

Cervical Screening Manual

Standardized Procedures for Cervical Screening and Follow-up

Georgia Department of Human Resources
Division of Public Health
Cancer Control Section
And
Office of Women's Health Services

FOREWORD

This manual has been revised in the interest of improved quality and standardization of the Cervical Screening Program throughout the State of Georgia. It is the product of the collaborative work of the staff in the Cancer Control Section, Office of Women's Health Services, and Women's Health Nurses in the Waycross district.

This manual incorporates the changes in the Bethesda System in 2001 and most current treatment recommendations and follow-up. The revised standards apply to all clinical services performed in Public Health clinics.

ACKNOWLEDGEMENTS

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PAP SMEAR SCREENING

Guidelines are utilized for asymptomatic women. Women who are symptomatic or at high risk are approached on a case-by-case basis.

Screening Criteria/Frequency Guidelines

The Georgia Department of Human Resources, Division of Public Health adheres to the consensus screening recommendations developed by the American College of Obstetrics and Gynecology (ACOG), the American Cancer Society (ACS), the National Cancer Institute, the American Medical Association, the American Nurses Association, 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 Title X project and the Georgia Breast and Cervical Cancer Program have adopted the following Screening Guidelines published by ACOG and ACS, which are as follows:

- Annual cervical Pap screening should begin approximately 3 years after beginning sexual intercourse, but no later than age 21 years.
- Women younger than 30 years should undergo annual cervical Pap screening.
- Women aged 30 years and older who have had three consecutive negative cervical Pap screening tests and who have no history of CIN 2 or CIN 3, are not immunocompromised and are not HIV infected, and were not exposed to diethylstilbestrol in utero may extend the interval between cervical Pap examinations to every 3 years.
- Cervical cancer screening (Pap) of low risk women over age 70 is not recommended based on the recommendations of the American Cancer Society and the U.S. Preventive Services Task Force. Therefore, if a woman aged 70+ has at least 3 consecutive normal Pap smears in the past 10 years and no history of abnormal screening, at the discretion of the clinician, screening may be discontinued.

- For a woman who has had a hysterectomy:

- 1) Total Hysterectomy:

- (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 may discontinue routine vaginal cytology testing.
(ACOG Practice Bulletin No 45, p 8)

- (b) With pathology “positive” for cervical cancer: Vaginal Pap smear every 6 months for 2 years; if negative, then every year.

- 2) Partial Hysterectomy with cervical stump present: Routine annual screening then every three years after 3 consecutive negative Paps.

A Pap smear can be waived if written results of a Pap done within 12 months at another facility are available.

The guidelines for the Maternal and Child Health Program advise that a Pap smear be performed during pregnancy at the time of the first visit, unless the client 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 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.

Pap smear screening frequency schedules are listed in Table I

Table 1
Summary of Cervical Screening Recommendations

Client Profile	3 months	6 months	12-15 months	3 Years
Family Planning Annual/Initial			X Until age 30	X At age 30 and 3 previous consecutive negative Paps
Barrier contraceptives with 3 prior negative Paps			X Until age 30	X At age 30 and 3 previous consecutive negative Paps
Postpartum			X	
Referrals from other agencies with copy of negative Pap smear			X Until age 30	X At age 30 and 3 previous consecutive negative Paps
Prenatal			X	
Cancer Control Section Annual/Initial			X Until age 30	X At age 30 and 3 previous consecutive negative Paps
Hysterectomy Pathology positive for cancer		X Vaginal Pap for two years	X After 2 years of 6 months negative Paps	

Client Profile	3 months	6 months	12-15 months	3 years
Hysterectomy with Cervical stump and pathology negative for cervical cancer			X Annually for the first 3 years	X Every 3 yrs after 3 consecutive negative Paps
HIV +		X		
Unsatisfactory Pap smear	X			
Inadequate history			X Until age 30	X Every 3 yrs after 3 consecutive negative Paps
Negative for intraepithelial lesion or malignancy- no endocervical component, post-menopausal			X	

Screening Conditions

New clients should be instructed over the phone when scheduling their initial exam. Clinic phone clerks should routinely instruct clients making appointments for new and annual exams to:

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

When scheduling clients who are returning for repeat Paps, regardless of the reason, inform client about optimal preparation:

1. Patient is not on 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 smear or cultures).
4. No cervicitis (if present, treat first and have patient return in 12 weeks near mid-cycle).

If Pap smear is deferred, the rest of the exam can be done and the client 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.

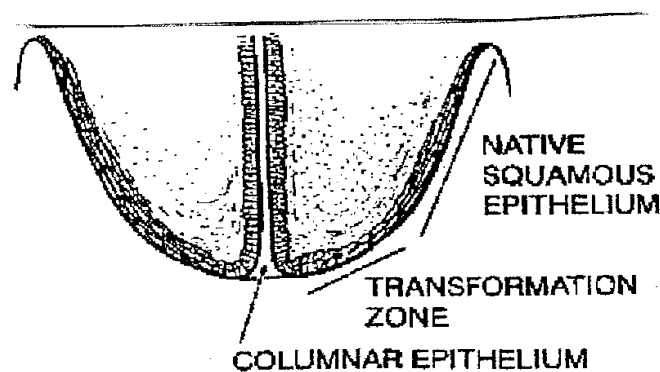
Good light illumination and bivalve specula of different types and sizes should be available for either test method.

Procedure

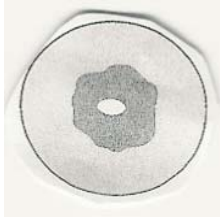
1. Utilize adequate space, time, light, and privacy for the exam.
2. Have the patient void and assist with undressing if needed.
3. To enhance the relaxation and comfort of the patient, explain all procedures carefully and use a mirror if the patient desires.
4. Assist the patient into the lithotomy position if needed. For women with disabilities or the elderly, other positions can be effectively used. See Appendix 2, "Table Manners".
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 smear.

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 smear. 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 smear until the infection has been treated.
12. Use this recommended order for cervical specimen collection for women 29 years and younger:
 - Vaginal pH
 - Wet Mount (Taking the wet prep specimen first does not disturb the cervix and avoids contamination from blood or cervical mucus).
 - Chlamydia/Gonorrhea DNA probe
 - Pap SmearIn 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.

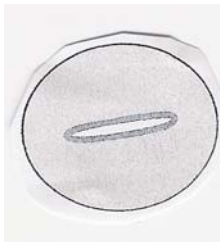
Figure 1



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 clients, premenopausal nulliparous clients, or clients on birth control pills.



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

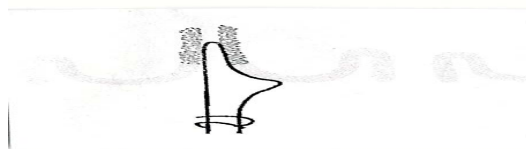


Ectocervix with small or stenotic os may be found in premenopausal nulliparous patients, postmenopausal clients, or clients with history of treatment for abnormal Pap(s). SCJ is completely inside canal.

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. Hold the sample.

Figure 2

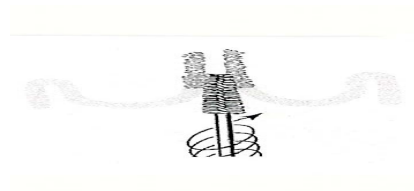


To collect the endocervical sample:

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.

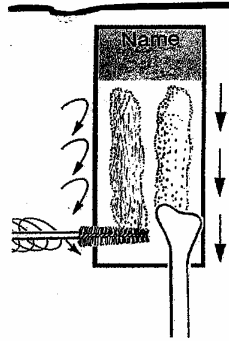
3. Withdraw carefully to avoid vaginal contamination.

Figure 3



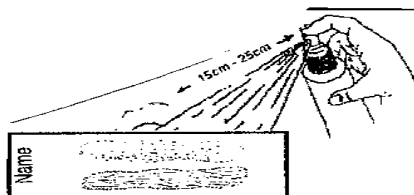
4. Spread the spatula sample(s) evenly on the glass slide using moderate pressure. Apply the endocervical sample, to the same slide by rolling the brush along the slide using moderate pressure. (Figure 4)

Figure 4



5. 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



6. For liquid based Pap smears, 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.
7. Always confirm the labeling of the specimens before leaving the patient. An assistant may complete the lab requisition; however it is the clinician's responsibility to ensure complete and accurate labeling. 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.
8. 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.
9. Keep a tracking record to ensure that all Pap smear reports are received.

BETHESDA SYSTEM 2001

Classification

Specimen Type

Indicate conventional smear vs liquid-based vs other

Specimen Adequacy

1. Satisfactory for evaluation (describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g. ., partially obscuring blood, inflammation, etc.)
2. Unsatisfactory for evaluation...*(specify reason)*
 - a. Specimen rejected/not processed (*specify reason*)
 - b. Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (*specify reason*)

General Categorization (Optional)

1. Negative for Intraepithelial Lesion or Malignancy
2. Epithelial Cell Abnormality: See Interpretation/Result (*specify "squamous" or as appropriate "glandular"*)
3. Other: See Interpretation/Result (e.g. endometrial cells in woman ≥ 40 years of age)

Automated Review

If case examined by automated device, specify device and result

Ancillary Testing

Provide a brief description of the test methods and report the result so that it is easily understood by the clinician.

Interpretation/Result

Negative for Intraepithelial Lesion or Malignancy

(when there is no cellular evidence of neoplasia, state this in the General Categorization above and/or in the Interpretation/Result section of the report, whether or not there are organisms or other non-neoplastic findings).

ORGANISMS:

Trichomonas vaginalis

Fungal organisms morphologically consistent with Candida

Shift in flora suggestive of bacteria vaginosis

Bacteria morphologically consistent with Actinomyces

Cellular changes consistent with herpes simplex virus

OTHER NON-NEOPLASTIC FINDINGS (*Optional to report; list not inclusive*)

Reactive cellular changes associated with

- Inflammation
- Radiation
- Intrauterine Device (IUD)

Glandular Cells status post hysterectomy

Atrophy

Other

- Endometrial cells in a woman ≥ 40 years of age
(Specify if “negative for squamous intraepithelial lesion)

Epithelial Cell Abnormalities

Squamous Cell

Atypical squamous cells

-of undetermined significance (ASC-US)

- cannot exclude HSIL (ASC-H)

Low grade squamous intraepithelial lesion (LSIL)

-encompassing : HPV/mild dysplasia/CIN I

High grade squamous intraepithelial lesion (HSIL)

-encompassing: moderate and severe dysplasia,

CIS/CIN II/CIN III

-with features suspicious for invasion (*if invasion suspected*)

Squamous cell carcinoma

Glandular Cells

Atypical

-endocervical cells (NOS or specify in comments)

-endometrial cells (NOS or specify in comments)

-glandular cells (NOS or specify in comments)

Atypical

-endocervical, favor neoplastic

-glandular cells, favor neoplastic

Endocervical adenocarcinoma in situ
Adenocarcinoma
-endocervical
-endometrial
-extrauterine
-not otherwise specified (NOS)

Other Malignant Neoplasms specify

Educational Notes and Suggestions (optional); suggestions should be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications may be included).

Descriptive Pathology of Pap Smear Results

The following descriptions of Pap smears are based on descriptive pathology and the Bethesda System of classification:

2001 Specimen Adequacy

“Satisfactory” indicates that the specimen is adequate for interpretation by the laboratory. Endocervical cells in a Pap smear are a normal finding that documents sampling above the squamous columnar junction. Their presence suggests, but does not prove, that the cervix was adequately sampled. However, **their absence does not prove that the cervix was inadequately sampled** and a repeat Pap is not necessary. Immature metaplastic squamous cells also indicate that the smear was taken from the transformation zone, but the identification of these cells is less reliable than identification of endocervical cells. The presence of endocervical mucus also indicates sampling above the squamous columnar junction.

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 smears lacking an endocervical component should review and improve their technique.

“Unsatisfactory” indicates that the Pap smear cannot be adequately interpreted, and no interpretation will be given by the pathologist. **However, if abnormal cells are detected, the specimen is never labeled unsatisfactory.** The laboratory should offer some explanation to help the clinician improve his/her technique and handling of the specimen (Table 2). If the clinician or laboratory rate of unsatisfactory Pap results is over 5-10% unsatisfactory Pap smears consistently, this suggests a significant problem requiring investigation and correction. Because invasive cancer can also cause an unsatisfactory Pap smear, follow-up and re-evaluation is very important. Ordinarily, the Pap smear should be repeated 3 months after appropriate management.

Table 2

Cause of Unsatisfactory Pap	Appropriate response
Smear too bloody (excess red blood cells); 75% or more of the slide is obscured.	Repeat Pap in 3 months; may need to screen for Chlamydia if not on menses.
Smear too inflammatory: 75% or more of slide covered with white blood cells	Diagnose and treat infection; repeat Pap in 3 months
Cells air-dried	Fix slide promptly
Cells are cytolized	Avoid water from douching or over-moist speculum; avoid lubricants or vaginal medication

Cause of Unsatisfactory Pap	Appropriate response
Scanty cellular matter	Firmer scrape to obtain more cellular material
Cellular material too thick	Spread more evenly over slide or use two slides for heavy material
Cells too atrophic	Prescribe intravaginal estrogen; repeat Pap 1 week after completion of therapy.
Foreign material	Avoid medications and lubricant; repeat Pap

Interpretation/Result

Negative for intraepithelial Lesion or Malignancy

This result implies an adequate specimen with no cellular abnormalities. Cells are fully differentiated. Mild inflammation or metaplasia may be present. Squamous metaplasia is a normal response at the squamous columnar junction. Its incidence may be increased in teenagers, during pregnancy, or in women using oral contraceptives.

Infections, inflammation and reparative changes are included in this category. Pap smears indicating inflammation reveal a nuclear enlargement and infiltration cells (white blood cells). This is a benign process resulting from one of the following infections, with appropriate action indicated:

- Candida- vaginal or oral fungicidal agents
- Trichomonas- metronidazole for woman and her partner as appropriate.
- Herpes or cytomegalovirus- notify client and counsel if not previously diagnosed.
- Bacterial vaginosis (clue cells)- evaluate and treat if symptomatic
- Actinomyces- evaluate if client has an IUD
- Other inflammation- test for gonorrhea and Chlamydia (these tests may be routinely done at initial or annual exams.

Inflammation stimulates cell division, increasing the chance for abnormal DNA and cell changes or dysplasia to occur. Wait for resolution after treatment and repeat Pap in 12-15 months.

Squamous Cell Abnormalities

- Atypical squamous cells of undetermined significance (ASC-US)
This diagnosis by itself does not justify treatment because it is not diagnostic of a cancerous or precancerous lesion. ASC does require further evaluation to exclude the presence of a higher-grade disease that might require treatment. Conservative recommendations include repeating the Pap in 4-6 months, if Pap remains ASC, then colposcopy is recommended. Treatment may be initiated if there is biopsy proven dysplasia.
- Atypical squamous cells- cannot exclude high-grade intraepithelial lesion (HSIL); also known as ASC-H. Further evaluation to exclude the presence of HSIL is warranted. Colposcopy is indicated in this case [instead of repeating Pap in 4-6 months].
- Low grade squamous intraepithelial lesion (LSIL) includes koilocytosis (HPV) and mild dysplasia. In mild dysplasia, the disordered growth is restricted to the basal portion of the epithelium, with more ordered growth present toward the surface of the epithelium. 60% of LSIL regress spontaneously. HPV can be detected in 90% of pre-invasive and invasive squamous neoplasms.
- High grade intraepithelial lesion (HSIL) includes moderate and severe dysplasia, and carcinoma in situ (CIS). A cytological report of HSIL identifies a woman at significant risk for having CIN 2, 3, or invasive cancer. In moderate dysplasia HSIL shows abnormal proliferation involving up to two-thirds of the thickness of the epithelium.
- Squamous cell carcinoma/malignant cells suggestive of invasive cancer

With such Pap smear results, severely dyskaryotic or anaplastic cells with hyperchromic, pleochromatic, and irregular nuclei, sometimes with mitotic figures, are present. There are usually many red and white blood cells and much necrotic material. Histological confirmation can only be made by biopsy.

Glandular Cell Abnormalities

- Atypical glandular cells (AGC): endocervical, endometrial or glandular, not otherwise specified (NOS)
- AGC, favor neoplastic, endocervical, endometrial, or NOS

The categories AGC favor neoplastic are more likely associated with significant disease than AGC NOS. For example, biopsy proven CIN 2, 3, AIS or invasive carcinoma is present in only 9-41 % of AGC NOS as compared to 27-96% of AGC favor neoplastic

- Endocervical adenocarcinoma in situ (AIS)

Adenocarcinoma in situ (AIS) of the cervix is characterized by endocervical glands lined by atypical columnar epithelial cells that cytologically resemble those of cervical adenocarcinoma. Proliferation of these glands results in a crowded, cribriform pattern without invasion. Multifocal disease is common: approximately 50% of women with AIS have concomitant squamous CIN.

- Adenocarcinoma

Adenocarcinoma is determined by the presence of dyskaryotic cells in palisade formation characteristic of glandular epithelium. Cells show enlarged active nuclei, prominent nucleoli, and high nuclear cytoplasmic ratio.

Other

Endometrial Cells in a woman \geq 40 years of age

Endometrial cells- these are normal in the menstruating woman in the first half of the menstrual cycle, or in women using oral contraceptives, hormones, or an IUD. They are also present with abnormal bleeding. They may be associated with endometrial hyperplasia, especially in older women. The presence of abnormal endometrial cells suggests endometrial hyperplasia or endometrial cancer. The presence of unexplained endometrial cells in women over age 50 or any abnormal endometrial cells requires endometrial sampling.

FOLLOW-UP AND MANAGEMENT BY DESCRIPTIVE CATEGORY

The following policy is intended for clinic staff to use for the education of patients and clinicians on the follow-up of Pap smear findings. This policy is based on the 2001 Consensus Guidelines for the Management of Women with Cervical Cytological Abnormalities.

ANY PATIENT WITH A SUSPICIOUS CERVICAL LESION(S) MUST BE REFERRED FOR DIAGNOSIS EVEN IN THE ABSENCE OF ABNORMAL PAP RESULTS.

Specimen Adequacy

1. **Satisfactory for evaluation** – Indicates that the specimen is not obscured by blood or inflammation, has enough cellular material and endocervical or SCJ cells present for evaluation by the pathologist.
2. **Unsatisfactory** – The cytopathologist was not able to process the specimen.
 - A. Repeat the Pap smear in 12 weeks, not sooner.
 - B. If the repeat smear is negative, no further follow-up is needed.

Descriptive Category

1. Negative for Intraepithelial lesions:

- A. Notify the patient that Pap results are negative. Document.
- B. Repeat the Pap smear in 12 to 36 months depending on specific client assessment.
- C. If any inflammatory/infection/reactive changes are specified:
 1. Treat the infection according to recommended protocol.
 2. Repeat smear is not necessary.

2. Atypical Squamous Cells of Undetermined Significance (ASC-US):

- A. Repeat Pap smear in 4 to 6 months.
Special Circumstances:
 1. Immunosuppressed women with ASC-US results must be referred for diagnostics.

2. If post-menopausal refer to algorithms for consideration of treatment with vaginal estrogen cream prior to repeat Pap.
- B. Refer for diagnostic follow-up if repeat Pap continues to be abnormal.
 - C. Repeat Pap smears every 4 to 6 months until 2 consecutive negative smears are obtained.
 - D. Follow client contact procedure: Notify client about necessary follow up. Notification will include 2 phone calls and/or 2 letters if necessary. See page 4.

3. Low Grade Squamous Intraepithelial Lesion (LSIL)

- A. Repeat Pap smear every 4 to 6 months for 2 years. If abnormal results persist, colposcopy with directed biopsy is indicated.
-or-
Refer to a diagnostic clinic or physician for colposcopy directed biopsy. Based on results, further diagnostic tests may be necessary i.e. repeat colposcopy/biopsy, LEEP, and/or conization.
- B. Following diagnosis/treatment
Repeat the Pap smear every 4 to 6 months x 3, unless otherwise recommended by the clinic/physician.
 1. If Pap results remain negative, resume routine screening at 12 months x 3 and if Pap results remain negative, every 36 months for life.
 2. If any of the subsequent repeat smears are abnormal, manage according to clinical guidelines for result.
- C. Follow client contact procedure: Notify client about necessary follow-up. Notification will include 2 phone calls and/or 2 letters if necessary. See page 4.

4. Atypical Squamous Cells – High Grade Cannot Be Excluded (ASC-H)

- A. Refer to a diagnostic clinic or physician for colposcopy directed biopsy. Other diagnostic tests may be necessary i.e., repeat colposcopy/biopsy, LEEP, and/or conization.
- B. Follow client contact procedure - **Rigorous attempts at contact must be made for these clients.** This consists of at least 2 phone contacts, 3 letters (1 certified), and 1 home visit. Receipt from the certified letter must be kept in the client's record. See page 4.

- C. Following diagnosis/treatment:
1. Repeat the Pap smear every 4 to 6 months x 3 Paps, unless otherwise recommended by the clinic/physician.
 2. If Pap results remain negative, resume routine screening at 12 months x 3 and if Pap results remain negative, every 36 months for life.
 3. If any of the subsequent repeat smears are abnormal, manage according to clinical guidelines for result.

-or-

Refer to diagnostic clinic or physician for HPV DNA testing at 12 months if available. *NOTE- BCCP funds will not pay for HPV DNA testing.*

5. High Grade Squamous Intraepithelial Lesion (HSIL), Squamous Cell Carcinoma, Atypical Glandular Cells (AGC):

- A. Refer to diagnostic clinic for workup. This workup may include colposcopy, biopsy, LEEP, endometrial biopsy, D&C, and/or conization.
- B. Follow client contact procedure - **Rigorous attempts at contact must be made for these clients.** This consists of at least 2 phone contacts, 3 letters (1 certified), and 1 home visit. Receipt from the certified letter must be kept in the client's record. See page 4.
- C. Following diagnosis/treatment:
1. Repeat the Pap smear every 4 to 6 months x 3 Paps, unless otherwise recommended by the clinic/physician.
 2. If Pap results remain negative, resume routine screening at 12 months x 3 and if Pap results remain negative, every 36 months for life.
 3. If any of the subsequent repeat smears are abnormal, manage according to clinical guidelines for result.

PROCEDURE FOR CONTACTING CLIENT ABOUT ABNORMAL RESULTS

1. Notify the patient by phone or letter to schedule an appointment for discussion of her Pap results. Document the letter or call in the medical record.
2. When counseling the client, inform her regarding:
 - The need for diagnostic testing and further evaluation. If the first referral resource does not comply with current diagnostic or treatment guidelines, the patient should return for referral for a second opinion.
 - Inform client about the need for a release of information as the health department will need to obtain records from any provider involved with her care because State and Federal regulations require reporting/documentation of any follow-up, diagnosis, and/or treatment. Health departments operate in compliance with the Health Insurance Portability and Accountability Act (HIPAA) Guidelines.
 - Document all follow-up or attempts at follow-up in the medical record.
 - Unless otherwise indicated under the Pap Interpretation (above), a patient with abnormal Pap results must be followed up with a minimum of at least two phone calls or letters that prove successful. Contacts with patient must be documented. If these are not successful contacts, a certified letter with return receipt requested must be sent. Evidence that the letter was sent must be in the client's medical record.
 - Records of any follow-up performed at diagnostic clinics/physician's offices must be requested and placed in the medical record.
 - Any variance in the steps listed above must be carefully documented in the client's medical record.
 - In performing case management, contacting the client through family members or other persons, the following guidance applies:
 - HIPPA does allow a covered entity to leave messages for clients on answering machines, but the information disclosed should be limited to a contact name and phone number and a brief message that the call is a follow-up.
 - HIPPA also allows a covered entity to leave messages with a family member or other person when the client is not home. In this case, professional judgment should be used to assure that any such

disclosures are in the client's best interest.

- The only way HIPPA prohibits contact with someone other than the client, is if the client has requested confidential communication. For example, the client can ask that phone calls be at work and not at home, or that mailings be sent in envelopes and not as a postcard.

- If staff is unable to locate the client, the record may be closed and the client will be considered "lost to follow-up."

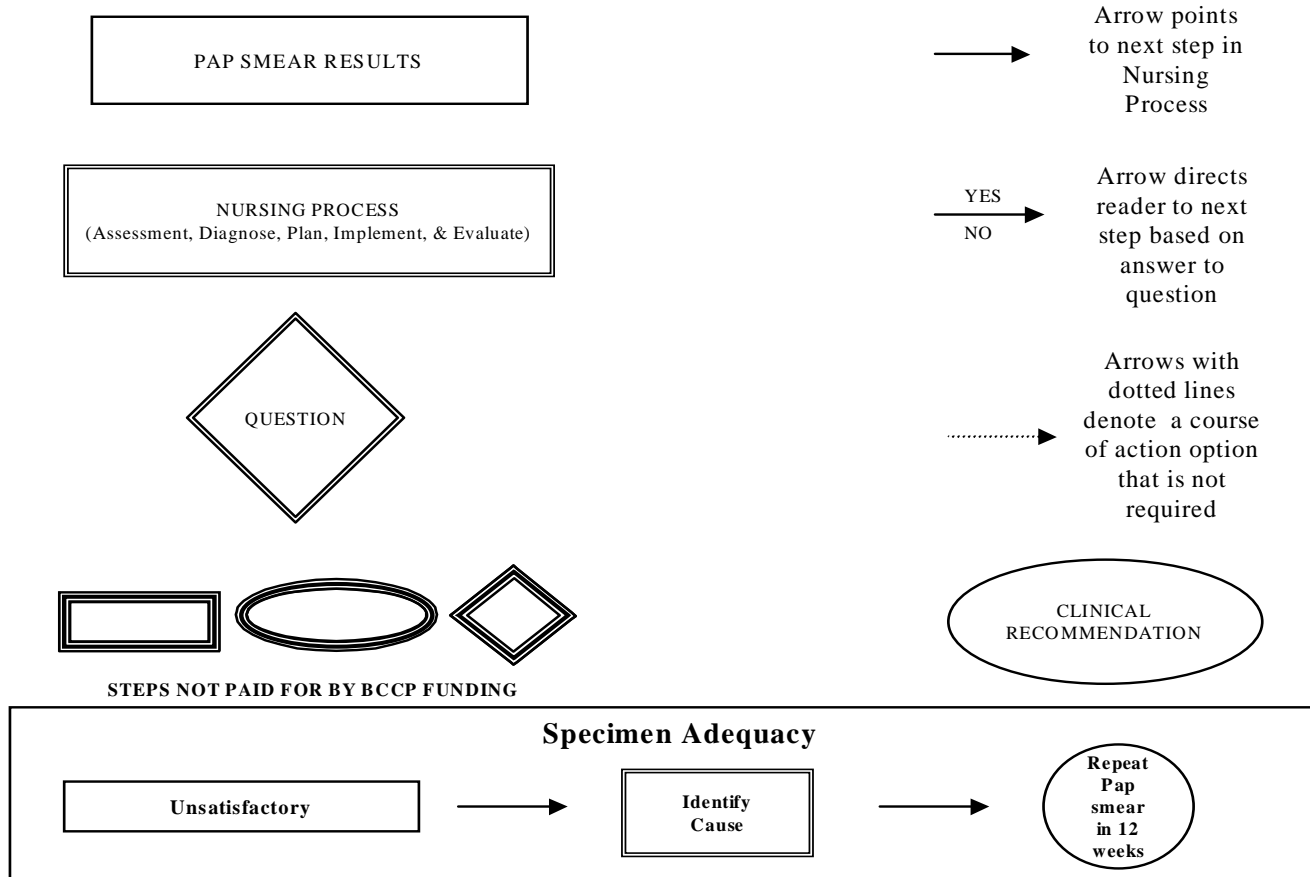
- If a client is reached and refuses to complete follow-up:
 - a. Inform the client of the possible consequences of her refusal.
 - b. Attempt to identify barriers, i.e. fear, lack of transportation, etc. An attempt to resolve these barriers should be made.
 - c. If the client refuses care, every attempt should be made and documented to get her to sign a refusal statement. The statement must be kept in the client's medical record.
 - d. Ongoing intermittent contact with the client is recommended.

Pap Smear Algorithm Key

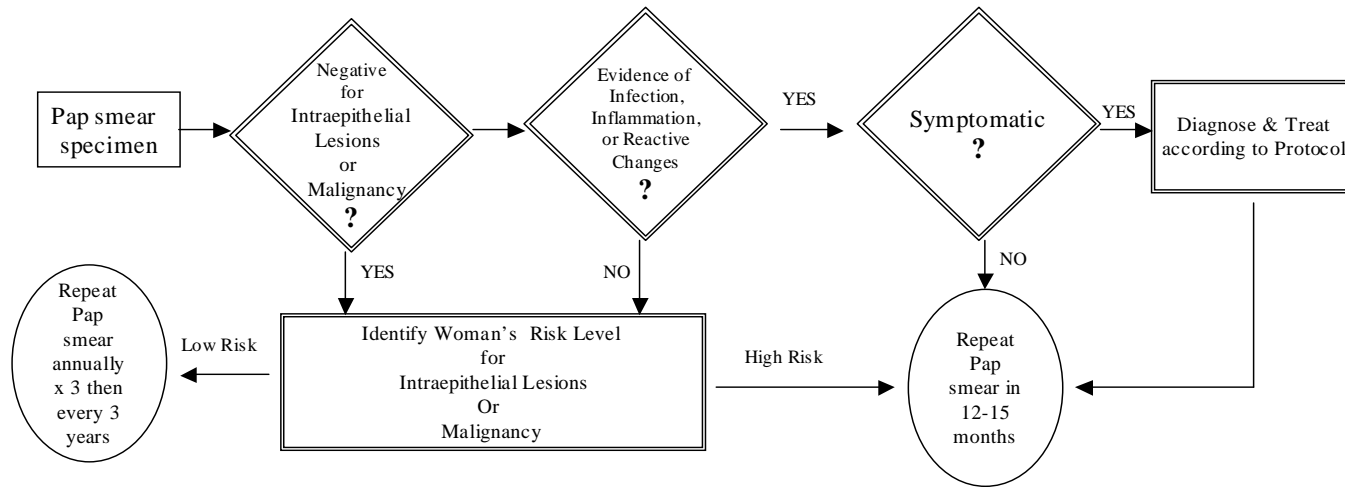
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Section III

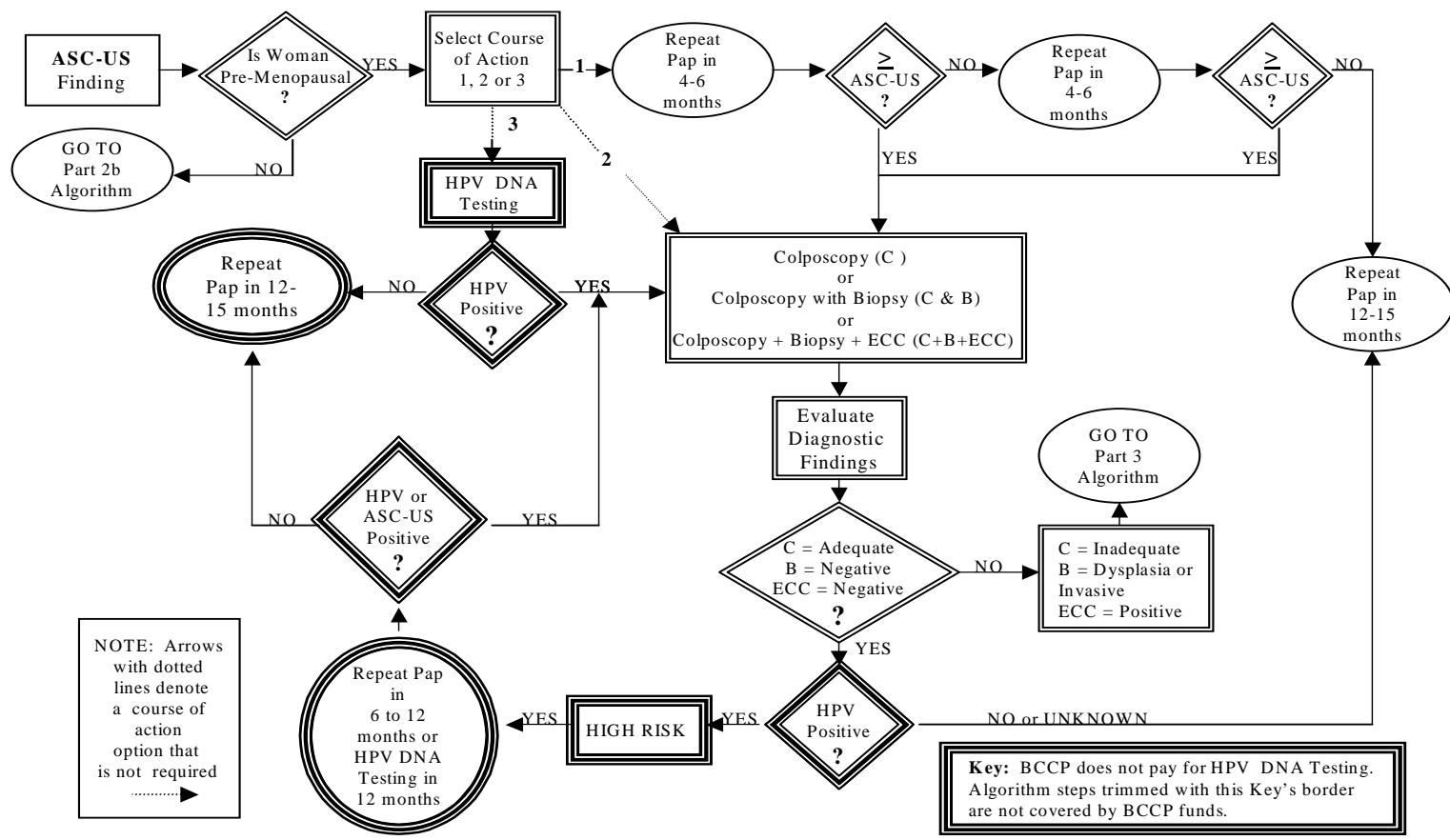


Part 1- Negative for Intraepithelial Lesions or Malignancy Pap Smear Follow-Up & Management



Part 2a- Pre-Menopausal Women ASC-US Pap Smear Follow-Up & Management

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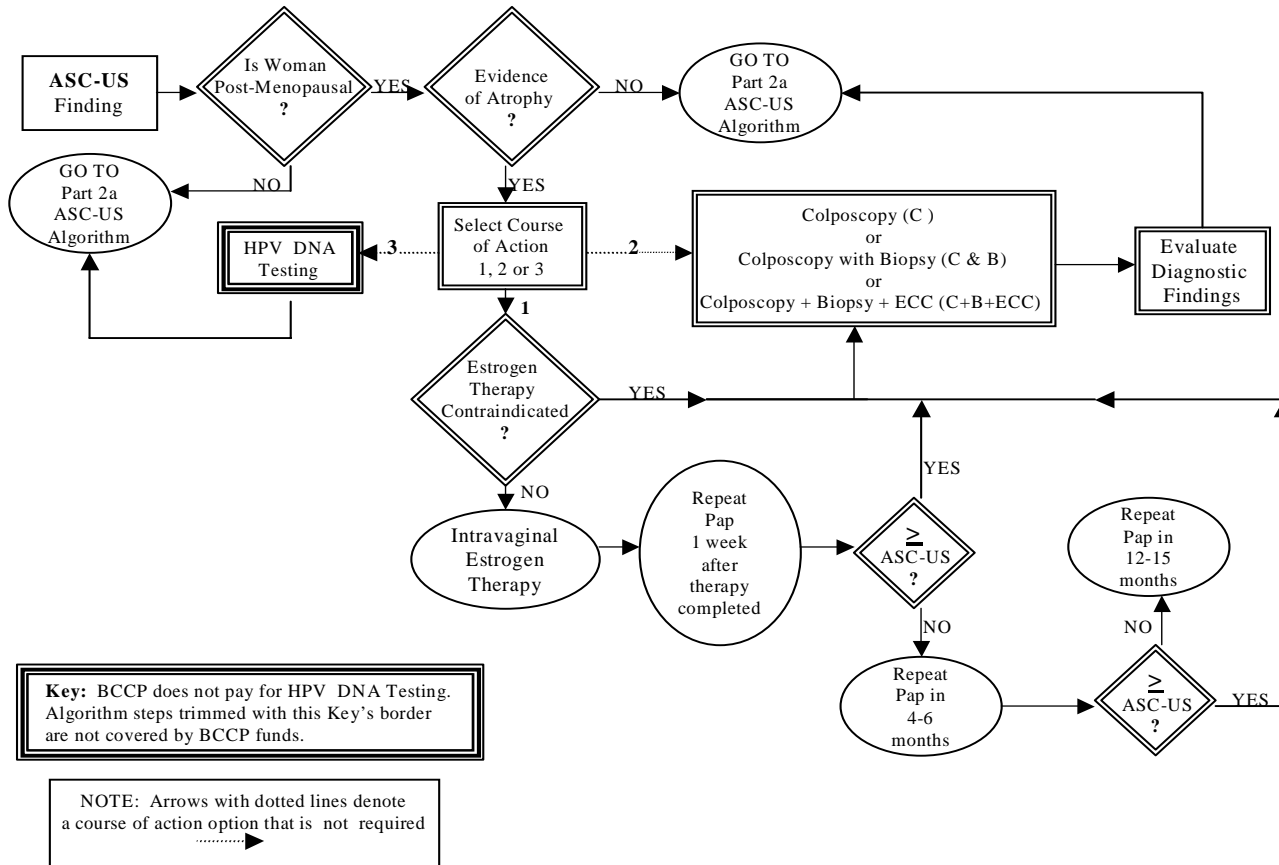
NOTE: Arrows with dotted lines denote a course of action option that is not required

Key: BCCP does not pay for HPV DNA Testing. Algorithm steps trimmed with this Key's border are not covered by BCCP funds.

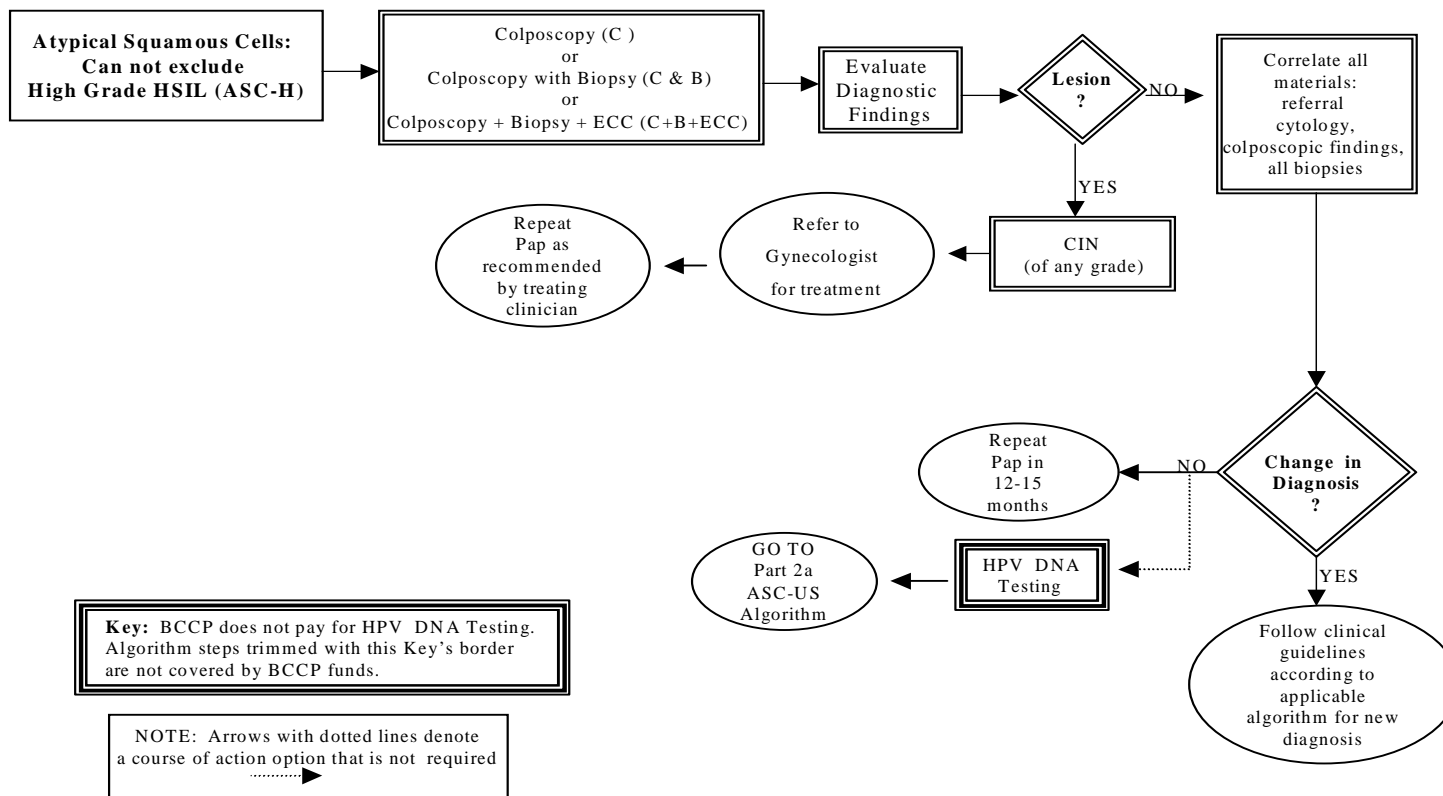
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Part 2b- Post-Menopausal Women with Special Circumstances ASC-US Pap Smear Follow-Up & Management



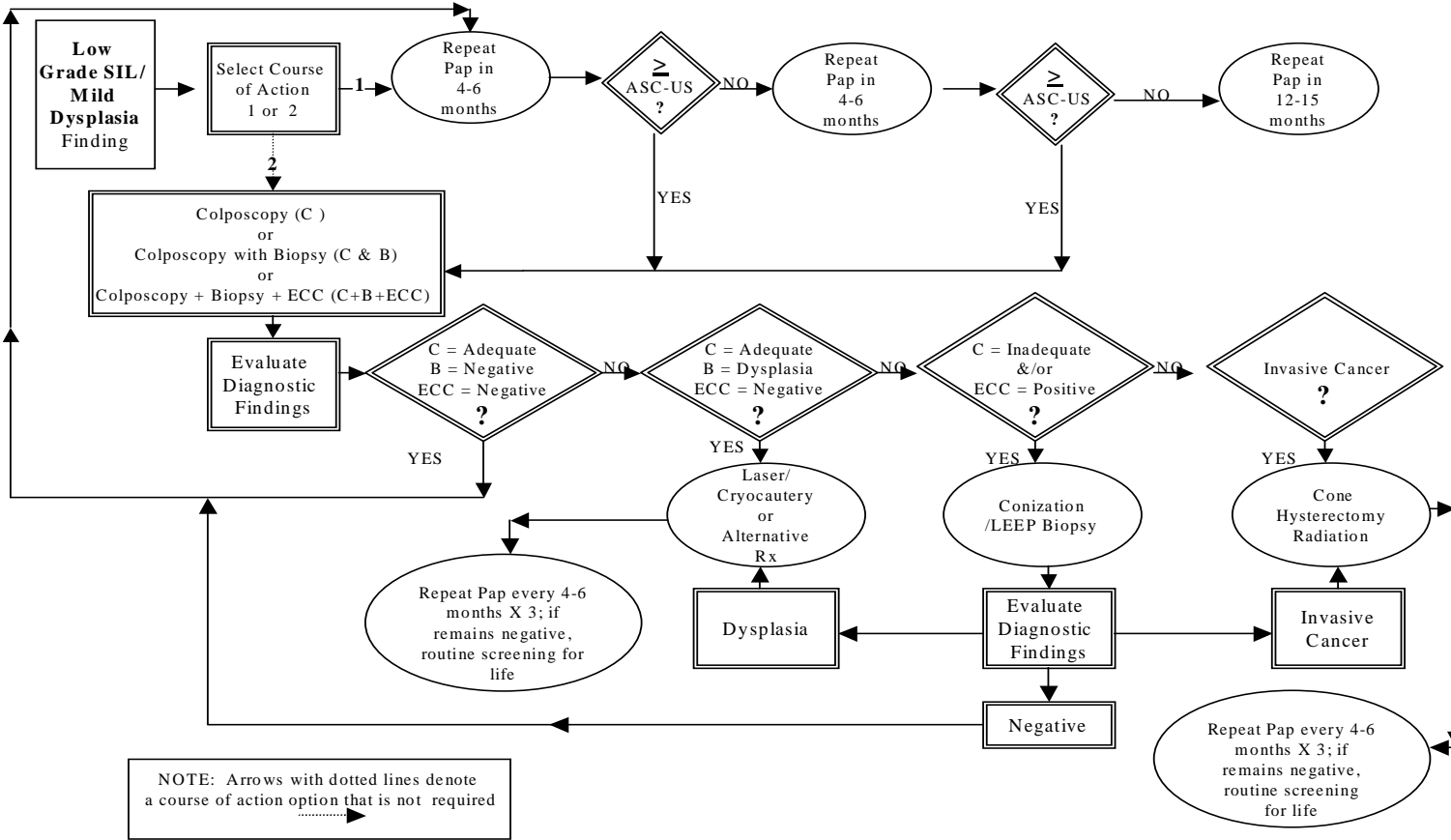
Part 2c- Atypical Squamous Cells: Can not Exclude High Grade HSIL (ASC-H) Pap Smear Follow-Up & Management



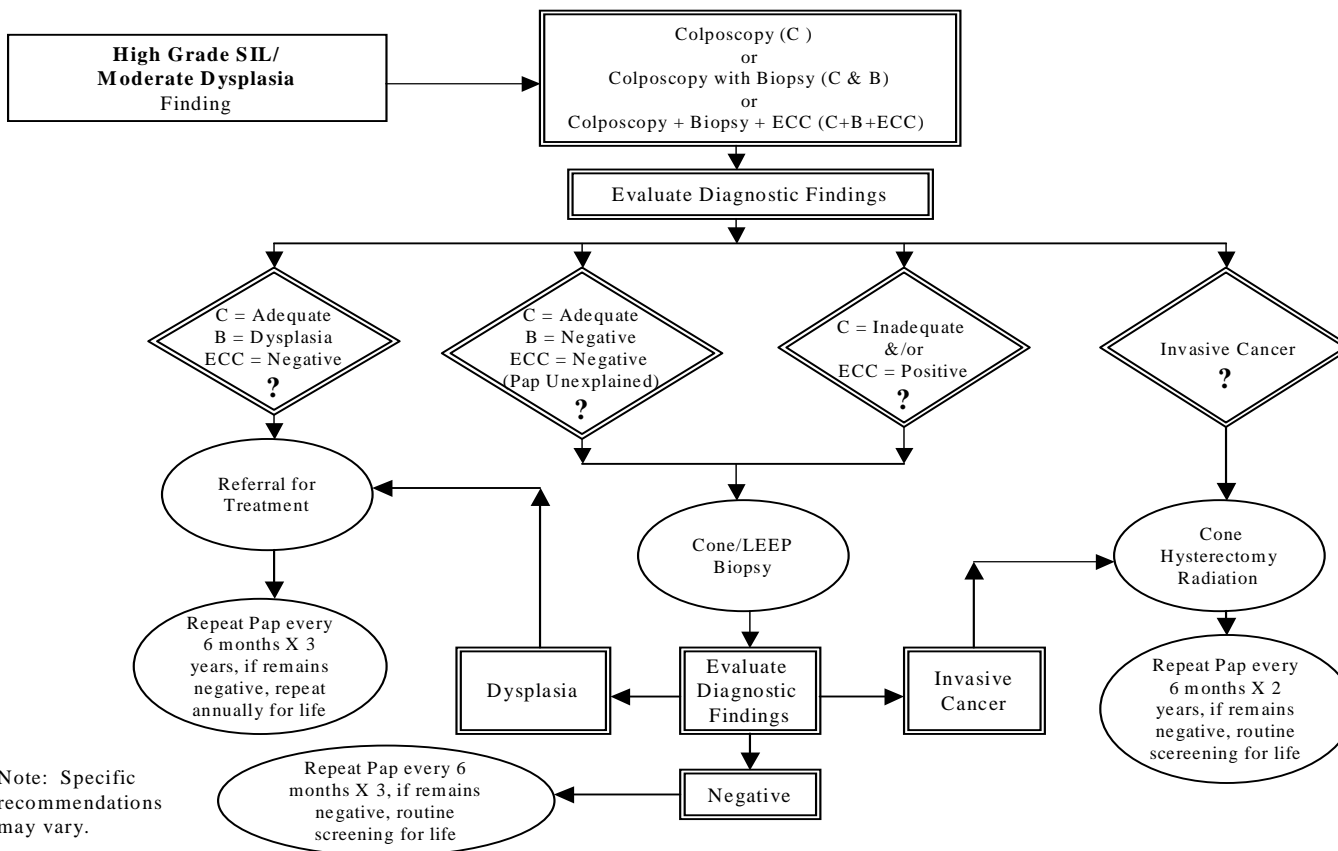
Part 3- Low Grade SIL/ Mild Dysplasia Pap Smear Follow-Up & Management

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Section III

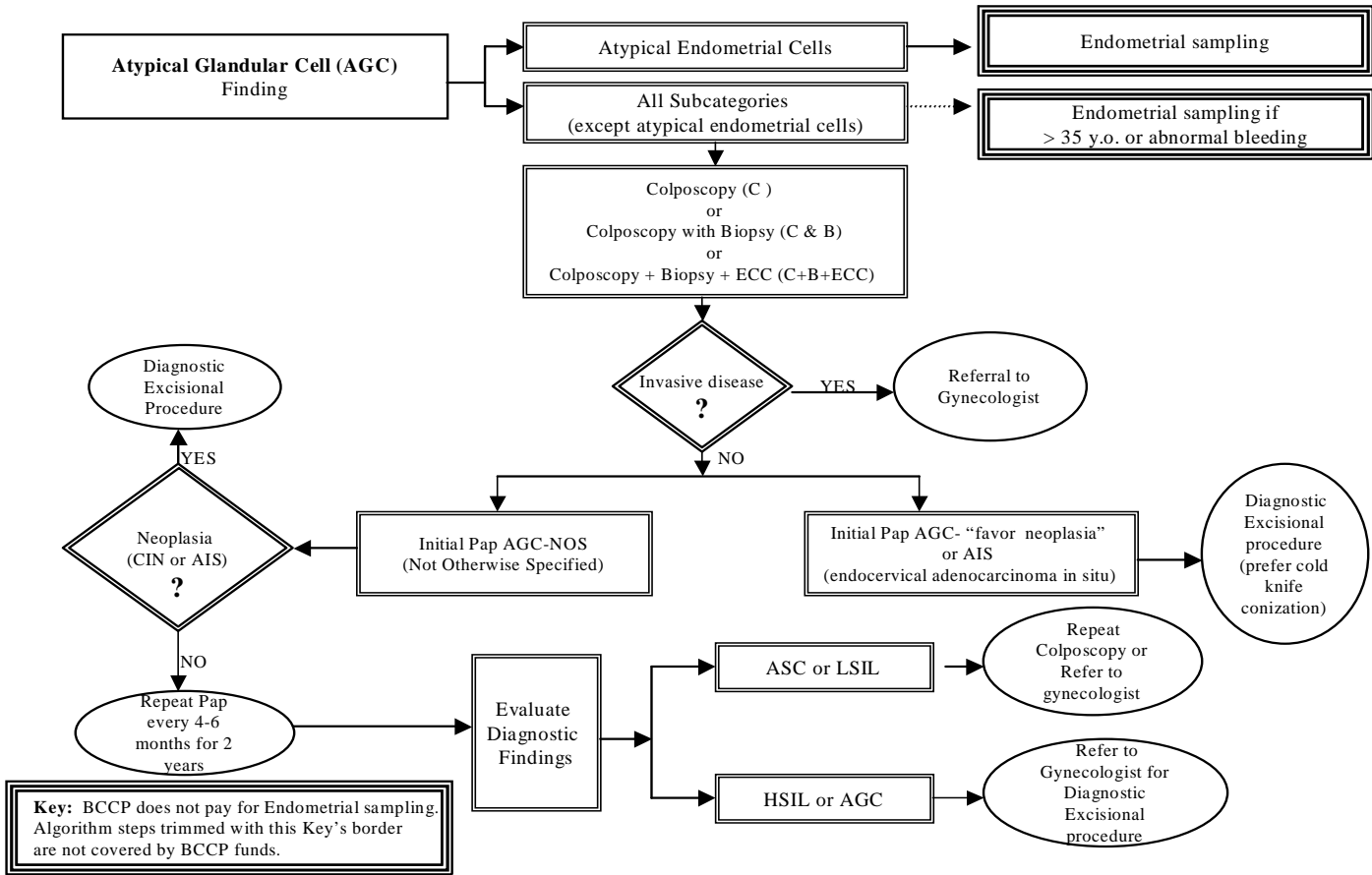


Part 4- High Grade SIL/ Moderate or Higher Dysplasia Pap Smear Follow-Up & Management



Part 5- Atypical Glandular Cell (AGC) Pap Smear Follow-Up & Management

NOTE: Arrows with dotted lines denote a course of action option that is not required



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 preinvasive and invasive disease. The prediction of histopathologic diagnosis based on colposcopic patterns requires experience and practice.

Colposcopy should only be performed by clinicians who have completed an approved training course. In addition, nurse practitioners must satisfactorily pass a supervised preceptorship. This preceptorship must include examination of a large number of abnormal cervixes. Nurse practitioners must function under written protocols in accordance with O.C.G.A. § 43-34-26.1.

The indications for colposcopy include:

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

Equipment

1. Colposcope
 - A. The colposcope is an instrument that provides magnification and illumination. By varying the magnification, the clinician can identify patterns of normal or abnormal tissue.
 - B. 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
 - A. Forceps are available in a variety of types and sizes. Careful selection of the appropriate instrument based on assessment is important.
 - B. Keeping instruments sharp assures a quality sample and produces less discomfort when the biopsy is obtained.
3. Endocervical Curettes
 - A. Allows for sampling of the endocervical canal.
 - B. Sharp instruments assure obtaining an adequate sample.
4. Endocervical Specula
 - A. Used as an aid to visualize the endocervical canal.

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

Procedure

1. Enhance the client's comfort and relaxation by thoroughly explaining all procedures. Be sure the client is not menstruating.
2. Obtain pertinent history from the client:
 - A. Obstetric and gynecologic
 - B. Menstrual pattern
 - C. Sexually transmitted disease
 - D. Previous abnormal Pap(s) and treatment (including gynecology surgery)
 - E. Number of sexual partners
 - F. Smoking, drug abuse
 - G. Immunosuppression
 - H. Allergies
 - I. Current medical problems
3. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed.
 - A. Potential risks and complications include:
 1. Excessive post procedure bleeding,
 2. Infection.
 - B. There are no contraindications to the procedure.
4. Some clinicians 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.
5. Apply 3-5% acetic acid (vinegar) liberally to the cervix and vagina. This cleans and dehydrates the surface cells for better viewing.
6. Systematically inspecting the cervix and surrounding area lowers the chance of missing a lesion.
7. Assess the adequacy of the procedure:
 - A. Can the squamocolumnar junction (SCJ) be visualized completely?

1. 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.
 2. 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.
 3. If the entire SCJ cannot be seen after the above techniques, an excisional biopsy may be necessary.
- B. Is the squamous columnar junction normal or abnormal?
1. 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.
 2. Lugol's solution may be used if the diagnosis is in question, to confirm the colposcopic impression, or to outline the lesion limits.
 3. Assess if the colposcopy findings correlate with the Pap smear results.
- C. If abnormalities are seen, locate the most atypical area(s) for biopsy.
8. Tissue samples are taken from the most atypical area(s) to verify the extent of the disease.
 - a. Perform cervical biopsies first.
 - b. Endocervical curettage (ECC) is performed last. This causes cramping and discomfort. Let the client know prior to performing the ECC.
 9. Control bleeding from the biopsy site(s) by applying Monsel's or Silver Nitrate.
 10. Instructions for post-biopsy care including danger signs and emergency phone numbers should be carefully explained and given in writing to the client.
 11. Schedule a follow-up appointment for the client either at the colposcopy clinic or the referring clinic to discuss the results of the biopsy and recommendations for treatment and follow-up.
 12. A thorough record should be made of the colposcopic exam for correlation with the biopsy report.

Excisional Diagnostic 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, and low risk of affecting childbearing ability.

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

Procedure

1. Enhance the client's comfort and relaxation by thoroughly explaining all procedures. Be sure the client is not menstruating.
2. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed.
 - A. Potential risks and complications include:
 1. Excessive bleeding post procedure
 2. Infection
 3. Cervical stenosis
 - B. Contraindications include:
 1. Pregnancy
 2. Pelvic infection
 3. Invasive cancer
3. Assess the client's allergies, especially to local anesthetic agents.
4. Have the client 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 client'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.
8. Control bleeding from the biopsy site by applying Monsel's solution and/or by using the ball electrode to cauterize the tissue.
9. Observe the client for 15 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 client.
11. Schedule a follow-up appointment for the client.
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. Microinvasive 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

Stages of Cervical Cancer

- | | |
|--------------|---|
| 1. Stage 0 | No evidence of primary tumor; Carcinoma-in-situ |
| 2. Stage I | Cervical carcinoma confined to the uterus |
| a. IA | Invasive carcinoma diagnosed only microscopy |
| b. IA1 | Invasion depth 3mm or less and width 7mm or less |
| c. IA2 | 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 of Precancerous Abnormalities

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 client's comfort and relaxation by thoroughly explaining all procedures. Be sure the client is not menstruating.
2. Informed consent including contraindications to the procedure, potential risks, and complications (although rare), must be explained and signed.
 - A. Potential risks and complications include:
 1. Potential for vaginal injury
 2. Post procedure infection or hemorrhage
 3. 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
 4. Acute cervicitis, mucopurulent cervicitis, or PID
 5. Cervical size and/or contour that would prevent making good contact with the cryo probe
 6. Large lesion cannot be adequately covered with cryo probe
3. Have the client 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 client. 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 it 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 client to take home. Ensure the client understands all instructions. Carefully explain to the client 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 8-10 mm deep effectively removing any involved glands in the ecto- or endocervix.

Treatment of Cervical Cancer

Treatment for cervical cancer is dependent upon:

1. The stage of cancer diagnosed
2. The age of the client
3. Desire to preserve fertility

Treatment options include:

1. Cold knife cone
2. LEEP
3. Laser
4. Partial cervical amputation
5. Hysterectomy (simple or radical)
6. Radiation (intracavitary and or external beam)
7. Chemotherapy

See Appendix 1, “ The Treatment Options”, Section VIII, for more detailed discussion of Cervical Cancer Treatment options by stage.

PATHOPHYSIOLOGY OF CERVICAL CANCER

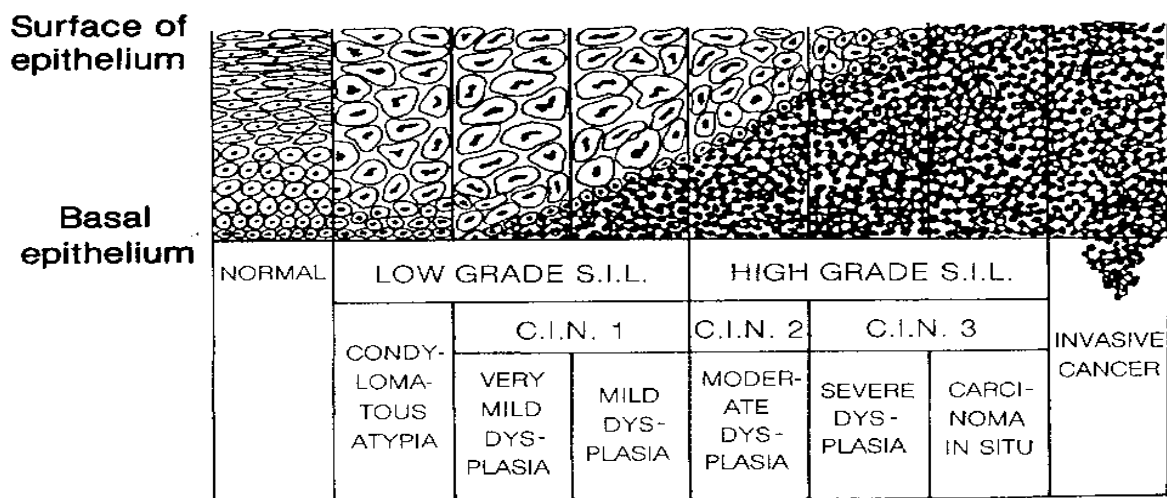
The cervix is a dynamic structure that changes with the different stages of a woman's lifetime. These changes can be in response to normal maturation, trauma from intercourse, infections (viral/bacterial), pregnancies, hormonal changes, smoking, and/or other treatments and procedures.

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 6)

Figure 6



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).

Figure 7

Natural history of cervical cancer



Presentation by Herschel W. Lawson, MD
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Division of Cancer Prevention and Control

Risk Factors for Cervical Cancer

Women with a history of previous CIN (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:

- ◆ Smoking
- ◆ Increased number of sexual partners
- ◆ Early age at first intercourse
- ◆ Low socioeconomic status
- ◆ High parity

CLIENT 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 smear screening. Public Health and other community based clinics can provide clients and their partners with complete information about cervical cancer and the Pap smear 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 client and her partner(s), in the education materials provided to the client and her partners(s), and in appropriate community education presentations.

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. Clients 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.

Major risk factors for cervical cancer are noted in the previous section. A woman with any of these risk factors should inform her clinician so she/he can make sure the woman is appropriately managed and gets Pap smear screening 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 smears.
- Avoiding sex with men with genital condyloma accuminata or other sexually transmitted diseases.
- Using condoms during **all** sexual intercourse.
- Quitting or not smoking.

- If exposed to DES, asking her clinician about colposcopy and extra Pap smears.

Pap Smear Screening

The Pap smear 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 smears at the frequencies recommended.

Preparation for Screening

The 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 smear 1-2 weeks after the end of the menses.
- Having bleeding and vaginal discharge treated before the Pap smear is scheduled and returning for the Pap smear at the optimum time.
- Client should be educated that she is receiving a Pap Smear that is for detecting pre-cancer or cancer.
- Client should be educated about diagnostic and treatment procedures.

Keeping Good Records

The woman owes it to herself to keep good gynecological records. For the client who has not kept good records, clinic personnel should educate the client, so in the future the following information will be available for the client and the physician:

- Correct demographic information- full name (including all name changes), birth date, current address and a permanent address where the woman can be reached, and telephone number (home, work, and cell phone number, if applicable)
- Last menstrual period
- Any symptoms of bleeding or discharge
- Use of hormones or other medication
- Risk factors
- Dates and results of prior Pap smears and the types of treatment, if applicable.
- Copies of previous Pap smears results and copies of any procedure done such as colposcopy, biopsy, LEEP, or conization and the final diagnoses.

Complying with Follow-up Care Recommended by the Clinician

For the client, 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 smears as requested by the physician.
- 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 physician'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 physician to give a second opinion. The local health department or community clinics are also good sources for referrals to other competent physicians.

For the clinic nurses, compliance with case management, governmental, professional education and documentation standards is extremely important.

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