

2. Pelvic exam, if indicated.

3. Current and local availability of oral levonorgestrel, or ulipristal acetate.

ASSESSMENT Patient requests EC; no contraindications or allergies to any component of the emergency contraceptive.

PLAN

THERAPEUTIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

PHARMACOLOGIC

1. Levonorgestrel 1.5 mg (e.g., Plan B® One-Step, My Way®, React®, EContra EZ®, Aftera®, etc.): one single dose of 1.5 mg levonorgestrel PO as soon as possible within 120 hours after unprotected intercourse.

For those who use levonorgestrel-only as an ECP:

a. **If initiating an ongoing contraceptive method is desired,** initiate the method according to manufacturer's directions at the next menstrual cycle or begin the method the day after ECP treatment is complete.
b. **DMPA or** a subdermal implant can be initiated on the same day as this ECP.
c. Encourage use of a back-up method for 7 days and repeat urine pregnancy testing in 2-3 weeks.

NOTE**:** Antiemetics not needed with progestin only ECP. Consider repeating the dose of ECP if vomiting occurs within 2 hours of Levonorgestrel.

OR

2. If a candidate for ulipristal acetate, one tablet of 30 mg ulipristal acetate PO as soon as possible, with or without food. Ulipristal acetate works better than levonorgestrel-only ECP between 72-120 hours and for women who have BMI greater than 30. For women in these situations, clinicians should preferentially offer Ulipristal acetate or Paragard if available due to their higher efficacy.

    a. Consider repeating the dose of ECP if vomiting occurs within 3 hours of ulipristal acetate.
    b. **If initiating an ongoing contraceptive method is desired**, for those who use ulipristal acetate as ECP, a back-up barrier method is encouraged until her next menses. Patient may initiate a hormonal contraceptive method according to manufacturer's directions at the next menstrual cycle or she may initiate hormonal contraceptives 5 days after taking the ulipristal acetate for ECP. She should be provided contraceptive supplies and instructions about when to begin. Women who are interested in DMPA or a subdermal implant should return in 5 days or at the time of next menses for the injection or implant placement.

3. If **initiating** an ongoing method is desired, ParaGard should be considered as it provides the most effective EC and provides highly effective long-acting contraception. Refer patient to APRN for copper IUD placement if interested in copper IUD as emergency contraception.

4. ECPs (Ella (ulipristal acetate) or Levonorgestrel only) are not indicated for use in children or adolescents prior to menarche. Adolescents (postmenarchal) who need ECPs should follow adult dosing schedule. If there is any situation in which a clinician feels that a minor's request for EC is a result of a sexual act that was not consensual, the clinician should report the concern according to clinical guidelines regarding Mandatory Reporting Laws.

5. Offer STD screening if sexual encounter also placed at risk of contracting STDs. If patient has been raped, refer to local authorities and clinical setting where an exam can be performed for collecting evidence (if your clinic does not do this). Provision of the ECP should not be delayed for this referral.

PATIENT EDUCATION/COUNSELING

1. Provide exact directions for taking medication. This will include taking one dose of the levonorgestrel based ECP or ulipristal acetate as soon as possible.

2. Encourage patient to choose an ongoing method of birth control if that is acceptable. ECP is not intended for routine contraception. Repeated use within the same menstrual cycle is not recommended. If initiating a hormonal method and using levonorgestrel-only ECP, encourage use of a back-up method for 7 days. For those who use ulipristal acetate as ECP, a back-up method is encouraged until next menses. Emergency contraception does not protect from pregnancy going forward (except for use of Paragard as EC) and future acts of sex require additional contraception.

3. Counsel that the next menstrual period may start a few days earlier or later than usual. The next menstrual period should begin within the next 2 or 3 weeks. If no menses in 3 weeks advise patient to return to clinic for pregnancy test. (This can also be done by a home pregnancy test if patient desires).

4. If an ongoing method is initiated immediately after ECP, the next cycle may also be delayed. In this setting, offer a urine pregnancy test in 2-4 weeks. (This can be done by a home pregnancy test if the patient desires).

5. Patients who use ulipristal acetate for EC and who begin a hormonal contraception should use a back-up method until her next menses.

6. Provide counseling on preconception health counseling and future fertility.

7. Advise that ECP does not protect against STD/HIV. Counsel on the use of condoms to reduce the risk of STD/HIV.

8. Provide information for the Emergency Contraception Hotline (1-888-NOT-2-LATE). The Hotline is an automated, toll-free confidential service available 24 hours a day in English and Spanish. In addition to basic information, each caller hears a recording of the names and telephone numbers of the five closest ECP providers.

FOLLOW-UP

1. Return to clinic if menses has not started in 3 weeks or if next menses is unusually light or painful.

2. Return to clinic for ongoing birth control method if not provided at visit.

CONSULTATION/REFERRAL

1. Refer patient to physician immediately for symptoms concerning for an ectopic pregnancy.

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STANDARD NURSE PROTOCOL FOR INITIATION OF CONTRACEPTIVES

DEFINITION

Contraceptive initiation can occur on the day of the clinical visit when a provider is reasonably certain that a woman is not pregnant.

ETIOLOGY

This protocol discusses initiation of contraceptive methods including the following: combined hormonal contraception (OC, Vaginal Ring, Contraceptive Patch); Progestin-only Pills (POP); medroxyprogesterone acetate (commonly known as DMPA); subdermal contraceptive implants and intrauterine devices (IUD).

Requiring a patient to return for contraceptive initiation or to remember when to start a method at some point in the future opens opportunity not only for failure to initiate the method but also for pregnancy to occur while waiting to do so. Initiating contraceptives immediately can streamline patient education regarding initiation. It can make instructions easier to provide and to understand. For DMPA, it can increase access by 81%.

A sensitive urine pregnancy test is positive when the hormone human chorionic gonadotropin (HCG) is present in sufficient quantities in the body. This will generally be positive by 14 days after an act of intercourse. A pregnancy test done on any given day would not reliably identify pregnancies from more recent intercourse. Initiation of hormonal contraception during this two-week window does not alter whether previous intercourse will result in pregnancy that is not yet detectable. There is a low rate of pregnancy for those who initiate hormonal contraceptives while not on their menses (~3%). In general, when inadvertently used early in pregnancy, combined hormonal and progestin only contraceptive methods do not harm a pregnancy.

SUBJECTIVE

1. Patient is interested in starting contraception.

2. Medical, menstrual, and coital history. Patient does not have any contraindication to using the selected contraceptive in accordance with the individual Standard Nurse Protocol and the CDC Medical Eligibility Criteria.

OBJECTIVE

1. Clinicians can be reasonably certain a woman is not pregnant by her history if she has no signs or symptoms of pregnancy and she meets any of the following:
   a. Has not had intercourse since her last normal menstrual period.
   b. Has been consistently and correctly using a reliable method of contraception.
   c. Is within the first seven days of a normal menstrual period.
   d. Is within four weeks postpartum (lactating or non-lactating).

e. Is within seven days of a miscarriage or abortion.

NOTE: If a woman has not had sex since a miscarriage or abortion, a provider can be reasonably certain that she is not pregnant and can initiate any method. A pregnancy test is not indicated and may still be positive.

f. Is fully breastfeeding, is amenorrheic and is less than six months postpartum.

ASSESSMENT Patient desires contraception

PLAN

DIAGNOSTIC STUDIES

1. Sensitive urine pregnancy test (UCG) as indicated.

THERAPEUTIC (See chart below)

PHARMACOLOGIC

1. If a pregnancy test is performed and is positive, provide options counseling.

2. If a provider can be reasonably certain that a woman is not pregnant, any contraceptive may be initiated on that day.

3. In situations where a provider cannot be reasonably certain that a woman is not pregnant, the benefits of initiating hormonal contraceptives (combined hormonal contraceptives, DMPA, POP, subdermal implant) outweigh the risks and contraception can be initiated immediately. Offer initiation of hormonal contraception immediately:
   a. Starting hormonal contraception on the day of the visit can be easier for patients and can increase access.
   b. Hormonal contraception will not prevent a pregnancy from sex that has already occurred.
   c. Most studies show no increased risk for adverse outcomes (congenital anomalies, neonatal or infant death) in infants exposed to contraception.
   d. The likelihood of pregnancy in previous studies of immediate initiation in situations like these was 3%.
   e. If patient wants to begin hormonal contraception (OC, contraceptive ring, contraceptive patch, DMPA, subdermal implant) that day, initiate method.
   f. Encourage condoms or abstinence for 7 days. Repeat UCG in 14-28 days (this can be done by a home pregnancy test if the patient desires).
   g. If patient declines initiation of hormonal contraception on that day, provide the method to begin on the first day of the next menstrual cycle or advise her to return to clinic to receive a DMPA shot or implant when her next period begins.
   h. If the patient desires an IUD and the provider cannot be reasonably certain that patient is not pregnant, the patient should be provided an alternate method of

contraception and should return for IUD placement when the provider can be reasonably certain she is not pregnant.

i. If patient has had unprotected sex in the last 120 hours, offer emergency contraception (emergency contraceptive pills or Paragard IUD). See Emergency Contraceptive Pills protocol

PATIENT EDUCATION/COUNSELING

1. Provide method-specific counseling and consent for the method that the patient is initiating.

2. Provide condoms for backup protection (or encourage abstinence) for at least 7 days. Counsel on the continued use of condoms to reduce the risk of STD/HIV.

3. Schedule well-woman care as needed.

FOLLOW-UP

1. Routine follow-up for situations when the provider can be reasonably certain the patient is not pregnant when initiating contraception, refer to table below.

TABLE D1. Routine follow-up after contraceptive initiation

	Contraceptive method				
Action	**Cu-IUD or LNG-IUD**	**Implant**	**Injectable**	**CHC**	**POP**
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use.*

2. For situations when a provider cannot be reasonably certain patient is not pregnant, a urine pregnancy test should be repeated in 2-4 weeks (this can be done by a home pregnancy test if patient desires).

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m²]) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

CONSULTATION/REFERRAL

1. Patients with chronic medical conditions should be encouraged to discuss their contraceptive decision with the provider managing those medical conditions. This is particularly important for people who have serious or multiple medical conditions, rare medical conditions not listed in these protocols, and those who take medications that can interact with contraception (some medications used to treat HIV, tuberculosis, epilepsy and certain fungal infections).

2. Seek consultation, as applicable, if patient has health screening laboratory values (not covered by a nurse protocol) or has abnormal laboratory values and/or physical findings.

REFERENCES:

1. https://www.cdc.gov/reproductivehealth/contraception/pdf/when-to-start_508tagged.pdf

2. CDC, U.S. Selected Practice Recommendations for Contraceptive Use, 2016. MMWR 2016; 65:4 http://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6504.pdf (Current)

STANDARD NURSE PROTOCOL FOR COMBINED HORMONAL CONTRACEPTIVES

DEFINITION

Combined hormonal contraceptives are birth-control methods that include a combination of an estrogen and a progestin. Estrogen and progesterone are two hormones which direct many of the processes surrounding the menstrual cycle. Combined hormonal contraceptives include oral contraceptives (OCs or pills), transdermal patch and vaginal ring. There are many different OC formulations with varying amounts of estrogen and progestins. There are currently three formulations of the patch and for the ring.

ETIOLOGY

Combined hormonal contraceptives work primarily by preventing ovulation. The progestin in combined hormonal contraceptives provide most of the birth control activity by: thickening cervical mucus to prevent sperm penetration into the upper genital tract, blocking the luteinizing hormone (LH) surge prohibiting ovulation, and inhibiting capacitation of the sperm which may delay sperm transport. Estrogen may contribute to the contraceptive effect by decreasing folliculogenesis by suppressing release of FSH but serves primarily to allow menstrual cycle control. Estrogen and progestins have other effects on the reproductive tract, however, there is no significant evidence that these effects contribute to the contraceptive efficacy.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the CDC *US Medical Eligibility Criteria for Contraceptive Use*.

2. If breastfeeding, is at least 30 days postpartum without co-morbidities that increase venous thromboembolism risk (such as age 35 or older, immobility, transfusion at delivery, BMI 30 or greater, postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking). For breastfeeding post-partum patients with above co-morbidities, patient must be at least 42 days postpartum before initiating combined hormonal contraception.

3. If non-breastfeeding, must be at least 21 days postpartum without co-morbidities that increase venous thromboembolism risk (listed above). For non-breastfeeding post-partum patient with above co-morbidities, patient must be at least 42 days postpartum before initiating combined hormonal contraception.

4. If age 35 or older, does not smoke. Use of e-cigarettes does not preclude use of any contraceptive method.

5. If age 35 or older and has two or more co-morbidities (to include the following: BMI of 30 or greater, diabetes, low HDL, high LDL or high triglycerides) must use non-estrogen containing methods as first line.

6. If on anticonvulsant therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine, lamotrigine). Consult drug interactions data base (e.g., Lexicomp) for more detailed information.

7. If on antimicrobial therapy, does not take a rifamycin (Rifampin, rifabutin, or Rifapentine) derivative.

8. For those requesting pills, has not had a history of malabsorptive bariatric surgery (Roux-en-Y gastric bypass, biliopancreatic diversion).

9. If on antiretroviral therapy, does not take Fosamprenavir. Consult drug interactions data base (e.g., Lexicomp) for more detailed information.

10. Refer to CDC *US Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for taking combined hormonal contraceptives. Medical conditions include:
    a. Hypertension; >140 systolic or >90 diastolic
    b. Deep vein thrombosis (DVT) / Pulmonary embolism
    c. Known thrombogenic mutations
    d. History of superficial venous thrombosis
    e. Ischemic heart disease
    f. Stroke
    g. Valvular heart disease-complicated (pulmonary hypertension, risk for atrial fibrillation, history of subacute bacterial endocarditis)
    h. Peripartum cardiomyopathy
    i. Lupus with positive (or unknown) antiphospholipid antibodies
    j. Migraine headaches with aura (at any age)
    k. Multiple sclerosis with prolonged immobility
    l. Breast cancer
    m. Diabetes: nephropathy/retinopathy/neuropathy, other vascular disease or diabetes of greater than 20 years' duration
    n. Inflammatory bowel disease (ulcerative colitis or Crohn's disease) who are at increased risk for venous thromboembolism (those with active or extensive disease, surgery, immobilization, corticosteroid use, vitamin deficiencies or fluid depletion)
    o. Gall-bladder disease (symptomatic) – medically treated, current symptomatic
    p. History of cholestasis: past related to CHCs
    q. Viral Hepatitis: acute or flare (initiation of combined hormonal contraception)
    r. Cirrhosis: severe (decompensated)
    s. Liver Tumors: benign hepatocellular adenoma, malignant (hepatoma)
    t. Major surgery with prolonged immobilization
    u. Solid organ transplant, complicated (graft failure, rejection, cardiac allograph vasculopathy)

v. Less than 21 days postpartum, if not breastfeeding and no increased risk factor for venous thromboembolism (e.g. age 35 years or older, immobility, transfusion at delivery, BMI 30 kg/m^2 or greater, postpartum hemorrhage, post-cesarean delivery, pre-eclampsia, smoking).
w. Less than 30 days postpartum, if breastfeeding and no increased risk factor for venous thromboembolism (see list above)
x. Less than 42 days postpartum, breastfeeding or not, if have risk factors present for postpartum venous thromboembolism (see list above)

OBJECTIVE

1. Provider should assess whether they can be reasonably certain that the patient is not pregnant (see Initiation of Contraception protocol).

2. Physical examination and laboratory tests, as indicated. See Standard Nurse Protocol for Preventive Care and Health Screening.

ASSESSMENT

Patient desires combined hormonal contraception and has no condition representing an unacceptable health risk for taking combined hormonal contraceptives. Patient is not allergic to any component of the contraceptive.

PLAN

DIAGNOSTIC STUDIES

1. Blood pressure is below 140/90.

2. Urine pregnancy test, as indicated.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

1. Select a method based on the hormonal dose, the patient's medical history (clinical picture), preference, past experiences with contraceptives, cost and potential side effects.
   a. For those interested in a pill, both WHO and FDA recommend using the lowest dose pill (35 mcg or less) that is effective. (See Appendix A).
   b. For those interested in the patch:
      1) The contraceptive patch receives a CDC MEC category 2 (generally considered safe for use) for obesity. However, the FDA brochures for the contraceptive patches list BMI equal or greater to 30 as a contraindication

because the risk of venous thromboembolism may be higher in people with higher BMIs. Clinicians should share this information with patients who have a BMI equal to or over 30 and used shared decision-making to decide on the contraceptive method chosen. Women who use the contraceptive patch, Xulane® or Zafemy® (35 mcg ethinyl estradiol/150 mcg norelgestromin), are exposed to about 60% more estrogen than if they were taking a typical birth control pill containing 35 mcg of estrogen. In general, increased estrogen exposure may increase the risk of developing serious blood clots (for instance, in the legs or lungs) that can block blood vessels and cause death or serious disability. However, it is not known whether women using the contraceptive patch are at a greater risk of having these serious problems. One study found a doubling of this risk and another study found no increased risks. Twirla® (30 mcg ethinyl estradiol and 120mcg levonorgestrel) has a lower dose of estrogen and a different progestin than that in Xulane® and Zafemy® (ethinyl estradiol 35 mcg and norelgestromin 150 mcg per day). The manufacturers of the contraceptive patch options are doing studies on this.

2) The transdermal contraceptive patches may be less effective in women with body weight of 198 lbs (90 kg) or higher. May consider back-up method such as condoms if weight is 198 lbs (90 kg) or higher.

c. For those interested in the contraceptive ring:
   1) Storage of NuvaRing® and EluRyng® (etonogesterel/ethinyl estradiol): Prior to dispensing to the patient, refrigerate at 2-8° C (36-46° F). After dispensing to the patient, NuvaRing® and EluRyng® can be stored for up to 4 months at room temperature out of direct sunlight. When dispensed to the patient, place an expiration date on the label not to exceed either, 4 months from the date of dispensing or the expiration date, whichever comes first.
   2) Annovera (segesterone acetate/ethinyl estradiol): Prior to dispensing, store at 20°C to 25°C (68°F to 77°F) Do not refrigerate or freeze. Avoid exposure to direct sunlight. Avoid excessive heat.

2. Provide instructions on selected combined hormonal contraceptive usage to include initiation of method, routines for method use. If a provider can be reasonably certain that a woman is not pregnant, combined hormonal contraceptives may be initiated on that day of clinic visit (See Initiation of Contraceptives protocol). Encourage back up contraception for 7 days.

   Certain barrier methods (e.g., diaphragm, cervical cap, female condom) may interfere with proper ring placement, and therefore, are not recommended for use as the backup method as an additional form of contraception.

3. In situations where a provider cannot be reasonably certain that a woman is not pregnant, the benefits of initiating combined hormonal contraceptives outweigh the risks and contraception can be initiated immediately.
   a. Offer initiation of hormonal contraception immediately.
      1) Starting hormonal contraception, the day of clinic visit can be easier for patients and can increase access.

2) Hormonal contraception will not prevent a pregnancy from sex that has already occurred.
3) Most studies have shown no increased risk for adverse outcomes (congenital anomalies, neonatal or infant death) in infants exposed to contraception.
4) The likelihood of pregnancy in previous studies of immediate initiation in situations like these was 3%.
5) If patient wants to begin combined hormonal contraception (OC, Contraceptive Ring, Contraceptive Patch) the day of clinic visit, initiate it. Encourage condoms or abstinence for 7 days. Repeat UCG in 14-28 days (this can be done by home pregnancy test if the patient desires).
6) If patient declines initiation of hormonal contraception on that day, provide the method to begin on the first day of her next menstrual cycle.
7) If patient has had unprotected sex in the last 120 hours, offer emergency contraception (emergency contraceptive pills or Paragard IUD). See Emergency Contraceptive Pills Protocol. If providing ulipristal acetate for EC, start CHC in 5 days and encourage condoms or abstinence to continue for the following 7 days after starting the CHC.

4. Switching from other methods:
   a. When switching from a non-hormonal method, start combined hormonal contraceptive immediately.
   b. For patients with an IUD, it may be reasonable to start combined hormonal contraceptives when the appointment for IUD removal is made.
   c. When switching from a hormonal method that works primarily by inhibiting ovulation (Combined hormonal contraception, DMPA, implant), start combined method immediately after stopping the other method with no breaks.

5. Provide education/counseling to include details of method use side effects and danger signs, effectiveness and back-up methods, preconception health and future fertility, and risks of STD/HIV.

6. Can provide up to a one-year supply of combined hormonal method.

7. Instruct patient to follow the method-specific instructions (See PATIENT EDUCATION/COUNSELING below).

8. Schedule follow-up exam, as indicated.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to the seven basic elements of informed consent using the pneumonic, BRAIDED. Benefits- (benefits of using the method), Risks (major risks and side effects), Alternatives (other methods available), Inquiries (all patient's questions have been answered), Decision (patient can make a decision to stop the method at any time), Explanation (instructions on use of the method), Documentation.

2. For those who request the pill, explain instructions for combined OCs use:
    a. Take pills at the same time every day to encourage and develop routing for taking the pill.
    b. Can encourage patient to set an alarm as a reminder or to sign up for services to trigger reminders (e.g., Bedsider.org).
    c. Use a back-up barrier method (or abstinence) for the first 7 days of combined OCs initiation, as indicated above.
    d. Use a back-up barrier method if a pill is missed. A missed pill(s) increases the risk of pregnancy. Refer to pill package insert for missed pill(s) instructions.
    e. Offer emergency contraceptive pills (ECP) in advance and instruct women to use it if 2 or more OC pills were missed and patient had unprotected sex in the last 5 days. See Emergency Contraceptive Pills Protocol.

3. OPTIONAL for those who request the pill: If menstrual suppression is desired, additional instructions for extended use of OCs:
    a. Take one monophasic OC each day (recommend 20mcg).
    b. Skip the placebo pills (the 7 pills at the end of the month that are a different color) and start the next pill pack. If calling in a prescription, include “skip the placebo pills” in the sig instructions.
    c. This means that the woman should take one active pill each day (no placebo pills) until she desires a period. Common extended cycles include bi-cycling two pill packs in a row followed by one week of placebo pills and the resulting menstrual period), tri-cycling (three pill packs in a row followed by one week of placebo pills and the resulting menstrual period), or continuous (no placebo pills, no menstrual periods).
    d. This will require more pill packs over the course of the year. Alternatively, a provider can order an extended version of pills (e.g., Seasonale, Lybrel) if covered by insurance and desires menstrual suppression.

4. If requesting the patch provide instructions for use:
    a. The first day of the week the patch is applied is designated as “Patch Change Day.”
        1) Remove the patch and apply a new patch on Patch-Change Day on weeks 2 and 3. Apply the new patch to a different area of skin to reduce skin irritation.
        2) No patch is applied on week 4. Menstrual period will begin during week 4.
    b. Remove liner and apply the sticky surface of the patch on clean, dry skin of the lower abdomen, buttocks, or upper torso (not on the breasts). The upper outer arm may also be used for Xulane. The absorption is the same when applied to any of these areas.
        1) Press down firmly on the patch with the palm of the hand for 10 seconds. Make sure that the edges stick well.
        2) Location of patch should not be altered in mid-week.
        3) Check the patch every day to make sure it is sticking. Avoid touching the sticky surface.
    c. Do not apply creams, oils, or cosmetics near the patch site.

d. Patients using Twirla should avoid swimming or contact with water for long periods of time (30 minutes or more).
e. If the patch becomes loose and is still sticky, try to reattach it. If it is not sticky, replace it with a new patch, and then change the new patch on the usual Patch-Change Day.
f. Do not attempt to tape down a patch that has become loosened.
g. To remove the patch, grasp it by an edge and pull it off. Fold it closed on itself on the adhesive side to seal in the medication. Discard the patch in the garbage; do not flush it into the toilet.
h. Remove any stickiness or adhesive that remains on the skin by using baby oil or lotions.
i. Management of Missed/Forgotten Patches:
    1) 1st Week:
        a) Apply new patch as soon as possible.
        b) Record this day of the week as new Patch**-**Change Day.
        c) Use back-up method for first 7 days of patch use.
        d) If new patch was applied 3 or more days late (patch was left off for 10 days or more in a row) and patient had unprotected sex in last 120 hours, offer emergency contraception. See Emergency Contraceptive Pills Protocol.
    2) 2nd or 3rd week and 1-2 days late:
        a) Apply a new patch as soon as remembered.
        b) Keep the same Patch-Change Day.
        c) No need for back-up method.
    3) 2nd or 3rd week and more than 2 days late:
        a) Stop current cycle and start a new 4-week cycle by applying a new patch immediately.
        b) Record this day of the week as the new Patch-Change Day.
        c) Use back-up method for first 7 days of patch use.
    4) 4th Week:
        a) Remove the patch.
        b) Start the next cycle on the usual Patch-Change Day.
        c) No need for back-up method.

1. If requesting the ring provide instructions for ring use. Currently available contraceptive rings have an estrogen and progestin hormone in a soft flexible ring that is placed vaginally. They are FDA approved for 3 weeks of continuous use with one week without a ring (during which time menses will occur). NuvaRing® and EluRyng® (etonogesterel/ethinyl estradiol) require a new ring for each month. Annovera (segesterone acetate/ethinyl estradiol) has sufficient hormone for 13 cycles, or one year, **if initial insertion occurs prior to product expiration.**
    a. Insertion:
        1) Remove ring from the pouch.
        2) Press opposite sides of the ring together and gently push the folded ring into your vagina while lying down, squatting, or standing with one leg up. If discomfort after inserting ring, instruct to slide it farther in until it feels comfortable. Once in the vagina, the exact position of ring is not important

for it to be effective. Once inserted, keep the ring in place for 3 weeks in a row.

3) The ring does not require fitting or placement in a specific position, nor the use of spermicidal jelly. It does not need to surround the cervix. If discomfort is felt, the device is probably not placed high enough in the vagina.
4) The ring does not need to be removed for intercourse.
5) Keep the protective pouch for later ring disposal and/or storage.

b. Continuation:
1) For those using NuvaRing® or EluRyng®, after 7 ring-free days, insert a new ring into the vagina to begin the cycle again.
2) For those using Annovera®, after 7 ring-free days, reinsert the same ring.
3) Insert the ring on the same day of the week the previous ring was inserted, even if the menses is not finished.

c. Late Replacement or Removal:
1) The ring can be accidentally expelled when it has not been inserted properly, while removing a tampon, or when straining to move the bowels. If expelled, rinse ring with cool/lukewarm water and re-insert promptly (within 3 hours from the time it was expelled for NuvaRing or Eluryng and within 2 hours for Annovera).
2) During the first or second week, if the ring is out of the vagina for more than 3 hours (or 2 hours for Annovera), rinse and re-insert the ring as soon as possible. Use a back-up method for the next 7 days. If ring is lost, insert a new one. Offer emergency contraception if patient had unprotected intercourse in the last 120 hours (5 days). See Emergency Contraceptive Pills Protocol.
3) During the third week, if the ring is out of the vagina for more than 3 hours or 2 hours for Annovera, a new ring can be inserted or reinsert the Annovera immediately to begin a new 3-week cycle

OR

if the ring was used continuously for the preceding 7 days, choose to have a withdrawal bleed and insert a new ring no later than 7 days from the last ring removed/expelled. For either option, use a back-up method until the new ring has been used continuously for 7 days.
4) If the ring was inserted 3 or more days late or the NuvaRing® or EluRyng ® was in place longer than 4 weeks, follow Initiation of Contraceptives Protocol for restart. Use an additional contraceptive method until new ring has been in place for at least 7 days. Offer emergency contraception if patient had unprotected sexual intercourse in the last 120 hours (5 days). See Emergency Contraceptive Pills Protocol.

d. Removal & Disposal:
1) Remove the ring by hooking the index finger around the ring and pulling it out.
2) Place the used monthly ring in the foil pouch and throw it away in a trash container out of the reach of children and pets (do not flush it down the toilet).

3) For Annovera, wash ring with mild soap and lukewarm water, dry, and store in provided case until next insertion. Do not discard in toilet.

2. OPTIONAL for the contraceptive ring: If menstrual suppression is desired, additional instructions for extended use of vaginal ring:
   a. Menstrual suppression can be accomplished with the NuvaRing or EluRyng without requiring additional product over the course of the year.
   b. Place one ring vaginally on any calendar day (e.g., April 14).
   c. One month later (May 14), remove the ring and place another.

3. Discuss side effects and danger signs (ACHES). ACHES is a pneumonic for thrombotic diseases that may be attributable to CHCs (severe Abdominal pain; Chest pain, coughing up blood, dyspnea; Headaches, weakness, numbness; Eye problems such as complete or partial loss vision; leg pain, Swelling, redness inflammation).

4. The primary side effects of hormonal contraception are headache, nausea, application site reactions, and breast discomfort. Women using the patch are more likely to experience breakthrough bleeding and/or spotting during the first 2 months compared with users of a combined OC. Some women using the ring may experience vaginal irritation or infection.

5. Discuss effectiveness of combined methods and back-up methods.
   a. For those using the ring, do not rely on a diaphragm, cervical cap or internal condom as a back-up method because ring may interfere with the correct placement and position of the method. One should also not use Phexxi concurrently with the ring.
   b. For those using Annovera, avoid oil-based lubricants or oil-based vaginal medications.

6. Provide counseling on preconception health counseling and future fertility.

7. Counsel on the use of condoms to reduce the risk of STD/HIV.

FOLLOW-UP

Patient should return as needed (see table below) for evaluation or contact clinic if side effects, danger signs, or symptoms of pregnancy develop. Outside of clinic hours, seek physician or emergency care if danger signs develop. Patients with blood pressures 130-140 systolic **or** 80-90 diastolic should receive follow-up for a blood pressure check in 1-2 months.

CONSULTATION/REFERRAL

1. Refer patient to PCP/clinic MD or APRN if patient develops any of the following danger signs:
   a. Abdominal pain (severe).

b. Eye problems (vision loss or blurring).
c. Speech problems.
d. Chest pain (severe), coughs, shortness of breath.
e. Severe leg pain (calf or thigh).
f. Severe headaches that start or become worse after beginning to take combined OCs.
g. Dizziness, weakness, numbness or depression.

2. Consult with delegating physician/PCP/clinic MD or APRN, as applicable, on serious health concerns expressed by patient.

3. Advise patient to continue treatment with physician if under physician care for a health problem.

4. Consult with delegating physician/PCP/clinic MD or APRN, as applicable, if patient has health screening laboratory values (not covered by a nurse protocol) or has abnormal laboratory values and/or physical findings that indicate combined hormonal contraceptives should not be continued.

5. Seek consultation with delegating physician/PCP/clinic MD or APRN, if high blood pressure develops while on combined hormonal contraception.
   a. Immediately refer patient with severe hypertension to the Emergency Room. Severe hypertension is characterized by systolic pressure 180 mmHg or greater or diastolic pressure 110 mmHg or greater on any occasion. Instruct the patient to stop the combined OCs and discuss non-estrogen containing methods.
   b. For blood pressure 140 mmHg or greater systolic, or 90 mmHg or greater diastolic, on two measurements 6 hours apart, discuss changing method to one that does not contain estrogen (IUD, Implant, progestin-only method). Anyone experiencing symptoms with blood pressures over 140/90 should be referred to the ER.
   c. A diagnosis of hypertension requires two abnormal readings more than six hours apart. If the patient has a single elevated reading (using an appropriately sized blood pressure cuff) and desires to continue to use combined hormonal contraception, ask patient to return for a repeat blood pressure check in 1-7 days.
      1) If patient has an elevated blood pressure when they return to the clinic, discuss the need to change to a method that does not contain estrogen. Use the CDC *US Medical Eligibility for Contraceptive Use* guidance for women with hypertension. Refer for primary care management of her blood pressure.
      2) If patient has a normal blood pressure when they return to the clinic may continue combined hormonal contraception but may warrant more frequent blood pressure monitoring**.**

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m²] at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

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STANDARD NURSE PROTOCOL FOR PROGESTIN-ONLY PILL

DEFINITION

Progestin-only pills (POP) do not contain estrogen. Historically, the only POPs available were also known as minipills. Minipills contain only a progestin, norethindrone 35 mg, and are taken daily with no hormone free days. Minipills have lower progestin doses than combined pills and no estrogen. The amount of progestin in the minipill is less than the amount in the lowest-dose combination oral contraceptives.

Recently, a new POP has been approved called Slynd. Slynd is 4 mg drospirenone. It also has no estrogen but has a higher progestin level, which is similar to that in CHC. This protocol will cover POPs generally and differentiates between minipills and Slynd, as needed.

ETIOLOGY

Minipills prevent pregnancy primarily by thickening and decreasing cervical mucus preventing sperm penetration. This effect on cervical mucus rapidly resolves, so punctual daily dosing is essential for optimizing contraceptive efficacy. Secondary mechanism of action may include: suppressing mid-cycle peaks of LH and FSH, inhibiting progesterone-receptor synthesis, reducing number/size of endometrial glands associated with a thin atrophic endometrium, reducing activity of the cilia in the fallopian tubes, arresting movement of the blastocyst, and premature luteolysis (diminished function of the corpus luteum). Slynd's primary mechanism of action is via ovulation inhibition.

POPs do not suppress the milk supply once breastfeeding is well established and studies have found no adverse effects on infant health. The POPs may be used for women who cannot use estrogen according to the CDC *US Medical Eligibility for Contraceptive Use* guidance and for those who cannot tolerate estrogen-excess side effects.

SUBJECTIVE

1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the CDC *Medical Eligibility Criteria for Contraceptive Use*.

2. If breastfeeding, patient may initiate immediately. However, there is minimal likelihood of ovulating before one month postpartum in a woman who is breastfeeding.

3. If on anticonvulsant therapy, does not take certain anticonvulsants (e.g., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine). Consult drug interactions database (e.g., Lexicomp) for more detailed information.

4. If on antimicrobial therapy, does not take a rifamycin derivative (Rifamycin, Rifabutin or Rifapentine). Consult drug interactions database (e.g., Lexicomp) for more detailed information.

5. Does not have a history of malabsorptive procedures (e.g., Rouxen-Y gastric bypass or biliopancreatic diversion)

6. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for taking POPs. Medical conditions include:
   a. Lupus with positive (or unknown) antiphospholipid antibodies
   b. Breast cancer
   c. Cirrhosis, severe (decompensated)
   d. Liver Tumors: benign hepatocellular adenoma; malignant (hepatoma)
   e. Adrenal insufficiency (contraindicated for Slynd only)
   f. Renal impairment (contraindicated for Slynd only)
   g. **Hepatic dysfunction (contraindicated for Slynd only)**

7. Refer to CDC Medical Eligibility Criteria for Contraceptive Use for medical conditions that represent an unacceptable health risk if they develop while taking the POPs. Patients with these conditions may initiate POPs. If did not have these conditions at the time of initiation but develop these conditions after being on POPs, the POPs should not be continued. Medical conditions include:
   a. Ischemic heart disease
   b. Stroke

8. May report estrogen-excess side effects while taking combined hormonal contraceptives, such as headaches, breast tenderness, nausea and chloasma.

9. May want lowest-dose oral contraceptive available (for minipills).

OBJECTIVE

1. Provider assessment of whether they can be reasonably certain that the woman is not pregnant (see Initiation of Contraception protocol).

2. Physical examination and laboratory tests, as indicated. See Standard Nurse Protocol for Preventive Care and Health Screening.

ASSESSMENT Patient has no condition representing an unacceptable health risk if taking selected POP. Not allergic to any component of the selected POP.

PLAN

DIAGNOSTIC STUDIES

Pregnancy test, if indicated, is negative.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

1. Order any FDA approved progestin-only OC. (See Appendix A)

2. Determine appropriate pill initiation method to begin taking pills. See Patient Education/Counseling below.

3. Provide instructions on selected progestin-only pill usage to include: pill initiation method, daily pill routines, and missed pills.

4. Provide education/counseling to include informed consent, side effects and danger signs, effectiveness and back-up methods, preconception health and future fertility, and risks of STD/HIV.

5. May provide up to a one-year supply of progestin only OCs.

6. Instruct patient to take one pill daily by mouth at the same time of day.

7. Schedule follow-up exam, as indicated (see table below).

PATIENT EDUCATION/COUNSELING

1. Counsel according to seven basic elements of informed consent: Benefits Risks Alternatives Inquiries Decision Explanation Documentation (BRAIDED).

2. Provide education on when to initiate the method (see Initiation of Contraceptives Protocol) and table below.

3. Switching from other methods:
   a. When switching from a non-hormonal method, start progestin only pills immediately following the guidelines for the quick start method.
   b. For patients with an IUD, it may be reasonable to start POPs when the appointment for IUD removal is made.
   c. When switching from a hormonal method that works primarily by inhibiting ovulation, start POPs immediately after stopping the other method with no breaks.

4. Explain instructions for POP use:
   a. Always take one pill every day at the same time.
   b. Advise patient to refer to the pill package insert for missed pill(s) instructions.
   c. For those taking a minipill, taking the pill more than a few hours late increases the risk of pregnancy and missing two or more pills in a row greatly increases the risk. When the minipill is missed or taken more than three hours late, use a barrier method or avoid sex for two days. Take the last missed pill as soon as possible and continue taking one pill each day as usual. When one packet is finished, take the first pill from the next packet on the very next day. All pills are active, hormonal pills. There is no wait between packets.
   d. For those taking Slynd, Slynd has 24 white (active) pills (days 1-24) and 4 green (placebo) pills (days 25-28). Slynd should be taken at the same time each day, but it has a 24-hour grace period. Take a missed pill as soon as possible and continue taking one pill each day as usual.
   e. If vomiting or severe diarrhea (for any reason or duration) occurs within 4 hours after taking minipill, the patient should be instructed to keep taking the pills on schedule and use back-up contraception (e.g., condoms) or avoid sexual intercourse until 2 days vomiting or diarrhea has resolved.
   f. Offer emergency contraceptive pills (ECP) in advance to be used if pill was missed or taken more than 3 hours late (for minipill) or missed two consecutive doses (Slynd) and patient had unprotected sex in the past 120 hours. ECP reduce the risk of pregnancy. See Nurse Protocol of Emergency Contraceptive Pills.

5. Discuss effectiveness of POPs and back-up methods:
   a. There appear to be no significant metabolic effects and there is an immediate return to fertility upon discontinuation of the POP.
   b. The POP may cause irregular bleeding or amenorrhea.
   c. Breakthrough bleeding (BTB) is common with minipills and is generally not a sign that there is anything wrong. The patient should keep taking the minipills. If the bleeding lasts longer than 8 days, is particularly heavy, or is interested in switching to another contraceptive method, return to the clinic. BTB may be less with Slynd.

6. Discuss danger signs:
   a. Abdominal pain that may be due to an ovarian cyst or ectopic pregnancy.
   b. A delayed period after several months of regular cycles may be a sign of pregnancy.
   c. Repeated, very severe headaches.

7. Slynd (drosperinone) may lead to hyperkalemia. Do not use in patients with medical conditions that predispose to hyperkalemia (eg, renal insufficiency, hepatic dysfunction, adrenal insufficiency).

8. Use Slynd with caution in patients taking other medications which may increase potassium levels (eg, ACE inhibitors, Angiotensin Receptor Blockers,

spironolactone, chronic Ibuprofen, azole antifungals, HIV/HCV protease inhibitors, clarithromycin). Consult drug interactions database (e.g., Lexicomp) for more detailed information. Check serum potassium levels prior to starting Slynd and during the first cycle for those taking a medicine that can cause hyperkalemia. Consult with MD for any values out of normal range or for substantial increase between first and second check. Consult with MD for symptoms that may be associated with high potassium (nausea, weakness, tingly feeling, chest pain, irregular heartbeat, loss of movement). **For patients who are not taking one of these medicines, there is no need to routinely check potassium levels before or during use of Slynd.**

9. Instruct patients that Slynd can increase potassium levels and to share this information with any other clinical provider that prescribes them medications. That provider may check potassium levels, as indicated, by the medication they prescribe.

10. Provide counseling on preconception health counseling and future fertility.

11. Counsel on the use of condoms to reduce the risk of STD/HIV.

FOLLOW- UP

Patient should return as needed (see table below) for evaluation or contact clinic if side effects, danger signs, or symptoms of pregnancy develop. Outside of clinic hours, seek physician or emergency care if danger signs develop.

CONSULTATION/REFERRAL

1. Refer to physician if danger signs develop.

2. Consult with delegating physician for abnormal health screening laboratory values (not covered by a nurse protocol) or if abnormal laboratory values and/or physical findings develop that indicate the POP should not be continued.

3. Refer to physician for suspected pregnancy (e.g., missed menses after several regular cycles), especially if signs of ectopic pregnancy such as abdominal pain or tenderness, or fainting are present.

4. Consult delegating physician for potassium levels outside of normal range, or for substantial increase, for those taking Slynd.

5. Consult delegating physician for patients who are on Slynd who report symptoms that may be related to high potassium level (nausea, weakness, tingly feeling, chest pain, irregular heartbeat, loss of movement).

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m²] at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

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STANDARD NURSE PROTOCOL FOR MEDROXYPROGESTERONE ACETATE (DMPA) INJECTABLE CONTRACEPTIVE

DEFINITION

Medroxyprogesterone acetate is a progestin-only (estrogen-free) hormonal contraceptive birth control which is injected every 3 months or 12 weeks. Medroxyprogesterone acetate is commonly known as DMPA.

ETIOLOGY

DMPA inhibits ovulation by suppressing levels of follicular-stimulating hormone (FSH) and luteinizing hormone (LH) and by eliminating the LH surge. The pituitary gland remains responsive to gonadotropin-releasing hormone, which suggests that the site of action of medroxyprogesterone acetate is the hypothalamus.

SUBJECTIVE

1. Desires DMPA as choice of contraception.

2. Health history (includes menstrual, sexual, contraception, personal health and family history) does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the *CDC Medical Eligibility Criteria for Contraceptive Use*.

3. Refer to *CDC Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for taking DMPA. Medical conditions include:
   a. Multiple risk factors for arterial cardiovascular disease (examples of risk factors include, but are not limited to, the following: age over 35, smoking, diabetes, low HDL, high LDL or high triglycerides, obesity and hypertension). Women with multiple risk factors for arterial cardiovascular disease should be encouraged to consider long-acting reversible contraceptives. For women with three or more risk factors, consult with the delegating physician prior to initiating DMPA.
   b. Elevated blood pressure levels with systolic equal to or greater than 160 mmHg or diastolic equal to or greater than 100 mmHg. Patients with well controlled hypertension or those with blood pressures less than 160/100 are candidates for DMPA.
   c. Vascular disease.
   d. Ischemic heart disease.
   e. Stroke.
   f. Lupus with positive (or unknown) antiphospholipid antibodies.
   g. Severe thrombocytopenia at the time of initiation.
   h. Rheumatoid arthritis receiving long term corticosteroid immunosuppressive therapy with a history of or risk factors for nontraumatic fractures.

i. Unexplained vaginal bleeding (suspicious for serious condition before evaluation).
j. Breast cancer.
k. Diabetes: nephropathy/retinopathy/neuropathy, other vascular disease or diabetes of greater than 20 years duration.
l. Cirrhosis: severe (decompensated).
m. Liver Tumors: benign hepatocellular adenoma; malignant (hepatoma).

OBJECTIVE

Physical examination and laboratory tests, as indicated. See Standard Nurse Protocol for Preventive Care and Health Screening.

ASSESSMENT Patient has no condition representing an unacceptable health risk if using DMPA. Not allergic to any component of injection.

PLAN

DIAGNOSTIC STUDIES

Pregnancy test, if indicated, is negative.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

NOTE: Allergic reactions may occur. Encourage patient to remain in the clinic at least 20 minutes after the first injection. Refer to the Emergency Preparedness Allergic Reaction Nurse Protocol as needed.

1. Availability: DMPA is provided either IM or subQ. IM: 1 mL vials or prefilled syringes containing 150 mg/1mL.subQ:104mg/0.65mL

2. Storage:
   a. DMPA IM is to be stored at room temperature 20° to 25°C (68° to 77° F). Both the vial and the pre-filled syringe should be vigorously shaken at least one minute just before use to ensure the dose is uniformly suspended (refer to package insert).
   b. DMPA subQ is to be stored at room temperature 20° to 25°C (68° to 77° F). Shake vigorously prior to administration.

3. Administration: DMPA 150mg IM, injected deeply into the deltoid or gluteus maximus muscle. Depending on the size of the patient, may need to use a 1.5-inch needle. Do not massage the injection site and counsel patient not to massage

site. (Massaging area may reduce duration of action and thereby effectiveness). Rotate administration site with each injection.

DMPA 104mg subQ, administer by subQ injection in the anterior thigh or abdomen. Avoid boney areas and the umbilicus. Administer over 5-7 seconds. Do not rub the injection area (refer to package insert). Rotate administration site with each injection. **The uptake and metabolism of DMPA when injected in the upper arm may be different from the abdomen and thigh.**

4. Initiation:
   a. Provide education on when to initiate the method.
   b. If a provider can be reasonably certain that a woman is not pregnant, DMPA may be initiated that day. Back up for 7 days.
   c. In situations where a provider cannot be reasonably certain that a woman is not pregnant, the benefits of initiating DMPA outweigh the risks and contraception can be initiated immediately.
      1) Starting DMPA the day of clinic visit can be easier and can increase contraceptive access.
      2) Hormonal contraception will not prevent a pregnancy from sex that has already occurred.
      3) Most studies have shown no increased risk for adverse outcomes including congenital anomalies, neonatal or infant death in infants exposed to contraception.
      4) The likelihood of pregnancy in previous studies of immediate initiation in situations like these was 3%.
      5) Initiate DMPA the same day of the clinic visit if patient desires to start that day. Encourage condoms or abstinence for 7 days. Repeat UCG in 14-28 days. This can be done by home pregnancy test if patient desires.
      6) If patient declines initiation of hormonal contraception on the day of clinic visit, advise them to return to the clinic during the first 5 days of the next menstrual cycle to start DMPA.
      7) If unprotected sex in the last 120 hours, offer emergency contraception (EC pills or Paragard IUD). See Emergency Contraceptive Pills Protocol. If ulipristal acetate is provided as the EC method, start DMPA in 5 days.

5. Switching from other methods:
   a. For patients with an IUD, it may be reasonable to start the DMPA when the appointment for IUD removal is made.
   b. When switching from a hormonal method that works primarily by inhibiting ovulation, give the DMPA immediately after stopping the other method with no breaks.

6. Continuation:
   a. The manufacturer recommends re-injection of DMPA IM between 11 and 13 weeks after a previous injection and subQ between 12 and 14 weeks after a previous injection.

b. At each re-injection follow-up visit, ask the date of the last menses, ask about any problems or concerns, specifically signs and symptoms of pregnancy, any changes in contraceptive or STD prevention needs. If the patient is not having any unacceptable symptoms or problems, she may receive re-injection.
c. Contraceptive coverage will be maintained in switching from IM (150 mg/mL) to subcutaneous (104mg per 0.65 mL) DMPA provided the next injection is given within the prescribed dosing period for the IM (150 mg/mL).
d. Contraceptive coverage will be maintained in switching from DMPA 104mg subQ to 150mg IM, provided the next injection is given within the prescribed dosing period for DMPA 104mg subQ.

7. Managing Late Injections:
   a. Patients who present after 13 weeks for DMPA IM and 14 weeks for DMPA subQ but on or prior to 15 weeks 0 days may receive their next injection without additional evaluation.
   b. If patient presents greater than 15 weeks 0 days from last IM or subQ of DMPA injection and patient desires to continue with DMPA, treat as re-initiation.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent BRAIDED: Benefits Risks Alternatives Inquiries Decision Explanation Documentation.

2. Emphasize the importance of the schedule associated with use of this method of contraception. Instruct to use back-up contraception during the first week after the injection if injections are late.

3. Discuss danger signs and other warning signs including repeated painful headaches, heavy bleeding, severe depression, jaundice, severe lower abdominal pain (may be sign of pregnancy), and pus, prolonged pain, or bleeding at the injection site.

4. Common side effects may include bleeding/menstrual irregularities, weight changes, headache, nervousness, abdominal pain, dizziness, and weakness or fatigue. Less common side effects include decreased libido, backache, leg cramps, depression, nausea, acne, vaginitis, breast pain, hair loss, bloating, rash, and hot flashes. Common side effects may not be relieved until the drug clears the body 6-8 months after the last injection. Bleeding irregularities are very common, 30% in the first year and 10% thereafter. If necessary, bleeding can be treated with medication (as noted below in follow-up).

5. Call or return if there are questions about possible side effects or development of reasons to avoid use, such as weight gain, heavy bleeding, headaches, or depression.

6. Counsel that amenorrhea is common on DMPA and is not harmful. Approximately 50% of women are amenorrheic after one year of use, and this increases to 80% by 5 years.

7. Review the FDA black box warning and WHO and CDC recommendations on DMPA and bone mineral density. Counsel patient on adequate calcium intake from foods like milk, cheese, yogurt or ice cream or a calcium/vitamin D supplement daily; regular exercise; and avoiding alcohol, smoking and excessive intake of sodas and caffeine. Advise patient after 2 years of continuous DMPA use, re-evaluation regarding bone health, risk and continuation of DMPA for contraception is appropriate. Women and their providers should continually reassess contraceptive medical eligibility over time, but for healthy women 18-45 years old, the duration of use for DMPA need not be limited**.**

8. Please see details below for black box warning:

NOTE: In November 2004, the FDA issued the following "black box warning" in the Depo-Provera package labeling. Clinicians are advised to review the following warning, which has been added to the prescribing information:

"Women who use Depo-Prover Contraceptive Injection may lose significant bone mineral density. Bone loss is greater with increasing duration of use and may not be completely reversible. It is unknown if use of Depo-Provera Contraceptive Injection during adolescence or early adulthood, a critical period of bone accretion, will reduce peak bone mass and increase the risk of osteoporotic fracture in later life. Depo-Provera Contraceptive Injection should be used as a long-term birth control method (e.g., longer than 2 years) only if other birth control methods are inadequate."

The WHO and many others have reviewed the evidence on this subject and concluded: *"There should be no restriction on the use of Depo-Provera (DMPA), including no restriction on duration of use, among women aged 18-45 who are otherwise eligible to use the method."*

Most studies have found that women lose bone mineral density while using Depo-Provera but regain bone mineral density after discontinuing Depo-Provera. Depo-Provera may decrease the amount of calcium in the bones. It is not known if use during the reproductive years affects the risk of fracture in later postmenopausal years.

Therefore, all Depo-Provera users should have the FDA black box warning clearly explained to them and a discussion of alternatives if they choose to change methods.

Women with medical co-morbidities that place them at risk for osteoporosis and fracture, such as chronic corticosteroid use, disorders of bone metabolism, a strong family history of osteoporosis or women with anorexia nervosa, may not be well suited for long-term Depo-Provera use. Consider alternative contraceptives in patients with significant risk factors for osteoporosis.

WHO further recommended: *"Among adolescents (menarche to age 17) and women over 45, the advantages of using Depo-Provera usually outweigh the theoretical safety concerns regarding risk of fracture. Since Data are insufficient to determine if this is the case with long-term use among these age groups, the overall risks and benefits for continuing use of the method should be reconsidered over time with the individual user."*

9. Discuss effectiveness of DMPA and back-up methods.

10. Advise that DMPA is a long acting contraceptive and not immediately reversible. It takes at least 3 months for fertility to return after last injection. Anovulation may linger after discontinuation. The average is about 9 months (range of 4-31 months) after the last injection and does not increase with longer duration of use.

11. There is no apparent increased risk for breast cancer.

12. No adverse effects have been noted in infants of mothers using DMPA during lactation. Quality and quantity of breast milk is not adversely affected.

13. Provide counseling on preconception health counseling and future fertility.

14. Counsel on the use of condoms to reduce the risk of STD/HIV. DMPA offers no protection from STD/HIV.

FOLLOW-UP

1. Return for re-injection of DMPA IM between 11 and 13 weeks after previous injection and subQ between 12 and 14 weeks after previous injection.

2. Treatment of bleeding irregularities:
   a. Ibuprofen 400mg PO every 4 to 6 hours or 800mg PO every 8 hours as necessary for 5 to 7 days, with food. (Maximum dose 2400 mg/day for those 12-17 years and 3200 mg/day for those 18 years and older.)
   b. Additional guidance:
   STANDARD NURSE PROTOCOL FOR SPOTTING OR BREAKTHROUGH BLEEDING WHILE USING HORMONAL CONTRACEPTIVES

3. Signs or symptoms of allergic reaction (rash, difficulty breathing, redness and swelling at injection site, etc.).

4. Signs or symptoms of infection (fever, severe pain, redness or swelling at injection site, etc.).

5. Intolerable bleeding pattern.

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m^2] at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

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STANDARD NURSE PROTOCOL FOR COITALLY DEPENDENT PRESCRIPTION CONTRACEPTIVES

DEFINITION

The diaphragm and contraceptive gel offer patient-controlled, hormone-free contraception at the time of sex. Currently, both methods require a prescription from a provider.

The diaphragm is a dome-shaped rubber cup that is inserted into the vagina before intercourse. It consists of soft rubber, latex or silicone that is fitted for size. There are some diaphragms on today's market that do not require special fitting.

The contraceptive gel (Phexxi®) is placed vaginally prior to sex to reduce the risk of pregnancy.

ETIOLOGY

The dome of the diaphragm covers the cervix. The posterior rim rests in the posterior fornix and the anterior rim fits snugly behind the pubic bone. The diaphragm acts as a barrier and prevents sperm from entering. Spermicidal cream or jelly placed in the dome prior to insertion add to its effectiveness by killing any sperm that might slip around the edge of the diaphragm.

The contraceptive gel (Phexxi®) is a vaginal gel composed of lactic acid, citric acid and potassium bitartrate that lowers the pH of the vagina and reduces sperm motility to prevent pregnancy.

SUBJECTIVE

1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and the CDC *Medical Eligibility Criteria for Contraceptive Use*.

2. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for using diaphragm or contraceptive gel. Medical conditions include:
   a. HIV/AIDS or high risk of HIV infection (for diaphragm)
   b. Antiretroviral Therapy (for diaphragm)
   c. History of Toxic Shock Syndrome (for diaphragm)
   d. Known allergy or hypersensitivity to diaphragm material or gel ingredients
   e. Recurrent urinary tract infections or urinary tract abnormalities (for contraceptive gel
3. Reports no full-term delivery within the past 6 weeks (for diaphragm).

OBJECTIVE

1. Physical examination and laboratory tests, as indicated. See Standard Nurse Protocol for Preventive Care and Health Screening.

2. Pelvic exam findings (for diaphragm only):
   a. Adequate vaginal tone to hold the diaphragm in place.
   b. Absence of uterine prolapse, severe cystocele or rectocele.
   c. Uterus is not fixed in retroflexed or retroverted position.
   d. Notch behind the symphysis pubis is adequate to support the rim of the diaphragm.

3. Patient is physically able to insert a diaphragm or place vaginal gel.

ASSESSMENT Patient has no condition representing an unacceptable health risk if using the diaphragm or gel.

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Diaphragm:
   a. Use diaphragm with contraceptive jelly/cream containing spermicide.
   b. For patients with latex allergies, provide latex-free diaphragm (e.g., Lea's Shield).

NOTE: Increased use of nonoxynol 9 is associated with risk of vaginal irritation, therefore increased risk of HIV transmission.

2. Vaginal contraceptive gel (Phexxi®):
   a. Each pre-filled single-dose vaginal applicator delivers 5 grams of gel containing lactic acid (1.8%), citric acid (1%), and potassium bitartrate (0.4%).

NON-PHARMACOLOGIC MEASURES

Fit patient for appropriate size and type of diaphragm.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to the seven basic elements of informed consent (BRAIDED – Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. Provide counseling on preconception health counseling and future fertility.

3. Counsel on the lack of protection from sexually transmitted infections and the use

of condoms to reduce the risk of STD/HIV.

4. For patients who select the diaphragm:
   a. Insertion, removal and care of diaphragm, with return demonstration.
   b. Once in position, the diaphragm provides effective contraceptive protection for 6 hours.
   c. After intercourse, the diaphragm must be left in place for at least 6 hours, but it should be removed as soon as possible thereafter. Continuous wearing of a contraceptive diaphragm for more than 24 hours is not recommended.
   d. If more than one act of intercourse in 6 hours, do not remove diaphragm. Add additional spermicide before each act of intercourse. Increased use of nonoxynol 9 is associated with risk of vaginal irritation, therefore increased risk of HIV transmission.
   e. Prevention of toxic shock syndrome:
      1) Do not use diaphragm during menses.
      2) Do not leave diaphragm in place for more than 24 hours.
   f. Seek care for danger signs of toxic shock:
      1) Temperature of 101° F or higher.
      2) Diarrhea.
      3) Vomiting.
      4) Muscle aches.
      5) Rash appearing like sunburn.
   g. Diaphragm will need to be refitted and replaced with new diaphragm at least every 2 years or
      1) After vaginal delivery.
      2) After gynecologic or lower abdominal surgery.
      3) After weight loss or gain of over 10 pounds.
      4) After second trimester **pregnancy loss or** abortion.
   h. Discuss risks that decrease the effectiveness of the diaphragm (e.g., petroleum jelly and vaginal medications, can weaken latex causing

5. For patients who select the contraceptive vaginal gel:
   a. Place one pre-filled single dose applicator of contraceptive gel vaginally immediately or up to one hour before each episode of vaginal sex. If more than one act of vaginal sex occurs within 1 hour, additional doses must be applied. Administer an additional dose if vaginal intercourse does not occur within 1 hour of administration.
   b. May be used at any time in the menstrual cycle.
   c. Phexxi may be used with hormonal contraceptives, latex, polyurethane and polyisoprene condoms, and vaginal diaphragms. Avoid PHEXXI use with vaginal rings.
   d. PHEXXI may be used with other products for vaginal infections including miconazole, metronidazole, and tioconazole.
   e. May provide up to a one-year supply, per patient preference

FOLLOW-UP

Return to clinic in one month, with diaphragm in place, to assess for proper fit. Return to clinic as needed for those who select the contraceptive vaginal gel.

REFERRAL/CONSULTATION

1. Signs/symptoms of toxic shock syndrome (for diaphragm only).

2. Recurrent urinary tract infection or vaginal infection.

3. Signs/symptoms of cystocele or rectocele (for diaphragm only).

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STANDARD NURSE PROTOCOL FOR SPOTTING OR BREAKTHROUGH BLEEDING WHILE USING HORMONAL CONTRACEPTIVES

DEFINITION

Breakthrough bleeding (BTB) is uterine bleeding that occurs between menstrual periods in women using oral contraceptive but can also occur with other combined hormonal contraception (patch and ring). Irregular bleeding is also common for progestin only methods (pill, injection and implant). A light amount of BTB is referred to as spotting. Spotting and BTB are generally not signs of any serious problems.

ETIOLOGY

Spotting and BTB are most common (30-50%) in women taking combined OCs, but also may occur with other hormonal contraceptives. Spotting and BTB are most likely to occur during the first few months after a woman begins taking a new hormonal contraceptive and generally resolves by the third or fourth month of use. This may not be the case for some progestin only methods.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health history, and family history).

2. May have a recent history which includes the following:
   a. started new hormonal contraceptive
   b. missed contraceptive or incorrect usage
   c. inter-menstrual spotting/bleeding for several months
   d. GI problems such as vomiting or diarrhea
   e. abnormal vaginal discharge and/or odor
   f. dyspareunia or pelvic pain
   g. history of abnormal cervical cancer screening test
   h. pain during menses
   i. pain or bleeding with sexual intercourse
   j. new sex partner
   k. smoking
   l. new medications

3. History of taking anti-seizure medications (phenobarbital, phenytoin, carbamazepine, lamotrigrine, topiramate or primodone, rifampin, or griseofulvin). Consult drug interactions database (e.g., Lexicomp) for more detailed information.

OBJECTIVE

Pelvic exam, if indicated, is negative for other causes of bleeding. (Pelvic exam is indicated for signs and symptoms of infection, pregnancy, malignancy or to assess heavy bleeding).

ASSESSMENT Spotting or BTB while taking hormonal contraceptive.

PLAN

DIAGNOSTIC STUDIES

1. Urine dipstick, if indicated.
2. Gonorrhea and chlamydia tests, if indicated.
3. Pregnancy test, if indicated.
4. Hemoglobin/hematocrit, if indicated.
5. Wet prep, if indicated.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

For combined hormonal contraception:

NOTE: Please refer to Appendix A for information on combined hormonal formulations.

1. Combined OCs:
   a. Women with persistent irregular bleeding after 2-3 months while taking OCs, offer changing to other formulations; although no research indicates any specific OCs is best at eliminating spotting or bleeding. Breakthrough bleeding and spotting are most commonly seen in very low dose formulations (20 mcg). Offering a switch to a monophasic, 35 mcg pill or to a tri-phasic pill may help these symptoms. Instructions for taking these pills should be one pill orally daily

   OR

   b. For extended-cycle users who have taken at least 21 days of pills, can stop taking pills for 3 to 4 days to allow a withdrawal bleed to start, then restart the active pills, taking them again for at least 21 days. The length of time between unscheduled bleeding episodes should increase with the duration of use**.** It is not recommended that this is done more than once per month because it can reduce contraceptive efficacy.

2. For Patch or Ring:
   a. For those using the contraceptive patch or vaginal ring, ensure that the patient is placing it and changing it on the appropriate time schedule. Reassure that BTB should improve over the first several months.
   b. Extended-cycle users who have used the ring for at least 21 days can stop using the ring for 3 to 4 days to allow a withdrawal bleed to start, then restart use of the ring, using it again for at least 21 days. The length of time between

unscheduled bleeding episodes should increase with the duration of use. It is not recommended that this is done more than once per month because it can reduce contraceptive efficacy.

3. For DMPA:
   a. For unscheduled or light bleeding offer NSAIDs. If not allergic may order Ibuprofen 400 mg PO every 4 to 6 hours or 800 mg PO every 8 hours as necessary for 5 to 7 days with food. (Maximum dose 2400mg/day for those 12-17 years and 3200mg/day for those 18 years and older.)
   b. For heavy or prolonged bleeding, offer NSAIDs. If not allergic may order Ibuprofen 400 mg PO every 4 to 6 hours or 800 mg PO every 8 hours as necessary for 5 to days with food. (Maximum dose 2400mg/day for those 12-17 years and 3200mg/day for those 18 years and older.)

      OR

   c. Hormonal treatment (if medically eligible).
      1) Pack of combined OC

         OR

      2) Estrogen (suggest conjugated equine estrogen 0.625 mg PO daily or estradiol 0.5mg PO daily) but may be given up to four times daily for 10-20 days if needed.

4. For Contraceptive Implant:
   a. For unscheduled spotting, light or heavy/prolonged bleeding, offer NSAIDs, if not allergic and no contraindications. Ibuprofen 400mg PO every 4 to 6 hours or 800 mg PO every 8 hours as necessary for 5 to 7 days with food. (Maximum dose 2400mg/day for those 12-17 years and 3200mg/day for those 18 years and older.)

      OR

   b. Hormonal treatment (if medically eligible)
      1) Pack of combined OC or
      2) Estrogen (suggest conjugated equine estrogen 0.625 mg PO daily or estradiol 0.5mg PO daily). May be given up to four times daily for 10-20 days if needed.

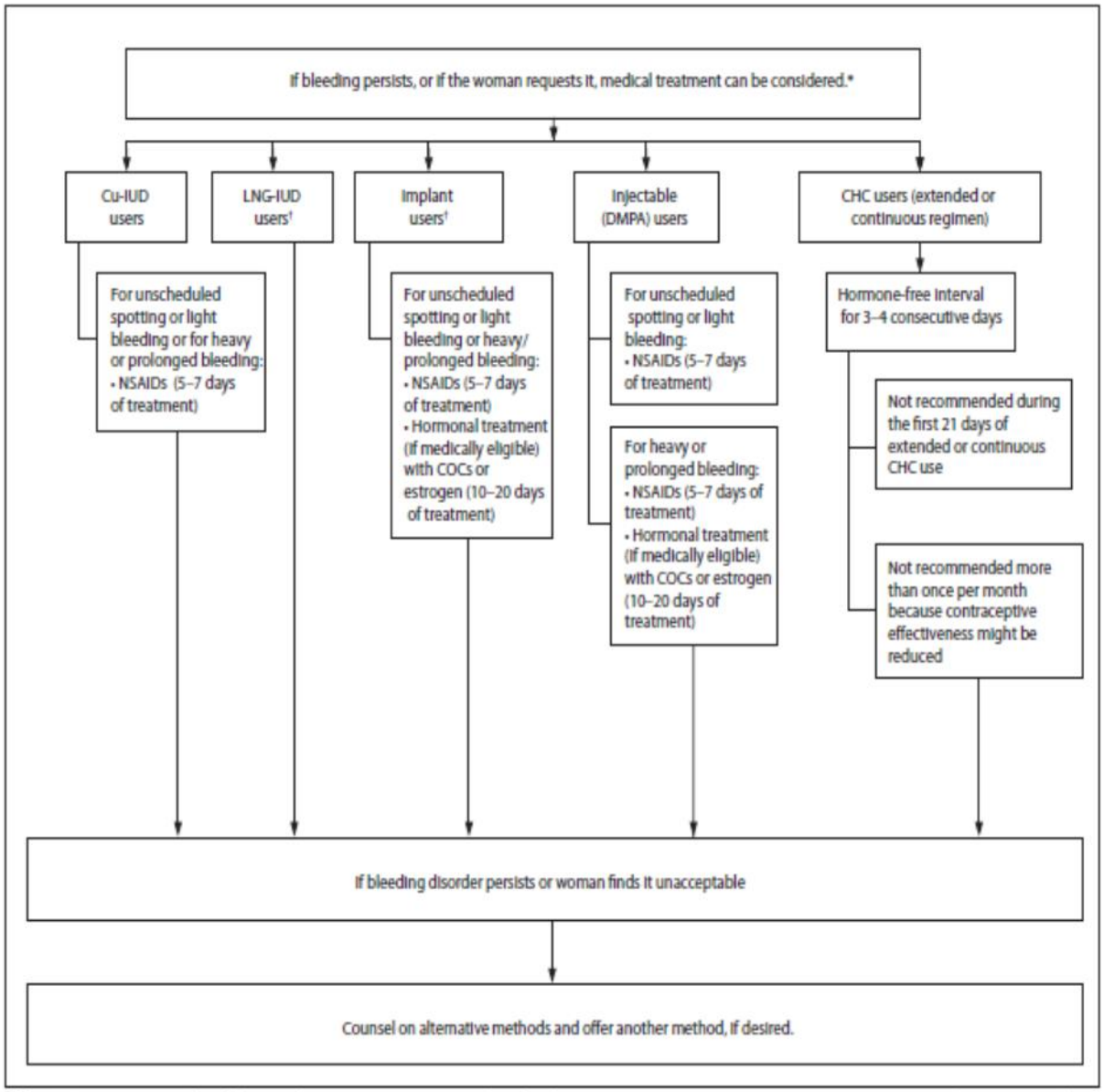
5. For POPs:
   a. There is not consensus about how to manage BTB with POPs. BTB is common with POPs and is generally not a sign that there is anything wrong. The patient can be reassured if there is no objective concern from history, exam, or diagnostic findings as described above. Discuss alternative contraceptive methods if preferred by patient.

6. For all methods:
   a. If symptoms are bothersome or persist despite interventions, consider changing method. If a woman desires trial of alternate approach (e.g., NSAIDs after unsuccessful hormonal treatment), that is acceptable. If a woman desires a longer course of therapy with either NSAID or hormonal treatment, that is acceptable. See chart from SPR below for Management of Women with

Bleeding Irregularities While Using Contraception.

Appendix E

Management of Women with Bleeding Irregularities While Using Contraception



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.
* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.
† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

PATIENT EDUCATION/COUNSELING

1. Reassure new hormonal contraceptive users that breakthrough bleeding generally decreases dramatically over the first 3-4 months of initiation.

2. Reinforce proper administration of hormonal contraceptive, especially the importance of taking pills each day.

3. Counsel on use of alternate contraceptive method if hormonal contraceptive is discontinued.

4. Counsel on use of condoms to reduce the risk of STD/HIV.

5. BTB occurs at a higher rate in women who smoke. Refer patient to local cessation program and/or Georgia Tobacco Quit Line, 1-877-270-STOP (7867), if smoker or tobacco user.

FOLLOW-UP

Reassess spotting or BTB in 3 months depending on the acuity of the problem.

CONSULTATION/REFERRAL

1. Seek consultation with, as applicable, if spotting or BTB continues.

2. Seek consultation with MD, as applicable, if patient has abnormal screening tests not covered by nurse protocol or abnormal diagnostic test results.
3. Refer to physician for pelvic pathology.

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STANDARD NURSE PROTOCOL FOR IUD-RELATED DYSMENORRHEA

DEFINITION

Dysmenorrhea is pain during menstruation that interferes with daily activities. Intrauterine device (IUD) related dysmenorrhea is painful menses during IUD use.

ETIOLOGY

The main symptom of dysmenorrhea is pain with menses. The pain is concentrated in the abdomen, pelvic region, or lower back. Symptoms often co-occurring with menstrual pain include nausea, vomiting, diarrhea, headaches, weakness, dizziness or lightheadedness. Moderate to severe dysmenorrhea may be an indication for removal of the IUD. However, the Levonorgestrel IUD helps reduce menses and dysmenorrhea in many women**.**

Differential diagnosis includes mechanical pressure of IUD against wall of uterus, partial expulsion, pelvic inflammatory disease (PID), endometriosis, cancer, leiomyomata, and ectopic pregnancy. Since cramping and abdominal pain may be signs of pregnancy or infection, those two problems must always be ruled out.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health history and family history).

2. Reports painful menses and gives history of current IUD

3. Patient may have a recent history which includes the following:
   a. Heavy or late menses
   b. PID/STD
   c. Vaginal infection/abnormal discharge
   d. Recent sexual partner change or multiple sexual partners
   e. Pain with IUD in past

4. Provides IUD type, insertion date, and date of last string check if applicable.

5. Does not report fever or abnormal vaginal discharge.

OBJECTIVE

1. External exam usually within normal limits.

2. Internal exam usually within normal limits; may note vaginal discharge or partially expelled IUD. Note length of IUD strings.
3. Bimanual exam usually within normal limits. May note tenderness on examination. May palpate partially expelled IUD.

4. Cervical motion tenderness or pain in the uterus or adnexa are more characteristic of PID.

ASSESSMENT IUD-related dysmenorrhea

PLAN

DIAGNOSTIC STUDIES

1. Urine pregnancy test.
2. Hemoglobin/hematocrit, if indicated.
3. Gonorrhea and chlamydia tests; vaginal wet mount, if indicated.

THERAPEUTIC

PHARMACOLOGIC

1. Prostaglandin inhibitors/nonsteroidal anti-inflammatory drugs may be taken if patient is not allergic and no contraindications, such as:
   a. Ibuprofen 400mg every 4-6 hours or 800mg PO every 8 hours as needed for pain with food. (Maximum daily dose 2400 mg/day for those ages 12-17 years and 3200mg/day for those 18 years and older)

      OR

   b. Naproxen 500mg PO for one dose, then 250mg PO every 6-8 hours as needed for pain with food. (Day 1 maximum daily dose 1250mg/day, subsequent daily dose maximum of 1000mg/day)

      OR

   c. Over the counter strength products (e.g., Advil, Nuprin, Aleve, Motrin IB, coated aspirin, or acetaminophen) as needed for pain per package directions.

NOTE: Do not order NSAIDS if patient has a history of allergic reaction to aspirin. Acetaminophen per package instructions would be acceptable in this case.

   d. For optimal relief, encourage starting these medicines 24-48 hours before menses begin and continue through the first two days of the cycle.

NON-PHARMACOLOGIC MEASURES

1. Heating pad or hot-water bottle to pelvic region, hot baths or showers and/or warm liquids taken orally.

2. A progestin-releasing IUD may be associated with decreased pain. Discuss with patient and refer to APRN or physician if she wants a progestin-releasing IUD.

3. Remove the IUD (refer to APRN or physician) for the following:
   a. Partial expulsion.

b. Excessive pain not relieved by the above measures.
c. Patient's request for removal of IUD for any reason.

PATIENT EDUCATION/COUNSELING

1. Discuss findings, treatment rationale.

2. Counsel on the use of condoms to reduce the risk of STD/ HIV.

3. Discuss correct use and side effects of medications.

4. If providing an NSAID, remind not to take additional over the counter NSAIDs.

FOLLOW-UP

Return to the clinic if symptoms are not relieved or if foul discharge begins.

CONSULTATION/REFERRAL

1. Immediately refer patient to physician if suspect ectopic pregnancy or PID (See STD Nurse Protocol) that does not improve with 2-3 days of antibiotic treatment, or concerns for other gynecologic pathology causing the pain.

2. Refer patient to physician if symptoms not relieved by the above measures.

3. Presence of actinomyces on Pap smear report with evidence of pelvic infection; if no evidence of infection, no action is necessary.

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STANDARD NURSE PROTOCOL FOR COPPER IUD-RELATED MENORRHAGIA

DEFINITION

Menorrhagia refers to menstrual periods that occur at regular intervals but are marked by prolonged bleeding (greater than 7 days) or excessive blood loss (greater than 80 mL). IUD-related menorrhagia is prolonged or excessive bleeding with an IUD in place.

ETIOLOGY

Presence of IUD in utero. Bleeding problems constitute one of the more common IUD complications. Women using the copper-releasing IUD (Copper T380A) usually have heavier menses. Excessive bleeding with the Copper T380A can be treated with NSAIDs. Since local prostaglandin production is involved with excessive bleeding, any prostaglandin synthetase inhibitor should help. Starting in advance of menses does not give better results than starting with the onset of flow. If hemoglobin levels drop, oral iron supplementation can be started. Excessive menstrual bleeding may be an indication for removal of the IUD. The levonorgestrel IUD is associated with decreased menstrual bleeding.

Other causes to consider may be: PID, partial expulsion of the IUD, dysfunctional uterine bleeding as a result of an endocrine imbalance, cancer of the cervix or endometrium, cervical or uterine polyps, abnormal perimenopausal bleeding, fibroids, and pregnancy.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).

2. Reports prolonged or excessive menstrual bleeding and gives history of current IUD.

3. May have a recent history which includes the following:
   a. dizziness, weakness or tiredness
   b. pale skin color

OBJECTIVE

1. External exam usually within normal limits.

2. Internal exam may be within normal limits**;** may note partially-expelled IUD or feel IUD in the cervical canal.

3. Bimanual exam may be within normal limits**.** Cervical motion tenderness or pain in uterus and adnexal areas is more characteristic of PID.

ASSESSMENT IUD-related menorrhagia.

PLAN

DIAGNOSTIC STUDIES

1. Hematocrit or hemoglobin.

2. Urine pregnancy test.

3. Gonorrhea and chlamydia tests; vaginal wet mounts, if indicated.

THERAPEUTIC

PHARMACOLOGIC

1. If hemoglobin below normal, treat according to Nurse Protocol for Iron-Deficiency Anemia.

2. Prostaglandin inhibitors/NSAIDs as needed to help reduce menstrual blood loss and for relief of pain, if not allergic and no contraindications. Begin at the onset of menses (or if the patient also has dysmenorrhea begin 24-48 hours prior to the onset) and continue for 3-4 days.
   a. Ibuprofen 400 mg PO every 4 hours or 800mg three times daily as needed for pain or to help relieve menstrual blood loss for 5 to 7 days with food. (Maximum dose 2400mg/day for those 12-17 years and 3200mg/day for those 18 years and older.)

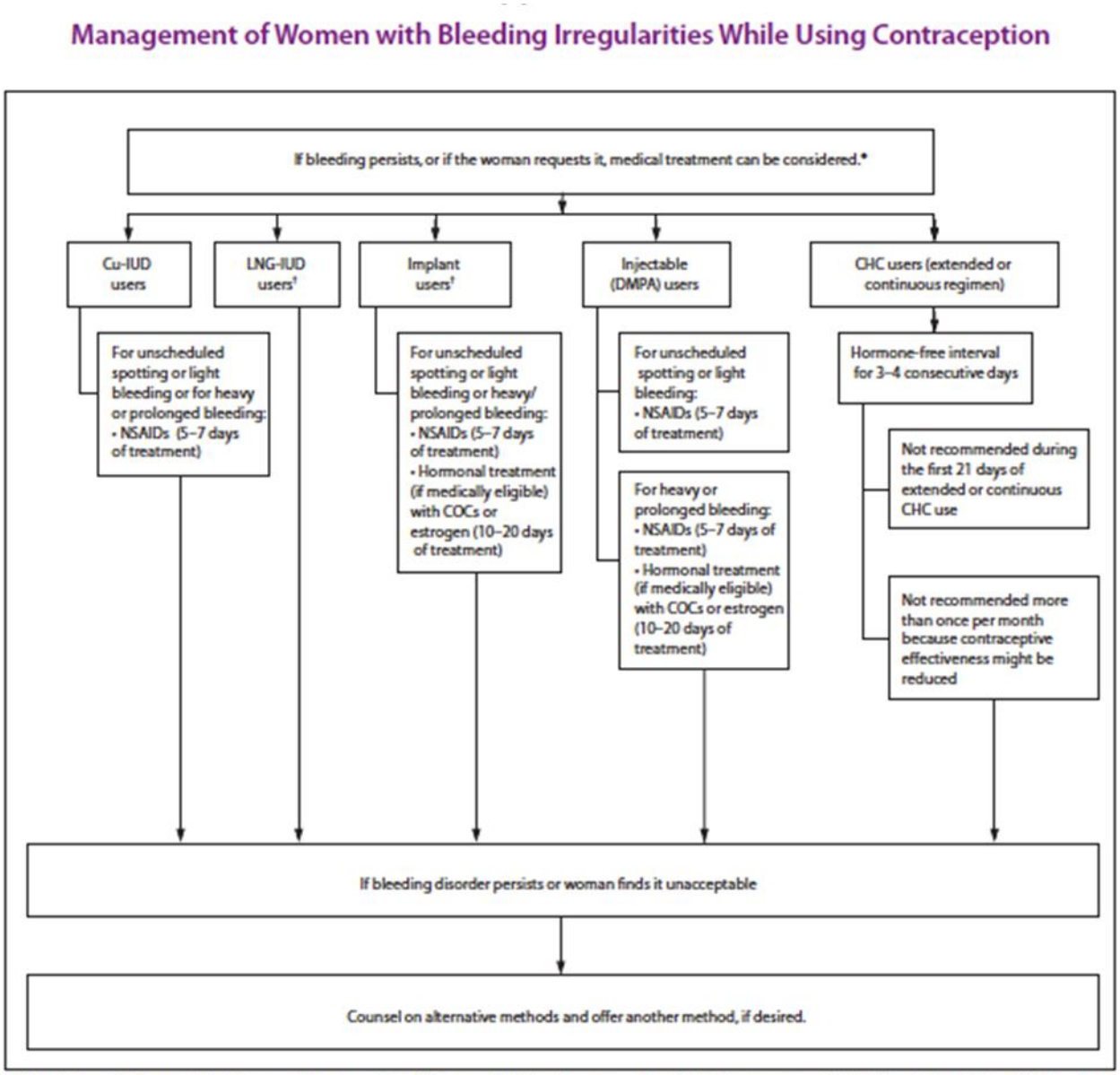
      OR

   b. Naproxen 500 mg PO for one dose, then 250 mg PO every 6-8 hours as needed for pain or to help relieve menstrual blood loss with food. (Maximum dose 1250mg/day)

      OR

   c. Over-the-counter-strength products (e.g., Advil, Nuprin, Aleve, Motrin IB, coated aspirin, or acetaminophen) per package directions as needed.

Table 1. Management of Women with Bleeding Irregularities, from the CDC's US Selected Practice Recommendations



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.
* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.
† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

NON-PHARMACOLOGIC MEASURES

1. IUD removed by APRN or physician for the following:
   a. Partial expulsion.
   b. Excessive menstrual blood loss.
   c. Patient's request for removal of IUD for any reason.

2. Consult with APRN or physician to discuss possible need for removal if any of the following:
   a. hemoglobin has dropped 2 gm/dL or more from previous reading.
   b. hemoglobin is less than 9 gm/dL.
   c. hematocrit has dropped 6% or more over 4-6 weeks.
   d. hematocrit is less than 27%.

3. If IUD is removed, may initiate alternate contraceptive method. Hormonal contraceptives (combined oral pills, transdermal contraceptive patch, Nuvaring, DMPA) may decrease bleeding and blood loss. The Levonorgestrel IUD also significantly improves menorrhagia. Refer to *CDC Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for the selected contraceptive method.

PATIENT EDUCATION/COUNSELING

1. Counsel patient on the importance of iron rich foods in the daily diet of menstruating women.

2. Discuss signs of possible pelvic infection and excessive bleeding.

FOLLOW-UP

Return in 4-6 weeks for evaluation of bleeding and hematocrit/ hemoglobin.

CONSULTATION/REFERRAL

1. Immediately refer patient to physician if suspect ectopic pregnancy or PID that has not improved with 2-3 days of antibiotics. See STD Nurse Protocol.

2. Refer patient to physician if menorrhagia continues for 1-2 menstrual periods after pharmacologic measures started.

3. Refer patient to APRN or physician if no improvement in anemia after 4 weeks of iron supplemental therapy.

4. Refer to APRN or physician for removal.

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STANDARD NURSE PROTOCOL FOR CONTRACEPTIVE IMPLANT INSERTION

NOTE: All clinicians performing insertions and/or removals of the contraceptive implant must complete the manufacturer's (**Organon**) Clinical Training Program, a required comprehensive hands-on workshop. For those who have never been certified to place the contraceptive implant, in-person training is required. The training is free **and for APRNS** it can be scheduled by calling 1-877-467-5266. **Expanded-role registered nurse training must be approved by the District and the training must be scheduled by the DPH Office of Nursing.**

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Completion of the training program is required to order the product and only advanced practice clinicians, physicians, and **expanded-role registered nurses with Women's Health experience who receive District approval** may attend. **After completion of the Organon Clinical Training Program, a clinical preceptorship that includes a minimum of five contraceptive implant insertions is required prior to practicing under this protocol.**

DEFINITION

Nexplanon® is a small, thin, implantable hormonal contraceptive that is effective for at least three years. The product has FDA approval for three years, but evidence indicates that the contraceptive effect is present for five years and longer. The subdermal contraceptive implant is an etonogestrel-impregnated 4cm plastic rod. It is placed under the skin of the upper arm. It does not contain estrogen. It prevents pregnancy primarily by inhibiting ovulation. Other contraceptive effects include thickening cervical mucus and thinning the endometrial lining. Nexplanon® is identical to its predecessor, Implanon®, except that it is radio-opaque and the inserter has been changed**.**

SUBJECTIVE

1. Desires an implant for long-term contraception.

2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the CDC *Medical Eligibility Criteria for Contraceptive Use*.

3**.** If breastfeeding, she may initiate immediately. However, there is minimal likelihood of ovulating before one month postpartum in a woman who is breastfeeding.

4. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk for using the contraceptive implant. Medical conditions include:
   a. Lupus with positive (or unknown) antiphospholipid antibodies
   b. Breast cancer
   c. Cirrhosis – severe (decompensated)

d. Liver Tumors – benign hepatocellular adenoma; malignant (hepatoma)
e. Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.

5. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if *they develop while using* the contraceptive implant. Women with these conditions may initiate the implant. However, if women who did not have these conditions at the time of initiation develop these conditions after using the implant, the implant should not be continued. Medical conditions include:
   a. Ischemic heart disease
   b. Stroke

6. May report estrogen-excess side effects while taking combined hormonal contraceptives, such as headaches, breast tenderness, weight gain, nausea and thus prefer a method that does not contain estrogen.

OBJECTIVE

1. Physical examination and laboratory tests as indicated. See protocol for Preventive Care and Health Screening.

2. Timing of insertion of implant; see Initiation of Contraceptives Protocol.

ASSESSMENT Patient has no condition representing an unacceptable risk if using the contraceptive implant. No allergy to any component of the implant.

PLAN

DIAGNOSTIC STUDIES

1. Pregnancy test if indicated to rule out pregnancy.
2. Hemoglobin, if indicated

THERAPEUTIC

1. Initiation:
   a. If a provider can be reasonably certain that a woman is not pregnant, implant may be initiated that day with back up x 7 days.
   b. In situations where a provider cannot be reasonably certain that a woman is not pregnant the benefits of initiating the implant outweigh the risks and contraception can be initiated immediately.
      1) Starting the implant the day of the clinic visit can be easier for patients and can increase access Hormonal contraception will not prevent a pregnancy from sex that has already occurred.

2) Most studies have shown no increased risk for adverse outcomes (congenital anomalies, neonatal or infant death) in infants exposed to contraception.
3) The likelihood of pregnancy in previous studies of immediate initiation in situations like these was 3%.
4) If patient wants to have implant inserted that day, insert implant. Encourage condoms or abstinence for 7 days. Repeat UCG in 14-28 days (this can be done by home pregnancy test if the patient desires).
5) If patient declines initiation of the implant on that day of clinic visit, have her return on the first day of her next menstrual cycle for placement.
6) If she has had unprotected sex in the last 120 hours, offer EC (ECPs or Paragard IUD). See Emergency Contraceptive Pills Protocol.

2. Switching from other methods:
   a. For patients with an IUD, the implant insertion can be planned when the appointment for IUD removal is made.
   b. When switching from a hormonal method that works primarily by inhibiting ovulation, insert the implant immediately after stopping the other method with no breaks. If patient has been using a contraceptive injection, the implant may be initiated any time within the window of contraceptive coverage. Recommend back up method for 7 days.

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

1. Local anesthesia, **for example,** with 2-3 mL's of 1% lidocaine (should be injected under the skin and along the insertion track).

2. Insert the contraceptive implant per manufacturer's directions. Before insertion, the patient must read and sign the program's method specific consent form.
   a. The implant should be palpated by both the clinician and patient before patient goes home to ensure proper placement.

3. The provider should fill out the Contraceptive Implant Placement procedure note as indicated.

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/ fainting). Allow the patient to lie still several minutes after insertion. Ask about pain or feeling faint. If the patient says she feels like she can sit up, have her sit up slowly while being supported. If no problems in 1-2 minutes, allow her to stand.

2. Treat signs of vasovagal reaction (pallor/cyanosis, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines**,** Policies and Procedures Nurse Protocol.

3. Ice to insertion area for discomfort as needed.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. The User Card from the product package should be filled out and given to the patient after the contraceptive implant insertion so she will have a record of the location of implant and when it should be removed.

3. Review warning signs and symptoms of possible insertion site problems: redness, swelling, or purulent discharge at insertion site. Encourage patient to keep insertion site bandaged for the next 3-5 days.

4. Counsel patient on common side effects: menstrual changes or bleeding irregularities (spotting, light bleeding, prolonged bleeding, or no bleeding), emotional lability, weight gain, headache, acne, depression.

5. Further counsel patient regarding unpredictable bleeding irregularities, so that she knows what to expect. Women who use the contraceptive implant are likely to have changes in their vaginal bleeding patterns, especially during the first three months of use, which are often unpredictable. These may include changes in bleeding frequency or duration, or amenorrhea. Amenorrhea and oligomenorrhea are common.

6. Take over-the-counter ibuprofen or acetaminophen (follow package instructions) and/or apply ice to insertion area for discomfort.

7. If inserted more than 5 days from LMP and patient not currently on hormonal contraception, recommend back-up or abstinence for 7 days.

8. Provide counseling on preconception health counseling and future fertility.

9. Use condoms to reduce the risk of STD, including HIV.

10. Counsel patient to discuss all medications and herbal supplements with clinician because they can alter the metabolism of hormonal contraception and cause side effects, and/or decrease effectiveness.

11. The contraceptive implant is approved for use for 3 years. However, clinical data demonstrates its effectiveness for 5 years, and maybe longer. This information can be used when counseling women at the time of initiation as well as at the end of

the FDA approval window. If the patient is satisfied with the method at the end of the FDA approval window and would like to continue using it, evidence indicates that it still provides contraception as noted above. If she would like to have it removed, this should be honored.

FOLLOW-UP

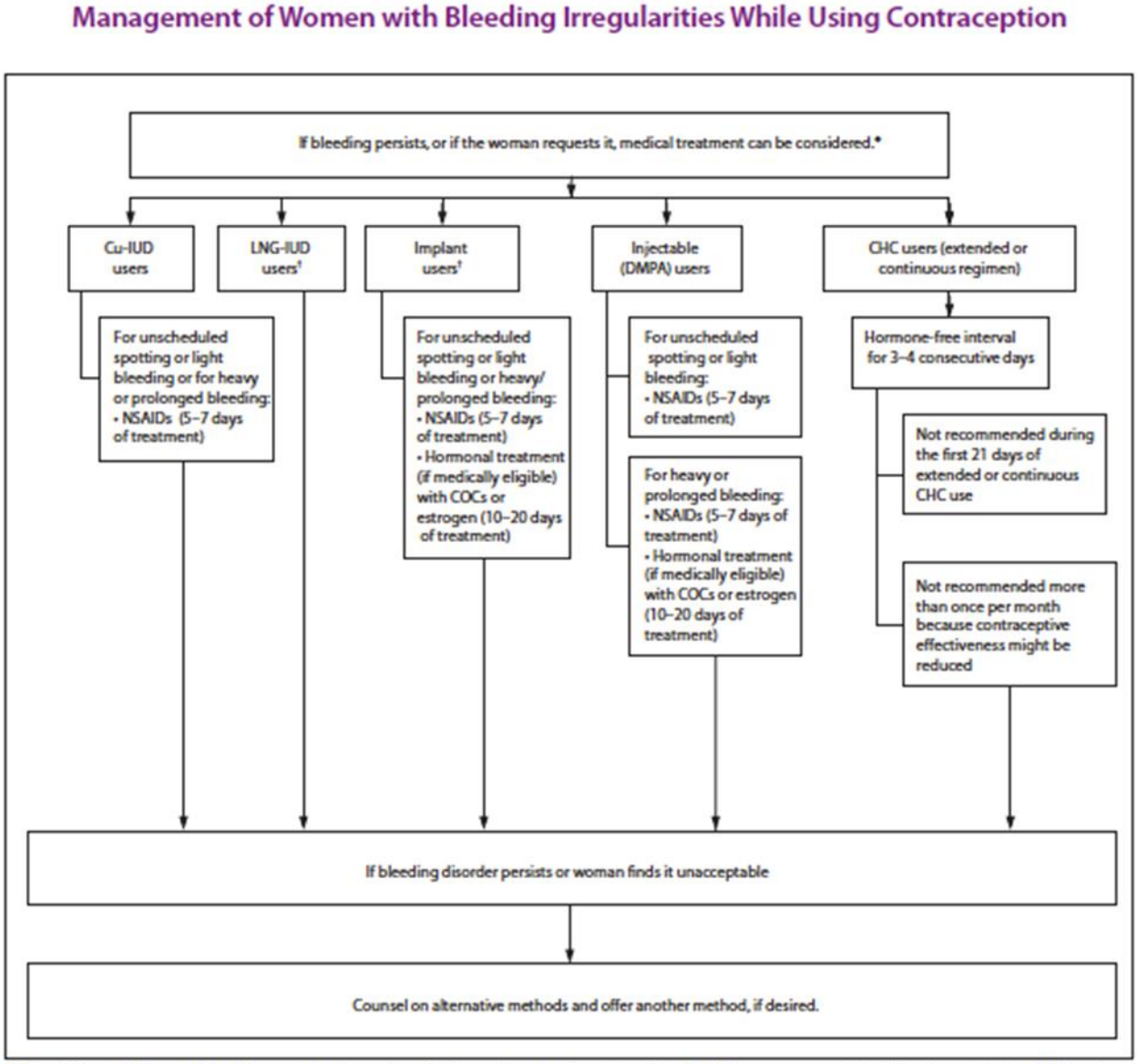
1. Return as scheduled for evaluation or contact clinic if side effects or danger signs develop. See table below, Routine follow-up after contraceptive initiation.

2. Outside of clinic hours, seek physician or emergency care if warning signs develop.

3. Treatment of side effects: None of the following has been proven to be effective for treatment of bothersome bleeding while using the implant. Often continuation of use of the implant is the best treatment, but for some women the bleeding profile may not improve**.** If a woman is interested in continuing the implant and would like to try one of the following, it may be reasonable. If she desires removal, this request should be accommodated.

4. For bleeding irregularities see Nurse Protocol for Spotting and Breakthrough Bleeding while on Hormonal Contraception**.** Please see table below from the CDC's Selected Practice Recommendations

Table 1. Summary from the CDCs Selected Practice Recommendations for Contraceptive Use



Abbreviations: CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; LNG-IUD = levonorgestrel-releasing intrauterine device; NSAIDs = nonsteroidal antiinflammatory drugs.
* If clinically warranted, evaluate for underlying condition. Treat the condition or refer for care.
† Heavy or prolonged bleeding, either unscheduled or menstrual, is uncommon.

CONSULTATION/REFERRAL

1. Difficult implant insertion or removal
2. Allergy to local anesthetic.
3. Suspected ectopic pregnancy.
4. Other complications related to implant use.

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m^2] at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

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STANDARD NURSE PROTOCOL FOR CONTRACEPTIVE IMPLANT REMOVAL

NOTE: All clinicians performing insertions and/or removals of the contraceptive implant must complete the manufacturer's (**Organon**) Clinical Training Program, a required comprehensive hands-on workshop. For those who have never been certified to place the contraceptive implant, in-person training is required. The training is free **and for APRNS** can be scheduled by calling 1-877-467-5266. **Expanded-role registered nurse training must be approved by the District and the training must be scheduled by the DPH Office of Nursing.**

Completion of the training program is required to order the product and only advanced practice clinicians**,** physicians**, and expanded-role registered nurses with Women's Health experience who receive District approval may attend. After completion of the Organon Clinical Training Program, a clinical preceptorship to include removal of a minimum of five contraceptive implants is required prior to practicing under this protocol.** For those who completed training for Implanon, a web-based training can be completed for certification in Nexplanon placement. There is no difference in removal between these devices.

DEFINITION

Removal of the contraceptive implant at the patient's request **for any reason. May be** due to clinical findings such as pregnancy, side effects**, desire to switch methods,** or at the end of the implant's period of contraceptive efficacy.

SUBJECTIVE

1. Patient desires contraceptive implant removal.
2. May be pregnant.
3. Complains of **bothersome** side effects.
4. The window of contraceptive efficacy has passed.

OBJECTIVE

1. Positive pregnancy test.
2. Clinical findings of side effects or a contraindication for continuing with the implant.

ASSESSMENT Removal of the contraceptive implant is desired or recommended.

PLAN

DIAGNOSTIC STUDIES

1. Implant palpable under skin and exact position localized. **Push down the end of the implant closest to the shoulder to stabilize it; a bulge should appear indicating the tip of the implant that is closest to the elbow. If the tip does not pop up, removal of the implant may be more challenging.**
   a. If implant is not palpable, do not attempt to begin removal process.

   NOTE**:** Implants placed in other countries may be a two-implant system. If the patient received the implant outside of a Georgia public health clinic setting, ask where and document. If the implant was placed in another country, ask if the patient if there are one or two implants and palpate for confirmation. **If the patient has a two-rod contraceptive implant (e.g., Jadelle, Levoplant/Sino-implant), refer the patient to an APRN for implant removal.**

2. **Pregnancy test, if indicated.**

3. **Hemoglobin, if indicated.**

4. **Gonorrhea and chlamydia tests, if indicated**.

THERAPEUTIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

NOTE: Before removal, the patient must read and sign the consent form for removal. Per manufacturer's instructions, remove the contraceptive implant capsule through a very small incision over the tip that is closest to the elbow.

1. Per manufacturer's removal instructions:
   a. **Mark the distal end with a surgical marker.**
   b. **Clean the site with antiseptic solution.**
   c. Inject local anesthetic under the distal tip of the implant. Anesthetize the site, for example, with 0.5 to 1 mL 1% lidocaine.
      1) **Be sure to inject the local anesthetic under the implant to keep the implant close to the skin surface. Injection of local anesthetic over the implant may make removal more difficult.**
   d. **Wearing sterile gloves, push down the end of the implant closest to the shoulder to stabilize it throughout the procedure. Starting over the tip of the implant closest to the elbow, make a longitudinal (parallel to the implant) incision of 2 mm towards the elbow. Take care to not cut the tip of the implant.**
   e. Gently push the tip of the implant through the incision and grasp with hemostat or forceps for removal. **If needed, gently remove adherent tissue from the tip of the implant using blunt dissection.**
   f. **Confirm that the entire implant, which is 4 cm long, has been removed.**

g. A new implant may be inserted immediately after the old implant is removed**, following the Standard Nurse Protocol for Contraceptive Implant Insertion,** using the same incision as long as the site is in the correct location.
h. **Apply a sterile adhesive wound closure, sterile gauze, and pressure** bandage over incision **to minimize bruising**.

2. **Some clinicians prefer the "pop out" technique (video link here):**
   a. **Push down on the end of the implant closest to the shoulder and causing the distal end to bulge the skin over your thumb. Mark the distal end/bulge with a surgical marker.**
   b. **Clean the site with antiseptic solution.**
   c. **Inject local anesthetic under the distal tip of the implant. Anesthetize the site, for example, with 0.5 to 1 mL 1% lidocaine.**
      1) **Inject the local anesthetic under the implant to keep the implant close to the skin surface. Injection of local anesthetic over the implant may make removal more difficult.**
   d. **Wearing sterile gloves, make a longitudinal (parallel to the implant) incision of 2 mm towards the elbow at the mark. You do not need to hold the implant while making the incision. Take care to not cut the tip of the implant.**
   e. **Gently push the tip of the implant through the incision**. **If needed, gently remove adherent tissue from the tip of the implant using sharp dissection with the scalpel. The implant will "pop out" of the incision when the scar tissue has been released.**
   f. **Confirm that the entire implant, which is 4 cm long, has been removed.**
   g. **A new implant may be inserted immediately after the old implant is removed, following the Standard Nurse Protocol for Contraceptive Implant Insertion, using the same incision as long as the site is in the correct location.**
   h. **Apply a sterile adhesive wound closure, sterile gauze, and pressure bandage over incision to minimize bruising.**

NOTE for ERN Removals: For either removal technique, if more than 15 minutes have passed without successful removal, stop the procedure, bandage the skin, and refer to an APRN.

3. If implant is not palpable but has been localized by ultrasound **or x-ray** and is found to be deeply inserted, referral to a specialist with expertise in deep removals is **required.** This specialist should have a good understanding of the vessels and nerves of the arm. **If an implant is not palpable and not seen on imaging, call the manufacturer, Organon, for further instructions. Also,** any adverse events associated with removal should be reported to **Organon** at 1-877-467-5266.

4. The provider should complete the Contraceptive Implant Removal procedure note as indicated.

PATIENT EDUCATION/COUNSELING

1. Provide instructions for care. **The pressure bandage and gauze should be kept clean and dry and may be removed after 24 hours. The sterile adhesive wound closure may be removed after 3 to 5 days.**

2. **Advise to take over-the-counter ibuprofen or acetaminophen (follow package directions) for discomfort if needed.**

3. Discuss alternative contraceptive method, if desired. Another implant can be placed during the same procedure, as noted above.

4. Menses may be delayed or irregular for a month or more after removal.

FOLLOW-UP

1. May follow-up in 1-2 weeks for incision check, if desired.

2. Return, as needed, for contraception or preventative care and health screening.

CONSULTATION/REFERRAL

1. **Refer the patient to a public health APRN if the patient has a two-rod contraceptive implant.**

2. **Refer the patient to a public health APRN if the implant is broken.**

3. **Refer the patient to a public health APRN for any** difficult **or** failed removals.

4. Successful removal, patient pregnant.

5. Persistent side effects.

6. **Refer non-palpable implants that have been localized by ultrasound or x-ray to a specialist. Do not attempt removal.**

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STANDARD NURSE PROTOCOL FOR BACTERIAL CYSTITIS

NOTE: Persons under age 18 can consent for sexual and reproductive health services. For this protocol, those under age 18 must be established Women's Health patients or be accompanied by a parent or guardian who consents to treatment.

DEFINITION

Cystitis is a bladder inflammation.

ETIOLOGY

Cystitis is a common lower urinary tract infection that affects the bladder and not the kidneys. Cystitis is usually caused by bacteria (generally e-coli) which travel to the bladder from the urethra and is more likely to develop after sexual intercourse. Bacterial cystitis may be characterized by dysuria, frequency, urgency, and low-grade fever.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health and family health) that may reveal factors that increase the risk for bacterial cystitis.

2. May report recent history which includes the following:
   a. Frequency, burning on urination
   b. Urgency, with or without incontinence
   c. Suprapubic pain and/or tenderness

3. No symptoms of vaginal infection. If indicated, do work-up for possible vaginal infection, chlamydia and gonorrhea

4. No recent history of fever, shaking chills, unilateral flank pain, inability to urinate **n**or a sudden decrease in urine volume. No history of kidney disease.

OBJECTIVE

1. Lower abdominal tenderness on palpation.

2. No flank pain or CVA tenderness on exam.

3. Temperature less than 100ºF.

4. Diagnostic criterion: Dipstick urinalysis positive for either white blood cells (WBC) and/or nitrites. Patients may also have hematuria, abnormal urine discoloration or odor.

ASSESSMENT Bacterial cystitis

PLAN

DIAGNOSTIC STUDIES

1. Dipstick urinalysis positive for either white blood cells (WBC) and/or nitrites.

2. If diagnosis is unclear (e.g., the dipstick is negative for WBCs and nitrates, but patient has symptoms consistent with bacterial cystitis), obtain clean-catch urine for urinalysis and culture and sensitivity.

3. If abnormal vaginal discharge or discharge from the urethra, perform wet prep and tests for gonorrhea and chlamydia. For those less than 25 years old, follow guidelines for screening for STDs as these infections may be present without vaginal discharge.

4. Urine pregnancy test, if indicated.

THERAPEUTIC

PHARMACOLOGIC

1. Trimethoprim 160 mg/sulfamethoxazole 800 mg (Bactrim DS, Septra DS, Sulfatrim DS). 1 tablet PO with food, twice daily for 3 days.

NOTE: Do not give if patient has a history of allergy to the drug components; asthma, kidney or liver disease, folic acid deficiency states, G6-PD deficiency, or any other blood dyscrasia; is pregnant; or, is breastfeeding an infant less than 2 months old, or with or an elevated bilirubin. Not recommended for persons taking warfarin, phenytoin or methotrexate. Other potentially significant drug interactions may exist. Consult drug interactions database (e.g., Lexicomp) for more detailed information. See Referral/Consultation.

OR

2. Nitrofurantoin monohydrate macrocrystals, 100mg PO twice daily for 5 days (with meals).

NOTE: Do not give if history of nitrofurantoin allergy, kidney or liver disease, optic neuritis, G6-PD deficiency or anemia; is breastfeeding an infant less than one month old or if infant has G6-PD deficiency. Not recommended for persons taking probenecid or other uricosuric medications. Consult drug interactions database (e.g., Lexicomp) for more detailed information. Antacids containing magnesium trisilicate (ex. Gaviscon) should be avoided during nitrofurantoin therapy.

3. For non-curative symptomatic relief, if age 12 or older, is not pregnant or breast-feeding and no history of liver disease:

a. Phenazopyridine Hydrochloride (Pyridium®) 200mg, 1 tablet PO 3 times a day after meals as needed for 2 days when used concomitantly with an antibacterial agent.

OR

b. Nonprescription phenazopyridine hydrochloride 95 mg for less than 2 days. Follow package directions.

NOTE: Do not give if a history of allergy to any of the drug components. Discontinue medication immediately if any yellowish or orange discoloration of skin or eyes is noted. This medication may stain contact lenses.

NON-PHARMACOLOGIC MEASURES

Increase fluid intake (cranberry juice might be suggested) and empty bladder frequently.

PATIENT EDUCATION/COUNSELING

1. Stress the importance of completing the full course of treatment unless serious side-effects occur.

2. Discuss common drug-specific instructions and cautions.
   a. For trimethoprim/sulfamethoxazole: avoid sun exposure, discontinue drug immediately if develop a rash or signs of liver problems. Drink a full glass of water with each dose.
   b. For nitrofurantoin: discontinue drug if develop peripheral neuropathy, visual problems, diarrhea or symptoms of liver or lung problems.
   c. Phenazopyridine may cause discoloration of urine and may stain underwear. Suggest pantyliners.

3. Discuss potential risk factors for cystitis and prevention strategies.
   a. Empty bladder frequently
   b. Urinate after sex
   c. Wipe from front to back
   d. Do not douche
   e. If using vaginal spermicides, consider switching to a different contraceptive method

4. Seek medical care immediately if medication side effects or systemic symptoms develop.

5. Discuss that post-menopausal women may have increased susceptibility for cystitis because of a decrease in vaginal lactobacilli and an increased pH.

FOLLOW-UP

1. Patient should call the clinic if cystitis symptoms are not improved within 48 hours of starting therapy or if symptoms of severe systemic illness begin.

2. If no improvement in 48 hours after starting therapy or if symptoms persist after therapy is complete, either perform complete UA, culture and sensitivity and treat or refer for testing.

REFERRAL/CONSULTATION

1. Refer to physician if pregnant.

2. Refer to physician if any of the following:
   a. Gross hematuria in a specimen uncontaminated by menses.
   b. Systemic complaints such as temperature equal to or greater than 100°F, fast pulse, shaking chills or unilateral flank pain.
   c. Recurrent cystitis within one month, or more than 3 episodes in one year.
   d. If follow-up urinalysis reveals unexplained (non-menstrual) microhematuria without WBC or nitrite.

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STANDARD NURSE PROTOCOL FOR DYSMENORRHEA (PRIMARY)

NOTE: Persons under age 18 can consent for sexual and reproductive health services. For this protocol, those under age 18 must be established Women's Health patients or be accompanied by a parent or guardian who consents to treatment.

DEFINITION

Primary dysmenorrhea is painful menstruation without identifiable causes.

ETIOLOGY

Elevated levels of prostaglandins E2 and F in the endometrium cause uterine contractions. This increases intrauterine pressure, creating uterine ischemia and spasmodic pain. The main symptom of dysmenorrhea is pain with menses that is concentrated in the abdomen, pelvic region, or lower back. Symptoms often co-occurring with menstrual pain include nausea, vomiting, diarrhea, headaches, weakness, dizziness or lightheadedness. Differential diagnosis includes pelvic inflammatory disease, endometriosis, adenomyosis, endometrial hyperplasia, endometrial cancer, leiomyomata, ectopic pregnancy, IUD with partial expulsion.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health and family history).Note history of: parity, menarche, method of contraception, pelvic inflammatory disease/sexually transmitted diseases, onset of symptoms/changes over time, family history of dysmenorrhea, nutritional status.

2. Reports cramping pain in the lower abdomen just before or during menstruation.

3. May report symptoms of congestive (secondary) dysmenorrhea: irritability, depression, nervousness, exhaustion, backache, constipation, bloating, weight gain, breast tenderness, dull ache, and/or onset of symptoms prior to menses.

4. May report symptoms of spasmodic dysmenorrhea: nausea, vomiting, diarrhea, weakness, dizziness, pelvic cramping, abdominal/back/thigh cramping, sweating, pallor, and/or headache.

OBJECTIVE

Physical examination usually within normal limits, unless secondary factors are present.

ASSESSMENT Primary dysmenorrhea

PLAN

DIAGNOSTIC STUDIES

As indicated:

1. Cervical cancer screening
2. Gonorrhea/chlamydia tests
3. Vaginal wet mount
4. Pregnancy test

THERAPEUTIC

PHARMACOLOGIC

1. Over the counter analgesics: Coated aspirin, Aleve®, Motrin IB®, Nuprin®, acetaminophen (e.g., Tylenol®), follow package directions.

OR

2. Ibuprofen if not allergic and no contraindications 400mg to 800mg PO every 6-8 hours as needed for pain for up to 10 days as needed with food. (Maximum daily dose 2400mg/day for those 12-17 years and 3200mg/day for those 18 years and older)

OR

3. Naproxen 500mg PO for one dose, then 250mg PO every 6-8 hours as needed for pain with food. (Day 1 maximum daily dose 1250mg/day, subsequent daily dose maximum of 1000mg/day)

NOTE: Do not order NSAIDs if patient has a history of allergic reaction to aspirin. Acetaminophen per package instructions would be acceptable in this case.

4. For optimal relief, encourage starting these medicines 24-48 hours before menses begin and continue through the first two days of the cycle.
5. May initiate contraceptive method if method poses no unacceptable health risk: OC, medroxyprogesterone acetate, transdermal contraceptive patch, NuvaRing®, LNG IUD, contraceptive Implant may decrease symptoms.

NON-PHARMACOLOGIC

1. Topical heat.
2. Regular exercise may be helpful.

PATIENT EDUCATION/COUNSELING

1. Inform patient that primary dysmenorrhea probably does not affect fertility.

2. Assess patient's knowledge of activities that may provide relief.

3. Caution patient if taking prostaglandin inhibitors (Aleve®, Motrin Ibuprofen®, Nuprin®, aspirin).
   a. Prolonged chronic use may cause kidney problems and GI upset.
   b. Discuss that one should not simultaneously use several different NSAIDs at the same time**.**
   c. Stop medication and report severe persistent headaches, fever and muscle aches, which may be signs of aseptic meningitis.

FOLLOW-UP

Return to clinic if no relief from therapy after two menstrual cycles.

CONSULTATION/REFERRAL

1. Refer to physician for differential diagnosis, as indicated.

2. Refer to physician if no relief from therapy or if patient develops severe side effects of medication.

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STANDARD NURSE PROTOCOL FOR IRON-DEFICIENCY ANEMIA IN NON-PREGNANT WOMEN

NOTE: Persons under age 18 can consent for sexual and reproductive health services. For treatment of anemia under this protocol, those under age 18 must be established Women's Health patients or be accompanied by a parent or guardian who consents to treatment.

DEFINITION

Anemia is a condition in which the body does not have enough healthy red blood cells. Red blood cells provide oxygen to the body. Iron deficiency anemia develops due to low iron levels.

NOTE: The purpose of this protocol is to help manage the most common cause of anemia in premenopausal women but not to manage the full scope of possible anemias. Attention to the guidance for consultation/referral is recommended.

ETIOLOGY

Iron-deficiency anemia, the most common type of anemia, is present in 20% of all premenopausal women in the United States. The primary cause of iron-deficiency anemia in premenopausal women is loss of blood through menstruation. In postmenopausal women, bleeding is usually from the GI tract (chronically bleeding lesions, reflux esophagitis, peptic ulcers, gastric or colorectal adenocarcinomas). Iron-deficiency anemia also commonly occurs during pregnancy. Iron-deficiency anemia can usually be corrected with iron supplementation.

SUBJECTIVE

1. Provides a detailed health history (includes menstrual, sexual, contraception, personal health history and family history).

2. May be asymptomatic if anemia is mild.

3. May report history which includes the following:
   a. Pallor, fatigue**,** malaise, and/or anorexia
   b. History of GI bleeding
   c. Changes in stool color or bleeding from hemorrhoids
   d. Excessive blood loss during menses or history of fibroid tumors
   e. Poor dietary intake of iron rich foods and pica
   f. History of drug/medication use, especially aspirin and other NSAIDs
   g. Nonspecific complaints of headache, poor concentration, and/or palpitations
   h. Uncomfortable tingling or crawling feeling in the legs (restless leg syndrome)
   i. Frequent blood donations

4. With severe anemia, may also present with:

a. Weakness and faintness
b. Increased heart rate
c. Shortness of breath
d. Dizziness or lightheadedness
e. Symptoms of heart failure
f. Confusion and dementia
g. Nausea and loss of appetite
h. Headaches
i. Bleeding gums
j. Sore tongue

5. No history of major hemoglobinopathies (e.g., sickle cell anemia, sickle C disease, sickle beta thalassemia, hemoglobin c disease).

OBJECTIVE

1. May have the following:
   a. Pallor, best seen in conjunctivae.
   b. Atrophy of the surface or edges of the tongue.
   c. Inflammation/cracking of the lips.
   d. Spoon nails (thin and concave from side to side).
   e. Tachycardia, flow murmur.

ASSESSMENT Symptoms of anemia. Anemia in pre-menopausal women is most commonly iron deficiency, and may be due to increased loss with menses, low iron consumption and depleted stores from pregnancies.

PLAN

DIAGNOSTIC STUDIES

1. Hemoglobin below 11.8 gm/dL for non-pregnant women.

THERAPEUTIC

PHARMACOLOGIC

1. Treatment of (presumed) iron deficiency anemia:
   a. Ferrous Sulfate 325mg (contains 65mg of elemental iron) PO twice daily.
      OR
   b. Ferrous fumarate 325mg (contains 106mg of elemental iron) PO daily or twice daily. Ferrous fumarate has more elemental iron in it than ferrous sulfate**.**

NOTE: There are extended-release products on the market, and they are intended for once daily use. However, immediate release iron products are preferred for treatment of iron deficiency anemia. To avoid GI upset, start with a single daily dose and then increase by 1 tablet per day each week or as tolerated until desired daily dose is

achieved. Do not give if patient has sickle cell or hemoglobin variants. Do not give to patients with peptic ulcer, regional enteritis, or ulcerative colitis.

2. Efforts should be directed towards treatment of the underlying reason for the anemia (ex. menorrhagia, low consumption, etc.)

PATIENT EDUCATION/COUNSELING

1. For best absorption, take iron supplements on an empty stomach. If the iron upsets the stomach, take iron with a small amount of food but not with dairy products, antacids, eggs, whole grain breads, coffee, or tea. Foods that may decrease absorption include dietary fiber, soy products, spinach, and eggs. Foods that enhance dietary absorption of iron include broccoli, grapefruit, orange juice, peppers and strawberries.

2. Introduce iron gradually to minimize stomach upset. Take one tablet once a day x 1 week and then increase to twice daily if needed. Alternate-day dosing (e.g., Every other day or Monday, Wednesday, Friday) has been shown to result in greater absorption of iron. Reserve this dosing schedule for persons who can maintain adherence.

3. Beverages consumed with meals or supplements have a dramatic effect on iron absorption.
   a. Vitamin C (Orange juice, approximately 1 cup) doubles the absorption of iron.
   b. Tea, coffee or milk can reduce absorption to less than one half and should be consumed in moderation between meals or supplements.

4. Antacids, tetracycline, cimetidine, pancrelipase, and proton pump inhibitors interfere with iron absorption. Do not take iron within 3 hours of taking these medications. Iron affects other medications and a pharmacist or health care provider should be consulted before starting another medication. Consult drug interactions database (e.g., Lexicomp) for more detailed information

5. Iron supplements may cause black or dark green bowel movements, diarrhea, or constipation.

6. Counsel on other common side effects of iron therapy.

7. Too much iron is dangerous. Iron tablets may look like candy and a package of iron tablets can poison a child. Keep iron supplements out of the reach of children.

FOLLOW-UP

1. Recheck hemoglobin at the end of 4-6 weeks of initial treatment.
   a. If the hemoglobin has increased by 1 gm/dL or more, continue treatment for 2-3 months to replenish iron stores, then recheck hemoglobin.

b. If the hemoglobin is not increased at least 1 gm/dL, assess for compliance with therapy, diet, enteric parasites, and other possible anemia-causing conditions
c. In situations when the hemoglobin has not increased and the patient has not been compliant with the medicine, the provider should explore reasons (constipation, upset stomach, forgot, etc.) and work collaboratively with the patient to suggest a solution that works. Recheck hemoglobin in 4-6 weeks.

CONSULTATION/REFERRAL

1. Refer to physician if hemoglobin less than 9 gm/dL.

2. If after 4-6 weeks the hemoglobin does not increase at least 1 gm/dL, despite compliance with iron supplementation regimen and the absence of acute illness, refer to physician.

3. Refer any patient with peptic ulcer, regional enteritis, or ulcerative colitis, sickle cell or other hemoglobin variants to physician.

4. Refer to physician if there is evidence of other medical problems, including concerns for GI bleeding (black or tarry stools, patient history with symptoms of reflux or ulcer).

5. Refer if at risk for endometrial pathology (e.g., 35 years old or older with abnormal bleeding, chronic anovulation, Tamoxifen therapy) to MD for evaluation for possible endometrial sampling.

6. All post-menopausal women with anemia should be referred to physician for evaluation.

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STANDARD NURSE PROTOCOL FOR SCREENING MAMMOGRAPHY

DEFINITION

A mammogram is an x-ray image of the breast.

ETIOLOGY

Mammography may detect cancer up to three years before a breast mass is palpable. It is the only method of screening for breast cancer proven to decrease mortality. The goal of performing screening mammograms is the early detection of breast cancer, resulting in reduced morbidity and mortality. Various well-respected professional organizations have differing recommendations as to what age to initiate and how often to conduct the screenings.

SUBJECTIVE

1. Obtain health history, including family history of cancers.

2. Reports no breast symptoms requiring diagnostic evaluation.

3. Age 40 or older**.**

OBJECTIVE

Perform MammaCare clinical breast exam

ASSESSMENT Clinical breast exam normal

PLAN

THERAPEUTIC

PHARMACOLOGIC

None.

NON-PHARMACOLOGIC MEASURES

1. Annual or biennial screening mammogram for women ages 40-49. Women at increased risk for breast cancer should be screened annually.

2. Annual screening mammogram for women aged 50 and older (annual as defined by the CDC is every 12-18 months).

NOTE**:** It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that appropriate comparison exams are available to the interpreting radiologist.

PATIENT EDUCATION/COUNSELING

1. No lotions, deodorants, perfumes, or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.

2. Educate regarding current screening mammogram recommendations.

3. Any unusual breast changes (i.e., mass, skin changes, nipple discharge, and severe pain) that a patient discovers in the future should be evaluated by a clinician as soon as possible.

FOLLOW-UP:

1. If screening mammogram report is incomplete or abnormal, follow radiologist's recommendation for diagnostic mammography or breast ultrasound. Refer to Ordering Diagnostic Mammograms and Breast Ultrasound nurse protocol.

2. Notify patient of screening mammogram results and document in medical record.

CONSULTATION/REFERRAL

1. Refer to MD as needed for abnormal screening mammogram result.

2. Refer to the current DPH BCCP Policy and Procedure Manual's reimbursement guidelines for screening mammograms funded by BCCP.

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STANDARD NURSE PROTOCOL FOR ORDERING DIAGNOSTIC MAMMOGRAMS AND BREAST ULTRASOUNDS

DEFINITION

Breast diagnostic procedures may be requested to further evaluate an abnormal finding of the breast, enabling diagnosis. The diagnostic tests that the public health nurse may be asked to order include diagnostic mammogram and/or breast ultrasound. A diagnostic mammogram may include supplemental views and/or spot compressions and is performed under the immediate supervision of the radiologist.

A breast ultrasound uses sound waves to make pictures of the tissues inside the breast and can show all areas of the breast including the area closet to the chest wall, which is hard to study with a mammogram. A breast ultrasound determines whether an area of concern is solid, fluid-filled or a combination of both.

ETIOLOGY

A diagnostic mammogram is appropriate to further assess findings such as a palpable breast mass, persistent focal breast pain, clear (but not necessarily colorless) or bloody nipple discharge and/or skin changes. It is often requested by the radiologist when a screening mammogram requires further investigation. A diagnostic mammogram is also ordered for short-term follow-up of a probable benign finding indicated by a previous BIRADS 3 mammogram interpretation.

Breast ultrasounds evaluate palpable masses and areas of concern discovered on mammograms. In the woman under 30 years of age, initially, an ultrasound alone is often preferred to evaluate a breast mass due to the increased breast density in this population**.**

SUBJECTIVE

1**.** Obtain health history, including family history of cancers.

2. May report unilateral persistent focal pain not associated with menstrual cycle.

3. May report breast mass or skin changes of breast.

4. May have no outward symptoms (if diagnostic testing is requested for further evaluation of incomplete or abnormal screening breast imaging).

OBJECTIVE

Perform MammaCare clinical breast exam.

ASSESSMENT Document condition requiring diagnostic mammogram and/or breast ultrasound (i.e., breast mass, skin changes, BIRADS 0 mammogram report, BIRADS 3-short-term follow-up, unilateral focal breast pain**)**

PLAN

THERAPEUTIC

NON-PHARMACOLOGIC MEASURES

1. Follow BCCP New Palpable Breast Mass algorithm included in this protocol.

2. Order as appropriate (indicate right or left breast if unilateral procedure):
   a. Unilateral or bilateral diagnostic mammogram.
   b. Unilateral or bilateral breast ultrasound.

3. If not already enrolled, enroll patient in BCCP if patient is eligible and funding is available.

NOTE: It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that appropriate comparison exams are available to the interpreting radiologist.

PATIENT EDUCATION/COUNSELING

1. No lotions, deodorants, perfumes, or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.

2. Educate regarding current screening mammogram recommendations.

2. Any unusual breast changes (i.e., mass, skin changes, nipple discharge, and severe pain) that a patient discovers in the future should be evaluated by a clinical breast exam as soon as possible.

FOLLOW-UP:

1. For a newly diagnosed breast mass, follow BCCP New Palpable Breast Mass algorithm included in this protocol.

2. If a breast mass is discovered during the premenstrual time of the menstrual cycle the patient should return for a breast recheck during the week following the end of menses. If the mass remains present, proceed with diagnostic testing.

3. Continue to follow-up until condition proves benign. If malignancy is identified, follow-up until patient is under oncologic care.

CONSULTATION/REFERRAL

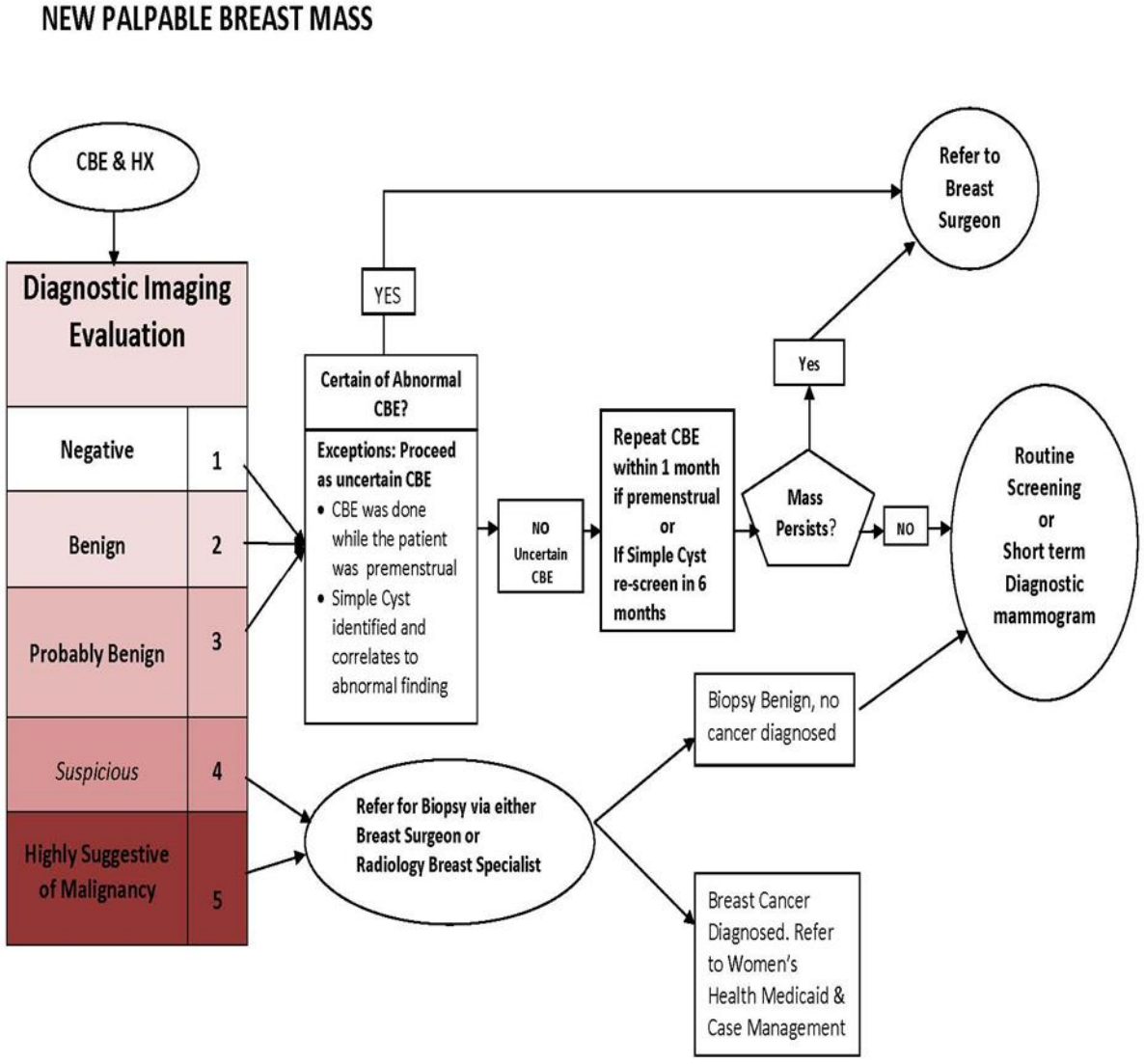
1. Refer to surgeon for evaluation of abnormal clinical findings and further

management.

2. Refer patients with bilateral nipple discharge with no evidence of a breast mass to MD for evaluation. The nipple discharge may be due to an underlying medical condition not related to an abnormality of the breast specifically.

3. For unilateral spontaneous nipple discharge refer to the Spontaneous Unilateral Nipple Discharge (Non-Lactating) nurse protocol.

Table 1: BCCP New Palpable Breast Mass Algorithm



REFERENCES

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2. American College of Radiology ACR Appropriateness of Criteria. https://acsearch.acr.org/list . Last review date: 5/17/21.

3. Women'shealth.gov. https://www.womenshealth.gov/a-z-topics/mammograms#j%20Content Content last updated: April 1, 2019

4. American College of Radiology Practice Parameter for the Performance of Breast Ultrasound Examination (Resolution 38) https://www.acr.org/-/media/ACR/Files/Practice-Parameters/US-Breast.pdf (Revised, 2016)

5. T Richards, A Hunt, S Courtney, and H Umeh Nipple Discharge: A Sign of Breast Cancer? Ann R Coll Surg Engl. Mar 2007; 89(2): 124–126. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1964556/ (October 9, 2014)

STANDARD NURSE PROTOCOL FOR SPONTANEOUS UNILATERAL NIPPLE DISCHARGE (NON-LACTATING)

DEFINITION

Spontaneous unilateral nipple discharge is discharge from the nipple that does not require manipulation of the nipple to visualize the discharge. Spontaneous leaking from the nipple should be absent within 6 months after breastfeeding cessation.

ETIOLOGY

Many conditions may cause spontaneous nipple discharge; most are benign. Benign conditions include intraductal papilloma, mammary duct ectasia, fibrocystic changes, endocrine disorders, and infection/abscesses. The most common cause for bloody nipple discharge in the absence of a breast mass is intraductal papilloma. Less than 10% of nipple discharge is associated with breast cancer.

SUBJECTIVE

1. Obtain health history, including family history of cancers.
2. Reports discharge from one nipple that flows spontaneously.
   Discharge may be described as a single or variety of colors (i.e., white, clear, yellow, green, or bloody).
3. Denies known breast mass.

OBJECTIVE

Perform MammaCare clinical breast exam.

ASSESSMENT Spontaneous unilateral nipple discharge observed
OR
Spontaneous unilateral nipple discharge reported

DIAGNOSTIC STUDIES

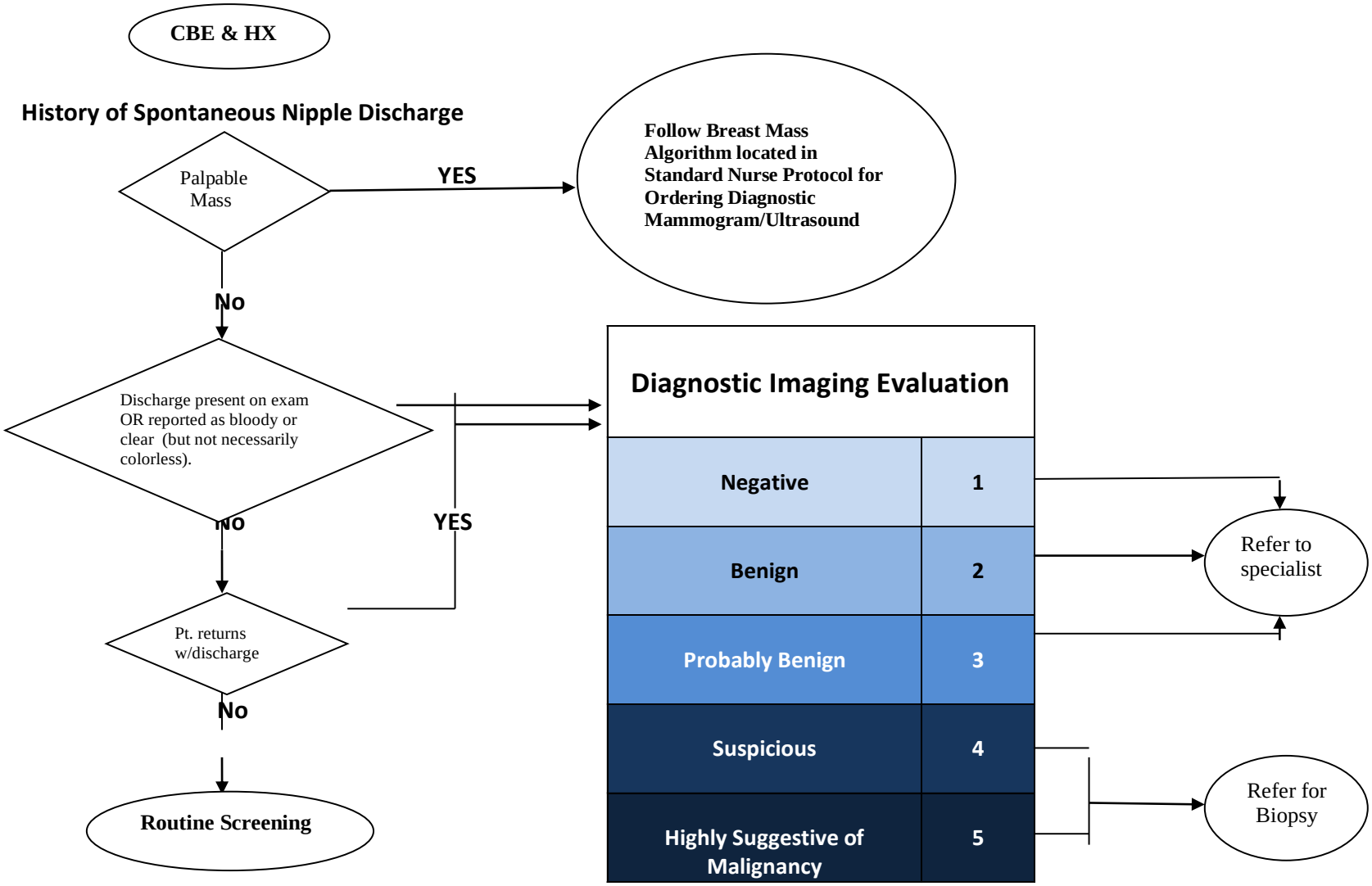
1. Order bilateral diagnostic mammogram and/or ultrasound of the breast with discharge
   a. NOTE: Contact MD breast specialist for recommended diagnostic studies, diagnostic mammogram or ultrasound if indicated.
2. Order TSH and Prolactin

THERAPEUTIC NON-PHARMACOLOGIC MEASURES

1. Follow guidance in Table 1:Spontaneous Unilateral Nipple Discharge (Non-Lactating) Algorithm that follows.

Table 1: Spontaneous Unilateral Nipple Discharge (Non-lactating) Algorithm

Spontaneous Unilateral Nipple Discharge (Non-Lactating)



PATIENT EDUCATION/COUNSELING

1. Counsel that less than 10% of nipple discharge is due to breast cancer but further diagnostic testing is warranted to rule out breast cancer.

2. No lotions, deodorants, perfumes, or powders should be used on breasts or under arms prior to mammogram. This may cause shadows to appear in the imaging.

3. It is important to ascertain where and when any prior mammograms or breast ultrasounds were done so that appropriate comparison exams are available to the interpreting radiologist.

4. Educate regarding current screening mammogram recommendations.

5. Any unusual breast changes (i.e., mass, skin changes, nipple discharge, severe pain) that a patient discovers in the future should be evaluated by a clinical breast exam as soon as possible.

FOLLOW-UP:

1. If no discharge present, follow routine recommendation for breast cancer screening.

2. Advise not to express nipple discharge because it can increase discharge.

3. If no unilateral discharge is noted upon exam and reported discharge is non-bloody, have patient return to clinic for exam if/when unilateral discharge returns.

4. Continue to follow-up until condition proves benign. If malignancy is identified, follow-up until patient is under oncologic care.

CONSULTATION/REFERRAL

1. Refer to surgeon for evaluation after mammogram results are received.

2. Radiologists' requests for galactogram to be reimbursed by BCCP must be pre-approved by a nurse consultant at the state office. A galactogram is not indicated unless the nipple discharge is spontaneous, unilateral, and expressed from a single pore.

3. All breast masses suspicious for cancer must be referred to surgeon for evaluation after thorough imaging, evaluation and minimally invasive biopsy if indicated.

4. Refer if bilateral nipple discharge with no evidence of a breast mass to MD for evaluation. The nipple discharge may be due to an underlying medical condition not related to an abnormality of the breast specifically.

REFERENCES

1. http://www.merckmanuals.com/professional/gynecology_and_obstetrics/breast_disorders/nipple_discharge.html Last full review/revision September 2013 by Mary Ann Kosir, MD; Content last revised May 2016.

2. Georgia Department of Public Health BCCP Policy and Procudure Manual, Current edition

3. Edward Azavedo, MD, PhD, John M Lewin, MD, Bernard D Coombs, MB, ChB, PhD http://emedicine.medscape.com/article/347305-overview#a01 Breast Imaging in Nipple Discharge Evaluation, Sep 4, 2013. Content last revised October 9, 2015

4. Women'shealth.gov. https://www.womenshealth.gov/a-z-topics/mammograms#j%20Content Content last updated: April 1, 2019

5. Alexander, K. C., Leung, M.B.B.S. and Daniele Pacaud, M.D., Diagnosis and Management of Galactorrhea Am Fam Physician. 2004 Aug 1;70(3):543-550.

STANDARD NURSE PROTOCOL FOR LACTATIONAL MASTITIS

DEFINITION

Mastitis is an inflammation of the breast. This is a common occurrence if lactating with 3-20% being impacted. It is more common in the first 6 weeks postpartum but can occur any time while lactating.

ETIOLOGY

Inflammation of the breast may or may not involve a bacterial infection. There may be a continuum from breast engorgement to non-infective mastitis to infective mastitis to breast abscess. These symptoms may occur with areas of breast engorgement or blockage because bacteria gain access to static milk via the nipple. Breast engorgement is different than mastitis in that engorgement is generally diffuse and bilateral. A plugged milk duct may cause a palpable tender mass. It is different from mastitis in that a plugged duct generally does not have systemic symptoms. An abscess is a severe outcome of mastitis and has the signs and symptoms of mastitis with the presence of a tender, fluctuant mass. When infective mastitis occurs, the most common bacterial cause is *S. aureus.*

SUBJECTIVE

1. Obtain health history, including family history of cancers.

2. Patient may report breast pain, redness, fever, chills, muscle aches and flu-like symptoms.

3. Denies known breast mass.

OBJECTIVE

Perform clinical breast exam noting skin changes, masses and/or any other signs and findings consistent with mastitis.

ASSESSMENT Symptoms and signs of lactational mastitis without underlying mass or signs of mass or abscess.

PLAN

THERAPEUTIC

PHARMACOLOGIC

1. Dicloxacillin 500mg PO four times daily for 7 to 14 days. Take 1 hour before or 2 hours after meals with at least 120mL of water. Do not take lying down or immediately before going to bed. Contraindicated in persons allergic to penicillin.

Significant drug interactions exist. Consult drug interactions database (e.g., Lexicomp) for more detailed information.

OR

2. Cephalexin 500mg PO four times daily for 7 to 14 days. May administer without regard to food. Contraindicated in persons allergic to any cephalosporin.

OR

3. May use Clindamycin 300mg to 450mg PO three times daily x 7 to 14 days for penicillin allergy. Take with a full glass of water to avoid esophageal irritation. Contraindicated in persons allergic to clindamycin or lincomycin. Warning: Can cause severe and possibly fatal colitis. Should be reserved for serious infections where less toxic antimicrobial agents are inappropriate. *C. difficile*-associated diarrhea (CDAD) must be considered in all patients who present with diarrhea following antibiotic use. CDAD has been observed >2 months post antibiotic treatment.

4. Prostaglandin inhibitors/NSAIDs may be taken for pain and fever if patient is not allergic and no contraindications, such as:
   a. Ibuprofen 400mg every 4 to 6 hours or 800 mg PO every 8 hours as needed for pain with food x 10 days or fever x 3 days. If no relief, may increase to 400mg every 4 to 6 hours as needed. (Maximum: 2400 mg/day for those 12-17 years and 3200 mg/day for those 18 years and older),

   OR

   b. Naproxen 500mg PO for one dose then, 250mg PO every 6-8 hours as needed with food for pain or fever. (Maximum daily dose for Day 1 is 1,250mg; subsequent daily doses should not exceed 1,000mg).

NOTE: Naproxen that is available OTC is 220mg each.

OR

   c. Acetaminophen 650mg PO every 4 to 6 hours as needed for pain of fever. (maximum daily dose: 3250mg/day)

NON-PHARMACOLOGIC MEASURES

1. Cold compresses or ice packs can help to reduce breast pain and swelling.

2. Women should be encouraged to completely empty the breast by continuing to breastfeed, pump or express milk by hand. It is safe to breastfeed while undergoing treatment.

3. A plugged mild duct does not require antibiotics for treatment. Women should follow instructions below and consider applying heat to the breast prior to feeding.

PATIENT EDUCATION/COUNSELING

1. Mothers should be encouraged to breastfeed more frequently starting on the affected breast.

2. If pain interferes with let-down, feeding may begin on the unaffected breast, switching to the affected breast as soon as let-down is achieved.

3. Positioning the infant at the breast with the chin or nose pointing to the blockage will help drain the affected area.

4. Massaging the breast during the feeding with an edible oil or nontoxic lubricant on the fingers may also be helpful to facilitate milk removal. Massage should be directed from the blocked area moving toward the nipple.

5. After breastfeeding, expressing milk by hand or pump may augment milk drainage and hasten resolution of the problem.

FOLLOW-UP:

1. Clinical response is generally rapid and dramatic.

2. If there is not improvement in 48 hours, the patient should be referred to MD for evaluation and/or consideration of breast ultrasound or culture of breast milk.

CONSULTATION/REFERRAL

1. Refer to MD if a breast mass concerning for abscess or malignancy is present on exam.

2. If patient is severely ill or cannot tolerate PO medications, refer to MD or to ER.

REFERENCES:

1. Academy of Breastfeeding Medicine Clinical Protocol #4: Mastitis, Revised March, 2014 https://abm.memberclicks.net/assets/DOCUMENTS/PROTOCOLS/4-mastitis-protocol-english.pdf

2. Wolters Kluwer.*Lexicomp Online®.*(May 8, 2021). Cephalexin. Retrieved on May 11,2021, at.https://online.lexi.com/crlsql/servlet/crlonline.

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WOMEN'S HEALTH APRN PROTOCOLS

STANDARD APRN PROTOCOL FOR AMENORRHEA

DEFINITION

Amenorrhea is defined as the absence of menses. Primary amenorrhea is defined as no menstrual period by the age of 15, lack of any secondary sexual characteristics by age 13 or no menses within 5 years after the development of breasts, pubic or axillary hair.

Secondary amenorrhea is defined as absence of menstrual periods for greater than 3 months in a woman who was previously menstruating.

ETIOLOGY

1. Primary:
   a. Gonadal failure.
   b. Congenital absence of uterus and vagina.
   c. Constitutional delay.

2. Secondary:
   a. Pregnancy; breastfeeding.
   b. Pituitary disease or tumor; disruption of hypothalamic- pituitary axis.
   c. Menopause.
   d. Too little body fat (about 22% required for menses).
   e. Excessive exercise (e.g., long-distance running, ballet dancing, gymnastics, figure skating, etc.).
   f. Rapid weight loss.
   g. Cessation of menstruation following use of CHC or DMPA.
   h. Recent change in lifestyle (e.g., increased stress).
   i. Thyroid disease.
   j. Polycystic ovary disease.
   k. Anorexia nervosa or other eating disorders.
   l. Premature ovarian insufficiency, ovarian dysgenesis, infection, hemorrhage, necrosis, neoplasm.
   m. Cushing Disease
   n. Asherman's Syndrome.
   o. Cervical stenosis.
   p. Medications including psychotropics.
   q. Chronic illness.
   r. Tuberculosis.

SUBJECTIVE

1. Patient provides a detailed health history (includes menstrual, sexual, contraception, personal health, and family history).

2. Patient reports absence of menses (as defined above).

3. Patient may have a history which includes the following**:**
   a. Changes in skin/hair, vision/hearing or voice
   b. Palpitations
   c. Breast size changes or galactorrhea
   d. Vasomotor symptoms
   e. Changes in weight, dietary habits
   f. Cold or heat intolerance
   g. Known medical problems
   h. Stress
   i. Exercise patterns (changes or rigorous)
   j. Recent pregnancy, risk for pregnancy
   k. Genital tract procedures

OBJECTIVE

1. May be obese or underweight for height.

2. May note on physical examination:
   a. Skin/hair changes – dry skin or warm, moist skin, excessive sweating, palmar erythema, acne, hirsutism, balding**,** purple abdominal striae, absence of pubic or axillary hair.
   b. Facial plethora, moon facies, exophthalmos, ocular signs, visual fields defect, impaired auditory acuity, abnormal thyroid size and consistency, fine silky scalp hair or alopecia pattern.
   c. Tachycardia.
   d. Breast tissue atrophy, galactorrhea.
   e. "Buffalo" hump of back.
   f. On pelvic exam:
      1) External – Vulvar atrophy, clitoromegaly.
      2) Internal – Atrophic vaginal mucosa, change in cervical mucous or imperforate hymen.
      3) Bimanual – Softening of cervix or cervical uterine junction, cervical stenosis, uterine or ovarian atrophy or enlargement.

ASSESSMENT Primary amenorrhea or Secondary amenorrhea with or without galactorrhea.

PLAN

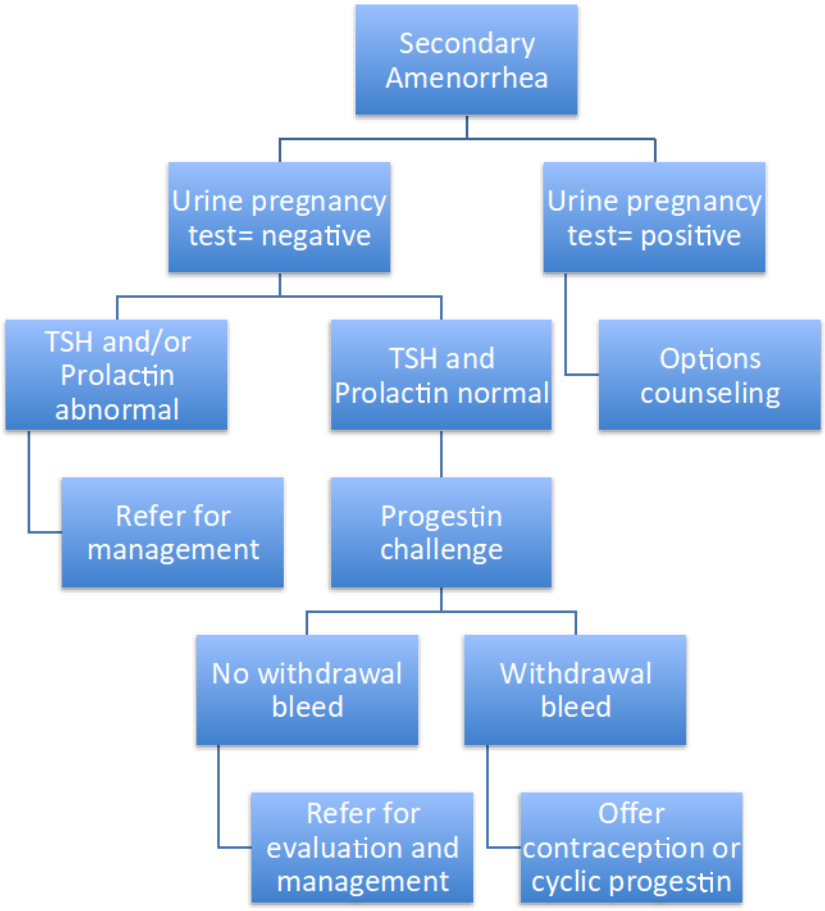
DIAGNOSTIC STUDIES

1. Pregnancy test for either primary or secondary amenorrhea.

2. For primary amenorrhea, refer these patients for further evaluation.

3. For secondary amenorrhea, consider TSH and prolactin followed by a progestin

challenge test as suggested in Table below. Clinicians may also refer these patients for further evaluation.



THERAPEUTIC

PHARMACOLOGIC

NOTE**:** Hazardous agent; use appropriate precautions for handling and disposal. More information found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

1. Progestin challenge test: Medroxyprogesterone Acetate 5mg-10mg (1 tab) PO daily for 5-10 days.

2. If bleeding occurs with progestin challenge test (usually within 2-7 days):

   AND

   a. Patient desires contraception, begin any desired contraceptive for which she meets the *CDC Medical Eligibility Criteria.* If she desires cyclic menses, encourage a combined hormonal contraceptive (pill, patch, or ring). (See Appendix A)

   OR

b. Patient does not desire contraception, give medroxyprogesterone acetate, 10 mg PO daily for the first 10 days of every month for 3 consecutive months. If she does not have spontaneous menses thereafter, refer.

3. If no bleeding occurs with progestin challenge test, repeat pregnancy test. If negative, refer patient for management and/or further evaluation.

PATIENT EDUCATION/COUNSELING

1. Give menstrual calendar and counsel on its use.

2. Inform that bleeding usually occurs within 2 weeks after treatment (frequently 2-7 days).

3. Discuss what can be expected during future evaluation. Explain that accurate diagnosis may take time.

4. Review female anatomy and menstrual cycle to help her understand the testing being done.

5. Discuss contraception, as indicated.

FOLLOW-UP

Return in two weeks if no withdrawal bleeding has occurred after medroxyprogesterone acetate.

CONSULTATION/REFERRAL

1. Primary amenorrhea.

2. Positive pregnancy test. Perform options counseling and refer as indicated.

3. No withdrawal bleed after progestin challenge test and negative pregnancy test, refer for further evaluation.

4. Fails to have spontaneous menses within 3 months after treatment.

5. Suspected eating disorders, or polycystic ovarian syndrome.

6. Abnormal symptoms, laboratory test(s), or exam findings.

7. Neurological symptoms such as headache or abnormal neurological exam.

8. May refer for diagnostic testing (i.e., prolactin level, TSH, FSH, LH).

REFERENCES

1. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecological Settings,* 11th ed., Springer Publishing Co., New York, 2015.

2. Master-Hunter and Hieman. Amenorrhea: Evaluation and Treatment. American Family Physicians. April 15, 2006, Volume 73, Number 8, Pg 1374-1382.

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STANDARD APRN PROTOCOL FOR IUD INSERTION: COPPER T380A

DEFINITION

The Copper T380A (ParaGard®) intrauterine device, is a copper-bearing contraceptive device that prevents pregnancy for at least 10 years. It prevents pregnancy by immobilizing sperm, inhibiting fertilization, and preventing implantation due to local inflammatory responses and endometrial effects. The copper IUD can also be used for emergency contraception. It is the most effective method of emergency contraception within 5 days of unprotected sex. For those seeking ongoing highly effective contraception, use of the copper IUD as emergency contraception may be ideal**.**

SUBJECTIVE

1. Desires an IUD for long-term contraception.

2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the *CDC Medical Eligibility Criteria for Contraceptive Use.* Conditions that present an unacceptable health risk for use of the copper IUD include:
   a. Currently pregnant
   b. Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.
   c. Postpartum sepsis
   d. Immediately post septic abortion
   e. Current PID or endomyometritis within the past 3 months
   f. Current purulent cervicitis or chlamydial infection or gonorrhea
   g. Uterine anomalies that distort the endometrial cavity
   h. Cervical or endometrial cancer waiting to be treated
   i. Gestational trophoblastic disease with persistently elevated β-hcg levels or malignant disease with evidence or suspicion of intrauterine disease
   j. Severe thrombocytopenia (at the time of initiation)
   k. Pelvic tuberculosis
   l. Complicated solid organ transplantation: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy

m. Wilson's disease

3. May desire hormone-free contraception

4. May desire the most effective emergency contraceptive possible.

OBJECTIVE

1. Physical examination and laboratory tests as indicated. Refer to the Preventive Care and Health Screening section of the Women's Health Protocols.

2. Pelvic exam must be completed.

3. No pelvic exam findings that are contraindications to placement at the time of insertion.

4. Determine if reasonably certain that the woman is not pregnant (see Initiation of Contraception Protocol) or needs emergency contraception if unprotected sex in the past 5 days.

ASSESSMENT

1. No condition representing an unacceptable risk if using a Copper T380A.

2. No allergy to any component of the IUD.

PLAN

DIAGNOSTIC STUDIES

1. Negative pregnancy test, if indicated.

2. Laboratory tests:
   a. Negative gonorrhea and chlamydia tests, if indicated. Tests may be performed on the day of placement. Patients will need to return for treatment for any positive test results. Additional clarification about STD screening and IUD insertion from the CDC's Selected Practice Recommendations: Most women do not require additional STD screening at the time of IUD insertion if they have already been screened according to STD Program's current Screening Criteria for Chlamydia and Gonorrhea.
   b. If patient has not been screened according to guidelines, screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with purulent cervicitis or current chlamydia or gonorrhea infection should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4).
   c. Wet mount, if indicated.

NOTE: Trichomonas, yeast and BV are not contraindications to IUD placement. Clinicians may diagnose, treat, and place an IUD on the same day.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Before insertion, the patient must read and sign the program's method specific consent form.

1. May encourage an over the counter (OTC) non-steroidal anti-inflammatory agent 30-60 minutes before the procedure to reduce discomfort.

2. Insert Copper T380A per manufacturer's directions. May be inserted any time in the cycle if pregnancy has been ruled out. The Copper T380A is effective immediately after insertion.

3. If lactating, there appears to be an increased risk of perforation.

4. If a provider can be reasonably certain that a woman is not pregnant, any contraceptive, including a Copper IUD may be initiated on that day.
   a. This includes women who were not on a contraceptive method.
   b. This also includes women who have been consistently and correctly using another method of contraception (CHC, injection, implant, POP, IUD). Insert on the same day that removal of the implant or other IUD occurs.

5. In situations where a provider cannot be reasonably certain that patient is not pregnant, an alternate method of contraceptive should be provided. The patient should return for IUD placement when the provider can be reasonably certain not pregnant. If a bridge hormonal method is not desired, the patient can be rescheduled to return within 5 days of the start of next menses.

   An exception to the above: If unprotected sex in the last 120 hours, has no other acts of unprotected sex since LMP and desires the Copper T380A for EC and for ongoing contraception, it may be placed immediately.

6. After childbirth it may be inserted immediately following delivery of the placenta; do not insert if puerperal sepsis is present. If IUD was not placed immediately postpartum and patient desires an IUD postpartum for contraception, wait a minimum of 6 weeks after delivery or until the uterus is fully involuted and pregnancy is ruled out.

7. Following medical or surgical abortion or miscarriage may be inserted on same day or within 7 days. Do not insert if septic abortion is present, signs of infection (cervical motion tenderness on bimanual exam and/or fever), or has current complications from abortion.

8. The provider should fully complete the IUD Placement procedure note, as indicated.

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/ fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the patient to lie still for at least 30 seconds. Ask about pain or cramping. If patient feels okay, advise them sit up slowly while being supported. If no problems in 30 seconds, allow to stand.

2. Treat signs of vasovagal reaction (pallor/cyanosis, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to the Emergency Guidelines, Policies, Procedures and Protocols.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED: Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. Discuss checking for IUD strings.
   a. The IUD can be expelled without being noticed. The package insert suggests that women check for the strings monthly however, checking for the strings has not been shown to add to optimal use of the IUD. If a patient is reassured by checking the strings, they may do so but they should not be instructed that this is necessary.
   b. If a patient check for strings routinely and cannot feel the strings, or if the plastic portion of the IUD is felt, advise them to use another method of contraception and return to the clinic.
   c. If an IUD was placed immediately postpartum, a string trim may be needed when they present for postpartum follow-up.
   d. The most likely cause of IUD failure is expulsion with risk highest during the first year, especially in the first 3 months following insertion.

3. Review warning signs and symptoms of possible problem: abdominal pain, vaginal discharge, pain with intercourse, missing string, pregnancy symptoms, heavy bleeding, post-coital spotting.

4. There is a small increased risk of PID, which is most likely to occur within the first 2-3 weeks after insertion. Patient should be instructed to return for signs and symptoms of infection.

5. Menstrual irregularities (spotting, light bleeding) are common in the first 3-6 months after insertion.

6. Take over-the-counter ibuprofen or naproxen sodium (follow package directions) if needed for discomfort.

7. Should strongly consider adding condoms for STD protection if patient is at risk for STDs (multiple partners, partner with multiple partners).

8. Provide counseling on preconception health counseling and future fertility.

9. Use condoms to reduce the risk of STD, including HIV.

10. The T380A is approved for use for 10 years, however clinical data demonstrates its effectiveness for 12 years, and maybe longer. This information can be used when counseling women at the time of initiation as well as at the end of the FDA approval window. If the patient is satisfied with the method at the end of the FDA approval window and would like to continue using it, evidence indicates that it still provides contraception as noted above. If she would like to have it removed, this should be honored.

FOLLOW-UP

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.

2. Re-examine and evaluate the patient as indicated. See table below.

3. If evidence of pelvic inflammatory disease, see STD Nurse Protocol for Pelvic Inflammatory Disease. IUD removal is not necessary unless no improvement after 2-3 days of antibiotic treatment.

4. If pregnancy occurs, counsel that IUD should be removed by an MD at time of diagnosis whether pregnancy is continued or terminated.

CONSULTATION/REFERRAL

1. Concern for anatomical abnormalities

2. Difficult IUD insertion or removal.

3. Suspected uterine or ectopic pregnancy.

4. To MD for IUD removal if pregnant.

5. Other complications related to IUD use.

6. Actinomyces on a pap by itself is not informative or predictive; however, if signs/symptoms of a pelvic abscess are present (fever/chills, abdominal pain, etc) prompt referral is appropriate.

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m^2] at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

REFERENCES

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2. Joellen Hawkins et al., Protocols for Nurse Practitioners in Gynecologic Settings, 11th ed., Springer Publishing Co., New York, 2015.

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STANDARD APRN PROTOCOL FOR IUD INSERTION:

Levonorgestrel (LNG) Releasing Intrauterine System®

DEFINITION

The LNG-releasing intrauterine systems (Mirena®, Liletta®, Skyla® and Kyleena) are available in the United States. The LNG-releasing system consists of a small T-shaped frame with a steroid reservoir that contains levonorgestrel, a potent progestin found in many combination oral contraceptives, progestin-only contraceptive pills, and implants.

The LNG intrauterine system releases a low dose of LNG into the uterine cavity, a system like LNG implants and LNG-containing mini-pills. As with those methods, thickening the cervical mucus and inhibition of ovulation, sperm motility and function are considered the primary means of preventing pregnancy. A weak foreign-body effect is also noted which could decrease implantation. Unlike the copper IUD, the LNG IUD is not approved for use as emergency contraception.

SUBJECTIVE

1. Desires an IUD for long-term contraception.

2. Has detailed health history (includes menstrual, sexual, contraception, personal health and family history) that does not reveal a condition representing an unacceptable health risk according to the product prescribing information and to the *CDC Medical Eligibility Criteria for Contraceptive Use.* Conditions that present an unacceptable health risk for use of the LNG IUD include:
   a. Currently pregnant
   b. Unexplained vaginal bleeding, suspicious for serious underlying condition, before evaluation.
   c. Postpartum sepsis.
   d. Immediately post septic abortion.
   e. Current PID or endomyometritis within the past 3 months.
   f. Current purulent cervicitis or chlamydial or gonorrhea infection
   g. Uterine anomalies that distort the endometrial cavity.
   h. Cervical or endometrial cancer waiting to be treated.
   i. Gestational trophoblastic disease with persistently elevated β-hcg levels or malignant disease with evidence or suspicion of intrauterine disease.
   j. Lupus with positive or unknown antiphospholipid antibodies.
   k. Breast cancer.
   l. Cirrhosis severe (decompensated).
   m. Liver Tumors: benign hepatocellular adenoma; malignant (hepatoma).
   n. Pelvic tuberculosis.
   o. Complicated solid organ transplantation: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy.

3. Refer to CDC *Medical Eligibility Criteria for Contraceptive Use* for medical conditions that represent an unacceptable health risk if they develop while using the **LNG-releasing intrauterine system**. Women with these conditions may initiate the implant. However, if women who did not have these conditions at the time of initiation develop these conditions after using the **LNG-releasing intrauterine system, the LNG-releasing intrauterine system** should not be continued. Medical conditions include:
   a. Ischemic heart disease.

4. May desire lighter periods or no periods at all.

OBJECTIVE

1. Physical examination and laboratory tests as indicated. Refer to Standard Nurse Protocol for Preventive Care and Health Screening.

2. Pelvic exam must be completed.

3. No pelvic exam findings that are contraindications to placement at the time of insertion.

4. Determine if reasonably certain that the woman is not pregnant (see Initiation of Contraception Protocol).

ASSESSMENT Patient has no condition representing an unacceptable risk if using a LNG IUD. Not allergic to any component of the IUD.

PLAN

DIAGNOSTIC STUDIES

1. Negative pregnancy test at the time of insertion.

2. Laboratory tests:
   a. Negative gonorrhea and chlamydia tests, if indicated. Tests may be performed on the day of placement and return for treatment if test(s) returns positive. Additional clarification about IUD insertion and STD testing from the CDC's Selected Practice Recommendations: Most patients do not require additional STD screening at the time of IUD insertion if they have already been screened according to STD Program's current Screening Criteria for Chlamydia and Gonorrhea.
   b. If have not been screened according to guidelines, screening can be performed at the time of IUD insertion, but insertion should not be delayed.
   c. If purulent cervicitis or current chlamydial infection or gonorrhea should not undergo IUD insertion (U.S. Medical Eligibility Criteria 4).

d. Wet mount, if indicated.

NOTE: Trichomonas, yeast and BV are not contraindications to IUD placement. Clinicians may diagnose, treat, and place an IUD on the same day.

THERAPEUTIC

PHARMACOLOGIC

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

NOTE: Before insertion, the patient must read and sign the program's method specific consent form.

1. May encourage an over the counter (OTC) non-steroidal anti-inflammatory agent 30-60 minutes before the procedure to reduce discomfort.

2. Insert LNG IUD per manufacturer's directions.

3. If lactating, there appears to be an increased risk of perforation.

4. If a provider can be reasonably certain patient is not pregnant, any contraceptive, including an LNG IUD may be initiated on that day.
   a. This includes patients who were not on a contraceptive method. If not inserted during the first 7 days of the menstrual cycle, a barrier method should be used for 7 days.
   b. This includes patients who have been consistently and correctly using another method of contraception (CHC, injection, POP, IUD). If inserted during active use of the previous method, continue the previous method for 7 days when possible.
   c. Insert on the same day that removal of an implant or other IUD occurs.

5. In situations where a provider cannot be reasonably certain that patient is not pregnant, they should be provided an alternate method of contraceptive and return for IUD placement when the provider can be reasonably certain the patient is not pregnant. If a bridge hormonal method is not desired, the patient can be rescheduled to return within 5 days of the start of next menses.

6. After childbirth the IUD may be inserted immediately following delivery of the placenta; do not insert if puerperal sepsis is present. If IUD had not been placed immediately postpartum and patient desires an IUD postpartum for contraception, wait a minimum of 6 weeks after delivery or until the uterus is fully involuted and pregnancy is ruled out.

7. Following medical or surgical abortion or miscarriage may be inserted on the same day. Do not insert if septic abortion is present, patient has signs of infection

(cervical motion tenderness on bimanual exam and/or fever) or has current complications from abortion.

8. Mirena® releases 20mcg per day initially then declines; is approved for use **for 8** years.

9. Skyla® releases 14mcg per day initially then declines; is approved for use for 3 years.

10. Liletta® releases 18.6mcg per day initially then declines; is approved for **8** years.

11. Kyleena® releases 17.5 mcg per day initially and then declines; is approved for use for 5 years.

12. The provider should fully complete the IUD Insertion Procedure Note as indicated**.**

NON-PHARMACOLOGIC MEASURES

1. Take precautions to avert a vasovagal reaction (syncope/ fainting) caused by uterine manipulation and sounding. After IUD insertion, allow the patient to lie still for at least 30 seconds. Ask about pain or cramping. If the patient says they feel okay, sit up slowly while being supported. If no problems in 30 seconds, allow to stand.

2. Treat signs of vasovagal reaction (pallor/cyanosis, pinched-face look, dilated pupils, weak and rapid pulse, rapid shallow breathing, hypotension) according to Emergency Guidelines, Policies, Procedures and Protocols.

PATIENT EDUCATION/COUNSELING

1. Counsel patient according to seven basic elements of informed consent (BRAIDED Benefits Risks Alternatives Inquiries Decision Explanation Documentation).

2. Discuss checking for IUD strings.
   a. The IUD can be expelled without being noticed. The package insert suggests that women check for the strings monthly however, checking for the strings has not been shown to add to optimal use of the IUD. If a patient feels reassured by checking the strings, they may do so but should be counseled that this practice is necessary.
   b. If the patient does check for strings routinely and cannot feel the strings, or if the plastic part of the IUD is felt, they should use another method of contraception and return to the clinic.
   c. If an IUD was placed immediately postpartum a string trim may be needed when they present for postpartum follow-up.
   d. The most likely cause of IUD failure is expulsion with risk highest during the first year, particularly within the first 3 months after insertion.

3. Review warning signs and symptoms of possible problem: abdominal pain, vaginal discharge, pain with intercourse, missing string, pregnancy symptoms, heavy bleeding.

4. There is a small increased risk of PID, which is most likely to occur within the first 2-3 weeks after insertion. Patient should be instructed to return for signs and symptoms of infection.

5. Discuss common side effects:
   a. 1 to 4 months: may have frequent spotting.
   b. After 3- 6 months: reduced duration and amount of bleeding.
   c. 90% reduction in menstrual bleeding.
   d. After 12 months, about 20% of women have no bleeding.
   e. The patient should keep a menstrual record and report a sudden change in menses or suspected pregnancy immediately.
   f. The Mirena system is the only one approved by FDA to reduce dysmenorrhea and leads to a significant reduction in the amount and length of bleeding. It is reasonable to believe that the other LNG IUDs would also result in improvements in dysmenorrhea and heavy bleeding.
   g. As with other progestin-only methods, persistent ovarian follicles can occur. They do not require treatment or removal of the LNG system, and they usually resolve spontaneously. However, regular follow-up by ultrasound is recommended until cysts disappear.
   h. Give patient copy of LNG system post-insertion instructions.

6. Take over-the-counter ibuprofen or naproxen sodium (follow package directions) if needed for discomfort.

7. Should strongly consider adding condoms for STD protection if patient is at risk for STDs (multiple partners, partner with multiple partners).

8. Provide counseling on preconception health counseling and future fertility.

9. Use condoms to reduce the risk of STD, including HIV.

10. Some drugs or herbal products may decrease the serum concentration of LNG, please advise to check with a health care professional for potential interactions.

FOLLOW-UP

1. Outside of clinic hours, seek physician or emergency care if warning signs develop.

2. Re-examine and evaluate as indicated. See table below.

3. If evidence of pelvic inflammatory disease, see STD Nurse Protocol for Pelvic Inflammatory Disease (PID). IUD removal is not necessary unless no improvement after 2-3 days of antibiotic treatment.

4. If pregnancy occurs, counsel patient that IUD should be removed by an MD at time of diagnosis whether pregnancy is continued or termination is preferred.

5. After the IUD has been in for the FDA-approved length of time, check with manufacturer regarding possible approval for a longer time.

CONSULTATION/REFERRAL

1. Concern for anatomical abnormalities

2. Difficult IUD insertion or removal.

3. Suspected uterine or ectopic pregnancy.

4. To MD for IUD removal if pregnant.

5. Other complications related to IUD use.

6. Actinomyces on a pap by itself is not informative or predictive; however, if she has signs/symptoms of a pelvic abscess (fever/chills, abdominal pain, etc.) prompt referral is appropriate.

How to Be Reasonably Certain That a Woman is Not Pregnant

A health-care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets any one of the following criteria:

- is ≤7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- is ≤7 days after spontaneous or induced abortion
- is within 4 weeks postpartum
- is fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

In situations in which the health-care provider is uncertain whether the woman might be pregnant, the benefits of starting the implant, depot medroxyprogesterone acetate (DMPA), combined hormonal contraceptives and progestin-only pills likely exceed any risk; therefore, starting the method should be considered at any time, with a follow-up pregnancy test in 2-4 weeks. For IUD insertion, in situations in which the health-care provider is not reasonably certain that the woman is not pregnant, the woman should be provided with another contraceptive method to use until the health-care provider can be reasonably certain that she is not pregnant and can insert the IUD.

When to Start Using Specific Contraceptive Methods

Contraceptive method	When to start (if the provider is reasonably certain that the woman is not pregnant)	Additional contraception (i.e., back up) needed	Examinations or tests needed before initiation[1]
Copper-containing IUD	Anytime	Not needed	Bimanual examination and cervical inspection[2]
Levonorgestrel-releasing IUD	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	Bimanual examination and cervical inspection[2]
Implant	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	None
Injectable	Anytime	If >7 days after menses started, use back-up method or abstain for 7 days.	None
Combined hormonal contraceptive	Anytime	If >5 days after menses started, use back-up method or abstain for 7 days.	Blood pressure measurement
Progestin-only pill	Anytime	If >5 days after menses started, use back-up method or abstain for 2 days.	None

Abbreviations: BMI = body mass index; IUD = intrauterine device; STD = sexually transmitted disease; U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

[1] Weight (BMI) measurement is not needed to determine medical eligibility for any methods of contraception because all methods can be used (U.S. MEC 1) or generally can be used (U.S. MEC 2) among obese women. However, measuring weight and calculating BMI (weight [kg]/height [m²]) at baseline might be helpful for monitoring any changes and counseling women who might be concerned about weight change perceived to be associated with their contraceptive method.

[2] Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC's STD Treatment Guidelines (http://www.cdc.gov/std/treatment), screening can be performed at the time of IUD insertion, and insertion should not be delayed. Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (U.S. MEC 4).

Source: For full recommendations and updates, see the U.S. Selected Practice Recommendations for Contraceptive Use webpage at http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm.

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National Center for Chronic Disease Prevention and Health Promotion

TABLE D1. Routine follow-up after contraceptive initiation

Action	Contraceptive method				
	Cu-IUD or LNG-IUD	Implant	Injectable	CHC	POP
General follow-up					
Advise women to return at any time to discuss side effects or other problems or if they want to change the method. Advise women using IUDs, implants, or injectables when the IUD or implant needs to be removed or when a reinjection is needed. No routine follow-up visit is required.	X	X	X	X	X
Other routine visits					
Assess the woman's satisfaction with her current method and whether she has any concerns about method use.	X	X	X	X	X
Assess any changes in health status, including medications, that would change the method's appropriateness for safe and effective continued use based on U.S. MEC (i.e., category 3 and 4 conditions and characteristics) (Box 1).	X	X	X	X	X
Consider performing an examination to check for the presence of IUD strings.	X	—	—	—	—
Consider assessing weight changes and counseling women who are concerned about weight change perceived to be associated with their contraceptive method.	X	X	X	X	X
Measure blood pressure.	—	—	—	X	—

Abbreviations: CHC = combined hormonal contraceptives; Cu-IUD = copper-containing intrauterine device; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG-IUD = levonorgestrel-releasing intrauterine device; POP = progestin-only pills; U.S. MEC = *U.S. Medical Eligibility Criteria for Contraceptive Use*.

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology,* 21st ed., Ardent Media Inc., New York, 2018. (Current)

2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings,* 11th ed., Springer Publishing Co., New York, 2015.

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STANDARD APRN PROTOCOL FOR LOST IUD STRINGS

DEFINITION

Inability to visibly locate IUD (intrauterine device) strings or inability to feel the IUD strings.

ETIOLOGY

Lost IUD strings may be the result of expulsion of the IUD, retraction of the strings into the uterine cavity, perforation of the IUD through the cervix or uterine wall, or use of an IUD (from another country) that never had a string attached. In some rare instances, clinicians have intentionally cut strings off or cut the strings short.

SUBJECTIVE

Patient may report that she cannot feel IUD strings on self-exam.

OBJECTIVE

No IUD strings visible upon careful examination of the vagina and cervical opening, and inability to feel the strings.

ASSESSMENT IUD strings not visible.

PLAN

DIAGNOSTIC STUDIES

1. Sensitive urine pregnancy test (HCG).

THERAPEUTIC

1. If pregnancy test is positive, immediately refer patient to physician.

2. If pregnancy is ruled out by HCG and exam:
   a. Prepare cervix os with insertion using betadine or other antiseptic.
   b. If the patient is not pregnant and the strings are not visible, attempt to retrieve the IUD string using cytobrush, curved forceps, alligator forceps, or IUD retriever. Use tenaculum if necessary to steady the cervix
      1) If unable to locate strings:
         a. Refer for pelvic ultrasound or if necessary, abdominal x-rays. Advise to use an alternative method of contraception while trying to locate IUD
         b. If the IUD is identified as properly positioned in the uterus, no additional action is necessary; provide reassurance.
         c. If IUD identified on ultrasound but unable to confirm uterine placement, refer to MD.

PATIENT EDUCATION/COUNSELING

Advise the patient to use another method of contraception until the IUD is confirmed to be located inside the uterus.

FOLLOW-UP

Return to clinic as needed for contraception or preventive care.

CONSULTATION/REFERRAL

1. Immediately refer patient to physician if pregnancy test is positive.

2. Consult with a physician for any questions regarding management (see APRN Protocol for IUD Removal/Complications and Actions).

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology,* 21st ed., Ardent Media, Inc., New York, 2018. (Current)

2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings,* 11th ed., Springer Publishing Co., New York, 2015.

3. M. Zieman, R.A. Hatcher. *Managing Contraception, 14th ed., Ardent Media Inc.,* New York, 2017.

STANDARD APRN PROTOCOL FOR IUD REMOVAL and IUD COMPLICATIONS AND ACTIONS

DEFINITION

Removal of an IUD by the clinician at the patient's request, due to clinical findings such as pregnancy or partial expulsion, or at the recommended time frame for the device. It is important to comply with request for IUD removal.

SUBJECTIVE

1. Requests IUD removal for any reason.

2. May report a condition that precludes IUD use, such as suspected or confirmed pregnancy or partial expulsion.

3. May complain of dysmenorrhea, dyspareunia, menorrhagia, aching, abdominal pains, and tenderness on ambulation, malaise, and chills/fever.

4. History of IUD use past its length of contraceptive effect.

OBJECTIVE

May have findings on pelvic exam or laboratory tests that require IUD removal such as partial expulsion, enlargement of uterus, positive pregnancy test, other pelvic infection/disease.

ASSESSMENT Indications for removal of IUD.

PLAN

DIAGNOSTIC STUDIES

If indicated:

1. Sensitive urine pregnancy test.

2. Wet mount.

3. Gonorrhea and chlamydia tests.

THERAPEUTIC (by APRN or MD)

NOTE: Hazardous agent; use appropriate precautions for handling and disposal which can be found at: https://www.cdc.gov/niosh/docs/2016-161/default.html

NOTE**:** Easier removal may be possible at the time of menses or at midcycle.

1. If patient is not pregnant, remove IUD slowly, applying gentle, steady traction to string with sponge forceps.

2. If patient is not pregnant and the IUD cannot be removed with gentle traction, use a tenaculum to steady the cervix and straighten the anteversion or retroversion.

3. If the patient is not pregnant and the strings are not visible, attempt to retrieve the IUD string using cytobrush, curved forceps, alligator forceps, or IUD retriever. Use tenaculum if necessary to steady the cervix.

4. If pregnant, advise that removal is recommended. Removal is associated with a slight risk of pregnancy loss at the time of removal, but the risk of infection, miscarriage and preterm birth are more serious if left in situ. Refer patient to physician for removal of IUD.

PATIENT EDUCATION/COUNSELING

1. Contraceptive method of choice if pregnancy not desired.

2. If seeking pregnancy, return to fertility is rapid. Initiate folic acid supplementation.

3. There are no known major long-term side effects after removal of an IUD.

4. Provide counseling on preconception health counseling and future fertility.

FOLLOW-UP

Return to clinic as needed, for contraception or preventive care.

CONSULTATION/REFERRAL

Refer or consult with physician if:

1. Difficult/failed removal.
2. Patient pregnant.
3. Unable to visualize and/or probe for strings.

TABLE OF IUD COMPLICATIONS AND ACTIONS

Condition	**Action**
Pain from tenaculum application to the cervix:	• May consider application of topical anesthetic if available such as Lidocaine gel
Persistently bleeding tenaculum sites:	• Apply steady pressure with cotton swab • May apply hemostatic agent (ex. Monsel's solution or silver nitrate) if pressure alone is unsuccessful
Pain with sounding of the uterus during insertion:	• Sound slowly and gently; consider smaller sound or os finder. • If severe, check alignment of uterine cavity. • Refer to MD
Cramping/pain with each Menses:	• See Nurse Protocol IUD - Related Dysmenorrhea.
Partial expulsion of an IUD:	• Removal of IUD, pregnancy test as needed
Increasing abdominal pain immediately/shortly after insertion:	• Evaluate for infection and perforation.
Actinomyces-like organisms on pap smear:	• Actinomyces on a pap by itself is not informative or predictive; however, if signs/symptoms of a pelvic abscess (fever/chills, abdominal pain, etc) prompt referral is appropriate.
Pelvic inflammatory disease:	• See Nurse Protocol for Pelvic Inflammatory Disease.
Pregnancy **(of any kind, ongoing, miscarriage, ectopic)**:	• Refer to MD

REFERENCES

1. Robert Hatcher et al., *Contraceptive Technology,* 21st ed., Ardent Media, Inc., New York, 2018. (Current)

2. Joellen Hawkins et al., *Protocols for Nurse Practitioners in Gynecologic Settings,* 11th ed., Springer Publishing Co., New York, 2015.

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STANDARD APRN PROTOCOL FOR COLPOSCOPY

Only a Nurse Practitioner or Certified Nurse Midwife (NP/CNM) provider who has completed an approved course on colposcopy and the associated preceptorship under a clinician experienced in colposcopy is eligible to practice under the Standard APRN Protocol for Colposcopy. Documentation of course completion/certificate must be on file in the NP/CNM's personnel folder. The delegating physician for the protocol must be available to be reached for emergency treatment and backup in each clinic where colposcopy is performed.

DEFINITION

Colposcopy is the real-time visualization and assessment of uterine cervix for the detection of cervical intraepithelial neoplasia and cervical cancer. Colposcopy uses a colposcope, which provides magnification and illumination. This instrument allows visualization of the cervix magnified several times normal size making it possible to view structures invisible to the naked eye. While colposcopy may be a valuable tool in the evaluation of multiple other situations (vulvar or vaginal evaluation, high resolution anoscopy, assessment of sexual assault victims), this protocol will focus on colposcopy for cervical cancer prevention and assessment for non-pregnant individuals.

ETIOLOGY

Colposcopy is used in the evaluation of abnormal or inconclusive cervical cancer screening tests. Colposcopy aids the identification of cervical precancers that can be treated, and it allows for conservative management of abnormalities unlikely to progress.

SUBJECTIVE

1. Abnormal cervical cytology, HPV testing, or pathology

2. Suspicious lesion on visual exam; large or friable cervical lesions may warrant immediate consultation with MD

3. Usually, asymptomatic

OBJECTIVE

1. Pregnancy test, if indicated, is negative.
2. Indications for colposcopy:
   a. Abnormal cervical cancer screening tests and cancer precursor recommendations from the 2019 American Society for Colposcopy and Cervical Pathology (ASCCP) consensus guidelines.

NOTE: The 2019 ASCCP guidelines reveal the evolution about the understanding of cervical cancer prevention. The guidelines offer recommendations that include an individual's risk for high grade disease and cancer. This provides decreased unnecessary intervention, but also increases the complexity of the recommendations. A link to the full document is in the references to this protocol. There is also an app for a web-based application to help guide clinical care decisions.

ASSESSMENT

Colposcopic assessment of cervix with or without cervical or endocervical biopsies to confirm or identify discrepancy with pap smear findings.

PLAN

THERAPEUTIC

1. Clinicians should follow the ASCCP Colposcopy Standards as well as those outlined in the Georgia Department of Public Health Breast and Cervical Cancer Prevention Cervical Procedure Manual.

2. A comprehensive colposcopy examination should include visualization of vulvar and vaginal areas and documentation of cervix visibility, squamocolumnar junction visibility, presence of acetowhitening, presence of a lesion(s), lesion(s) visibility, size and location of lesions, vascular changes, other features of lesion(s), and colposcopic impression.

3. Standard documentation should also be followed.

4. Minimum criteria for reporting include squamocolumnar junction visibility, presence of acetowhitening, presence of a lesion(s), and colposcopic impression.

PATIENT EDUCATION/COUNSELING

1. Reinforce pertinent information with handouts.
2. Explain all procedures to patient.
3. Obtain informed consent prior to procedure
4. Discuss findings, implications, and treatment rationale; allay anxiety.
5. Reassure that minimal bleeding and cramping following a colposcopy is not unusual.
6. Instruct to go to ER for heavy vaginal bleeding after hours or to call the health department for instructions during regular business hours.

FOLLOW-UP

1. Return to clinic for results in 1-2 weeks. Manage as per the ASCCP 2019 Guidelines.

CONSULTATION/REFERRAL

1. Pregnancy
2. Unsatisfactory colposcopy
3. High grade lesion on biopsy
4. Positive ECC results
5. Cervical biopsy results that do not correlate well with Pap smear results (e.g. Pap ASCUS or LGSIL and Biopsy = CIN3 or CIS)
6. Adenocarcinoma or Abnormal Glandular Cells, favor Neoplasia on Pap smear
7. Any indication for diagnostic excisional procedure per the ASCCP management guidelines
8. Abnormal vulvar or vaginal lesion found on exam
9. Absence of cervix with abnormal screening
10. Large or friable cervical lesion utilize shared decision making with delegating MD to determine if biopsy should be completed by APRN trained in colposcopy or immediate referral to MD for biopsy.

REFERENCES

1. Perkins, Rebecca B. MD, MSc1; Guido, Richard S. MD2; Castle, Philip E. PhD3; Chelmow, David MD4; Einstein, Mark H. MD, MS5; Garcia, Francisco MD, MPH6; Huh, Warner K. MD7; Kim, Jane J. PhD, MSc8; Moscicki, Anna-Barbara MD9; Nayar, Ritu MD10; Saraiya, Mona MD, MPH11; Sawaya, George F. MD12; Wentzensen, Nicolas MD, PhD, MS13; Schiffman, Mark MD, MPH14; for the 2019 ASCCP Risk-Based Management Consensus Guidelines Committee 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors, Journal of Lower Genital Tract Disease: April 2020 - Volume 24 - Issue 2 - p 102-131doi: 10.1097/LGT.0000000000000525 Link to full document: https://journals.lww.com/jlgtd/Fulltext/2020/04000/2019_ASCCP_Risk_Based_Management_Consensus.3.aspx

2. Link to web-based algorithms: https://app.asccp.org

3. Khan, Michelle J. MD, MPH1; Werner, Claudia L. MD2; Darragh, Teresa M. MD3; Guido, Richard S. MD4; Mathews, Cara MD5; Moscicki, Anna-Barbara MD6; Mitchell, Martha M. ARNP7; Schiffman, Mark MD8; Wentzensen, Nicolas MD8; Massad, L. Stewart MD9; Mayeaux, E.J. Jr MD10; Waxman, Alan G. MD, MPH11; Conageski, Christine MD12; Einstein, Mark H. MD13; Huh, Warner K. MD14 ASCCP Colposcopy Standards: Role of Colposcopy, Benefits, Potential Harms, and Terminology for Colposcopic Practice, Journal of Lower Genital Tract Disease: October 2017 - Volume 21 - Issue 4 - p 223-229doi: 10.1097/LGT.0000000000000338

4. Georgia Department of Public Health Breast and Cervical Cancer Program Policy and Procedure Manual, Current Edition.

STANDARD APRN PROTOCOL FOR ENDOMETRIAL BIOPSY

Only a Nurse Practitioner or Certified Nurse Midwife (NP/CNM) provider who has completed an approved course on colposcopy and the associated preceptorship under a clinician experienced in colposcopy is eligible to practice under the Standard APRN Protocol for Colposcopy. Documentation of course completion/certificate must be on file in the NP/CNM's personnel folder. The delegating physician for the protocol must be available to be reached for emergency treatment and backup in each clinic where colposcopy is performed.

DEFINITION

Endometrial biopsy, also called endometrial sampling, is a method of obtaining a sample of the non-pregnant uterine lining for purposes of cytologic and histologic examination. The specimen obtained is glandular epithelium.

NOTE: Endometrial biopsy is often used for the evaluation of abnormal bleeding in women 35 and older or younger who are at risk for endometrial neoplasia (e.g. prolonged anovulatory cycles) and for postmenopausal bleeding. However, for the purposes of these protocols, endometrial biopsy will be used when appropriate according to the American Society of Colposcopy and Cervical Pathology (ASCCP) guidelines.

INDICATIONS

1. Atypical endometrial cells on pap smear in women of any age
2. Atypical glandular cells on pap smear for women 35 years and older or for those under 35 years at increased risk of endometrial neoplasia (e.g. abnormal bleeding, obesity, chronic anovulation)
3. Benign endometrial cells on a pap smear for a postmenopausal patient

SUBJECTIVE

1. Patient may present with:
   a. Atypical Glandular Cells on a pap smear
   b. Atypical Endometrial Cells on a pap smear
   c. Benign endometrial cells on a pap smear for a postmenopausal patient

OBJECTIVE

1. Pregnancy test, if indicated, is negative
2. Speculum exam to assess for active cervical/vaginal infection
3. Bimanual examination to determine uterine position, flexion, size, shape and/or pain, rule out abnormalities of uterus or adnexa**.**

NOTE: BP should be taken at all visits

CONTRAINDICATIONS

1. Absolute:
   a. Pregnancy
   b. Active vaginal, cervical, uterine, or pelvic infection

2. Relative:
   a. Bleeding diathesis, coagulopathy or use of anticoagulant therapy
   b. Morbid obesity
   c. Cervical stenosis

PLAN

THERAPEUTIC

1. Cleanse cervix with iodine or other available prep

2. Place tenaculum on anterior lip of cervix

3. Insert pipelle gently through cervix until reaching the fundus. Note the depth of the sound.

4. Pull back on the piston of the pipelle to create suction.

5. Rotate the pipelle 360-degrees to reach all quadrants of the endometrium.

6. Transfer sample into formalin container. A second pass may be performed, if necessary, to obtain adequate tissue sample.

PATIENT EDUCATION/COUNSELING

1. Explain the procedure and possible complications

2. Obtain informed consent prior to procedure

3. Take over-the-counter ibuprofen or acetaminophen (follow package instructions)
4. Instruct patient to notify the clinic or go to the emergency room if any of the following SIGNS AND SYMPTOMS OF COMPLICATION OCCUR:
   a. severe cramping or pelvic pain
   a. heavy bleeding
   b. fever
   c. foul-smelling vaginal discharge

5. Advise that spotting may be experienced for 1-2 days.

FOLLOW UP

1. Schedule appointment for return visit to the clinic in two weeks
2. Notify M.D. of biopsy results and obtain recommendations
3. Review results and recommendations with patient at the return visit and assist in arranging follow-up as indicated

CONSULTATION/REFERRAL

1. Abnormal endometrial tissue identified on biopsy
2. Pregnancy
3. Bleeding diathesis, coagulopathy or use of anticoagulant therapy
4. Active vaginal, cervical, uterine or pelvic infection
5. Cervical stenosis
6. Morbid obesity
7. Women with contraindications to procedure
8. Notify M.D. of biopsy results and obtain recommendations
9. Review results and recommendations with patient at the return visit and assist in arranging follow-up as indicated

REFERENCES

1. Perkins, Rebecca B. MD, MSc1; Guido, Richard S. MD2; Castle, Philip E. PhD3; Chelmow, David MD4; Einstein, Mark H. MD, MS5; Garcia, Francisco MD, MPH6; Huh, Warner K. MD7; Kim, Jane J. PhD, MSc8; Moscicki, Anna-Barbara MD9; Nayar, Ritu MD10; Saraiya, Mona MD, MPH11; Sawaya, George F. MD12; Wentzensen, Nicolas MD, PhD, MS13; Schiffman, Mark MD, MPH14; for the 2019 ASCCP Risk-Based Management Consensus Guidelines Committee 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors, Journal of Lower Genital Tract Disease: April 2020 - Volume 24 - Issue 2 - p 102-131doi: 10.1097/LGT.0000000000000525

2. Will AJ, Sanchack KE. Endometrial Biopsy. [Updated 2020 Oct 30]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK541135/

APPENDIX A: CONTRACEPTIVES

Category	Brand Name	Label Name	Generic Name	Estrogen	mcg	Progestin	mg	NDC	Package Size Qty	Manufacturer Name
Monophasic LoDose										
Monophasic LoDose	MICROGESTIN FE	MICROGESTIN FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	51862001201	28	MAYNE PHARMA
Monophasic LoDose	MICROGESTIN FE	MICROGESTIN FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	51862001206	28	MAYNE PHARMA
Monophasic LoDose	BLISOVI FE	BLISOVI FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086511	28	LUPIN
Monophasic LoDose	BLISOVI FE	BLISOVI FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086513	28	LUPIN
Monophasic LoDose	BLISOVI FE	BLISOVI FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086573	28	LUPIN
Monophasic LoDose	BLISOVI 24 FE	BLISOVI 24 FE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086411	28	LUPIN
Monophasic LoDose	BLISOVI 24 FE	BLISOVI 24 FE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086413	28	LUPIN
Monophasic LoDose	BLISOVI 24 FE	BLISOVI 24 FE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180086473	28	LUPIN
Monophasic LoDose	LARIN 24 FE	LARIN 24 FE 1 MG-20 MCG TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	16714041603	28	NORTHSTAR RX LL
Monophasic LoDose	TAYTULLA	TAYTULLA 1 MG-20 MCG CAPSULE	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	00023586230	28	ALLERGAN
Monophasic LoDose	NORETHINDRON-ETHINYL ESTRADIOL	NORETHIND-ETH ESTRAD 1-0.02 MG	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	68462013281	21	GLENMARK
Monophasic LoDose	NORETHINDRON-ETHINYL ESTRADIOL	NORETHIND-ETH ESTRAD 1-0.02 MG	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	00378728053	21	MYLAN
Monophasic LoDose	NORETHINDRONE-E.ESTRADIOL-IRON	NORETH-EE-FE 1-0.02(21)-75 TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	00378728353	28	MYLAN
Monophasic LoDose	MICROGESTIN 24 FE	MICROGESTIN 24 FE 1 MG-20 MCG	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	51862064803	28	MAYNE PHARMA
Monophasic LoDose	MICROGESTIN	MICROGESTIN 21 1-20 TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	51862086806	21	MAYNE PHARMA
Monophasic LoDose	JUNEL FE 24	JUNEL FE 24 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	00093532862	28	TEVA
Monophasic LoDose	JUNEL	JUNEL 1 MG-20 MCG TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	00555902542	21	TEVA
Monophasic LoDose	LARIN FE	LARIN FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	16714040604	28	NORTHSTAR RX LL
Monophasic LoDose	MICROGESTIN	MICROGESTIN 21 1-20 TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	51862000706	21	MAYNE PHARMA
Monophasic LoDose	LARIN	LARIN 21 1-20 TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	16714040803	21	NORTHSTAR RX LL
Monophasic LoDose	JUNEL FE	JUNEL FE 1 MG-20 MCG TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	00555902658	28	TEVA
Monophasic LoDose	NORETHINDRONE-E.ESTRADIOL-IRON	NORETH-EE-FE 1-0.02(24)-75 CAP	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	59762159905	28	GREENSTONE
Monophasic LoDose	NORETHINDRONE-E.ESTRADIOL-IRON	NORETH-EE-FE 1-0.02(24)-75 CHW	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	70700010185	28	XIROMED, LLC
Monophasic LoDose	GEMMILY	GEMMILY 1 MG-20 MCG CAPSULE	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	70700015285	28	XIROMED, LLC
Monophasic LoDose	MERZEE	MERZEE 1 MG-20 MCG CAPSULE	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	71225013001	28	SLAYBACK PHARMA
Monophasic LoDose	LOESTRIN FE	LOESTRIN FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	51285012570	28	TEVA
Monophasic LoDose	LOESTRIN	LOESTRIN 21 1-20 TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	20	norethindrone acetate	1	51285013197	21	TEVA
Monophasic LoDose	TARINA 24 FE	TARINA 24 FE 1 MG-20 MCG TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	50102022423	28	AFAXYS
Monophasic LoDose	TARINA FE 1-20 EQ	TARINA FE 1-20 EQ TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	50102022823	28	AFAXYS
Monophasic LoDose	AUBRA	AUBRA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	50102012048	28	AFAXYS
Monophasic LoDose	AUBRA EQ	AUBRA EQ-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	50102022023	28	AFAXYS
Monophasic LoDose	LESSINA	LESSINA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	00555901467	28	TEVA
Monophasic LoDose	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.1-0.02 MG	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	68180085411	28	LUPIN
Monophasic LoDose	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.1-0.02 MG	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	68180085413	28	LUPIN
Monophasic LoDose	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.1-0.02 MG	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	68180085473	28	LUPIN
Monophasic LoDose	LARISSIA	LARISSIA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	69238153106	28	AMNEAL
Monophasic LoDose	VIENVA	VIENVA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	70700011885	28	XIROMED, LLC
Monophasic LoDose	AVIANE	AVIANE-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	00555904558	28	TEVA
Monophasic LoDose	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.1-0.02 MG	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	00378728753	28	MYLAN
Monophasic LoDose	LUTERA	LUTERA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	51862002806	28	MAYNE PHARMA
Monophasic LoDose	SRONYX	SRONYX 0.10-0.02 MG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	51862054506	28	MAYNE PHARMA
Monophasic LoDose	FALMINA	FALMINA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.1	16714035904	28	NORTHSTAR RX LL
Monophasic LoDose	DOLISHALE	DOLISHALE 90-20 MCG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.09	50742065928	28	INGENUS PHARMAC
Monophasic LoDose	GIANVI	GIANVI 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	00093542362	28	TEVA
Monophasic LoDose	LORYNA	LORYNA 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	70700011485	28	XIROMED, LLC
Monophasic LoDose	YAZ	YAZ 28 TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	50419040503	28	BAYER
Monophasic LoDose	BEYAZ	BEYAZ 28 TABLET	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	50419040703	28	BAYER
Monophasic LoDose	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.02 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	75834011629	28	NIVAGEN PHARMAC
Monophasic LoDose	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.02 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	00378729953	28	MYLAN
Monophasic LoDose	NIKKI	NIKKI 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	68180088611	28	LUPIN
Monophasic LoDose	NIKKI	NIKKI 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	68180088613	28	LUPIN
Monophasic LoDose	NIKKI	NIKKI 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	68180088673	28	LUPIN
Monophasic LoDose	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.02 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	68462072029	28	GLENMARK
Monophasic LoDose	VESTURA	VESTURA 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	00093400062	28	TEVA
Monophasic LoDose	DROSPIRENONE-ETH ESTRA-LEVOMEF	DROSP-EE-LEVOMEF 3-0.02-0.451	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	68180089413	28	LUPIN
Monophasic LoDose	DROSPIRENONE-ETH ESTRA-LEVOMEF	DROSP-EE-LEVOMEF 3-0.02-0.451	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	68180089473	28	LUPIN

Monophasic LoDose	DROSPIRENONE-ETH ESTRA-LEVOMEF	DROSP-EE-LEVOMEF 3-0.02-0.451	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	00781407515	28	SANDOZ
Monophasic LoDose	TYDEMY	TYDEMY 3-0.03-0.451 MG TABLET	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	68180090413	28	LUPIN
Monophasic LoDose	TYDEMY	TYDEMY 3-0.03-0.451 MG TABLET	drospir/eth estra/levomefol ca	ethinyl estradiol	20	drospirenone	3	68180090473	28	LUPIN
Monophasic LoDose	JASMIEL	JASMIEL 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	50102024023	28	AFAXYS
Monophasic LoDose	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.02 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	59746076343	28	JUBILANT
Monophasic LoDose	GIANVI	GIANVI 3 MG-0.02 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	20	drospirenone	3	00093542358	28	
Monophasic LoDose	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	68180090211	28	LUPIN
Monophasic LoDose Chewables										
Monophasic LoDose Chewables	NORETHINDRONE-E.ESTRADIOL-IRON	NORETH-EE-FE 1-0.02(24)-75 CHW	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	52544005872	28	Teva
Monophasic LoDose Chewables	MIBELAS 24 FE	MIBELAS 24 FE CHEWABLE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180091111	28	LUPIN
Monophasic LoDose Chewables	MIBELAS 24 FE	MIBELAS 24 FE CHEWABLE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180091113	28	LUPIN
Monophasic LoDose Chewables	MIBELAS 24 FE	MIBELAS 24 FE CHEWABLE TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68180091173	28	LUPIN
Monophasic LoDose Chewables	CHARLOTTE 24 FE	CHARLOTTE 24 FE CHEWABLE TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68462085229	28	GLENMARK
Monophasic LoDose Chewables	MINASTRIN 24 FE	MINASTRIN 24 FE CHEWABLE TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	00430054050	28	TEVA
Monophasic LoDose Chewables	MELODETTA 24 FE	MELODETTA 24 FE CHEWABLE TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	69238103107	28	AMNEAL
Monophasic LoDose Chewables	HAILEY 24 FE	HAILEY 24 FE 1 MG-20 MCG TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	20	norethindrone acetate	1	68462073129	28	GLENMARK
Monophasic LoDose Chewables	LAYOLIS FE	LAYOLIS FE CHEWABLE TABLET	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	52544006431	28	Teva
Monophasic LoDose Chewables	NORETHIN-ETH ESTRA-FERROUS FUM	NORETHIN-ESTRA-FE 0.8-0.025 MG	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	00378730853	28	MYLAN
Monophasic LoDose Chewables	HAILEY FE	HAILEY FE 1-20 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	25	norethindrone acetate	0.8	68462041929	28	GLENMARK
Monophasic LoDose Chewables	GENERESS FE	GENERESS FE CHEWABLE TABLET	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	00023603003	28	ALLERGAN
Monophasic LoDose Chewables	KAITLIB FE	KAITLIB FE 0.8-0.025MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	68180090311	28	LUPIN
Monophasic LoDose Chewables	KAITLIB FE	KAITLIB FE 0.8-0.025MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	68180090313	28	LUPIN
Monophasic LoDose Chewables	KAITLIB FE	KAITLIB FE 0.8-0.025MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	25	norethindrone acetate	0.8	68180090373	28	LUPIN
Monophasic Regular										
Monophasic Regular	BLISOVI FE	BLISOVI FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	68180086611	28	LUPIN
Monophasic Regular	BLISOVI FE	BLISOVI FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	68180086613	28	LUPIN
Monophasic Regular	LARIN FE	LARIN FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	16714040504	28	NORTHSTAR RX LL
Monophasic Regular	LARIN	LARIN 1.5 MG-30 MCG TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	16714040703	21	NORTHSTAR RX LL
Monophasic Regular	MICROGESTIN	MICROGESTIN 21 1.5-30 TAB	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	51862027906	21	MAYNE PHARMA
Monophasic Regular	MICROGESTIN FE	MICROGESTIN FE 1.5-30 TAB	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	51862029206	28	MAYNE PHARMA
Monophasic Regular	JUNEL FE	JUNEL FE 1.5 MG-30 MCG TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	00555902858	28	TEVA
Monophasic Regular	NORETHINDRONE-E.ESTRADIOL-IRON	NORETH-EE-FE 1.5-0.03MG(21)-75	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	00378728853	28	MYLAN
Monophasic Regular	JUNEL	JUNEL 1.5 MG-30 MCG TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	00555902742	21	TEVA
Monophasic Regular	NORETHINDRON-ETHINYL ESTRADIOL	NORETHIN-EE 1.5-0.03 MG(21) TB	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	00378727453	21	MYLAN
Monophasic Regular	HAILEY FE	HAILEY FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	68462050329	28	GLENMARK
Monophasic Regular	LOESTRIN FE	LOESTRIN FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	51285012870	28	TEVA
Monophasic Regular	LOESTRIN	LOESTRIN 21 1.5-30 TABLET	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	51285012797	21	TEVA
Monophasic Regular	HAILEY	HAILEY 21 1.5 MG-30 MCG TAB	norethindrone ac-eth estradiol	ethinyl estradiol	30	norethindrone acetate	1.5	68462050481	21	GLENMARK
Monophasic Regular	BLISOVI FE	BLISOVI FE 1.5-30 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	30	norethindrone acetate	1.5	68180086673	28	LUPIN
Monophasic Regular	PIRMELLA	PIRMELLA 1-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	68180089311	28	LUPIN
Monophasic Regular	PIRMELLA	PIRMELLA 1-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	68180089313	28	LUPIN
Monophasic Regular	PIRMELLA	PIRMELLA 1-35 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	68180089373	28	LUPIN
Monophasic Regular	DASETTA	DASETTA 1-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	16714034804	28	NORTHSTAR RX LL
Monophasic Regular	ALYACEN	ALYACEN 1-35 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	68462039429	28	GLENMARK
Monophasic Regular	NORTREL	NORTREL 1-35 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	00555901058	28	TEVA
Monophasic Regular	NORTREL	NORTREL 1-35 21 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	00555900942	21	TEVA
Monophasic Regular	CYCLAFEM	CYCLAFEM 1-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	00603752117	28	PAR PHARMA
Monophasic Regular	CYCLAFEM	CYCLAFEM 1-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	1	00603752149	28	PAR PHARMA
Monophasic Regular	VYFEMLA	VYFEMLA 0.4 MG-0.035 MG TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.4	68180087513	28	LUPIN
Monophasic Regular	VYFEMLA	VYFEMLA 0.4 MG-0.035 MG TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.4	68180087573	28	LUPIN
Monophasic Regular	PHILITH	PHILITH 0.4-0.035 MG TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.4	16714034704	28	NORTHSTAR RX LL
Monophasic Regular	BRIELLYN	BRIELLYN TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.4	68462031629	28	GLENMARK
Monophasic Regular	BALZIVA	BALZIVA 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.4	00555903458	28	TEVA
Monophasic Regular	VYFEMLA	VYFEMLA 0.4 MG-0.035 MG TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone	0.4	68180087511	28	LUPIN
Monophasic Regular	WERA	WERA 0.5/0.035 MG 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.5	16714037003	28	NORTHSTAR RX LL
Monophasic Regular	NECON	NECON 0.5-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.5	51862089203	28	MAYNE PHARMA
Monophasic Regular	NECON	NECON 0.5-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.5	51862031803	28	MAYNE PHARMA
Monophasic Regular	NORTREL	NORTREL 0.5-35-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35	norethindrone acetate	0.5	00555900867	28	TEVA

Monophasic Regular	ICLEVIA	ICLEVIA 0.15 MG-0.03 MG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	65862086583	91	AUROBINDO
Monophasic Regular	LILLOW	LILLOW-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	69238155406	28	AMNEAL
Monophasic Regular	PORTIA	PORTIA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	00555902058	28	TEVA
Monophasic Regular	ALTAVERA	ALTAVERA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	70700011685	28	XIROMED, LLC
Monophasic Regular	MARLISSA	MARLISSA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68462038829	28	GLENMARK
Monophasic Regular	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.15-0.03	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68180084311	91	LUPIN
Monophasic Regular	CHATEAL EQ	CHATEAL EQ-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	50102023023	28	AFAXYS
Monophasic Regular	LEVORA-28	LEVORA-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	51862009706	28	MAYNE PHARMA
Monophasic Regular	KURVELO	KURVELO-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68180084411	28	LUPIN
Monophasic Regular	KURVELO	KURVELO-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68180084413	28	LUPIN
Monophasic Regular	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.15-0.03	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	00378655053	28	MYLAN
Monophasic Regular	KURVELO	KURVELO-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68180084473	28	LUPIN
Monophasic Regular	BALCOLTRA	BALCOLTRA TABLET	levonorgest/eth.estradiol/iron	ethinyl estradiol	20	levonorgestrel	0.1	75854060203	28	AVION PHARMACEU
Monophasic Regular	CYRED EQ	CYRED EQ 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	50102025423	28	AFAXYS
Monophasic Regular	EMOQUETTE	EMOQUETTE 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	00254203373	28	PAR PHARMA
Monophasic Regular	EMOQUETTE	EMOQUETTE 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	00254203380	28	PAR PHARMA
Monophasic Regular	ISIBLOOM	ISIBLOOM 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	70700011385	28	XIROMED, LLC
Monophasic Regular	APRI	APRI 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	00555904358	28	TEVA
Monophasic Regular	RECLIPSEN	RECLIPSEN 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	00093330416	28	TEVA
Monophasic Regular	DESOGESTREL-ETHINYL ESTRADIOL	DESOGEST-ETH ESTRA 0.15-0.03MG	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	51862051403	28	MAYNE PHARMA
Monophasic Regular	JULEBER	JULEBER 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	16714046404	28	NORTHSTAR RX LL
Monophasic Regular	ENSKYCE	ENSKYCE 28 TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	68180089113	28	LUPIN
Monophasic Regular	ENSKYCE	ENSKYCE 28 TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	30	desogestrel	0.15	68180089173	28	LUPIN
Monophasic Regular	MONO-LINYAH	MONO-LINYAH 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	16714036004	28	NORTHSTAR RX LL
Monophasic Regular	MILI	MILI 0.25-0.035 MG TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	65862077685	28	AUROBINDO
Monophasic Regular	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-ETHIN ESTRA 0.25-0.035 MG	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	68180084011	28	LUPIN
Monophasic Regular	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-ETHIN ESTRA 0.25-0.035 MG	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	68180084013	28	LUPIN
Monophasic Regular	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-ETHIN ESTRA 0.25-0.035 MG	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	68180084073	28	LUPIN
Monophasic Regular	FEMYNOR	FEMYNOR 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	69238155106	28	AMNEAL
Monophasic Regular	PREVIFEM	PREVIFEM TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	00254202980	28	PAR PHARMA
Monophasic Regular	VYLIBRA	VYLIBRA 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	50102023511	28	AFAXYS
Monophasic Regular	VYLIBRA	VYLIBRA 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	50102023513	28	AFAXYS
Monophasic Regular	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-ETHIN ESTRA 0.25-0.035 MG	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	68462030929	28	GLENMARK
Monophasic Regular	YASMIN 28	YASMIN 28 TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	50419040203	28	BAYER
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	60505418303	28	APOTEX
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	68180090213	28	LUPIN
Monophasic Regular	SYEDA	SYEDA 28 TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	70700011585	28	XIROMED, LLC
Monophasic Regular	OCELLA	OCELLA 3 MG-0.03 MG TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	00555913167	28	TEVA
Monophasic Regular	SAFYRAL	SAFYRAL TABLET	drospir/eth estra/levomefol ca	ethinyl estradiol	30	drospirenone	3	50419040303	28	BAYER
Monophasic Regular	DROSPIRENONE-ETH ESTRA-LEVOMEF	DROSP-EE-LEVOMEF 3-0.03-0.451	drospir/eth estra/levomefol ca	ethinyl estradiol	30	drospirenone	3	00781410315	28	SANDOZ
Monophasic Regular	ZARAH	ZARAH TABLET	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	51862003603	28	MAYNE PHARMA
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	75834011529	28	NIVAGEN PHARMAC
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	31722094531	28	CAMBER
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	68462073329	28	GLENMARK
Monophasic Regular	DROSPIRENONE-ETHINYL ESTRADIOL	DROSPIRENONE-EE 3-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	30	drospirenone	3	00378730053	28	MYLAN
Monophasic Regular	ZUMANDIMINE	ZUMANDIMINE 3 MG-0.03 MG TAB	ethinyl estradiol/drospirenone	ethinyl estradiol	35	drospirenone	0.25	59651003085	28	AUROBINDO
Monophasic Regular	ESTARYLLA	ESTARYLLA 0.25-0.035 MG TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	70700011985	28	XIROMED, LLC
Monophasic Regular	SPRINTEC	SPRINTEC 28 DAY TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	00555901658	28	TEVA
Monophasic Regular	NYMYO	NYMYO 0.25-0.035 MG (28) TAB	norgestimate-ethinyl estradiol	ethinyl estradiol	35	norgestimate	0.25	51862064506	28	MAYNE PHARMA
Monophasic Regular	KELNOR 1-35	KELNOR 1-35 28 TABLET	ethynodiol d-ethinyl estradiol	ethinyl estradiol	35	ETHYNODIOL DIACETATE	1	00555906458	28	TEVA
Monophasic Regular	ETHYNODIOL-ETHINYL ESTRADIOL	ETHYNODIOL-ETH ESTRA 1MG-35MCG	ethynodiol d-ethinyl estradiol	ethinyl estradiol	35	ETHYNODIOL DIACETATE	1	00378730753	28	MYLAN
Monophasic Regular	ZOVIA 1-35E	ZOVIA 1-35E TABLET	ethynodiol d-ethinyl estradiol	ethinyl estradiol	35	ETHYNODIOL DIACETATE	1	51862026006	28	MAYNE PHARMA
Monophasic Regular	NEXTSTELLIS	NEXTSTELLIS 3-14.2 MG TABLET	drospirenone/estetrol	estetrol	14.2	drospirenone	3	51862025801	28	MAYNE PHARMA
Monophasic Regular Chewables										
Monophasic Chewables	WYMZYA FE	WYMZYA FE 0.4-0.035 MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	35	norethindrone acetate	0.4	68180087311	28	LUPIN
Monophasic Chewables	WYMZYA FE	WYMZYA FE 0.4-0.035 MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	35	norethindrone acetate	0.4	68180087313	28	LUPIN
Monophasic Chewables	NORETHIN-ETH ESTRA-FERROUS FUM	NORET-ESTR-FE 0.4-0.035(21)-75	noreth-ethinyl estradiol/iron	ethinyl estradiol	35	norethindrone acetate	0.4	00378729753	28	MYLAN
Monophasic Chewables	WYMZYA FE	WYMZYA FE 0.4-0.035 MG CHEW TB	noreth-ethinyl estradiol/iron	ethinyl estradiol	35	norethindrone acetate	0.4	68180087373	28	LUPIN

Monophasic HiDose										
Monophasic HiDose	KELNOR 1-50	KELNOR 1-50 TABLET	ethynodiol d-ethinyl estradiol	ethinyl estradiol	50	ethynodiol diacetate	1	00093807316	28	TEVA
Monophasic HiDose	ETHYNODIOL-ETHINYL ESTRADIOL	ETHYNODIOL-ETH ESTRA 1MG-50MCG	ethynodiol d-ethinyl estradiol	ethinyl estradiol	50	ethynodiol diacetate	1	00378730653	28	MYLAN
Monophasic, Extended Cycle										
Monophasic, Extended Cycle	ZOVIA 1-35	ZOVIA 1-35 TABLET	ethynodiol d-ethinyl estradiol	ethinyl estradiol	35	ethynodiol diacetate	1	51862089406	28	MAYNE PHARMA
Monophasic, Extended Cycle	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.15-0.03	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68462067295	91	GLENMARK
Monophasic, Extended Cycle	JOLESSA	JOLESSA 0.15 MG-0.03 MG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	00555912366	91	TEVA
Monophasic, Extended Cycle	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.15-0.03	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	68180084313	91	LUPIN
Monophasic, Extended Cycle	SETLAKIN	SETLAKIN 0.15 MG-0.03 MG TAB	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	16714036603	91	NORTHSTAR RX LL
Monophasic, Extended Cycle	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD 0.15-0.03	levonorgestrel/ethin.estradiol	ethinyl estradiol	30	levonorgestrel	0.15	00378728153	91	MYLAN
Monophasic, Extended Cycle	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRA 0.09-0.02 MG	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.09	68462063729	28	GLENMARK
Monophasic, Extended Cycle	AMETHYST	AMETHYST 90-20 MCG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.09	52544029528	28	Teva
Monophasic, Extended Cycle	DOLISHALE	DOLISHALE 90-20 MCG TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	20	levonorgestrel	0.09	50742065984	28	INGENUS PHARMAC
Biphasic LoDose, Extended Cycle										
Biphasic LoDose, Extended Cycle	LOSEASONIQUE	LOSEASONIQUE TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	51285009287	91	TEVA
Biphasic LoDose, Extended Cycle	AMETHIA LO	AMETHIA LO TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	51862004591	91	MAYNE PHARMA
Biphasic LoDose, Extended Cycle	LEVONORG-ETH ESTRAD ETH ESTRAD	LEVONOR-E ESTRAD 0.1-0.02-0.01	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	68180084811	91	LUPIN
Biphasic LoDose, Extended Cycle	LEVONORG-ETH ESTRAD ETH ESTRAD	LEVONOR-E ESTRAD 0.1-0.02-0.01	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	68180084813	91	LUPIN
Biphasic LoDose, Extended Cycle	CAMRESE LO	CAMRESE LO TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	00093614882	91	TEVA
Biphasic LoDose, Extended Cycle	LEVONORG-ETH ESTRAD ETH ESTRAD	LEVONOR-E ESTRAD 0.1-0.02-0.01	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	00378728490	91	MYLAN
Biphasic LoDose, Extended Cycle	LOJAIMIESS	LOJAIMIESS 0.1-0.02-0.01 TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/10	levonorgestrel	0.1/0	70700012487	91	XIROMED, LLC
Biphasic										
Biphasic	LO LOESTRIN FE	LO LOESTRIN FE 1-10 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	10/10	norethindrone acetate	1.0/0	00430042014	28	TEVA
Biphasic	DESOGESTR-ETH ESTRAD ETH ESTRA	DESOGESTR-ETH ESTRAD ETH ESTRA	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	00378729653	28	MYLAN
Biphasic	VIORELE	VIORELE 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	68462031829	28	GLENMARK
Biphasic	KARIVA	KARIVA 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	00555905058	28	TEVA
Biphasic	PIMTREA	PIMTREA 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	16714040404	28	NORTHSTAR RX LL
Biphasic	AZURETTE	AZURETTE 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	51862007206	28	MAYNE PHARMA
Biphasic	BEKYREE	BEKYREE 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	68180087913	28	LUPIN
Biphasic	VOLNEA	VOLNEA 0.15-0.02-0.01 MG TAB	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	70700012285	28	XIROMED, LLC
Biphasic	MIRCETTE	MIRCETTE 28 DAY TABLET	desog-e.estradiol/e.estradiol	ethinyl estradiol	20/0/10	desogestrel	0.15/0/.01	51285012058	28	TEVA
Biphasic, Extended Cycle										
Biphasic, Extended Cycle	SEASONIQUE	SEASONIQUE 0.15-0.03-0.01 TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	51285008787	91	TEVA
Biphasic, Extended Cycle	CAMRESE	CAMRESE 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	00093313482	91	TEVA
Biphasic, Extended Cycle	JAIMIESS	JAIMIESS 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	70700012387	91	XIROMED, LLC
Biphasic, Extended Cycle	DAYSEE	DAYSEE 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	68180084611	91	LUPIN
Biphasic, Extended Cycle	DAYSEE	DAYSEE 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	68180084613	91	LUPIN
Biphasic, Extended Cycle	AMETHIA	AMETHIA 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	51862004791	91	MAYNE PHARMA
Biphasic, Extended Cycle	ASHLYNA	ASHLYNA 0.15-0.03-0.01 MG TAB	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	68462064693	91	GLENMARK
Biphasic, Extended Cycle	LEVONORG-ETH ESTRAD ETH ESTRAD	LEVONO-E ESTRAD 0.15-0.03-0.01	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	30/10	levonorgestrel	0.15/0	00378728590	91	MYLAN
Triphasic Lo										
Triphasic Lo	TRI-LO-MARZIA	TRI-LO-MARZIA TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	68180083713	28	LUPIN
Triphasic Lo	TRI-LO-MARZIA	TRI-LO-MARZIA TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	68180083773	28	LUPIN
Triphasic Lo	TRI-LO-ESTARYLLA	TRI-LO-ESTARYLLA TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	70700012085	28	XIROMED, LLC
Triphasic Lo	TRI-LO-SPRINTEC	TRI-LO-SPRINTEC TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	00093214062	28	TEVA
Triphasic Lo	TRI-VYLIBRA LO	TRI-VYLIBRA LO TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	50102023113	28	AFAXYS
Triphasic	TRI-LO-MARZIA	TRI-LO-MARZIA TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	25/25/25	norgestimate	0.18/0.215/0.25	68180083711	28	LUPIN
Triphasic										
Triphasic	CAZIANT	CAZIANT 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	25/25/25	desogestrel	0.1/0.125/0.15	51862023803	28	MAYNE PHARMA
Triphasic	VELIVET	VELIVET 28 DAY TABLET	desogestrel-ethinyl estradiol	ethinyl estradiol	25/25/25	desogestrel	0.1/0.125/0.15	00555905167	28	TEVA
Triphasic	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-EE 0.18-0.215-0.25/0.035	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	68462056529	28	GLENMARK
Triphasic	TRI-ESTARYLLA	TRI-ESTARYLLA TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	70700012185	28	XIROMED, LLC
Triphasic	TRI FEMYNOR	TRI FEMYNOR 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	69238160706	28	AMNEAL
Triphasic	TRI-MILI	TRI-MILI 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	65862077785	28	AUROBINDO
Triphasic	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-EE 0.18-0.215-0.25/0.035	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	68180083811	28	LUPIN
Triphasic	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-EE 0.18-0.215-0.25/0.035	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	68180083813	28	LUPIN
Triphasic	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-EE 0.18-0.215-0.25/0.035	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	68180083873	28	LUPIN

Triphasic	TRI-SPRINTEC	TRI-SPRINTEC TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	00555901858	28	TEVA
Triphasic	NORGESTIMATE-ETHINYL ESTRADIOL	NORG-EE 0.18-0.215-0.25/0.035	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	00378729353	28	MYLAN
Triphasic	TRI-LINYAH	TRI-LINYAH TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	16714036304	28	NORTHSTAR RX LL
Triphasic	TRI-VYLIBRA	TRI-VYLIBRA 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	50102023313	28	AFAXYS
Triphasic	TRI-NYMYO	TRI-NYMYO 28 TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	51862064606	28	MAYNE PHARMA
Triphasic	TRI-PREVIFEM	TRI-PREVIFEM TABLET	norgestimate-ethinyl estradiol	ethinyl estradiol	35/35/35	norgestimate	0.18/0.215/0.25	00254203080	28	PAR PHARMA
Triphasic	LEVONORGESTREL-ETH ESTRADIOL	LEVONOR-ETH ESTRAD TRIPHASIC	levonorgestrel/ethin.estradiol	ethinyl estradiol	30/40/30	levonorgestrel	0.05/0.075/0.125	68180085773	28	LUPIN
Triphasic	LEVONEST	LEVONEST-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30/40/30	levonorgestrel	0.05/0.075/0.125	16714034004	28	NORTHSTAR RX LL
Triphasic	ENPRESSE	ENPRESSE-28 TABLET	levonorgestrel/ethin.estradiol	ethinyl estradiol	30/40/31	levonorgestrel	0.05/0.075/0.126	00555904758	28	TEVA
Triphasic	TILIA FE	TILIA FE 28 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20/30/35	norethindrone	1/1/1	51862089603	28	MAYNE PHARMA
Triphasic	TRI-LEGEST FE	TRI-LEGEST FE-28 DAY TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20/30/35	norethindrone	1/1/1	00555903270	28	TEVA
Triphasic	ESTROSTEP FE	ESTROSTEP FE-28 TABLET	norethindrone-e.estradiol-iron	ethinyl estradiol	20/30/35	norethindrone	1/1/1	00430000531	28	TEVA
Triphasic	NORTREL	NORTREL 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	00555901258	28	TEVA
Triphasic	PIRMELLA	PIRMELLA 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	68180089211	28	LUPIN
Triphasic	PIRMELLA	PIRMELLA 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	68180089213	28	LUPIN
Triphasic	PIRMELLA	PIRMELLA 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	68180089273	28	LUPIN
Triphasic	ALYACEN	ALYACEN 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	68462055629	28	GLENMARK
Triphasic	DASETTA	DASETTA 7/7/7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	16714034604	28	NORTHSTAR RX LL
Triphasic	CYCLAFEM	CYCLAFEM 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	00603752517	28	PAR PHARMA
Triphasic	CYCLAFEM	CYCLAFEM 7-7-7-28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/0.75/1	00603752549	28	PAR PHARMA
Triphasic	LEENA	LEENA 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/1/0.5	51862047106	28	MAYNE PHARMA
Triphasic	ARANELLE	ARANELLE 28 TABLET	norethindrone-ethin. estradiol	ethinyl estradiol	35/35/35	norethindrone	0.5/1/0.5	00555906667	28	TEVA
Quadriphasic										
Quadriphasic, Extended Cycle	NATAZIA	NATAZIA 28 TABLET	estradiol valerate/dienogest	estradiol valerate	00/2000/2000/10	dienogest	2/2/0/0	50419040903	28	BAYER
Quadriphasic, Extended Cycle	QUARTETTE	QUARTETTE TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/0	levonorgestrel	0.15/0.15/0.15/0.01	51285043165	91	TEVA
Quadriphasic, Extended Cycle	QUARTETTE	QUARTETTE TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/0	levonorgestrel	0.15/0.15/0.15/0.01	51285043187	91	TEVA
Quadriphasic, Extended Cycle	RIVELSA	RIVELSA TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/0	levonorgestrel	0.15/0.15/0.15/0.01	00093603182	91	TEVA
Quadriphasic, Extended Cycle	FAYOSIM	FAYOSIM TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/0	levonorgestrel	0.15/0.15/0.15/0.01	68180086012	91	LUPIN
Quadriphasic, Extended Cycle	FAYOSIM	FAYOSIM TABLET	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/0	levonorgestrel	0.15/0.15/0.15/0.01	68180086011	91	LUPIN
Quadriphasic, Extended Cycle	LEVONORG-ETH ESTRAD ETH ESTRAD	LEVONORG 0.15MG-EE 20-25-30MCG	l-norgest/e.estradiol-e.estrad	ethinyl estradiol	20/25/30/10	levonorgestrel	0.15/0.15/0.15/0	00378731685	91	MYLAN
Progestin Only										
Progestin Only	JENCYCLA	JENCYCLA 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087711	28	LUPIN
Progestin Only	JENCYCLA	JENCYCLA 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087713	28	LUPIN
Progestin Only	JENCYCLA	JENCYCLA 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087773	28	LUPIN
Progestin Only	INCASSIA	INCASSIA 0.35 MG TABLET	norethindrone			norethindrone	0.35	65862092585	28	AUROBINDO
Progestin Only	SHAROBEL	SHAROBEL 0.35 MG TABLET	norethindrone			norethindrone	0.35	16714044104	28	NORTHSTAR RX LL
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	00378727253	28	MYLAN
Progestin Only	DEBLITANE	DEBLITANE 0.35 MG TABLET	norethindrone			norethindrone	0.35	16714044004	28	NORTHSTAR RX LL
Progestin Only	NORLYDA	NORLYDA 0.35 MG TABLET	norethindrone			norethindrone	0.35	69238158306	28	AMNEAL
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	68462030529	28	GLENMARK
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	00378729253	28	MYLAN
Progestin Only	ERRIN	ERRIN 0.35 MG TABLET	norethindrone			norethindrone	0.35	51862088603	28	MAYNE PHARMA
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087611	28	LUPIN
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087613	28	LUPIN
Progestin Only	HEATHER	HEATHER 0.35 MG TABLET	norethindrone			norethindrone	0.35	68462030329	28	GLENMARK
Progestin Only	NORETHINDRONE	NORETHINDRONE 0.35 MG TABLET	norethindrone			norethindrone	0.35	68180087673	28	LUPIN
Progestin Only	NORA-BE	NORA-BE TABLET	norethindrone			norethindrone	0.35	52544062928	28	Teva
Progestin Only	CAMILA	CAMILA 0.35 MG TABLET	norethindrone			norethindrone	0.35	51862088403	28	MAYNE PHARMA
Progestin Only	TULANA	TULANA 0.35 MG TABLET	norethindrone			norethindrone	0.35	50102020013	28	AFAXYS
Progestin Only	LYLEQ	LYLEQ 0.35 MG TABLET	norethindrone			norethindrone	0.35	50102030013	28	AFAXYS
Progestin Only	SLYND	SLYND 4 MG TABLET	drospirenone			drospirenone	4	00642747001	28	EXELTIS USA
Emergency OC										
Emergency	ELLA	ELLA 30 MG TABLET	ulipristal acetate				30	73302045601	1	HRA PHARMA AMER
Emergency, Progestin	MY WAY	MY WAY 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	68180085212	2	LUPIN
Emergency, Progestin	LEVONORGESTREL	LEVONORGESTREL 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	70700016406	1	XIROMED, LLC
Emergency, Progestin	MY CHOICE	MY CHOICE 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	62756072060	1	SUN PHARMA
Emergency, Progestin	PLAN B ONE-STEP	PLAN B ONE-STEP 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	69536014619	1	FOUNDATION CONS
Emergency, Progestin	PLAN B ONE-STEP	PLAN B ONE-STEP 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	69536016288	1	FOUNDATION CONS
Emergency, Progestin	TAKE ACTION	TAKE ACTION 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	69536020088	1	FOUNDATION CONS

Emergency, Progestin	ECONTRA ONE-STEP	ECONTRA ONE-STEP 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	50102021116	6	AFAXYS
Emergency, Progestin	NEW DAY	NEW DAY 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	16714080901	1	NORTHSTAR RX LL
Emergency, Progestin	MY WAY	MY WAY 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	68180085211	1	LUPIN
Emergency, Progestin	LEVONORGESTREL	LEVONORGESTREL 1.5 MG TABLET	levonorgestrel	levonorgestrel		levonorgestrel	1.5	00536114263	1	MAJOR PHARMA
Vaginal Ring										
Vaginal Ring	NUVARING	NUVARING VAGINAL RING	etonogestrel/ethinyl estradiol	ethinyl estradiol	15	etonogestrel	0.12	00052027303	1	MERCK
Vaginal Ring	ETONOGESTREL-ETHINYL ESTRADIOL	ETONOGESTREL-EE VAGINAL RING	etonogestrel/ethinyl estradiol	ethinyl estradiol	15	etonogestrel	0.12	66993060536	1	PRASCO
Vaginal Ring	ELURYNG	ELURYNG VAGINAL RING	etonogestrel/ethinyl estradiol	ethinyl estradiol	15	etonogestrel	0.12	65162046935	1	AMNEAL
Vaginal Ring	ETONOGESTREL-ETHINYL ESTRADIOL	ETONOGESTREL-EE VAGINAL RING	etonogestrel/ethinyl estradiol	ethinyl estradiol	15	etonogestrel	0.12	00093767902	1	TEVA
Vaginal Ring	Annovera	SEGESTERONE AC- EE VAGINAL RING	segesterone AC/Ethinyl estradiol	ethinyl estradiol	13	segesterone	0.15			
Contraceptive Patches										
Patches	XULANE	XULANE 150-35 MCG/DAY PATCH	norelgestromin/ethin.estradiol	ethin.estradiol	35	norelgestromin	0.15	00378334053	3	MYLAN
Patches	ZAFEMY	ZAFEMY 150-35 MCG/DAY PATCH	norelgestromin/ethin.estradiol	ethin.estradiol	35	norelgestromin	0.15	65162035803	3	AMNEAL
Patches	Twirla	Twirla 120-30 mcg/day patch	levonorgestrel/ethin.estradiol	ethin.estradiol	30	levonorgestrel	0.12			AGILE THERA
Non-Hormonal Contraception Gel										
Non-Hormonal Contraception	PHEXXI	PHEXXI 1.8-1-0.4% VAGINAL GEL	lactic acid/citric/potassium	Lactic acid/citric/potassium				69751010012	5	EVOFEM BIOSCIEN
Injectible DMPA										
Injectible DMPA	MEDROXYPROGESTERONE ACETATE	MEDROXYPROGESTERONE 150 MG/ML	medroxyprogesterone acetate			medroxyprogesterone ace	150	00703680101	1	TEVA
Injectible DMPA	MEDROXYPROGESTERONE ACETATE	MEDROXYPROGESTERONE 150 MG/ML	medroxyprogesterone acetate			medroxyprogesterone ace	150	00703680104	1	TEVA
Injectible DMPA	MEDROXYPROGESTERONE ACETATE	MEDROXYPROGESTERONE 150 MG/ML	medroxyprogesterone acetate			medroxyprogesterone ace	150	59762453701	1	GREENSTONE/PRAS
Injectible DMPA	DEPO-PROVERA	DEPO-PROVERA 150 MG/ML SYRINGE	medroxyprogesterone acetate			medroxyprogesterone ace	150	00009737611	1	PFIZER
Injectible DMPA	DEPO-PROVERA	DEPO-PROVERA 150 MG/ML VIAL	medroxyprogesterone acetate			medroxyprogesterone ace	150	00009074630	1	PFIZER
Injectible DMPA	DEPO-PROVERA	DEPO-PROVERA 150 MG/ML VIAL	medroxyprogesterone acetate			medroxyprogesterone ace	150	00009074635	1	PFIZER
Injectible DMPA	DEPO-SUBQ PROVERA 104	DEPO-SUBQ PROVERA 104 SYRINGE	medroxyprogesterone acetate			medroxyprogesterone ace	104	00009470913	0.65	PFIZER
Implant										
Long Term Reversible Contraception	NEXPLANON	NEXPLANON 68 MG IMPLANT	etonogestrel			etonogestrel	68	00052433001	1	MERCK
IUD										
Long Term Reversible Contraception	LILETTA	LILETTA 52 MG SYSTEM	levonorgestrel			levonorgestrel	52	00023585801	1	ALLERGAN
Long Term Reversible Contraception	MIRENA	MIRENA 52 MG SYSTEM	levonorgestrel			levonorgestrel	52	50419042301	1	BAYER
Long Term Reversible Contraception	SKYLA	SKYLA 13.5 MG SYSTEM	levonorgestrel			levonorgestrel	13.5	50419042201	1	BAYER
Long Term Reversible Contraception	KYLEENA	KYLEENA 19.5 MG SYSTEM	levonorgestrel			levonorgestrel	19.5	50419042401	1	BAYER
Long Term Reversible Contraception	PARAGARD T 380-A	PARAGARD T 380-A IUD	copper			copper		59365512801	1	COOPERSURGICAL

APPENDIX

LEGAL REFERENCES

LEGAL REFERENCES

O.C.G.A. § 43-34-23 - Delegation of authority to nurse or physician assistant to order or dispense drugs, medical treatments or diagnostic studies. The nurse protocol statute law may be accessed online at http://www.lexisnexis.com/hottopics/gacode/Default.asp

Rules of Georgia Board of Nursing: Regulation 410-11-.13 and 410-11-.14 (Advanced Practice Registered Nurse Protocols). Georgia Board of Nursing Laws, Rules, Regulations and Policies may be accessed online at http://sos.ga.gov/index.php/licensing/plb/45

Rules of Georgia State Board of Pharmacy: Chapter 480-30, Dispensing of Drugs under Authority of Job Description or Nurse Protocol: 480-30-.01-.07 Georgia Board of Pharmacy Policies and Laws may be accessed online at http://gbp.georgia.gov/lawspolicies-rules

O.C.G.A. § 26-4-130 – Dispensing drugs; compliance with labeling and packaging requirements; records available for inspection by board may be accessed on line at http://gbp.georgia.gov/laws-policies-rules

O.C.G.A. § 43-26-5 - Georgia Registered Professional Nurse Practice Act: General Powers and responsibilities of board may be accessed on line at http://www.lexisnexis.com/hottopics/gacode/Default.asp OR http://sos.ga.gov/index.php/licensing/plb/45

O.C.G.A. § 43-34-103 (Physician Assistant Act) - may be accessed on line at http://www.lexisnexis.com/hottopics/gacode/Default.asp

O.C.G.A. § 43-26-1 Georgia Registered Professional Nurse Practice Act may be accessed on line at http://sos.ga.gov/index.php/licensing/plb/45 OR http://sos.ga.gov/PLB/acrobat/Forms/38%20Reference%20-20Nurse%20Practice%20Act.pdf

APRN COMPOSITE MEDICAL BOARD PRESCRIPTIVE AUTHORITY

Georgia Composite Medical Board Nurse Protocol Agreement for APRNs

APRNs who will be providing services beyond what is included in the Standard Nurse Protocol Manual can establish a Nurse Protocol Agreement for prescriptive authority through the Georgia Composite Medical Board. A Nurse Protocol Agreement is a written document, mutually agreed upon and signed by an APRN and a physician, by which the physician delegates to the APRN the authority to perform certain medical acts pursuant to Code Section 43-34-25, which may include without being limited to, the ordering of drugs, medical devices, medical treatments, diagnostic studies, or in life-threatening situations radiographic imaging tests.

To set up a Nurse Protocol Agreement and be delegated prescriptive authority in Georgia, a Nurse Protocol Agreement must be developed and submitted to the Georgia Composite Medical Board. Once signed and dated by both the APRN and the delegating physician, the Nurse Practitioner may begin seeing patients and signing prescriptions for non-scheduled medications under the provisions of the agreement. The Nurse Protocol Agreement must be submitted to the Georgia Composite Medical Board within 30 days after being signed by the APRN and the delegating physician. Once the Nurse Protocol Agreement has been approved by the Georgia Composite Medical Board, the APRN can apply for a DEA license if needed. If a DEA license is applied for and approved, the APRN can prescribe Schedules III-V medications. An APRN can never write prescriptions for Schedule I-II medications. A DEA license is only required if a nurse plans to prescribe Schedule III-V medications. For a list of frequently asked questions, visit APRN Protocol Registration Forms | Georgia Composite Medical Board

To begin the process, the APRN should review the FAQs found on the Composite Board site and complete the following steps and forms:

1. Download and follow the guidance in the APRN Application Checklist found in: How to Get Your File Reviewed the First Time
2. Complete and sign the Nurse Protocol Agreement
3. Complete and sign the APRN Protocol Agreement Addendum
4. Complete and sign the APRN Nurse Protocol Registration Form
5. Complete and sign the APRN Form A
6. Complete and sign the APRN Form B
7. Complete and sign the APRN Form C
8. Include the $150 Fee (check or money order made payable to: GCMB)
9. Include license verification
    - Submit copy of current APRN license
    - Submit copy of national certification

All completed applications should be mailed to:

Please send application to: GCMB, APRN Department, 2 Peachtree Street, N.W., 6th Floor, Atlanta, GA 30303