



Cervical Procedure Manual

**Georgia Department of Public Health
Division of Health Promotion
Chronic Disease Prevention Section
Office of Prevention Screening and Treatment
Breast and Cervical Cancer Program**

FOREWORD

This manual has been revised in the interest of improved quality and standardization of the Cervical Cancer Screening Program in the State of Georgia. It is the product of the collaborative work of the BCCP State Office clinical staff and BCCP Coordinators in the public health districts and the American Cancer Society.

This manual includes the current guidelines for screening and management of abnormal Pap test, **(2001 Bethesda System, and the 2012 ASCCP Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities)**. These standards apply to clinical services performed in Public Health clinics and by BCCP participating contractors.

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SECTION I

PAP TEST SCREENING

The following Pap test screening guidelines are to be utilized for asymptomatic women. Symptomatic women and/or those at high risk will need to be screened/evaluated on an individual basis.

Screening Criteria/Frequency Guidelines

The Georgia Department of Public Health adheres to the consensus screening recommendations developed by the federally funded Breast and Cervical Cancer Program and the American Cancer Society (ACS). Consideration has also been given to the recommendations of the American College of Obstetrics and Gynecology (ACOG), the National Cancer Institute, the American Medical Association, the American Nurses Association, and the American Academy of Family Physicians, and the American Medical Women's Association. The recommendations are for the early detection of asymptomatic women for cervical cancer screening.

The Georgia Family Planning Program and the Georgia Breast and Cervical Cancer Program have adopted the following Screening Guidelines published by NBCCEDP, which are as follows:

- Cervical Pap screening should begin at age 21 regardless of sexual history.
- The intervals for cervical cancer screening (Pap) are as follows:
 - Ages 21-29 should be screened every 3 years
 - Ages 30-65 may be screened with cytology every 3 years or HPV co-testing with cytology every 5 years
 - Women considered high risk should be screened annually
 - Conventional Pap Testing or Liquid Based Cytology(LBP) may be used, as insufficient evidence exists to determine if LBP is more effective than Conventional Pap Testing
- Guidelines for when to stop screening are as follows:
 - Women age 65 who have had 3 negative Pap tests in the 10 years prior to cessation of screening, and are not high risk. (Women at risk for cervical cancer should receive more frequent screening.)
 - Women with a history of cervical neoplasia should continue screening for at least 20 years after spontaneous regression or appropriate management of a high-grade precancerous lesion.
- For a woman who has had a hysterectomy:

1) Cervix has been surgically excised

- a. With pathology “benign” for cancer: Women who have undergone hysterectomy with removal of the cervix for benign indications and who have no prior history of CIN 2 or CIN 3 or worse will discontinue routine vaginal cytology testing. (ACOG Practice Bulletin No 45, p 8 and NBCCEDP guidelines)
- b. With history of a cervical dysplasia, continue to screen with a vaginal Pap test every 3 years or HPV co-testing with cytology every 3 years for 20 years before screening stops. (NBCCEDP October 2012)
- c. With pathology “positive” for cervical cancer neoplasia or invasive cervical cancer, continue to screen indefinitely as long as the patient remains healthy. (NBCCEDP April 2006/2012)

2) Cervical stump present:

- a. Follow routine Pap test screening interval described on previous page.

If the clinic can obtain results of the patient’s previous Pap test history from another facility/provider, they should be considered as part of the patient’s Pap test history. It is not necessary that a Pap test be done if the history indicates there is not a need according to the recommended screening guidelines (previous page).

The guidelines for the Maternal and Child Health Program advise that a Pap test be performed during pregnancy at the time of the first visit, unless the patient has written results of a Pap performed at another facility within the past 12 months. It is recommended that pregnant women **not have a pelvic/pap examination** after the **beginning of the 36th week of pregnancy**, unless medical resources are in close proximity due to the possibility of rupturing of the membranes with speculum and/or stimulating labor by performance of the procedure.

The Georgia Breast and Cervical Cancer Program Cervical Screening Guidelines

	National Breast and Cervical Cancer Early Detection Program. ¹ (Georgia FP/BCCP, October 2012) At age 21 (regardless of sexual history)	American Cancer Society ² (ACS, Nov. 2011) 21 years of age	US Preventive Services Task Force ³ (USPTF, April 2012) 21 years of age	American College of Obstetrics and Gynecology ⁴ (ACOG, Sept. 2013) At age 21 (regardless of sexual history) and should be avoided before age 21 years
When to Start Pap Testing Intervals Conventional Pap Testing or Liquid Based Cytology used (LBP) Insufficient evidence to determine if liquid-based cytology is more effective than conventional Pap test screening	<ul style="list-style-type: none"> • Ages 21-30 should be screened every 3 years. • Ages 30-65 may be screened with cytology every 3 years or HPV co-testing with cytology every 5 years. • Women considered high risk* should be screened annually 	<ul style="list-style-type: none"> • Ages 21-30 should be screened every 3 years. • Ages 30-65 may be screened every 3 years or HPV co-testing with cytology every 5 years. • Women considered high risk* should be screened annually 	<ul style="list-style-type: none"> • Ages 21-65 should be screened every 3 years. • Ages 30-65 may be screened every 3 years or HPV co-testing with cytology every 5 years. • Women considered high risk* should be screened annually. • Insufficient evidence to determine if liquid-based cytology is more effective than conventional Pap test screening 	<ul style="list-style-type: none"> • Ages 21-30 should be screened every 3 years. • Ages 30-65 may be screened with cytology every 3 years or HPV co-testing with cytology every 5 years • Women considered high risk* should be screened annually
When to Stop	<ul style="list-style-type: none"> • Women age 65 who have adequate screening (3 negative Pap test in the 10 years prior to cessation of screening) and are not high risk*. • Women with a history of Cervical Neoplasia should continue screening for at least 20 years after spontaneous regression or appropriate management of a high-grade precancerous lesion. 	<ul style="list-style-type: none"> • Women age 65 who have adequate screening (3 negative Pap test in the 10 years prior to cessation of screening) and are not high risk*. • Women at risk should continue annual screening for at least 20 years after spontaneous regression or appropriate management of a high-grade precancerous lesion 	<ul style="list-style-type: none"> • Women age 65 who have adequate screening (3 negative Pap test in the 10 years prior to cessation of screening) and are not high risk*. • Women at risk should continue annual screening for at least 20 years after spontaneous regression or appropriate management of a high-grade precancerous lesion 	<ul style="list-style-type: none"> • Women 65-70 and older with: <ul style="list-style-type: none"> • 3 or more recent consecutive negative tests • No abnormal tests in prior 10 years
Post Hysterectomy and Cervix is not present	<ul style="list-style-type: none"> • If hysterectomy was performed for benign reasons and cervical stump is absent and no prior history of CIN 2 or CIN3, no further cervical screening should be done. • If hysterectomy was done for CIN 2 or CIN 3 continue to screen** for 20 years. If invasive cervical cancer, continue annual screening indefinitely. 	<ul style="list-style-type: none"> • If hysterectomy was performed for benign reasons and cervical stump is absent and no prior history of CIN 2 or CIN3, no further cervical screening should be done. • If hysterectomy was done for CIN 2 or CIN 3 continue to screen annually for 20 years using conventional method. If invasive cervical cancer, continue annual screening indefinitely. 	<ul style="list-style-type: none"> • If hysterectomy was performed for benign reasons and cervical stump is absent and no prior history of CIN 2 or CIN3, no further cervical screening should be done. • If hysterectomy was done for CIN 2 or CIN 3 continue to screen annually for 20 years using conventional method. If invasive cervical cancer, continue annual screening indefinitely. 	Discontinue screening: <ul style="list-style-type: none"> • If hysterectomy for benign reasons • No prior history of CIN 2 or CIN 3

*Women at risk for cervical cancer, including those who are HIV infected, are immunocompromised, and/or were exposed to diethylstilbestrol (DES) in utero and require more frequent cervical cytology screening. **Screening intervals for these patients would be a vaginal Pap test every 3 years or HPV co-testing with cytology every 5 years or 20 years before screening stops.

¹ Centers for Disease Control (CDC), National Breast and Cervical Cancer Early Detection Program, Policy, April 2012

² Saslow, D et al. American Cancer Society Guidelines for Early Detection of Cervical Neoplasia and Cancer. CA Cancer Journal for Clinicians 2002;52:342-362. Available at <http://caonline.amcancersoc.org/2002/52/342>

³US Preventive Services Task Force, Screening for Cervical Cancer. March 2012. Available at <http://www.ahrp.gov/clinic/uspstf/uspstf/cerv.htm>.

⁴ Cervical Cytology Screening. ACOG Practice Bulletin No. 109. American College of Obstetricians and Gynecologists. Obstet Gynecol 2009, 114:1409-20

SCREENING CONDITIONS:

Clinic clerical staff should routinely instruct all patients making appointments for new and annual exams to:

1. Make their appointment 1-2 weeks after their menstrual period.
2. Avoid having sexual intercourse 24-36 hours before Pap test.
3. Not to douche or put anything into the vagina for at least 48 hours before the Pap test appointment.

When scheduling patients who are returning for a repeat Pap test regardless of the reason, inform patient about optimal preparation:

1. Patient is not on her menses.
2. No contamination of the cervix (e.g., creams lubricants, semen).
3. No recent abrasion of the cervix (e.g., sex, douching, vaginal contraceptives, recent Pap test or cultures).
4. No cervicitis (if present, treat first and have patient return in 12 weeks near mid-cycle).

If Pap test is deferred, the rest of the exam can be done and the patient should be rescheduled at a later date when conditions are more optimal.

Clinicians should remember that women with unexplained abnormal bleeding should be referred for a complete gynecological evaluation to rule out endometrial/uterine abnormalities, i.e., fibroid tumors, carcinoma.

PROCEDURE FOR PAP SPECIMEN COLLECTION

Equipment and Supplies

Supplies should be assembled before beginning exam.

If conventional testing is used, the following items are essential:

1. Glass slide with frosted end;
2. Extended tip spatula (either wood or plastic);
3. Endocervical brush (not for use during pregnancy or for friable cervix); and
4. Fixative spray (specifically designated cytology spray only).

If liquid based testing is used, the following supplies are essential:

1. Extended tip plastic spatula or cervical broom;
2. Endocervical brush (not for use during pregnancy); and
3. Vial with liquid base preservative.

Good light illumination and bivalve specula of different types and sizes should be available for either test method.

Procedure

1. Utilize adequate space, time, light, and privacy for the exam.
2. Have the patient void and assist with undressing if needed.
3. To enhance the relaxation and comfort of the patient, explain all procedures carefully and use a mirror if the patient desires.
4. Assist the patient into the lithotomy position if needed. For women with disabilities or the elderly, other positions can be effectively used.
5. Write the patient's name on the frosted end of the glass slide with a # 2 lead pencil (or label the liquid based preservative vial). Make sure the name is correct.
6. Clean technique is used. Wear gloves when obtaining all specimens. Universal precautions must be used during the entire procedure taking care not to touch clean materials or equipment with the contaminated glove.
7. Inspect and palpate, with one gloved hand, the perineum, labia, vulva, and vagina. Look for lesions, masses, drainage, or discoloration.
8. Avoid palpating the cervix prior to obtaining the Pap test.

9. Choose the appropriate size and type of bivalve speculum. Lubricate the speculum with water if necessary - DO NOT USE other lubricants. Following the path of least resistance, insert the speculum gently keeping the blades closed until completely inserted. Do not turn the speculum to insert.
10. Open the speculum gently. If the cervix is not visible, move the speculum slightly to bring the cervix into view. The entire cervix should be visible to ensure the best possible specimen collection.
11. Do not wipe the cervix before collecting the Pap test. Excessive mucus should be removed gently with a cotton swab without disturbing the epithelium. If heavy vaginal discharge or infection is present, it may be better to delay the Pap test until the infection has been treated.
12. Use this recommended order for cervical specimen collection for women 29 years and younger:
 - Vaginal pH, if indicated
 - Wet Mount, if indicated (Taking the wet prep specimen first does not disturb the cervix and avoids contamination from blood or cervical mucus).
 - Pap Test
 - Chlamydia/Gonorrhea DNA probe

In women 30 years and older, the cervical Pap is obtained first and other tests as indicated based on history and symptoms.

13. Collect cells from the cervix with specific emphasis on obtaining cells from the squamocolumnar junction (SCJ) or transformation zone (TZ) (Figure 1). The TZ is the area where most abnormal cell changes occur.

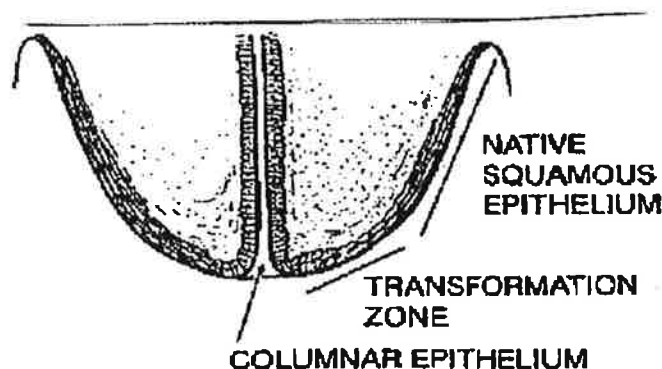
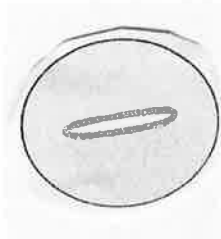


Figure 1

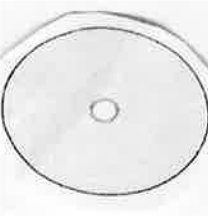
Variations exist in the location of the squamocolumnar junction (SCJ) or transformation zone (TZ), as follows:



Ectocervix with ectropion (SCJ visible) may be found in adolescent patients, premenopausal nulliparous patients, or patients on birth control pills.



Ectocervix without ectropion may be found in parous patients. SCJ is mainly inside canal, but a small portion is usually visible.



Ectocervix with small or stenotic os may be found in premenopausal nulliparous patients, post menopausal patients, or patients with history of treatment for abnormal Pap(s). SCJ is completely inside canal.

1. To collect the ectocervix sample:

1. Place the spatula against the cervix; rotate it 360 degrees using firm pressure keeping continuous contact with the cervix. (Figure 2)
2. Multiple scrapes may be necessary in a parous or large cervix
3. Hold the spatula horizontally and withdraw carefully to avoid vaginal Contamination
4. You can apply the cellular material to the slide or hold the sample.

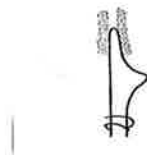


Figure 2

2. To collect the endocervical sample:

1. Insert the instrument into the endocervical canal far enough that only a few bristles of the brush are visible. (Figure 3)
2. Rotate slowly, turning the brush 180 degrees.
3. Withdraw carefully to avoid vaginal contamination.



Figure 3

3. To set the cellular material on the slide
4. Spread the spatula sample(s) evenly on the glass slide using moderate pressure.
5. Apply the endocervical sample, to the same slide by rolling the brush along the slide using moderate pressure. (Figure 4)

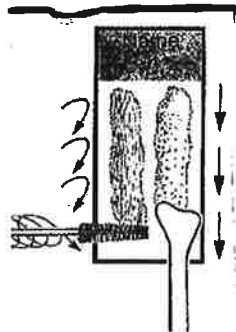


Figure 4

4. Spray the slide immediately (within 10 seconds) with cytology fixative. Hold 8-10 inches away from the slide to avoid spraying cells off the slide. (Figure 5) Do not use hair spray.

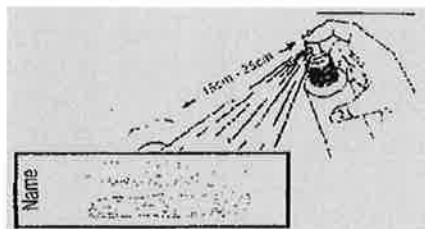


Figure 5

5. For liquid based Pap test, place the spatula into the liquid vial and swirl vigorously 10 times. Remove the spatula and place the brush into the vial of liquid preservative and rotate 10 times while pushing against the wall of the vial. Swirl vigorously to further release material. If the SurePath™ test pack is used, the end of the broom is released directly into the vial. Place the cap on the vial.
6. Always confirm the labeling of the specimens before leaving the patient. It is the clinician's responsibility to ensure complete and accurate labeling of the specimen. Complete the lab requisition (3150 form). The clinician should verify that the correct name is on the frosted end of the slide and the specimen is properly packaged with the correct lab requisition enclosed.
7. Package and ship slides in containers as recommended by the lab. Containers should be substantial enough to avoid breakage during transport. Pap slides are sent to the lab daily, but several specimens may be batched together, providing more protection and economical shipping. Biohazard labels are not required. Local labs often pick up slides, which limits breakage and helps prevent mishandling.
8. Keep a tracking record to ensure that all Pap test reports are received.

Section II

Bethesda System 2001

Objectives: To create a universal language to standardize reporting and description of the Pap test, and to provide evidence-based consensus guidelines for the management of women with cervical cytological abnormalities and cervical cancer precursors.

Specimen Adequacy:

Satisfactory:

- Indicates that the specimen is adequate for interpretation.
- Describes the presence or absence of EC/TZ or metaplastic components – the presence of endocervical cells suggests that the cervix was adequately sampled, however, their absence does not prove that the cervix was inadequately sampled.
- Endocervical cells are absent in 10% of Pap test obtained from perimenopausal women and as many as 50% in post menopausal women. Pregnancy and use of Oral Contraceptives have demonstrated a decrease in the number of endocervical cells.
- Other quality indicators such as infection, partially obscuring blood, etc.
- Includes old category of “satisfactory but limited by...”

Unsatisfactory:

- Specimen was rejected/not processed because it could not be adequately interpreted by pathologist.
- Specimen was processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of scanty cellular material, excessive red blood cells obscuring more than 75% of the slide, inflammation which causes white blood cells to obscure the slide, patient use of douching, vaginal medication, or presence of lubricant.
- In situations of inflammation, treat infections, counsel patient regarding preparation for a Pap test and repeat Pap in 3-4 months preferable 2 weeks post menses.

Bethesda System 2001 Categorization and Interpretation of Results

Negative for Squamous Intraepithelial Lesion or Malignancy

- ◆ Adequate specimen with no cellular abnormalities
- ◆ Includes old category of non-neoplastic Reactive/Reparative – which is a benign process resulting from one of the following infections:
 - Candida
 - Trichomonas
 - Herpes or cytomegalovirus
 - Bacterial vaginosis (clue cells)
 - Actinomyces
 - Other inflammations such as GC or Chlamydia
- ◆ Metaplasia, a benign finding that may be increased in teenagers, during pregnancy, or in women using oral contraceptives.
- ◆ If inflammation noted, treat as indicated and repeat Pap test in 12-15 months.

Epithelial Cell Abnormality (cellular or glandular)

Squamous Cell Abnormalities

- ◆ **Atypical Squamous Cell – Unknown Significance (ASC-US)**
 - Changes may be suggestive of LSIL
 - Result is not diagnostic of a cancerous or precancerous lesion.
 - Requires further evaluation to exclude presence of a higher grade disease
 - Recommend repeat Pap test according to the 2006 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities
 - If repeat Pap remains ASC and patient is over 20 years of age, colposcopy is recommended. (See 2006 Consensus Guidelines for Management of Women with Cervical Cytological Abnormalities for management of patient less than 20 years old).
- ◆ **Atypical Squamous Cells (ASC-H) - cannot rule out HSIL**
 - Changes suggestive of HSIL but not definitive
- ◆ **Low grade squamous intraepithelial lesion, (LSIL)**
 - Includes HPV/mild dysplasia/CIN 1
 - Suggestive of stable HPV infection

◆ **High grade squamous intraepithelial lesion, (HSIL)**

- Includes moderate and severe dysplasia
- Suggestive of CIN 2/CIN 3 and possible Carcinoma in Situ (CIS)

◆ **SCC - Squamous Cell Carcinoma**

Glandular Cell Abnormalities

◆ **Atypical Cell**

- Endocervical cells
 - NOS or specify in comments
 - Favor neoplastic
- Endometrial cells
 - NOS or specify in comments
- Glandular cells
 - NOS or specify in comments
 - Favor neoplastic
- Endocervical adenocarcinoma *in situ*, (ACIS)
- Adenocarcinoma

Recommended follow-up for women with a negative (for intraepithelial lesion or malignancy) Pap test lacking an endocervical/transformation zone (EC/TZ) component

For women age 21-29 years with negative cytology and absent or insufficient EC/TZ component, routine screening is recommended. HPV testing is not an acceptable follow-up. For women age 30 years and older with negative cytology and absent or insufficient EC/TZ component; none or unknown HPV test result, HPV testing is preferred. Repeating cytology in 3 years is acceptable if HPV testing is not done. If HPV testing is test is negative, return to routine screening. If the HPV test is positive, repeating both tests in 1 year.

The presence of endocervical material should be used by the clinician for self-monitoring of his/her technique. All clinicians with a high percentage of Pap tests lacking an endocervical component should review and improve their technique.

Recommended follow-up for women with a negative (for intraepithelial lesion of malignancy) Pap test that has partially obscuring blood, inflammation, other partially obscuring factors, or partial air drying (unsatisfactory cytology)

For women with an unsatisfactory cytology result and HPV is: unknown any age, repeat cytology in 3-4 months. Triage using reflex HPV is not recommended. Treatment to resolve atrophy or obscuring inflammation when a specific infection is present is acceptable. For women age 30 years and older who are co-tested and have unsatisfactory cytology and a positive or negative HPV test, repeat cytology in 3-4 months. For women 30 or older with unsatisfactory cytology, a colposcopy is also an acceptable follow. Colposcopy is recommended for women with two consecutive unsatisfactory cytology tests.⁵

Endometrial Cells in Cervical Cytology:

Endometrial Cells in Cervical Cytology:

Review of Cytological Features and Clinical Assessment Conclusion:

2006 American Society for Colposcopy and Cervical Pathology

Normal exfoliated endometrial cells in perimenopausal women in the first half of the menstrual cycle are not associated with any significant endometrial pathology and need not be evaluated unless otherwise clinically indicated.

Benign endometrial cells in the second/half of the menstrual cycle in asymptomatic menstruating women over 40 are also rarely associated with significant pathology and do not need further evaluation.

Clinicians should be continually encouraged to provide the best demographic and clinical information to the pathologist, so that more specific educational notes can be rendered. However, it is unrealistic to expect that this will happen in all cases and diagnosis should not be delayed until such information becomes available.

Women less than 40 years old are at very low risk of significant endometrial pathology; therefore endometrial cells should not be reported in their Pap tests.

Section III

Refer to the American Society for Colposcopy and Cervical Pathology for the 2012 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities (<http://www.asccp.org/Guidelines-2/Management-Guidelines-2>)

- Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)
- Management of Adolescent Women with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)
- Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL)
- Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)
- Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL)
- Management of Adolescent Women (20 Years and Younger) with High Grade Squamous Intraepithelial Lesion (HSIL)
- Initial Workup of Women with Atypical Glandular Cells (AGC)
- Subsequent Management of Women with Atypical Glandular Cells (AGC)
- Use of HPV DNA Testing as an Adjunct to Cytology for Cervical Cancer Screening in Women 30 Years and Older is not an allowable procedure per NBCCEDP and therefore, is not allowed by the GA BCCP.

Section IV

Diagnostic and Treatment Procedures

DIAGNOSTIC PROCEDURES

Colposcopy and Biopsy

Colposcopy is the magnified inspection of the cervix, the vagina, and the vulva. It is highly sensitive but has low specificity; therefore, it is not a good screening tool. However, colposcopy is a good diagnostic tool to identify abnormalities of the epithelium and vessels that are the hallmark of pre-invasive and invasive disease. The prediction of histopathologic diagnosis based on colposcopic patterns requires experience and practice.

The Colposcopy exam allows the colposcopist to obtain a biopsy of the cervix, with a punch biopsy, and/or of the endocervical tissue, by curettage, as indicated based on the findings of the Pap test and the microscopic inspection. Both biopsies will produce a specimen which can be studied by the pathologist.

Colposcopy should only be performed by clinicians who have completed an approved training course, with nurse practitioners satisfactorily passing a supervised preceptorship. This preceptorship must include examination of a large number of abnormal cervixes. Nurse practitioners, by Georgia law, must function under written protocols.

The indications for colposcopy include:

1. Abnormal Pap test
2. Suspicious lesion on visual exam
3. Diethylstilbestrol (DES) exposure in utero

Equipment

1. Colposcope
 1. The colposcope is an instrument that provides magnification and illumination. By varying the magnification, the clinician can identify patterns of normal or abnormal tissue.
 2. A variety of colposcopes are available some with video technology. The most practical instrument has a focal point of 300mm, magnification variability from low to high (4x to 20x+), a good light source with white light and a green filter.
2. Biopsy forceps
 1. Forceps are available in a variety of types and sizes. Careful selection of the appropriate instrument based on assessment is important.
 2. Keeping instruments sharp assures a quality sample and produces less discomfort when the biopsy is obtained.
3. Endocervical Curettes
 1. Allows for sampling of the endocervical canal.
 2. Sharp instruments assure obtaining an adequate sample.
4. Endocervical Specula

1. Used as an aid to visualize the endocervical canal.
 2. A variety of lengths and tips are available for nulliparous, parous, or stenotic cervixes.
5. Vaginal Sidewall Retractors
1. The vaginal walls may make colposcopic examination difficult if they obscure the cervix. Retractors may be placed inside the speculum or a condom or index finger of a glove may be placed over the speculum blades to keep walls out of the viewing path.

Procedure

1. Enhance the patient's comfort and relaxation by thoroughly explaining all procedures. Use of a "Colposcopy Exam Fact Sheet", (appendix A) may be beneficial in reviewing this information. Be sure the patient is not menstruating.
2. Obtain pertinent history from the patient (appendix B)
 - a. Obstetric and gynecologic
 - b. Last menstrual period (LMP)
 - c. Sexually transmitted disease
 - d. Previous abnormal Pap(s) and treatment (including gyn surgery)
 - e. Number of sexual partners
 - f. Smoking, drug abuse
 - g. Immunosuppression
 - h. Allergies
 - i. Current medical problems
 - j. Family Planning method if still menstruating
3. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed. (Appendix C).
 - a. Potential risks and complications include:
 1. Excessive post procedure bleeding
 2. Infection
 2. No contraindications to procedure
4. Colposcopy Procedure
 - A. Some Colposcopist prefer to moisten the cervix with saline to remove secretions. Inspect the cervix with the colposcope after the saline is applied. Atypical vessels are more prominent with the green filter under saline visualization. Leukoplakia is also more prominent after the saline wash.
 - B. Next, the colposcopist will apply 3-5% acetic acid (vinegar) liberally to the cervix and vagina. This cleans and dehydrates the surface cells for better viewing.
 - C. Systematically inspecting the cervix and surrounding area lowers the chance of missing a lesion.
 - D. Assess the adequacy of the procedure:

- 1) Can the squamocolumnar junction (SCJ) be visualized completely?
 - If not, try opening the speculum blades slightly to evert the endocervical canal. A small Q-tip can be used to lift the tissue at the os or a large swab can be placed in the opposite fornix in an attempt to further open the canal.
 - If these techniques do not work, insert an endocervical speculum into the os gently and open the tips slowly. Carefully move the speculum back and forth, rotating if necessary, until the SCJ limits can be seen.
 - If the entire SCJ cannot be seen after the above techniques, an excisional biopsy may be necessary.
- 2) Is the squamous columnar junction normal or abnormal?
 - If abnormal, entire lesion(s) should be visible. If the entire lesion(s) cannot be seen, the exam is not adequate and an excisional biopsy may be necessary.
 - Lugol's solution may be used if the diagnosis is in question, to confirm the colposcopic impression, or to outline the lesion limits.
 - Assess if the colposcopy findings correlate with the Pap test results.
 - If abnormalities are seen, locate the most atypical area(s) for biopsy.

E. Tissue samples are taken from the most atypical area(s) to verify the extent of extent of the disease.

F. May apply Monsel's or Silver Nitrate to control bleeding from the biopsy site(s).

5. Instructions for post-biopsy care including danger signs and emergency phone numbers should be carefully explained and given in writing to the patient, (Appendix D).
6. Schedule a follow-up appointment for the patient either at the colposcopy clinic or the referring clinic to discuss the results of the biopsy and recommendations for treatment and follow-up.
7. A thorough record should be made of the colposcopic exam for correlation with the biopsy report, (Appendix B).

Excisional Procedures

Loop Electrosurgical Excision Procedure (LEEP)

LEEP is an outpatient excisional procedure that removes the cervical squamous columnar junction using a thin wire loop connected to a high-frequency low-voltage alternating current. Abnormal cells are removed by cutting and coagulation. LEEP offers the advantage of excising the entire lesion, allowing a complete histological assessment to ensure the removal of all abnormal tissue.

A LEEP can be used as a diagnostic tool and/or a treatment procedure. Studies indicate it is 91% to 98% effective in treating cervical intraepithelial lesions.

Indications for use include:

1. Unsatisfactory colposcopy
2. Positive ECC on biopsy
3. Significant lesion entering into or inside the endocervical canal
4. Low or High grade SIL
5. Lack of correlation between cytology (Pap), histology (biopsy) and colposcopy

Contraindicated:

1. Pregnancy
2. Treatment of invasive cancer.

Procedure

1. As an outpatient procedure, the LEEP is performed utilizing a local anesthetic. Since the patient will be awake, she will need to be relaxed and calm during the procedure. Patients who are extremely nervous or unable to stay still on the exam table during the procedure may not be a candidate for this as an out-patient procedure. Enhance the patient's comfort and relaxation by thoroughly explaining all procedures. Use of a "LEEP Fact Sheet" (Appendix E) may be beneficial in reviewing this information. Be sure the patient is not menstruating
2. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed, (appendix F).
 - a. Potential risks and complications include:
 1. Excessive bleeding post procedure
 2. Infection
 3. Cervical stenosis
 4. Vasovagal Reaction – caused by allergic response to local anesthesia
 - b. Contraindications include:
 1. Pregnancy
 2. Pelvic infection
 3. Invasive cancer

3. Assess the patient's allergies, especially to local anesthetic agents.
4. Have the patient void; assist with undressing if needed. Advise her to remove all jewelry, navel rings, or other metal to avoid electrical shock.
5. Attach the grounding pad securely to the patient's thigh.
6. Insert the appropriate size coated speculum gently. Attach the smoke evacuator tubing to the speculum.
7. The appropriate size loop is chosen which allows removal of the entire lesion. Following excision of the lesion, the tissue should be placed in a specimen cup with formalin and sent to pathologist for exam.
8. Control bleeding from the biopsy site by applying Monsel's solution and/or by using the ball electrode to cauterize the tissue. If vaginal bleeding is not controlled by use of the Monsel's solution, suturing or vaginal packing may be required.
9. Observe the patient for 20 to 30 minutes following the procedure.
10. Instructions for post-LEEP care including danger signs and emergency phone numbers should be carefully explained and given in writing to the patient (Appendix G).
11. Schedule a follow-up appointment for the patient.
12. Keep a tracking record to ensure that the biopsy report is received.

Conization

Conization is an outpatient excisional procedure that involves removal of the entire cervical squamous columnar junction with extension into the endocervical canal. It removes a deeper portion of tissue than LEEP. Current methods used for conization include laser, cold knife, CO2, or loop diathermy. Conization is a surgical procedure, requiring anesthesia; therefore, it has a higher cost than LEEP. While it may be used as a diagnostic procedure as well as treatment, the standard diagnostic test is the colposcopy.

Indications for conization may include:

1. Unsatisfactory colposcopy
 - a. Lesion extends into the endocervical canal so that margins cannot be seen.
 - b. The entire SCJ cannot be seen.
2. Cytology re-evaluated by a pathologist suggests an invasive lesion but colposcopy does not correlate.
3. Micro-invasive or invasive lesion found on cytology, colposcopy, or biopsy.
4. Abnormal glandular lesion is suggested on cytology or colposcopy.
5. Significant discrepancy between cytology, colposcopy, and/or biopsy.
6. Endocervical curettage reveals a precancerous or cancerous lesion.

Potential risks and complications include:

1. General anesthesia
2. Hemorrhage during surgery or postoperatively
3. Infection
4. Partial or complete stenosis of the cervical os causing:
 - a. Infertility
 - b. Dysmenorrhea
5. Cervical incompetence
6. Contraindicated during pregnancy

TREATMENT PROCEDURES

Ablative Procedure - Cryotherapy

Cryotherapy is the outpatient use of extremely decreased temperatures to destroy pre-cancerous abnormalities of the cervix or warts on the cervix or vulva. This therapy predominantly utilizes nitrous oxide to achieve below freezing temperatures, but either liquid nitrogen or carbon dioxide may also be used.

Procedure

1. Enhance the patient's comfort and relaxation by thoroughly explaining all procedures. Use of Cryosurgery Fact Sheet may be beneficial in reviewing this information (Appendix H). Be sure the patient is not menstruating.
2. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed. (Appendix I)
 - A. Potential risks and complications include:
 - a. Potential for vaginal injury
 - b. Post procedure infection or hemorrhage
 - c. Cervical stenosis (this may affect future fertility or other diagnostic procedures)
 - B. Contraindications include:
 1. Invasive cancer
 2. Pregnancy
 3. Women exposed to DES in-utero
 - d. Acute cervicitis, mucopurulent cervicitis, or pelvic inflammatory disease (PID)
 - e. Cervical size and/or contour that would prevent making good contact with the cryo probe
 - f. Large lesion cannot be adequately covered with cryo probe
3. Have the patient void; assist with undressing if needed.

4. Insert the largest speculum that can be comfortably used. Open it to expose the entire cervix as widely as is comfortable for the patient. Vaginal sidewall retractors may be necessary to keep the vaginal walls away from the cryo probe.
5. Choose the appropriate sized cryo probe tip and attach to the machine securely.
6. Apply a small amount of water-soluble lubricant to the cryo tip. This eliminates air gaps, fills in tiny creases and contour irregularities, and allows better contact with the cervix.
7. Place the tip against the cervix with moderately firm pressure making sure the tip does not touch the vaginal walls.
8. Initiate the freeze until a 4-7 mm “iceball” is visualized. Allow the tip to defrost before removing from the cervix.
9. Allow the cervix to “thaw” for approximately 5 minutes or until the “iceball” is no longer visible. Refreeze using the same technique as previously described. The freeze-thaw-freeze technique has been proven to be the most effective in treating disease and is the current standard.
10. Post procedure instructions should be verbally explained and a handout provided for the patient to take home, (Appendix J). Ensure the patient understands all instructions. Carefully explain to the patient that she can expect a profuse, watery discharge for several weeks after cryotherapy.
11. Schedule a follow up appointment per district protocol.

Carbon Dioxide Laser Vaporization

Use of the CO₂ laser is widely accepted as one of the most effective forms of treatment for CIN. Precise use of the laser is guaranteed by direct observation with the colposcope. This also permits accurate measurement of the depth of tissue destruction. The aim of laser vaporization is to remove a block of tissue approximately 8-10mm deep effectively removing any involved glands in the ecto- or endocervix.

Hysterectomy – Surgical Removal of the Uterus

- a. Hysterectomy in the primary management of CIN is now rarely indicated.
- b. Indications for hysterectomy may include:
 1. Invasive cervical cancer
 2. Extensive High Grade Squamous Intraepithelial Lesions (HSIL)
 3. Pap tests that continue to be abnormal following conservative methods of management

4. Postmenopausal abnormal Pap test in the presence of a small uterus where cone biopsy may be difficult to perform or less effective in providing a diagnosis
5. Patient's fear of more conservative treatment or if there are doubts that the patient will adhere to follow-up recommendations
6. Intraepithelial disease at the margins of a conization specimen (current studies suggest that residual lesions do not seem to progress to invasion except in a very few cases, however, rigorous follow-up must be done on any woman with residual CIN after conservative treatment)

Cervical Cancer Treatment

Treatment for cervical cancer is dependent upon:

1. The stage of cancer diagnosed,
2. The age of the patient, and
3. The desire to preserve fertility.

Stages of Cervical Cancer

1. Stage 0 -No evidence of primary tumor; Carcinoma-in-situ

2. Stage I -Cervical carcinoma confined to the cervix
 - a. IA -Invasive carcinoma diagnosed only by microscopy; no visual lesion
 - b. IA1 -stromal invasion depth 3mm or less and width 7mm or less
 - c. IA2 -stromal invasion depth greater than 3mm, not more than 5mm; width 7mm or less
 - d. IB -Clinically visible lesion confined to the cervix or microscopic lesion greater than IA2
 - e. IB1 -Clinically visible lesion 4 cm or less
 - f. IB2 -Clinically visible lesion greater than 4 cm

3. Stage II -Cervical carcinoma invades beyond uterus but not to pelvic wall or lower third of vagina
 - a. IIA -Tumor without parametrial involvement
 - b. IIB -Tumor with parametrial involvement

4. Stage III -Tumor extends to the pelvic wall and/or involves the lower third of the vagina, and/or causes hydronephrosis or nonfunctioning kidney.
 - a. IIIA -Tumor involves lower third of vagina, no extension to pelvic wall
 - b. IIIB -Tumor extends to pelvic wall and/or causes hydronephrosis or nonfunctioning kidney

5. Stage IVA -Tumor invades mucosa of the bladder or rectum, and/or extends beyond true pelvis
 - a. IVB -Distant metastasis

Treatment Options

Conservative management

1. Cold knife cone
2. LEEP
3. Laser
4. Partial cervical amputation

These management options should only be considered for stages 0, I, and IA. If preserving fertility is desired, conservative management may be indicated with stages IA1 and/or IA2, only with close follow-up.

Hysterectomy

1. Total hysterectomy, (includes the cervix)
2. Radical hysterectomy with lymph node dissection

Radiation

1. Intracavitary radiation may be used alone or combined with external beam
2. External-beam radiation may be used alone, with intracavitary radiation, or postoperatively
3. Total pelvic irradiation

Chemotherapy

1. May be used alone or in combination with any of the above radiation therapies.

Long Term Follow up Recommendations for Cervical Screening :

1. If hysterectomy was done for CIN 2 or CIN 3 continue to screen for 20 years with no abnormal or positive cytology tests and documentation that the 3 most recent consecutive tests were satisfactory and interpreted as negative or normal. When this criteria is met, discontinue.
2. If invasive cervical cancer, continue annual screening indefinitely as long as the patient remains healthy.

Section V

Pathophysiology of Cervical Cancer

The cervix is a dynamic structure that changes with the different stages of a woman's lifetime. These changes can be in response to normal maturation, trauma from intercourse, infections (viral/bacterial), pregnancies, hormonal changes, smoking, and/or other treatments and procedures.

The cervix consists of two types of epithelium; squamous and columnar. Squamous epithelium or mature epithelium is found lining the vagina and the ectocervix. Columnar epithelium or immature grapelike clusters of cells, is found within the endocervical canal. The point at which these 2 types of epithelium meet is known as the squamocolumnar junction (SCJ).

At menarche, a process called metaplasia begins where columnar cells evolve into squamous cells. The tips of the columnar grapelike cells grow together and become mature smooth epithelium. The SCJ begins to move outward onto the ectocervix. The area between the original SCJ and the newly formed SCJ is known as the Transformation Zone (T-zone). This is the area where metaplasia occurs and is the site of most squamous cancers and their precursors.

As the T-zone proliferates and matures, it is vulnerable to outside stimuli that can cause atypical growth known as Cervical Intraepithelial Neoplasia (CIN or sometimes referred to as dysplasia). Most experts currently agree that the major cause of CIN is a DNA mutation in an immature metaplastic cell due to Human Papilloma Virus (HPV). The cells of the transformation zone can change from squamous metaplasia to CIN (dysplasia) and may progress to carcinoma in situ or invasive cancer. (Figure 1)

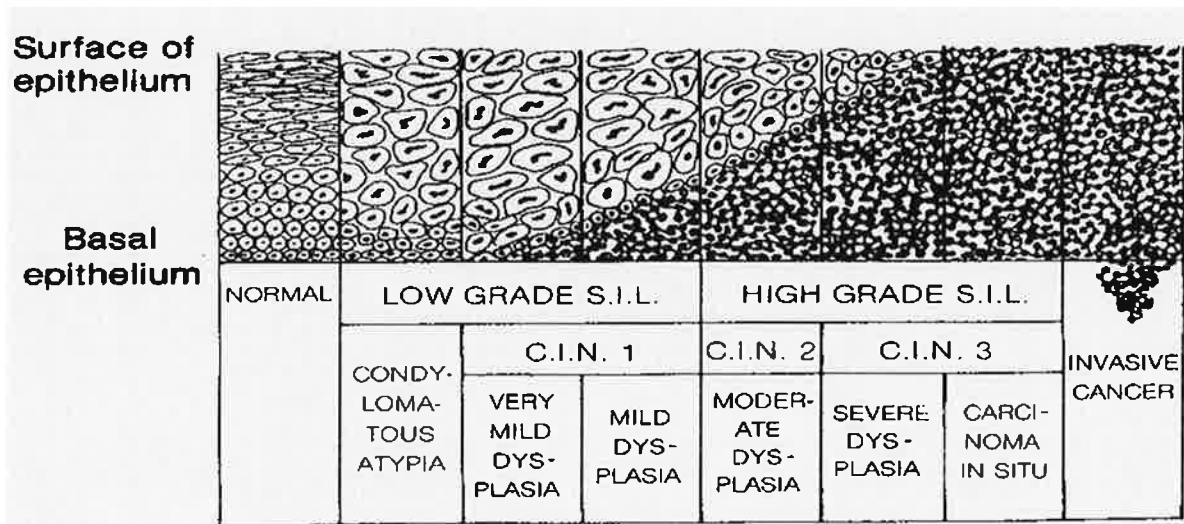


Figure 1

These changes may progress or regress over time. Progression most likely occurs in response to changes as listed in paragraph 1, and regression to immunological or healing factors. Women with a compromised immune system are at high risk for cervical neoplasia. Most references agree that the majority of low grade lesions regress spontaneously (Percentages vary).

Recent study of more than 1 million women used in the development of the ASCCP 2012-13 Consensus Guidelines revealed that 50% of CIN2 regressed spontaneously, (Massad, L.S., et.al. (2013).

Natural history of cervical cancer



Source: PATH, 2001

Presentation by Herschel W. Lawson, MD
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Risk Factors for Cervical Cancer

Women with a history of previous CIN 2/3 (dysplasia) are at greater risk of reoccurrence. Therefore, more frequent re-screening of these women may be necessary to prevent progression to cancer.

While epidemiological studies demonstrate HPV as the major risk factor for cervical cancer, there are other known risk factors including:

- ♦ Early age of sexual intercourse (under 18 years) increased risk of HPV infection
- ♦ Sexual intercourse with men who have had multiple partners or have had sexually transmitted diseases
- ♦ Exposure to diethylstilbestrol (DES) before birth
- ♦ Genital condyloma accuminata (human papillomavirus, HPV)
- ♦ Smoking cigarettes, or having a partner who smokes
- ♦ Low socioeconomic status

Section VI

Patient Education

What can women do to lower their risks of having cancer? The most significant first step they can take is to educate themselves about the disease and its prevention through behavior change and Pap test screening. Public Health and other community based clinics can provide patients and their partners with complete information about cervical cancer and the Pap test as a screening tool.

Educational materials used should be updated to reflect current knowledge of cervical cancer and its prevention. In an effort to decrease cervical cancer morbidity and mortality in the United States, information about the disease's risk factors, screening, follow-up, and record-keeping should be included in counseling sessions with the patient and her partner(s), in the education materials provided to the patient and her partners(s), and in appropriate community education presentations.

Educate both female and males regarding HPV vaccine, Gardasil. CDC recommends routine vaccination with GARDASIL for girls and boys ages 11 to 12, and for young women ages 13 through 26 and young men ages 13 through 21 who have not already been vaccinated. It is also recommended for individuals with compromised immune systems (including people living with HIV/AIDS) through age 26. Gardasil is available in the health centers through the "Vaccine for Children" program, and in some centers via the Family Planning and STD programs.

Reducing Risk Factors

Risk factors are characteristics or activities that seem to be related to the development of a disease. They may be important as inducers or causes of cancer, promoters of the growth of cancer, or indirect markers of persons who are at higher risk of developing cancer. Patients need to be told the risk factors which may change the course of the disease and delay or prevent the development of the disease. Risk reduction involves giving up specific activities for abstract ends.

A woman with any of these risk factors should inform her clinician so she/he can make sure the woman is appropriately managed and is screened at the appropriate intervals.

A woman can reduce her risk of cervical cancer by doing the following:

- Abstaining from sex.
- Avoiding early sexual intercourse.
- Limiting the number of sexual partners.
- Avoiding sex with men who have had multiple sex partners.
- Avoiding sex with men whose past partners have had abnormal Pap tests.
- Avoiding sex with men with genital condyloma accuminata or other sexually transmitted diseases.
- Using condoms during **all** sexual intercourse.
- Quitting or never smoking.
- If exposed to DES in utero, discuss with her clinician about colposcopy and extra Pap tests.
- **Routine Pap Test screening**

The Pap test is the one effective screening test for cervical cancer and its precursors because it is safe, inexpensive, widely available, and can usually detect abnormal cervical cells (dysplasia) long before the disease becomes invasive or progressive. The majority of cervical cancer deaths occur in women who have never been screened. Many more women fail to have Pap tests at the frequencies recommended.

Preparation for Screening

Information given to each woman prior to her appointment should include:

- Not washing the vagina or douching for 24 hours before the exam. This includes wash cloths, douches, cervical caps, vaginal medication, tampons, diaphragms, sponges, condoms and fingers.
- Having the Pap test 1-2 weeks after the end of the menses.
- Having bleeding and vaginal discharge treated before the Pap test is scheduled and returning for the Pap test at the optimum time.
- Patient should be educated that she is receiving a Pap Test that is for detecting pre-cancer or cancer.
- Patient should be educated about diagnostic and treatment procedures.

Complying with Follow-up Care Recommended by the Clinician

For the patient, compliance with any and all follow-up care is extremely important. Failure to follow-up could lead to progression of the disease, requiring more expensive and extensive treatment. What can the woman do? Here are a few suggestions:

- Have all infections treated, take all medicine prescribed and make sure all partners are treated, as needed.
- Return for repeat Pap tests as recommended by the clinician.
- Get recommended tests, such as colposcopy or biopsy, if indicated.
- Let the clinician know about changes in symptoms (i.e., symptoms getting worse or new symptoms).
- Obtain a second opinion, if unsure of referring clinician's recommendations for treatment. The American Cancer Society, local university hospital, or the American College of Obstetricians and Gynecologists are good places to start looking for another provider to give a second opinion. The local health department or community clinics are also good sources for referrals to other competent physicians.

Follow Up Protocol

Every effort should be made to contact the patient regarding an abnormal finding. At least 3 attempted contacts must be documented in the patient's medical record before executing an Administrative Closure. The following steps are recommended in the follow-up process.

- At least two telephone calls and/or letters. If these do not successfully reach the patient, proceed to the next step.
- A certified letter marked return receipt requested must be sent. Contact with a family member or other person is not considered contact.
- The dates and results of phone calls and letters must be documented in the patient's medical record.
- If a patient refuses follow-up, the nurse should identify barriers, (i.e., fear, lack of transportation, etc.). An attempt should be made to eliminate any barriers. Refusal of follow-up must be documented in the patient's medical record.
- If the patient is reached, but does not comply with recommended follow-up after following the above steps, the case is reported as "refused".
- If the patient has moved without a forwarding address or has died, the case should be reported as "lost to follow-up".
- Any variance from the written protocol should be explained in the patient's medical record. The reason for variance must be beyond the capability of the clinic staff to overcome.

Rigorous attempts must be made to complete diagnosis within 90 days of the abnormal Pap test.

- Case management efforts such as phone calls, letters, and home visits should be employed to encourage patient compliance.
- Mail a certified letter to patients who fail to comply stressing the importance of obtaining diagnostic follow-up.
- All attempts to contact the patient must be documented in the medical record. If a patient refuses follow-up, the nurse and/or patient navigator should attempt to identify barriers, (i.e.; fear, lack of transportation, etc.), and efforts made to eliminate the barriers.
- If certified letter return receipt states patient is no longer at that address or is deceased, report the patient as "Lost to Follow-up" and retain copy of receipt in the patient's medical record.
- If certified letter return receipt states patient refused, retain copy of the receipt and document patient refusal of follow-up in the medical record including date of refusal.
- Any variance from the written protocol should be explained in the patient's medical record. The reason for variance must be beyond the capability of the clinic staff to overcome. When possible obtain a signed "*Statement of Refusal of Care*" when a patient rejects care that been offered to her.

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Colposcopy and Cervical Biopsy Fact Sheet

Colposcopy and Cervical Biopsy have been recommended for one or more of the following reasons:

1. **Abnormal Pap test** which requires this test to find out where these abnormal cells are and what type of cells are present. Since the Pap test is a screening test, it may not give a complete picture of the problem. With the help of Colposcopy, the cervix, (the mouth of the womb), and vagina can be looked at closely and a biopsy, (tissue sample), can be taken to determine the cause of the abnormal tissue. This test is performed in a clinic or physician's office.
2. **An abnormal appearing area was seen on your cervix** at the time of your Pap test.
3. You are a **DES exposed daughter**, and it is important to look at your cervix and vagina to check for possible changes.

What is a Colposcopy?

Colposcopy is a painless examination of the cervix and vagina with a low power microscope. This procedure is usually done between menstrual periods and generally takes less than ten minutes. A woman lies down on the exam table in the same position like when the Pap test was done and a speculum is inserted into the vagina so as to be able to view the cervix and vagina.

Why is a woman advised to have a Colposcopy exam?

If during the Pap test, the cervix looks abnormal or the Pap test finds abnormal cells, a Colposcopy may help determine the cause and what treatment may be needed. Use of the Colposcopy microscope gives a closer view of cervical changes to see if they are abnormal. If an area of abnormal cells is found, a biopsy can be taken from that spot.

What is a Biopsy of the Cervix?

A biopsy of the cervix is the removal of a small piece or pieces of tissue from the cervix using a specially designed instrument. This can be done during the Colposcopy exam. The tissue will be sent to a laboratory where it will be examined under a microscope. The results of this tissue exam will be reviewed by your health care provider/ and recommendations for treatment or follow up will be made. This information and recommendations will be discussed with you on your next visit to the clinic which is usually 2 weeks after the Colposcopy exam. You should make that appointment for this visit as soon as possible after the Colposcopy.

Is the Biopsy painful?

Most women describe the biopsy as feeling like a sharp pinch. Some experience a menstrual like cramp. There may slight spotting or bleeding for a few days after the cervical biopsy.

What treatment will I need?

Sometimes treatment is not recommended, but repeating your Pap test at 6 month intervals will be needed as follow up. If treatment is required, your health care provider will discuss this with you at your 2 week follow up visit. Many of these treatments can be done in the local physician's office. Your health care provider can assist you in making these appointments.

If the Colposcopy determines that you have cervical cancer, you may be eligible to enroll in the Women's Health Medicaid program which will cover the cost of your cancer treatment.

Appendix B

Patient Label

Date

Colposcopy and/or Cervical Biopsy Exam Record

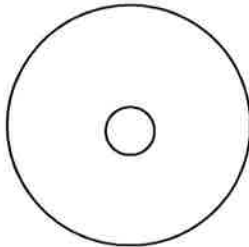
Subjective Data:

Reason for Colposcopy: _____
Prior Abnormal Pap test ___yes ___no When: _____ Prior Treatment: _____
Health History: _____
Allergies: _____ OB: Full Term___ Preterm___ AB___
Previous STD: _____ Immunosuppressed: ___yes ___no
FP method: _____ No. of Sexual Partners: ___ Date last intercourse _____
DES exposure in utero: ___yes ___no Alcohol/Drug use: _____
Medical Problems: _____

Objective Data:

BP: _____ Patient counseled and consent signed: _____ Pregnancy Test result, if indicated _____
Nurse's Signature: _____

Colposcopy: _____ Satisfactory
_____ Unsatisfactory



_____ Metaplasia
_____ Nabothian Cyst
_____ Transformation Zone
_____ Leukoplakia
_____ White Epithelium
_____ Mosaic
_____ Punctuation
_____ Atypical Vessels
Biopsy Sites: _____, _____, _____
ECC: _____
Polyp Removal: _____

Other Findings: Vagina: _____
Vulva: _____

Colposcopist Signature: _____ Date: _____

Assessment:

Pathology Review:
Assessment: _____ Date: _____

Plan:

Plan/Recommendations: _____

_____ Repeat Pap test in _____ months
_____ HPV DNA testing in _____ months

Comments: _____

Physician/Colposcopist Signature

Appendix C

Patient Label

Colposcopy and/or Cervical Biopsy Consent

I, _____, have received a Colposcopy Fact Sheet

Patient's Name

containing detailed information on the nature and purpose of colposcopy and cervical biopsy. I have read the Fact Sheet, (or had it read to me), it has been explained to me, and I understand the information.

I understand that the procedure of Colposcopy is looking at the cervix and vagina with a low powered microscope and that a biopsy is a removal of tissues from these areas by a special instrument for examination in the laboratory under a higher power microscope.

I consent to have Colposcopy and Cervical Biopsy performed on me. Being mentally competent, I hereby assume full responsibility and release the physician/colposcopist, the _____ Board of Health and/or their designee, and any other office staff of any and all liability for any adverse results that may occur from this procedure.

I understand that no examination or test is one hundred percent, 100%, accurate, and that no guarantee can be made as to the correctness of the diagnosis. I further understand that the tissue taken during the biopsy will be examined by a laboratory.

All of my questions regarding this procedure have been answered. I also understand that the physician/colposcopist and/or my health care provider at the _____ Board of Health are available to answer any additional questions I may have. I also acknowledge that I have been given post Colposcopy care instructions.

Signature of Patient

Date

I have witnessed the fact that the patient, signed above, has received the above mentioned information and has stated that she has read and understood the same.

Witness

Date

I have been provided information regarding all available procedures and options. The risks, benefits and alternatives of treatment have been discussed with me by _____, and all questions have been answered.

Signature of Patient: _____ Date: _____

Signature of Physician/Colposcopist: _____

Date: _____ Time: _____

Post Colposcopy and Cervical Biopsy Instructions

Patient Label

- ◆ You may have slight bleeding, spotting or a dark yellow brownish discharge for a few days after the biopsy.
- ◆ Through rare, possible infections or heavy bleeding can occur.
- ◆ **Care Instructions for after Colposcopy and/or Cervical Biopsy:**
 1. **Do not douche, use tampons or have intercourse (sexual relations) for 2 to 3 days until the discharge has stopped**
 2. **Call your health department at _____ and ask to speak with a nurse if you have :**
 - **Fever of 100.4 degrees or higher**
 - **Pain (especially in the lower abdomen)**
 - **Unusually heavy or bad smelling vaginal discharge**
 - **Heavy Vaginal Bleeding**
 - **Any unusual symptoms or problems**
 - **Any other questions**

Be sure to return to the health department for a follow-up visit to discuss the results of today's examination and recommendations for future care.

Your next visit is scheduled for:

Date: _____

Time: _____

Loop Electrosurgical Excision Procedure, (LEEP) Fact Sheet

What is a LEEP?

A LEEP, (Loop Electrosurgical Excision Procedure), has been recommended for you because your cervical biopsy report revealed a pre-cancerous abnormal cell growth call dysplasia. Although dysplasia is not cancer, it can lead to cervical cancer if you do not get early treatment. LEEP is a way to quickly remove the abnormal cells in your cervix.

A fine wire loop with a special high-frequency electric current allows the doctor to remove the abnormal tissue from your cervix. Because the wire is so thin, there is little damage to surrounding tissue. The loop also seals blood vessels which decreases bleeding.

The tissue sample removed from your cervix will be sent to a laboratory for examination to rule out further problems. You will receive the results of this examination when you return to the health department in 2 weeks for your follow up appointment.

What to expect during the LEEP

Your cervix will be numbed with a local medication. You may get a sensation such as feeling jittery or tingly, increased heart rate, ringing in your ears, or slight nausea from this medication. These sensations will pass quickly. During the procedure, you may smell a foul odor such as something burning.

What to expect after LEEP

After the LEEP you may experience a moderate amount of reddish, watery discharge during the first ten days (10) after the procedure. A protective sanitary pad should be used. You may experience a few cramps somewhat like menstrual cramps. **You should avoid sex, tampons, or douching for three, (3), weeks after the procedure.**

What are the risks from LEEP

Complications from LEEP are unlikely, but risks include the following: heavy vaginal bleeding, severe cramping, incomplete removal of abnormal tissue, narrowing of the cervix, or infection. Rare, but possible complications include: a weakening of the cervix which could cause an increase risk of premature labor, and accidental cutting or burning of normal tissue.

Appendix F

Consent for Loop Electrosurgical Excision Procedure (LEEP)

Patient Label

Date:

Date: _____

I, _____, have received a fact sheet containing detailed information on the nature and purpose of Loop Electrosurgical Excision Procedure, (LEEP). I have read the fact sheet, (or had it read to me), and it has been explained to me. I understand the information.

I understand that a LEEP is a procedure to remove abnormal cervical tissue using a fine wire loop with a special high-frequency electric current. I also understand the tissue sample that is removed from my cervix will be sent to a laboratory for examination by a pathologist.

I understand my cervix will be numbed with a local medication. I may get a sensation such as feeling jittery, increased heart rate, ringing of my ears, or slight nausea from this medication and these feelings will go away quickly.

I have consented to have a LOOP Electrosurgical Excision Procedure performed on my cervix. Being mentally competent, I hereby assume full responsibility and release the physician, the _____ Board of Health, and /or their designee, and other office staff of any and all liability for any adverse results that may occur from the LEEP.

All of my questions regarding this procedure have been answered. I also understand that the physician and the _____ Board of Health nurses are available to answer any addition questions I may have.

Signature of Patient

Date

I have witnessed the fact that this patient received the above mentioned information and acknowledged that she has read this information and understood the same.

Signature of Witness

Date

I have been provided information regarding all procedures and options. The risks, benefits, and alternative treatment(s) have been discussed with me by _____. All questions have been answered.

Signature of Patient

Date

Signature of Physician

Date

Appendix G

Post LEEP Instructions

After a LEEP is performed, your cervix will go through a healing process. This healing process will take a few weeks. You will be given an appointment to return to the health center in 2 weeks to review your test results and an assessment of the healing process. Your cervix will need to be closely monitored for the next two (2) years after a LEEP by having a Pap test every 6 months. If your Pap test continues to be abnormal, you may need additional treatment.

Following the LEEP, you may have:

1. thick, brownish-black discharge which is a result of the medication paste used at the end of your LEEP to help decrease bleeding.
2. mild cramping
3. slight vaginal bleeding
4. heavier bleeding during your next menstrual period

After the LEEP Instructions for care at home:

1. **DO NOT HAVE INTERCOURSE (No sexual relations for three (3) weeks)**
2. **DO NOT USE TAMPONS FOR THREE (3) WEEKS**
3. **DO NOT DOUCHE FOR THREE (3) WEEKS**

Please call us at _____ if you have:

- **Heavy Bleeding**
- **Severe abdominal pain unrelieved by Tylenol or Advil**
- **Fever (greater than 100.4 F)**
- **Foul smelling vaginal discharge**

Cryotherapy Fact Sheet

What is Cryotherapy?

Cryotherapy is a treatment in which the cervix, (mouth of the womb) , is touched by an instrument that rapidly freezes the tissue. It is used to treat abnormal cells on the cervix.

How is Cryotherapy performed?

Cryotherapy usually is performed after a Colposcopy which may have included a biopsy of the cervix. It is done with the patient in the same position you would be in for a Pap test exam and it take several minutes.

Is it painful?

Most women describe pelvic pressure or menstrual-like cramps

What can I expect after Cryotherapy?

All women will have a watery discharge which may last for several weeks. This discharge may be extremely heavy or may be blood-tinged in some women. You will be advised to not have intercourse or use tampons for several weeks so as to avoid an infection.

What are the risks of Cryotherapy?

Most women do not have any serious side effects after Cryotherapy. However, rarely serious complication can occur. This can include fainting, flare-up of pelvic infection, freeze burns of the vaginal wall, and excessive bleeding. Recurrence, (less than 10 in 100), of the abnormal cells that are left untreated may progress to cancer. Also, in a small number of women, the cervix may narrow and a condition called Cervical Stenosis may develop. This is why follow up Pap tests are very important so as to judge the success of the treatment.

Appendix I

Consent for Cryotherapy

Patient Label

Date: _____

I have received a fact sheet containing detailed information on the nature and purpose of Cryotherapy. I have read the fact sheet, (or had it read to me), and I understand the information.

I understand that Cryotherapy of the cervix is a treatment which involves freezing tissue.

I understand that this treatment is not 100% effective, and no guarantee can be made as to the success of the treatment.

I consent to have Cryotherapy performed on me. Being mentally competent, I hereby assume full responsibility and release the physician, the _____ Board of Health, or their designate of any and all liability for any adverse results that may occur from the cryotherapy.

All my questions regarding this procedure have been answered. I also understand that the physician or the _____ Board of Health will answer any additional questions regarding this procedure that I may have.

Signature of Patient

Date

I have witnessed the fact that this patient received the above mentioned information and acknowledged that she has read this information and understood the same.

Signature of Witness

Date

I have been provided with information regarding all available procedures and options. The risks, benefits, and alternative treatment have been discussed with me by _____, and all questions have been answered.

Signature of Patient

Date

Signature of Physician

Date

Post Cryotherapy Instructions

After “freezing” the cervix, or other tissue, the cells die and slowly disappear. The destroyed area heals over with new normal skin. Normally this takes approximately 4-6 weeks to complete this process. Even then, new cells are very “young” and are multiplying rapidly. It can take 4-6 months for the tissue to become fully thickened and the cells mature. For this reason, we need to wait 6 months before repeating the Pap test.

You may notice:

- **A heavy watery vaginal discharge** – This tends to be really heavy, frequently requiring use a menstrual pad. This is caused by the frozen cells becoming liquid and disappearing. This may last 3-4 weeks, but is usually gets much better after 1-2 weeks. It will have a characteristic odor.
- **Bloody Discharge** – This will usually occur from time to time during the early healing. It tends to be minimal, (a little), but could be heavy at first. It will usually decrease with rest. If it continues to be heavy, (saturating more than 4 pads in 12 hours), call your clinic. **Intercourse during this healing may cause increased bleeding.**
- **Menstrual Cramps** – Occasional cramps may occur and they tend to be quite mild. This usually occurs during the first few days following the procedure. Two tablets of Motrin, Advil, or Aspirin may be taken every 4-6 hours.

After Cryotherapy Instructions:

1. **Do not have intercourse (sexual relations) for 3-4 weeks.** It is important to use a latex condom to protect the cervix until your follow up Pap test. If bleeding occurs after you have had intercourse, stop all sexual relations for at least one week. Call the clinic if the bleeding becomes heavy or happens frequently.
2. **Do Not Use Tampons** for at least 3 weeks after Cryotherapy.
3. **Do Not Douche** for 6 weeks unless we ask you to do this.
4. **Use any Vaginal Medication prescribed by your clinic or doctor** according to directions.

Call the Clinic at _____ if you have:

- **Fever of 100.4 degrees or higher and chills**
- **Pain (steady, lower abdominal)**
- **Heavy Bleeding (soaking more than 4 pads in 12 hours)**
- **Vaginal Discharge (if it has a Bad Odor or changes for the discharge described above)**
- **Any unusual symptoms or problems or any other questions.**