The Cervical Screening Manual

A Guide for Health Departments and Providers

Collaboration Partners:

Chronic Disease and Injury Section
Breast and Cervical Cancer Control Program
Women's and Children's Health Section

North Carolina Department of Health and Human Services
Division of Public Health

State of North Carolina
Department of Health and Human Services
Division of Public Health • N.C. Breast and Cervical Cancer Control Program
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NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

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MEMORANDUM

To: Local Health Directors
Attention: Nursing Directors/Supervisors

From: Elizabeth Cuervo Tilson, M.D., MPH
State Health Director

Date: December 30, 2018

Subject: Revised Edition (December 2018)
Cervical Screening Manual: A Guide for Health Departments and Providers

Enclosed is the revised edition of the Cervical Screening Manual: A Guide for Health Departments and Providers, December 2018. Please replace the previous manual, dated September 2013 with this edition.

Numerous references have been consulted to assure that current standards and guidance on care of patients with abnormal Pap tests are used. These references include the:

- American Cancer Society (ACS), 2018
- U.S. Preventive Services Task Force (USPSTF), 2018
- American College of Obstetricians and Gynecologists (ACOG), 2018
- *The Bethesda System for Reporting Cervical Cytology, Third Edition,* Nayar, & Wilbur, 2015
- 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors
- National Breast and Cervical Cancer Early Detection Program (NBCCEDP) Program Manual, December 2017

Revisions were made by the Division of Public Health through a collaborative effort of the Chronic Disease and Injury Section, and the Women and Children's Health Section. The Division of Public Health supports these guidelines as a model for the care of patients at the local level. We hope this guide will enable you to develop written policies to better identify and control cervical cancer among women in North Carolina.

ACKNOWLEDGEMENTS

Cervical Screening Manual: A Guide for Health Departments and Providers

This guide was reviewed and revised through the collaborative efforts of representatives of the following Division of Public Health Sections:

Chronic Disease & Injury Section
Breast and Cervical Cancer Control Program
Women's & Children's Health Section

Members of the Revision Committee express deepest gratitude and appreciation to all of the individuals who worked toward the successful completion of the Guide.

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North Carolina Cancer Prevention and Control Branch/Breast and Cervical Cancer Control Program, Chronic Disease and Injury Section
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Cervical Screening Manual

A Guide for Health Departments and Providers

Table of Contents

Divider – Overview

Overview

Cervical cancer was once a leading cause of cancer death for women in the U.S. However, since the Pap test was introduced in 1948, the incidence and mortality of cervical cancer has decreased significantly. Between 2010 and 2014, the incidence of cervical cancer was 7.4 per 100,000 women and the mortality was 2.3 per 100,000 women in the U.S. While cervical cancer incidence and mortality continue to decrease, both are considerably higher among Hispanic and non-Hispanic Black women. In 2017, an estimated 12,820 new cases are expected to be diagnosed, and an estimated 4,210 women who will die from cervical cancer (National Cancer Institute SEER Stat Fact Sheets, Cervix Uteri Cancer). In North Carolina, an estimated 400 cervical cancer cases will be diagnosed in 2017, resulting in 120 deaths (American Cancer Society Cancer Statistics Center, 2018).

Detection and treatment of pre-cancerous cervical lesions identified by cervical screening (cervical cytology and/or HPV testing) can prevent cervical cancer from developing. Even when cancer has already developed, cervical screening may detect it while still in an early stage. With prompt diagnostic follow-up and appropriate treatment, survival of early stage cervical cancer is almost 100 percent.

The 2018 edition of the *Cervical Screening Manual* provides guidelines designed to support the goal of identifying pre-cancerous cervical lesions and early cervical cancer and providing appropriate treatment that saves lives. Numerous references have been consulted to assure that current standards and guidance on care of patients with abnormal cervical screenings are used. These references can be found in Appendix E.

The primary sources for the *Cervical Screening Manual* are:

> *The United States Preventive Services Task Force: Affiliations of The US Preventive Services Task Force (USPSTF) members:* University of Iowa, Iowa City (Curry); Fairfax Family Practice Residency, Fairfax, Virginia (Krist); Virginia Commonwealth University, Richmond (Krist); Veterans Affairs Palo Alto Health Care System, Palo Alto, California (Owens); Stanford University, Stanford, California (Owens); Harvard Medical School, Boston, Massachusetts (Barry); Oregon Health & Science University, Portland Caughey); Columbia University, New York, New York (Davidson); University of Pennsylvania, Philadelphia (Doubeni); Virginia Tech Carilion School of Medicine, Roanoke (Epling); Nationwide Children's Hospital, Columbus, Ohio (Kemper); Temple University, Philadelphia, Pennsylvania (Kubik); University of Alabama at Birmingham (Landefeld); University of California, Los Angeles (Mangione); Brown University, Providence, Rhode Island (Phipps); Boston University, Boston, Massachusetts (Silverstein); Northwestern University, Evanston, Illinois (Simon); University of Hawaii, Honolulu (Tseng); Pacific Health Research and Education Institute, Honolulu, Hawaii (Tseng); Tufts University, Medford, Massachusetts (Wong); The 2018 American Medical Association. *Screening for Cervical Cancer: US Preventive Services Task Force Recommendation Statement 2018: 320 (7) 674-686. Use of primary high-risk human papillomavirus testing for cervical cancer*

screening: Interim clinical guidance, Warner K. Huh, Kevin A. Ault, David Chelmow, Diane D. Davey, Robert A. Goulart, Francisco A.R. Garcia, Walter K. Kinney, L. Stewart Massad, Edward J. Mayeaux, Debbie Saslow, Mark Schiffman, Nicolas Wentzensen, Herschel W. Lawson, Mark H. Einstein in Gynecologic Oncology 136, 2015: 178–182. *The Bethesda System for Reporting Cervical Cytology, Third Edition,* Ritu Nayar, David C. Wilbur Editors, 2015. *American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology Screening Guidelines for the Prevention and Early Detection of Cervical Cancer,* Debbie Saslow, PhD; Diane Solomon, MD; Herschel W. Lawson, MD; Maureen Killackey, MD; Shalini L. Kulasingam, PhD; Joanna Cain, MD; Francisco A. R. Garcia, MD, MPH; Ann T. Moriarty, MD; Alan G. Waxman, MD, MPH; David C. Wilbur, MD; Nicolas Wentzensen, MD, PhD, MD; Levi S. Downs, Jr., MD; Mark Spitzer, MD; Anna-Barbara Moscicki, MD; Eduardo L. Franco, DrPH; Mark H. Stoler, MD; Mark Schiffman, MD; Philip E. Castle, PhD, MPH; Evan R. Myers, MD, MPH; the ACS-ASCCP-ASCP Cervical Cancer Guideline Committee, published in CA: Cancer J. Clin. 2012;62: 147-172.

2012 Updated Consensus Guidelines for The Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors, L. Stewart Massad, MD; Mark H. Einstein, MD; Warner K. Huh, MD; Hormuzd A. Katki, PhD; Walter K. Kinney, MD; Mark Schiffman, MD; Diane Solomon, MD; Nicolas Wentzensen, MD; and Herschel W. Lawson, MD, for the 2012 American Society for Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines Conference.

2012 Algorithms for the Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors, published by the American Society for Colposcopy and Cervical Pathology. 2015 Algorithm for use of primary high-risk human papillomavirus testing for cervical cancer screening interim clinical guidance, Gynecologic Oncology.

The guidelines are supported by the North Carolina Department of Health and Human Services, Division of Public Health, as a model for the care of patients at the local level. The guidelines are not program-specific. If local health care provider agency policy differs from these guidelines, the local health care provider agency will have written policies and protocols that are consistent with the clinical practice of its clinical providers and its referral resources.

It is important to recognize that these guidelines should never substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient.

Divider – 1. Patient Management and Follow-up of Cervical Cytology Results

PATIENT MANAGEMENT AND FOLLOW-UP OF PAP TEST RESULTS

A. Introduction

LOCAL POLICIES

Local policies and procedures should be developed for patient management. The North Carolina Department of Health and Human Services, Division of Public Health's Cancer Prevention and Control Branch and the Women's Health Branch recommends this Guide to develop local policies.

MULTIPLE PUBLIC PROGRAMS

The recommendations in this Guide are for all women regardless of the specific clinic where they are enrolled. When a patient receives care at more than one location, clinic staff should coordinate efforts to prevent duplication of unnecessary cervical cytology tests.

FINANCIAL ASSISTANCE

For eligible patients diagnosed through the North Carolina Breast and Cervical Cancer Control Program (NC BCCCP), Breast and Cervical Cancer Medicaid (BCCM) may be a source of financial assistance for treatment and other medical needs during treatment. See Appendix F for information on BCCM.

CERVICAL CYTOLOGY TESTS ARE NOT A SUBSTITUTE FOR MEDICAL JUDGMENT

Cervical cytology tests are screening tests meant to detect a variety of squamous epithelial lesions and neoplasias, including dysplasia, carcinoma-in-situ (CIS), and other types of neoplasia. Please note that a single negative cytology result (and occasionally multiple negative cytology results) **does not** rule out gynecologic neoplasia. Cervical cytology is a screening test. False negative tests may occur due to sampling problems, screening difficulties inherent in tests, or due to the subjective nature of cytodiagnosis.

It is important to recognize that these guidelines should never substitute for clinical judgment. Clinical judgment should always be used when applying a guideline to an individual patient because it is impossible to develop guidelines that apply to all situations.

CYTOLOGY RESULTS REQUIRING FOLLOW-UP

Any of the following abnormal findings should be reported to the physician consultant for the health care provider agency or managed according to local policies and procedures:

- Atypical Squamous Cells: Undetermined Significance (ASC-US) – if HPV positive, age 65 or older if appropriate or postmenopausal.

- Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)
- Low-grade Squamous Intraepithelial Lesion (LSIL). This category encompasses HPV infection and mild dysplasia.
- High-grade Squamous Intraepithelial Lesion (HSIL). This category encompasses moderate and severe dysplasia, as well as Carcinoma-in-situ (CIS).
- Squamous cell carcinoma
- Atypical glandular cells (AGC), including adenocarcinoma *in situ* (AIS) and adenocarcinoma
- Other malignant neoplasms

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1. REPORTING OF CERVICAL CYTOLOGY RESULTS

THE BETHESDA SYSTEM 2014

The Bethesda System 2014 (Nayar et al., 2015) updates the standard terminology for reporting cervical cytology findings. It has been the standard of reporting in North Carolina since October 1, 2014. See Appendix A for a summary of reporting categories.

The major features of the system are the following:

- Specimen type: indication of the conventional versus liquid-based cervical cytology preparation.
- Specimen adequacy is reported as either "Satisfactory" or "Unsatisfactory" for interpretation. Satisfactory also describes the presence or absence of endocervical/ transformation zone component and any other quality indicators, e.g., partially obscuring blood, inflammation, etc. The Bethesda 2014 system further divides the unsatisfactory category into two sections:
  (1) Unsatisfactory rejected/ not processed (specify reason)
  (2) Unsatisfactory specimen processed and examined, but unsatisfactory for evaluation of abnormality because of (specify reason) (See Sections I.B.2 through I.B.8 for a more complete discussion of unsatisfactory Pap test results)
- Quality indicators, such as the presence or absence of endocervical or transformation zone component, or obscuring inflammation or blood, are reported on all cases in the narrative portion of the report.
- The General Categorization is optional.
  (1) Negative for Intraepithelial Lesion or Malignancy.
  (2) Other: See Interpretation/ Result (e.g. endometrial cells in a woman $\geq$ 45 years of age)

(3) Epithelial Cell Abnormality: See Interpretation/Result (specify 'squamous' or 'glandular' as appropriate)

- Interpretation/Result
  - (1) Negative for Intraepithelial Lesion or Malignancy
    - a. Non-Neoplastic Findings
    - b. Reactive cellular changes
    - c. Glandular cells status post hysterectomy
  - (2) Organisms
    - a. Trichomonas
    - b. Fungal organism
    - c. Shift in flora suggestive of bacterial vaginosis
    - d. Bacterial morphologically consistent with Actinomyces spp.
    - e. Cellular changes consistent with herpes simplex virus
    - f. Cellular changes consistent with cytomegalovirus
- Other
  - (1) Endometrial cells (in a woman $\geq$ 45 years of age)
  - (2) Specify if negative for squamous intraepithelial lesion
- Epithelial Cell Abnormalities
  - (1) Squamous cells are divided into two sub-categories:
    - a. ASC-US (atypical squamous cells of undetermined origin)
    - b. ASC-H (atypical squamous cells, cannot exclude high-grade lesion)
  - (2) Low-grade squamous intraepithelial lesion (LSIL) (encompassing: HPV/ mild dysplasia/ CIN 1)
  - (3) High-grade squamous intraepithelial lesion (HSIL) (encompassing: moderate and severe dysplasia, CIS; CIN 2 and CIN 3)
  - (4) Squamous cell carcinoma
- Glandular Cell
  - (1) Atypical
    - a. Endocervical cells (NOS or specify)
    - b. Endometrial cells (NOS or specify)
    - c. Glandular cells (NOS or specify)
  - (2) Atypical
    - a. Endocervical cells, favor neoplastic

b. Glandular cells favor neoplastic

(3) Endocervical adenocarcinoma in situ

(4) Adenocarcinoma

a. Endocervical

b. Endometrial

c. Extrauterine

d. Not otherwise specified (NOS)

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2. WHO NEEDS TO HAVE A CERVICAL CYTOLOGY TEST AND WHEN TO SCREEN

EXPERT RECOMMENDATIONS

Guidelines for cervical cancer screening have been issued by the American Cancer Society (ACS), the U.S. Preventive Services Task Force (USPSTF), and the American College of Obstetricians and Gynecologists (ACOG). The 2012 consensus guidelines for the management of women with abnormal cervical cancer screening tests was developed by a group of 47 experts representing 23 organizations, including ACS, Center for Disease Control and Prevention, and ACOG and updated in 2015 and 2018 to include primary HrHPV screening for women aged 30 to 64 (Massad, et al., 2013, p. 526; USPSTF, Curry et al., 2018; (Huh, Ault, Chelmow, Davey, Goulart, Garcia, Kinney, Massad, Mayeaux, Saslow, Schiffman, Wentzensen, Lawson, Einstein, 2014).

WHEN TO BEGIN SCREENING:

Cervical cytology screening should begin at age 21 regardless of the age of sexual initiation or the presence of other behavior related risk factors.

RECOMMENDED SCREENING INTERVALS

All of the nationally recognized guidelines base their screening recommendations on age and clinical history. **No guidelines support screening women under age 21.** Women should not be screened annually at any age by any method unless as a follow up to an abnormal cytology result per algorithms. These screening guidelines were developed to address cervical cancer screening in the general population. These guidelines do not address special, high-risk populations who may need more intensive or alternative screening. These special populations include women 1) with a history of cervical cancer, 2) who were exposed *in utero* to diethylstilbestrol (DES), and 3) who are immune-compromised (e.g., HIV positive) (USPSTF, 2018; CDC, 2018; ACOG, 2018; Saslow et al., 2012).

- **For those women who are ages 21-29 years of age**, cytology alone is performed every three years. Annual screening should not be performed. For ASC-US cytology and HPV negative, rescreen with cytology in three years (this is determined through use of the HPV reflex test). For ASC-US and HPV positive or cytology of LSIL or more severe, refer to ASCCP Guidelines (discussed in depth later in manual).
- **For women who are ages 30-65 years of age**, screening every 3 years with cervical cytology alone, every 5 years with hrHPV testing alone, or every 5 years with hrHPV testing in combination with cytology (co-testing) is recommended. (A recommendation) The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion (i.e. cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer (USPSTF, 2018). Screening for cervical cancer in women older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer is not recommended. (D recommendation) (USPSTF, 2018; ACOG, 2018; CDC, 2018).

Adequate negative prior screening results are defined as three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years, with the most recent test performed within the past 5 years (ACS, 2018, USPSTF Curry et al., 2018; CDC, 2018).

Recommended Primary HPV Screening

Primary hrHPV screening is an important scientific and clinical advance in cervical cancer screening since it offers better reassurance of low cancer risk compared to cytology-only screening conducted at the same interval. Primary hrHPV screening can be considered as an alternative to current cytology-based cervical cancer screening approaches including cytology alone and co-testing. The use of HPV 16/18 genotyping and reflex cytology for women positive for the 12 other hrHPV genotypes achieves a reasonable balance of disease detection with the number of screening tests and colposcopies required to achieve that detection. Primary hrHPV testing has the potential to further reduce morbidity and mortality of cervical cancer in the US. However, to achieve the maximum benefit of screening, we need to continue to identify women who are either unscreened or under-screened (Huh et al., 2015).

PATIENT NOTIFICATION AND EDUCATION

Notify and counsel the patient regarding the benefits and risks of the hrHPV screening as well as the seriousness of the test report and the need for immediate medical care. Document your actions. Additional evaluation may be necessary. The 2014 screening guideline update and interim guidance was based on several guiding assumptions:

- No cancer screening test has the ability to detect all cases of prevalent or incipient cervical cancer.
- Higher detection of CIN3+ at the baseline screening round and reduced detection of CIN3+ at subsequent screening rounds are considered as benefits.
- Increased number of colposcopies is considered a surrogate for harms

of screening (Huh, et al., 2015).

CLINICAL MANAGEMENT

Current research indicates primary hrHPV screening detected approximately 50% more CIN3+ compared to cytology, it also resulted in approximately double the number of colposcopies compared to cytology. Based on data from European randomized controlled screening trials and the US-based data from the ATHENA trial, primary hrHPV screening is at least as effective as cytology, a currently accepted standard for screening in the US, at the same screening intervals.

Because of equivalent or superior effectiveness, primary hrHPV screening can be considered as an alternative to current US cytology-based cervical cancer screening methods.

Based on research data, triage of hrHPV-positive women using a combination of genotyping for HPV 16 and 18 and reflex cytology for women positive for the 12 other hrHPV genotypes appears to be a reasonable approach to managing hrHPV-positive women. Data from ATHENA and other studies support the use of genotyping for HPV 16 and 18 as a way to triage hrHPV-positive women and is considered an appropriate balance between safety and test utilization. Table 1 refers to CIN3+ and cancer risks 3 and 5 years after negative hrHPV and cytology (Huh, et al., 2015).

OPTIMAL INTERVAL FOR PRIMARY HrHPV SCREENING

- Re-screening after a negative primary hrHPV screen should occur no sooner than every 3 years.
- Current screening interval recommendations for cervical cancer screening include every 3 years for cytology, every 5 years for HrHPV and every 5 years for co-testing. According to current research literature, a screening interval of at least 5 years for hrHPV screening is safer than cytology every 3 years (Huh et al., 2015).
- Screening should not occur at intervals shorter than 3 years among women with negative screening results. Re-screening after a negative primary hrHPV screen should occur no sooner than every 3 years.
- Primary hrHPV screening should not be initiated prior to 30 years of age (USPSTF, 2018; CDC, 2018).
- Primary hrHPV screening should begin 3 years after the last negative cytology.
- Research suggests that primary hrHPV testing with a negative result with a 3-year screening interval is at least as effective as 5-year co-testing (Huh et al., 2015).
- Despite the improved sensitivity associated with primary hrHPV testing compared to cytology, clinicians should be aware that false negative results will continue to occur. Specimen adequacy, appropriate internal controls, and the impact of potential interfering substances (e.g., lubricants) are also important considerations when applying primary hrHPV testing to a screening population. All women with a HrHPV finding of Type 16/18 positive require IMMEDIATE referral for colposcopy. The health care provider agency should assure that referral is for colposcopic evaluation and treatment (Huh et al., 2015).

- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal test results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); follow-up appointment information (date, follow-up provider, and follow-up location); date the referral was made; and results of all referrals, including the report from the follow-up provider National Breast and Cervical Cancer Early Detection Program [NBCCEDP], 2017) .
- Patient navigation is required for all other malignant neoplasms results. See page 61.
- Treatment and follow-up are individualized as directed by the QHCP.

Algorithm Next page: Recommended Primary HPV Screening (Huh et al., 2015; USPSTF, Curry et al., 2018; CDC, 2018).

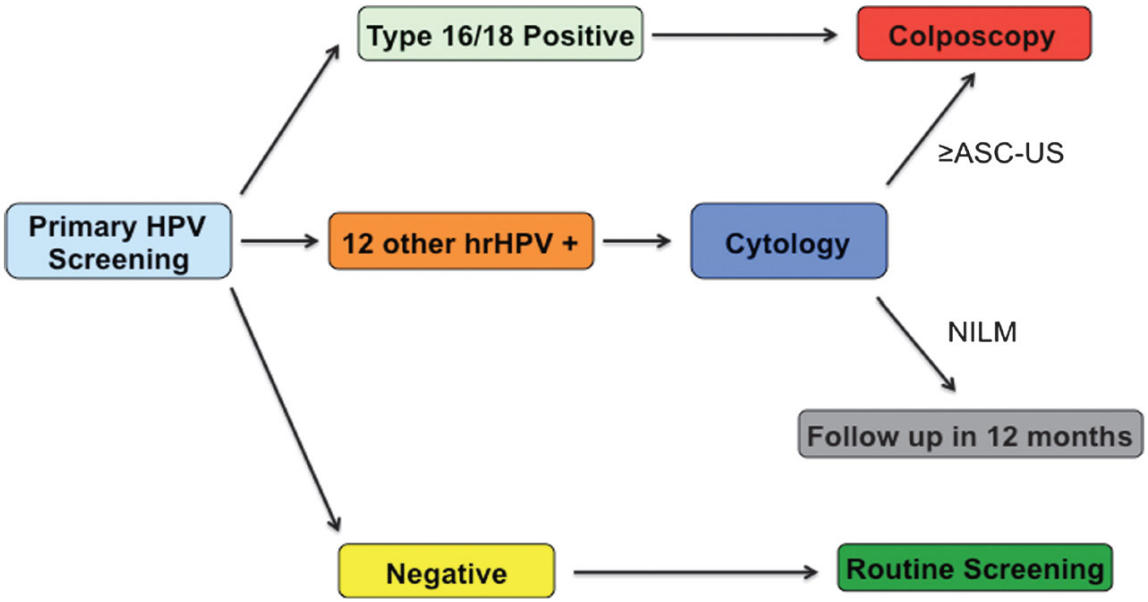

FIGURE 1. Recommended primary HPV screening algorithm. HPV, human papillomavirus; hrHPV, high-risk human papillomavirus; ASC-US, atypical squamous cells of undetermined significance; NILM, negative for intraepithelial lesion or malignancy.

MATERNAL HEALTH PATIENTS

Cervical cytology is completed as indicated according to ACOG, ACS/ASCCP/ASCP and USPSTF guidelines. Standard of care is to use a broom in place of a cytobrush. Otherwise, screening guidelines do not differ for women who are pregnant; however, follow up of abnormal findings may differ according to guidelines.

FAMILY PLANNING (TITLE X) PATIENTS

Cervical cytology is completed as indicated according to ACOG/ACS/ASCCP/ASCP/USPSTF guidelines.

SEXUALLY TRANSMITTED DISEASE / SEXUALLY TRANSMITTED INFECTION CLINIC PATIENTS

Cervical cytology is completed as indicated according to ACOG/ACS/ASCCP/ASCP/USPSTF guidelines. For asymptomatic women, cervical screening may occur at the time of Sexually Transmitted Disease or Sexually Transmitted Infection visits. If symptomatic, consult with a medical provider or plan to schedule the cervical screening following evaluation and/or treatment for sexually transmitted infection.

N.C. BREAST AND CERVICAL CANCER CONTROL PROGRAM (NC BCCCP) PATIENTS

See Appendix C for specifics of the policy.

WHEN TO DISCONTINUE SCREENING:

Screening may be discontinued in older women if they have had adequate recent screening (CDC, 2018; USPSTF, 2018) with normal cervical cytology tests and are not otherwise at high-risk for cervical cancer. Adequate negative prior screening results are defined as three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years, with the most recent test performed within the past 5 years (ACS, 2018, USPSTF Curry et al., 2018; CDC, 2018).

ACS/ASCCP/ASCP and ACOG: Women over 65 years of age with evidence of adequate negative prior screening and no history of CIN2+ within the last 20 years should not be screened for cervical cancer with any modality. Once screening is discontinued it should not resume for any reason, even if a woman reports having a new sexual partner (USPSTF, 2018; CDC, 2018; ACOG, 2018; Saslow et al., 2012).
USPSTF: The USPSTF recommends against screening for cervical cancer in women older than age 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer (USPSTF, 2018). Note: In their “clinical considerations” for women over the age of 65, they harmonize with the above consensus guidance.

SCREENING AFTER HYSTERECTOMY:

Screening may be discontinued in women who have had a hysterectomy for benign reasons.

ACS/ASCCP/ASCP: Cervical cancer screening is not indicated for women who have had a total hysterectomy (with removal of the cervix) for benign gynecologic disease at any age and they should not be screened for vaginal cancer using any modality. For women with a history of CIN2, CIN3, adenocarcinoma *in situ* (AIS), or cancer, routine screening should continue for twenty years after the diagnosis even if it extends screening past age 65 (USPSTF, 2018; CDC, 2018; Saslow et al., 2012).

ACOG: In women who have had a hysterectomy with removal of the cervix (total hysterectomy) and have never had CIN2 or higher, routine cytology and HPV testing should be discontinued and not restarted for any reason. Women should continue to be screened if they have had a history of CIN2 or higher in the past twenty years. Screening for the 20 years after the initial post treatment surveillance period is recommended (ACOG, 2018).

USPSTF: Cervical cancer screening is not recommended in women who have had a hysterectomy with removal of the cervix and do not have a history of a high-grade precancerous lesion or cervical cancer (D recommendation). Women should continue to be screened if they have had a history of CIN2 or higher in the past twenty years. Screening for the 20 years after the initial post treatment surveillance period is recommended (USPSTF, 2018; CDC, 2018).

NC BCCCP: Screening should be discontinued in women who have had a hysterectomy for benign reasons. Women should continue to be screened if they have had a history of CIN2 or higher in the past twenty years. Screening for the 20 years after the initial post treatment surveillance period is recommended (CDC, 2018).

See Appendix C for specifics of the policy.

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3. Cervical Screening for High Risk Patients

The following recommendations are based upon guidance for HIV positive patents from the Panel on Opportunistic Infections in HIV-Infected Adults and Adolescents, Guidelines for the prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America, the Department of Health and Human Services and the American Congress of Obstetricians and Gynecologists (ACOG) Practice Bulletin 168 (ACOG, 2016):

- In women and adolescents with HIV, initiation of cervical cancer screening with cytology alone should begin within 1 year of onset of sexual activity or, if already sexually active, within the first year after HIV diagnosis but no later than 21 years of age.
- Cervical cancer screening in women who are infected with HIV should continue throughout a woman's lifetime (ie, not stopping at age 65 years).
- In women infected with HIV who are younger than 30 years, if the initial cytology screening result is normal, the next cytology screening should be in 12 months. If the results of three consecutive annual cervical cytology screenings are normal, follow-

up cervical cytology screening should be every 3 years. Co-testing (cervical cytology and human papilloma- virus [HPV] screening) is not recommended for HIV-infected women younger than 30 years.

- Women infected with HIV who are 30 years and older can be screened with cytology alone or co-testing. After women screened with cytology alone have had three consecutive annual test results that are normal, follow-up screening can be every 3 years. Women infected with HIV who have one negative co-test result (normal cytology and HPV negative) can have their next cervical cancer screening in 3 years.
- In women with HIV infection, co-testing results that are cytology negative but HPV positive are managed as in the general population (see *"How should cytology-negative, HPV-positive co-test results be managed?"* in Practice Bulletin No. 168 (Interim Update), *Cervical Cancer Screening and Prevention*) (12).
- Women with HIV who have cervical cytology results of low-grade squamous intraepithelial lesions or worse should be referred for colposcopy.
- For women with HIV infection who are 21 years or older and have atypical squamous cells of undetermined significance (ASC-US) test results, if reflex HPV testing results are positive, referral to colposcopy is recommended. If HPV testing is not available, repeat cervical cytology in 6–12 months is recommended, and for any result of ASC-US or worse on repeat cytology, referral to colposcopy is recommended. Repeat cytology in 6–12 months, but not HPV testing, is recommended for HIV-infected women younger than 21 years with ASC-US test results. Although not explicitly stated in the Panel guidelines, women with HIV infection who have ASC-US, HPV-negative results (whether from reflex HPV testing or co-testing) can return to regular screening (CDC, 2009; ACOG, 2018).

Women who are otherwise at high-risk should continue to be screened annually. These women in an otherwise high-risk category include women who:

- Are immunosuppressed, such as those receiving renal transplant
- Were exposed to diethylstilbestrol (DES) *in utero*

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4. ADEQUACY/QUALITY OF THE PAP TEST SPECIMEN

The Bethesda System for reporting of cervical cytology tests requires the cytotechnologist to report on whether the specimen is adequate for meaningful evaluation (Nayar et al., 2015).

CERVICAL CYTOLOGY COLLECTION TECHNIQUE

A good cytology test specimen samples cells from the squamocolumnar junction (transformation zone or t-zone) of the cervix. When a test is correctly obtained from a pre-menopausal non-pregnant woman with a cervix, the specimen will usually contain both endocervical cells and cells from the ectocervix.

Possible causes of cytology tests lacking endocervical cells include:

- The transformation zone was not well sampled.

- The patient is pregnant.
- The transformation zone has receded into the canal in a woman who is post-menopausal.
- The transformation zone will be absent if the woman has had a hysterectomy and the cervix was removed. Endocervical cells may also be absent in Pap tests from women who have had cervical conization or LEEP procedures.
- The sampling device was not rinsed properly into the vial.

BETHESDA 2014 REPORTING

Specimen type is indicated: Indicate conventional smear (Pap smear) versus liquid-based preparation versus other.

Cervical cytology reports that use the Bethesda System of reporting will describe specimen adequacy in one of two categories:

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.)
    a. Presence or absence of endocervical t-zone cells
    b. Slightly more than 5,000 cells on the slide
    c. Cells partially obscured by elements such as blood cells or inflammatory exudate
    d. Other limitations described in the report.
2. *Unsatisfactory for evaluation.* This category is divided into two sub-categories:
    a. *Specimen rejected/ not processed (specify reason).* The cytologist did not attempt to evaluate these specimens. Possible reasons are:
        (1) Unlabeled specimens
        (2) Names on the specimen and on the form do not match
    b. Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality (specify reason). The cytologist attempted to evaluate the specimen but was not able to arrive at an interpretation/result. Possible reasons are:
        (1) Insufficient cells (less than 5,000 cells on the slide)
        (2) Cells obscured by too much blood or inflammatory exudate (Nayar et al., 2015)

NOTE: If abnormalities are found on an otherwise unsatisfactory specimen, it will, by definition, be considered satisfactory for interpretation.

Unsatisfactory cytology tests in premenopausal women who have a cervix should be repeated in two to four months, allowing sufficient time for the cervix to repair itself from the previous specimen collection.

The presence of the endocervical component (endocervical cells and/or metaplastic cells and/or cervical mucus with endocervical cells) in the cytology test indicates that the squamocolumnar junction (transformation zone) has been sampled. The endocervical

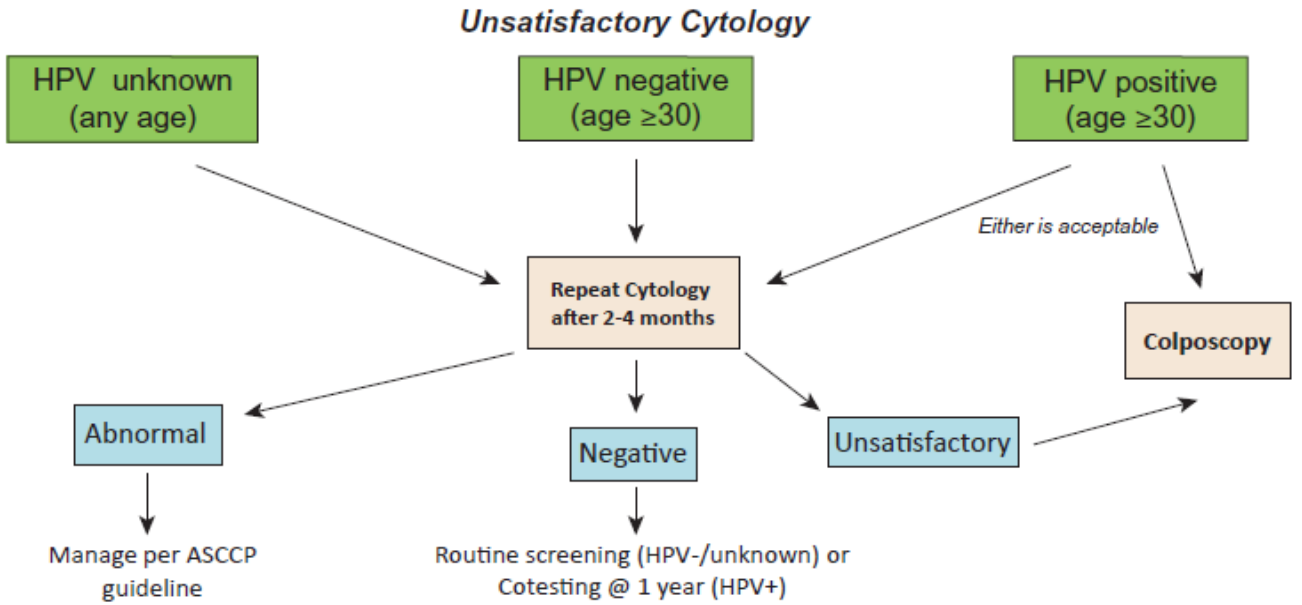
component should be present in the test collected from most premenopausal non-pregnant patients with a cervix; however, it is not necessary to re-sample before the routine screening interval (i.e., 3 years if previous cytology findings have been negative). **It is not uncommon for the endocervical component to be absent in a cervical cytology test from pregnant, post-hysterectomy and post-menopausal women, as well as those women who have had cervical conization and LEEP procedures.**

CLINICAL MANAGEMENT OF WOMEN WITH UNSATISFACTORY CYTOLOGY

For women with an unsatisfactory cytology result and HPV is negative, unknown, or not done, repeat cytology in 2-4 months is recommended. For women age 30 and older who are co-tested and have unsatisfactory cytology with a positive-HPV test, repeat cytology in 2-4 month or colposcopy is acceptable. Colposcopy is recommended for women with two consecutive unsatisfactory cytology tests.

Refer to ASCCP Published Algorithms

Unsatisfactory Cytology



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B. MANAGEMENT PROTOCOLS

The following pages describe appropriate management when cervical cytology test results indicate one of the following Bethesda System categories:

1. Negative for Intraepithelial Lesions or Malignancy
2. Negative for Intraepithelial Lesions or Malignancy, HPV+
3. ASC-US (Atypical Squamous Cells of Undetermined Significance)
4. LSIL (Low-grade Squamous Intraepithelial Lesion), including HPV and mild dysplasia/CIN I
5. ASC-H (Atypical Squamous Cells, cannot exclude high-grade lesion)
6. HSIL (High-grade Squamous Intraepithelial Lesion), including moderate dysplasia/CIN II, severe dysplasia/CIN III, and Carcinoma *in situ*/CIS
7. Squamous cell carcinomas
8. AGC (Abnormal Glandular Cells) and AIS (Adenocarcinoma *in situ*), including
    - Atypical glandular cells
    - Endocervical carcinoma
    - Endocervical adenocarcinoma *in situ*
    - Endometrial adenocarcinoma
    - Extrauterine adenocarcinoma
    - Adenocarcinoma not otherwise specified (NOS)
9. Other malignant neoplasms (Nayar et al., 2015).

1A. NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY

PATIENT NOTIFICATION

Notify the patient of normal cervical cytology results according to local policy.

PATIENT EDUCATION

Instruct your patient regarding the importance of returning for a cytology test and/ or hrHPV test at appropriate intervals, or if she notices symptoms of any gynecologic problems.

Appropriate intervals for routine screening are determined by each individual woman's risk status. See page 6 for RECOMMENDED SCREENING INTERVALS
Algorithm on page 10 is based on American Cancer Society Recommendations for screening intervals for women at average risk for cervical cancer.

NON-NEOPLASTIC COMMENTS ON NEGATIVE RESULTS

Cytologic findings not considered abnormal, but which nonetheless may be of concern, are noted on the cytology test report. These may include:

- Non-neoplastic cellular variations
  - (1) Squamous metaplasia
  - (2) Keratotic changes
  - (3) Tubal metaplasia
  - (4) Atrophy
  - (5) Pregnancy-associated changes
- Reactive cellular changes associated with:
  - (1) Inflammation (includes typical repair)
    - (a) Lymphocytic (follicular) cervicitis
  - (2) Radiation
  - (3) Intrauterine contraceptive device (IUD)
- Glandular cells status post hysterectomy
- Organisms
  - *Trichomonas vaginalis*
  - (1) Fungal organisms morphologically consistent with *Candida* spp.
  - (2) Shift in flora suggestive of bacterial vaginosis
  - (3) Bacteria morphologically consistent with *Actinomyces* spp.
  - (4) Cellular changes consistent with herpes simplex virus
  - (5) Cellular changes consistent with cytomegalovirus
  - (6) Other

    a. Endometrial cells (in a woman ≥45 years of age.)
    (Specify if “negative for squamous intraepithelial lesion”)

Do not repeat a cytology test for any of these findings, unless the specimen was unsatisfactory for evaluation. However, it is appropriate to address the cause of the non-neoplastic findings. Endometrial evaluation is recommended in postmenopausal women (Nayar et al., 2015).

INFECTION: Refer to local health care provider agency protocols for treatment of infection or inflammation.

1B. Management of Women with Cytology Reported as Negative but with Absent or Insufficient EC/TZ Component

PATIENT NOTIFICATION AND EDUCATION

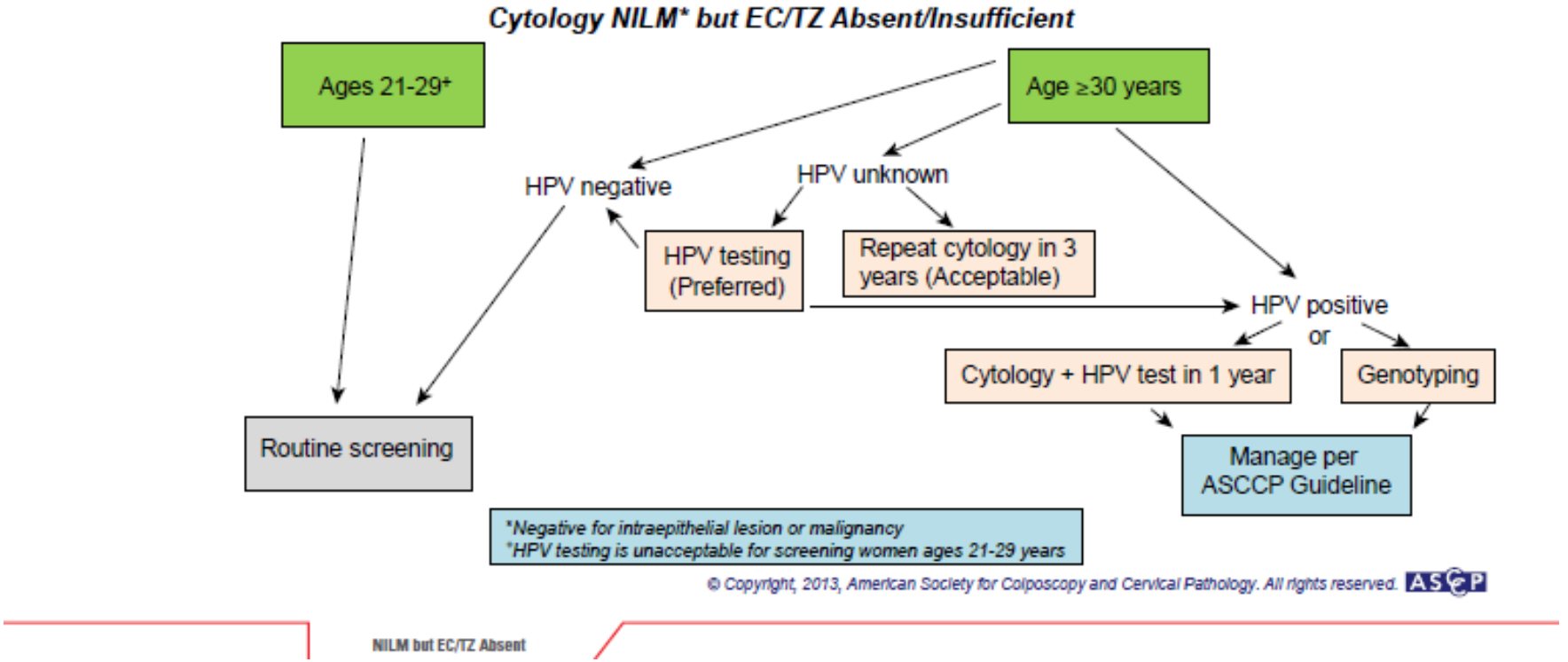
Notify the patient of normal cytology test results according to local policy if age 21-29 years. For women age 30 years and older with cytology reported as negative, advise according to clinical management described below. Instruct your patient regarding the importance of returning for a cytology test at appropriate intervals according to age and HPV status, or if she notices symptoms of any gynecologic problems.

CLINICAL MANAGEMENT

For women age 21-29 years continue with routine screening in three years. For those 30 years and older with cytology reported as negative and with absent or insufficient endocervical/transformation zone (EC/TZ) component and no or unknown HPV test result, HPV testing is preferred. Repeat cytology in 3 years is acceptable if HPV testing is not performed. If the HPV test is performed and negative, return to routine screening as recommended. If the HPV test is positive, repeating in 1 year is acceptable (Nayar et al., 2015; Huh et al., 2015).

Refer to ASCCP Published Algorithms

Cytology NILM but EC/TZ Absent/Insufficient



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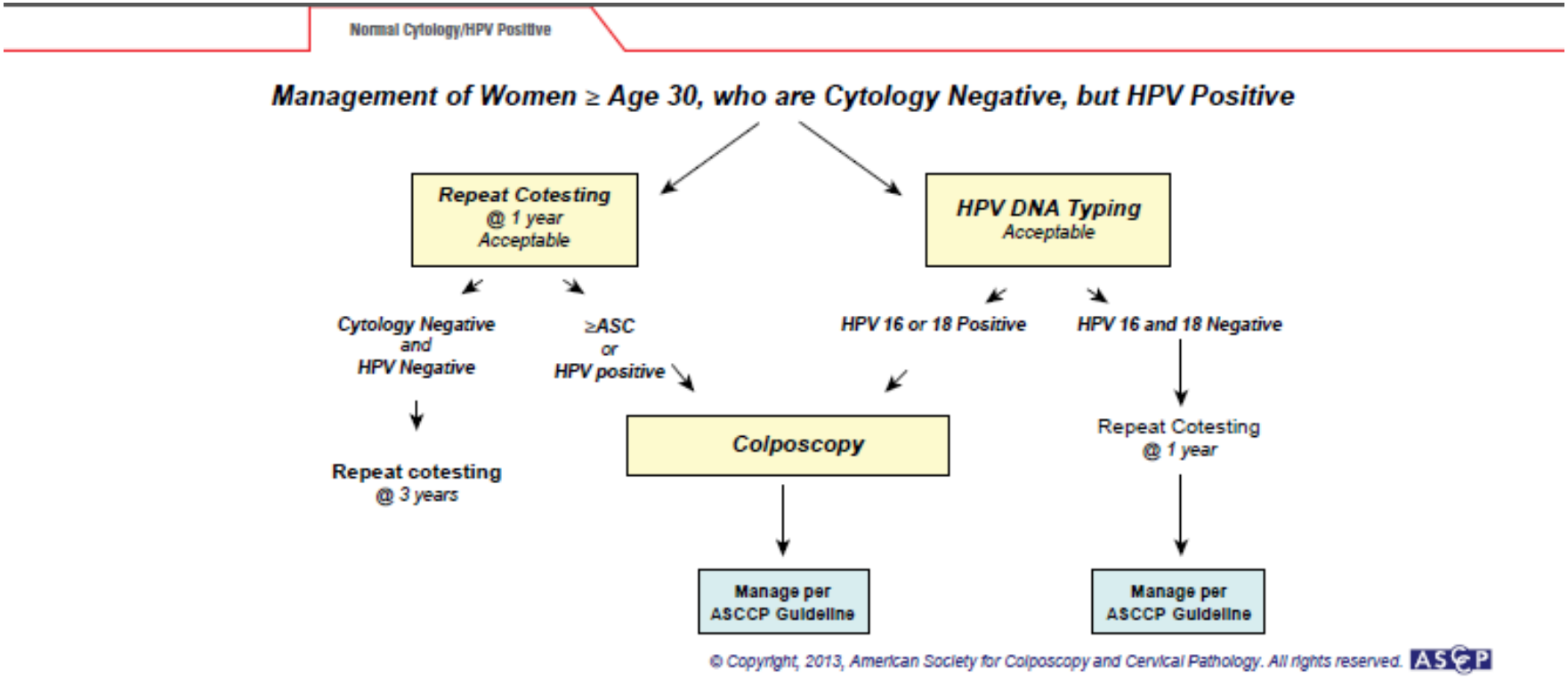
2. Management of Women age 30 and older who are Cytology Negative but HPV Positive

For women 30 years of age and older with HPV-positive but cytology negative co-testing, repeat at 1 year. At the one-year co-test, if the HPV test is positive or cytology is ASC-US or worse, colposcopy is recommended. If the one year repeat co-test is HPV-negative and cytology negative, repeat co-testing in three years (Nayar et al., 2015; Huh et al., 2015).

Refer to ASCCP Published Algorithms

Management of Women ≥ 30 who are Cytology Negative, but HPV positive



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

Atypical squamous cells (ASC) is a category the cytology lab uses to describe cells that are not quite normal, but do not meet criteria to be classified as dysplastic or neoplastic. The category is subdivided into Atypical Squamous Cells of Undetermined Significance (ASC-US) and Atypical Squamous Cells, cannot exclude HSIL (ASC-H). This section deals with ASC-US. For a discussion of ASC-H, see page 27.

The Centers for Disease Control and Prevention (CDC) reports that approximately 90% of HPV infections often regress spontaneously within two years to normal (CDC HPV fact sheet). With these recent advancements in scientific knowledge of the natural history of HPV, the management of ASC-US has changed. For women with ASC-US cytology, reflex HPV testing is preferred. The following guidelines are based on the 2012 Consensus Conference for the Management of Women with Abnormal Screening Tests (Massad et al*.,* 2013).

PATIENT NOTIFICATION AND EDUCATION

Notify the patient of cytology tests according to local policy. You will want to reassure her that a result of ASC-US does not mean she has cancer. The result may go back to normal on its own, but there is a slight chance it could progress to cancer. For this reason, it is important to monitor her tests closely.

CLINICAL MANAGEMENT

There are two options for management of women with ASC-US results.

Option 1: If no reflex HPV testing is performed with cytology, it is acceptable to repeat cytology at one year. If negative, return to cytology testing at three-year intervals is recommended. If the repeat cytology result is ASC-US or worse, refer for colposcopy.

Option 2: For women with ASC-US cytology, reflex HPV testing is preferred. For women with HPV-negative ASC-US, repeat co-testing at three years is recommended. For women with HPV-positive ASC-US, refer for colposcopy.

SPECIAL POPULATIONS

Women age 21-24 years. For women age 21-24 years with ASC-US, cytology alone at 12-month intervals is preferred, but HPV testing is acceptable. If reflex HPV testing is performed with ASC-US and the HPV result is positive, repeat cytology in 12 months is recommended. **Immediate colposcopy or repeat HPV testing is not recommended.** If cytology result is negative, ASC-US or LSIL, repeat cytology at one year and if negative x 2, return to routine screening. If cytology result is ASC-H, AGC or HSIL, refer to colposcopy. If reflex HPV testing is performed and is negative, return for normal screening with cytology alone in three years.

Women age 65 years and older if screening is appropriate. Postmenopausal women with ASC-US should be managed in the same manner as women in the general population, except when considering exit from screening for women age 65 and older. For those women, HPV-negative ASC-US results should be considered abnormal. Additional surveillance is recommended with repeat screening in one year, co-testing is preferred but cytology is acceptable.

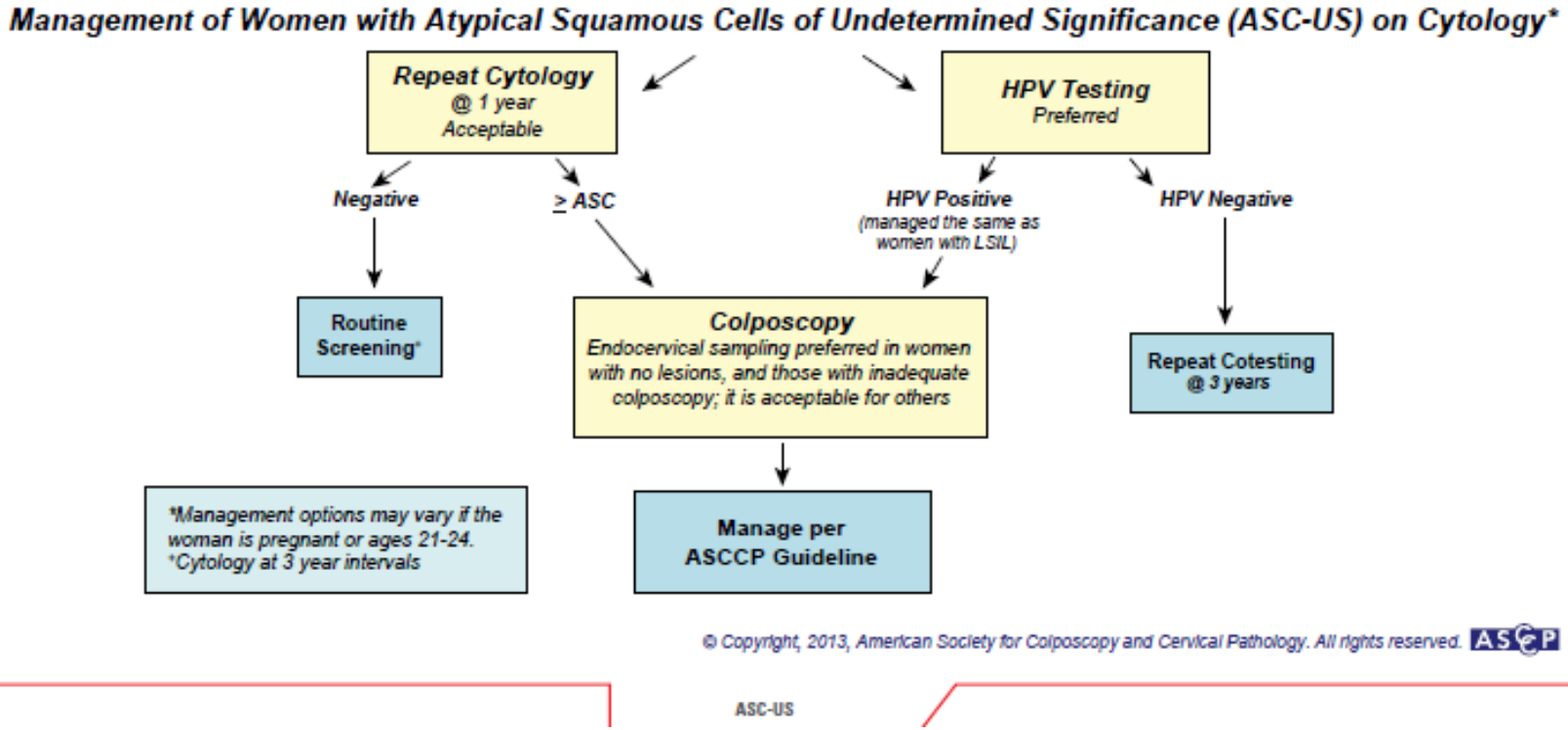
Pregnant women. Pregnant women with ASC-US should be managed in the same manner as non-pregnant women with ASC-US, with the exception that deferring colposcopy until six weeks postpartum is acceptable.

Postmenopausal women. Postmenopausal women with ASC-US should be managed in the same manner as women in the general population.

Refer to ASCCP Published Algorithms

Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US)

Management of Women 21-24 years with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



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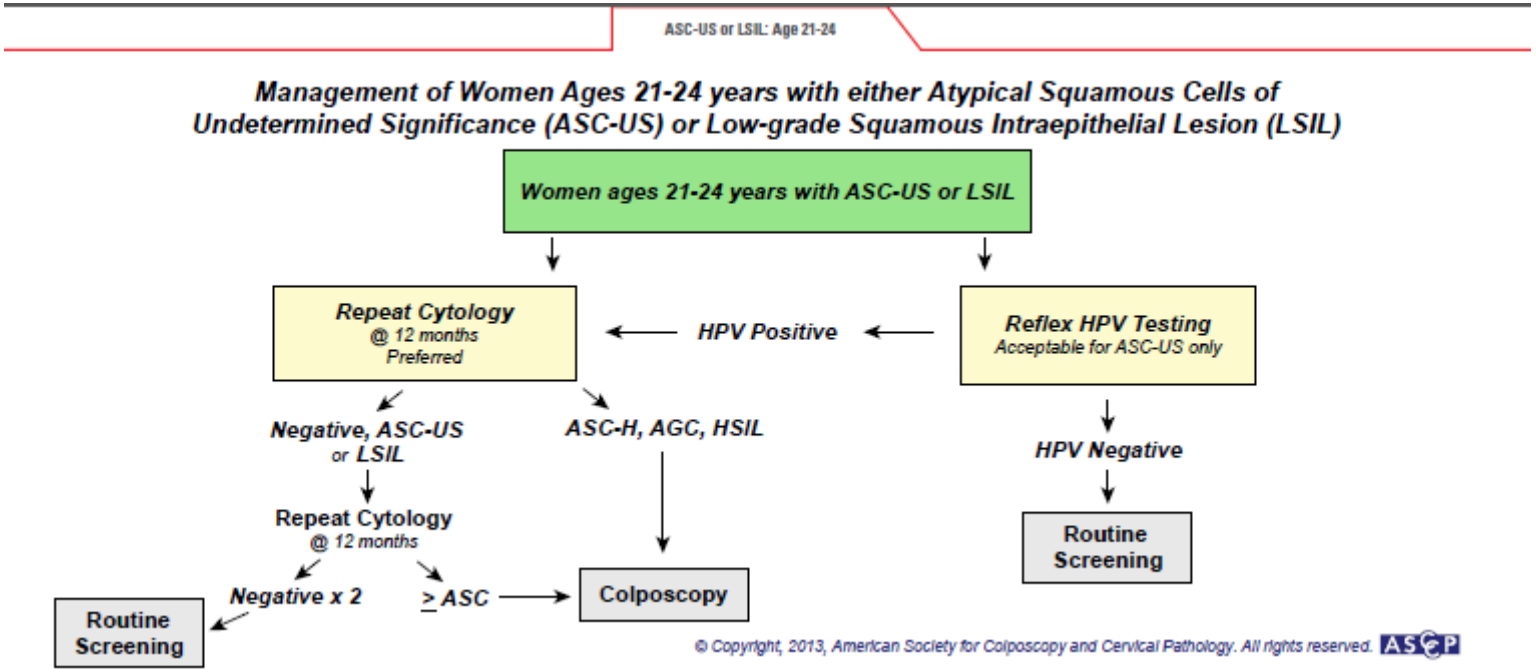

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4. LOW-GRADE SQUAMOUS INTRAEPITHELIAL LESION (LSIL)

PATIENT NOTIFICATION AND EDUCATION

Notify the patient and counsel regarding the seriousness of the cytology test report, and the need to follow the recommendations of the health care provider. Document your actions. Additional evaluation is necessary.

CLINICAL MANAGEMENT

A result of LSIL is a good indicator of HPV infection. Colposcopy is recommended for women with LSIL test results except in special circumstances (women age 21-24 years or HPV negative). If the colposcopy examination is satisfactory and a transformation zone lesion is identified, it is also acceptable to obtain an endocervical sample. If no lesion is identified or the colposcopic examination is unsatisfactory, endocervical sampling is preferred.

For women with a cytology result of LSIL and HPV-negative, repeat co-testing at one year is preferred, but colposcopy is acceptable. If repeat co-testing at one year is elected, and if the cytology is ASC-US or worse or the HPV test is positive, colposcopy is recommended. If the co-testing result at one year is HPV negative and cytology negative, repeat co-testing after an additional three years is recommended. If all tests are negative at that time, routine screening is recommended.

Since some patients with this cytology result require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record.

Patient navigation is required for all LSIL results. See page 61.

SPECIAL POPULATIONS

Women age 21-24 years. For women with LSIL ages 21 to 24 years, follow up with cytology at 12-month intervals is recommended. Colposcopy is not recommended. For women with ASC-H or HSIL+ at the 12-month follow up, colposcopy is recommended. For women with ASC-US or worse at the 24-month follow up, colposcopy is recommended. For women with two consecutive negative results, return to routine screening is recommended.

Pregnant Women. For pregnant women with LSIL, colposcopy is preferred. Endocervical curettage in pregnant women is unacceptable. For pregnant women age 21-24 years, follow-up according to the guidelines for management of LSIL in women age 21-24 years is recommended. Deferring colposcopy until 6 weeks postpartum is acceptable. For pregnant women who have no cytologic or colposcopically suspected CIN 2+ at the initial colposcopy, postpartum follow-up is recommended. Additional

colposcopic and cytologic examinations during pregnancy are unacceptable for these women.

Postmenopausal patient with LSIL. Acceptable options for the management of postmenopausal women with LSIL and no HPV test include 1) obtaining HPV testing, 2) repeat cytologic testing at 6 months and 12 months, and 3) colposcopy. If the HPV test is negative or if CIN is not identified at colposcopy, repeat cytology in 12 months is recommended. If either the HPV test is positive or repeat cytology is ASC-US or worse, colposcopy is recommended. If two consecutive repeat cytology tests are negative, return to routine screening is recommended.

TREATMENT OPTIONS

The following treatment options are based on the 2012 Consensus Conference for the Management of Women with Abnormal Screening Tests (Massad et al., 2013).

If biopsy confirms CIN 1 or no lesion is identified

If biopsy confirms CIN 1 or no lesion is identified after LSIL or ASC-US cytology, co-testing at 1 year is recommended. If both the HPV test and cytology are negative, then age-appropriate retesting 3 years later is recommended (cytology if age is younger than 30 years, co-testing if 30 years of age or older). If all tests are negative, then return to routine screening. If any test is abnormal, then colposcopy is recommended. If CIN 1 persists for at least 2 years, either continued follow-up or treatment is acceptable. If treatment is selected and the colposcopic examination is adequate, either excision or ablation is acceptable. A diagnostic excisional procedure is recommended if the colposcopic examination is inadequate; the endocervical sampling contains CIN 2, CIN 3, CIN 2,3 or ungraded CIN; or the patient has been previously treated. In patients with CIN 1 and an inadequate colposcopic examination, ablative procedures are unacceptable. Hysterectomy as the primary or principal treatment for CIN 1 is unacceptable.

CIN 1 in special populations

Women age 21-24 years. Treatment of CIN 1 in young women is not recommended.

Pregnant women. Follow-up without treatment is recommended. Treatment of pregnant women for CIN 1 is unacceptable.

If biopsy confirms CIN 2, CIN 3, or CIN 2,3

If biopsy confirms CIN 2, CIN 3, or CIN 2,3 refer for treatment promptly, except for pregnant women and young women.

CIN 2, CIN 3, and CIN 2,3 in special populations

Women age 21-24 years. For young women with CIN 2,3, either treatment or observation for up to 12 months using both colposcopy and cytology at six-month interval is acceptable, provided colposcopy is adequate.

When CIN 2 is specified for a young woman, observation is preferred but treatment is acceptable. If the colposcopic appearance of the lesion worsens or if HSIL cytology or a high-grade colposcopic lesion persists for one year, repeat biopsy is recommended.

After two consecutive negative cytology results, an additional co-test one year later is recommended. If the additional co-test is negative, then repeat co-testing in three years is recommended. Colposcopy is recommended if either the three-year or five-year co-test is abnormal.

Treatment is recommended if colposcopy is inadequate, if CIN 3 is specified, or CIN 2 or CIN 2,3 persists for 24 months.

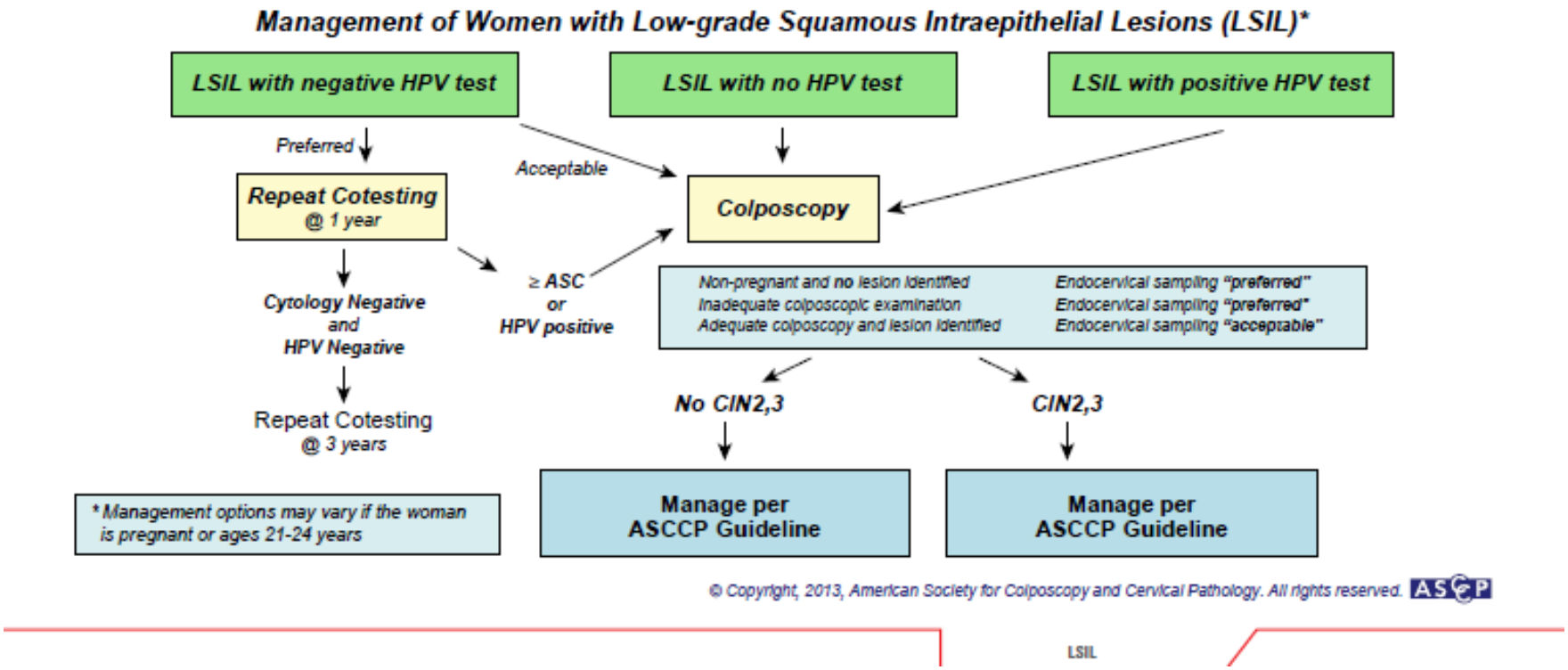
Pregnant women. In the absence of invasive disease or advanced pregnancy, additional colposcopic and cytologic examinations are acceptable in pregnant women with CIN 2, CIN 3, or CIN 2,3 at intervals no more frequent than every 12 weeks. Repeat biopsy is recommended only if the appearance of the lesion worsens or if cytology suggests invasive cancer. Deferring reevaluation until at least six weeks postpartum is acceptable. A diagnostic excisional procedure is recommended only if invasion is suspected. Unless invasive cancer is identified, treatment is unacceptable. Reevaluation with cytology and colposcopy is recommended no sooner than six weeks postpartum.

Refer to ASCCP Published Algorithms

Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL)

Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)

Management of Women ages 21-24 years with Either Atypical Squamous Cells of Undetermined Significance (ASC-US) or Low-grade Squamous Intraepithelial Lesion (LSIL)



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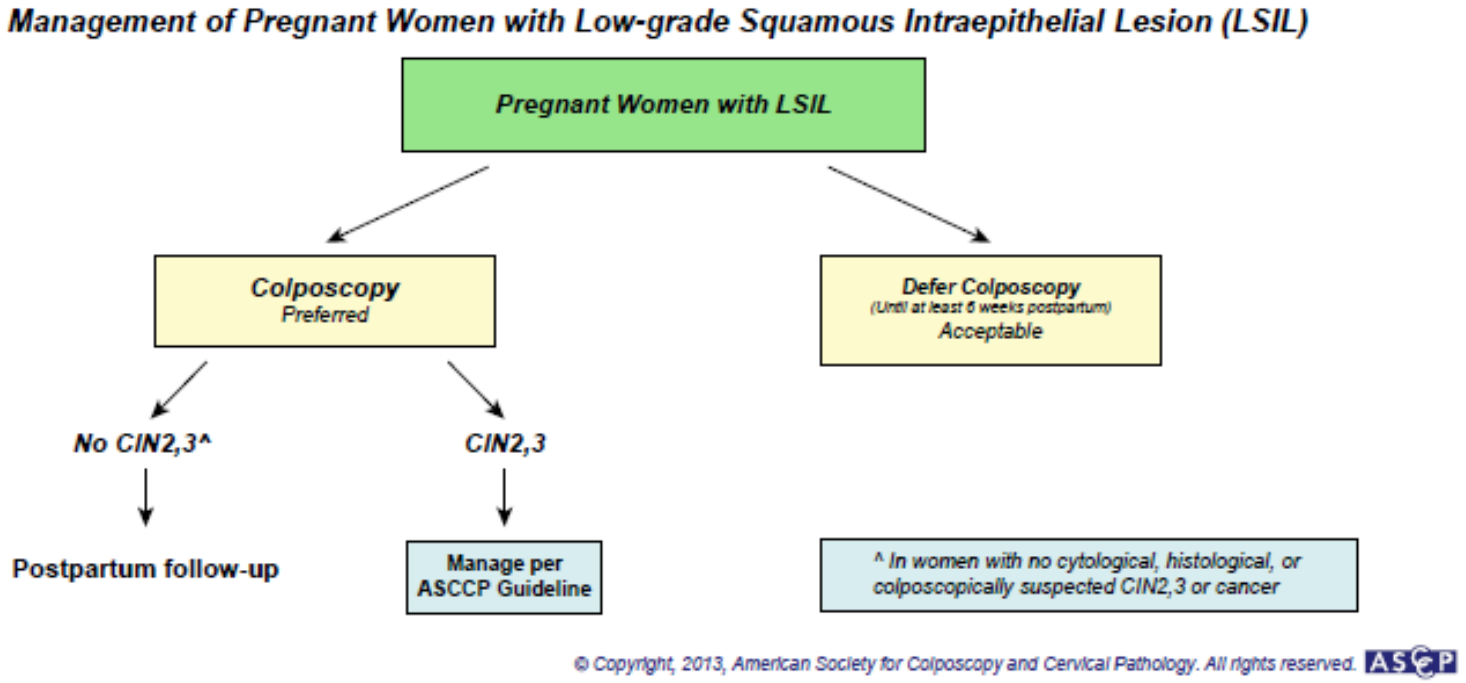

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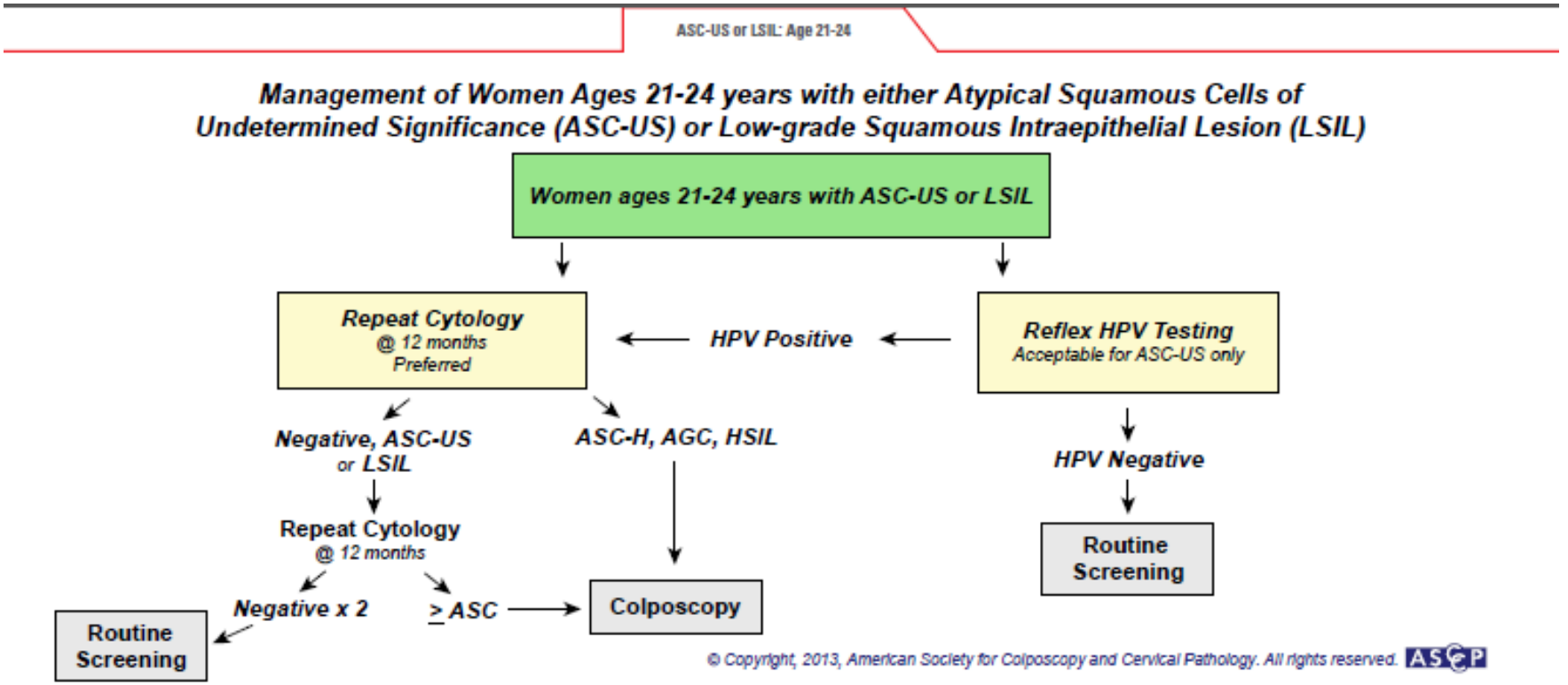

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5. ASC-H (ATYPICAL SQUAMOUS CELLS - CANNOT EXCLUDE HSIL)

Atypical squamous cells (ASC) is a category the cytology lab uses to describe cells that are not quite normal, but do not meet criteria to be classified as dysplastic or neoplastic. The category is subdivided into Atypical Squamous Cells of Undetermined Significance (ASC-US) and Atypical Squamous Cells cannot exclude HSIL (ASC-H). This section deals with ASC-H. For a discussion of ASC-US, see page 17.

PATIENT NOTIFICATION AND EDUCATION

Notify the patient and counsel regarding the potential seriousness of the cervical cytology test report, and the need to follow the recommendations of the health care provider. Document your actions. Additional evaluation is necessary.

CLINICAL MANAGEMENT

- Refer the patient to a (Qualified Health Care Provider (QHCP) for medical follow-up for colposcopy and treatment
- All women with ASC-H cytology require colposcopic evaluation regardless of HPV result. Reflex HPV testing is not recommended.
- Since patients with this test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment. Women having a cervical screening result shall receive patient navigation and be referred for assessment of the following findings: Pap result of LSIL, ASC-US with positive HPV, ASC-H, HSIL, squamous cell carcinoma, abnormal glandular cells (AGC) including AGUS or adenocarcinoma.
- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal Pap test results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); Follow-up appointment information (date, follow-up provider, and follow-up location); Date the referral was made; and results of all referrals, including the report from the follow-up provider.
- Patient navigation is required for all ASC-H results. See page 61.

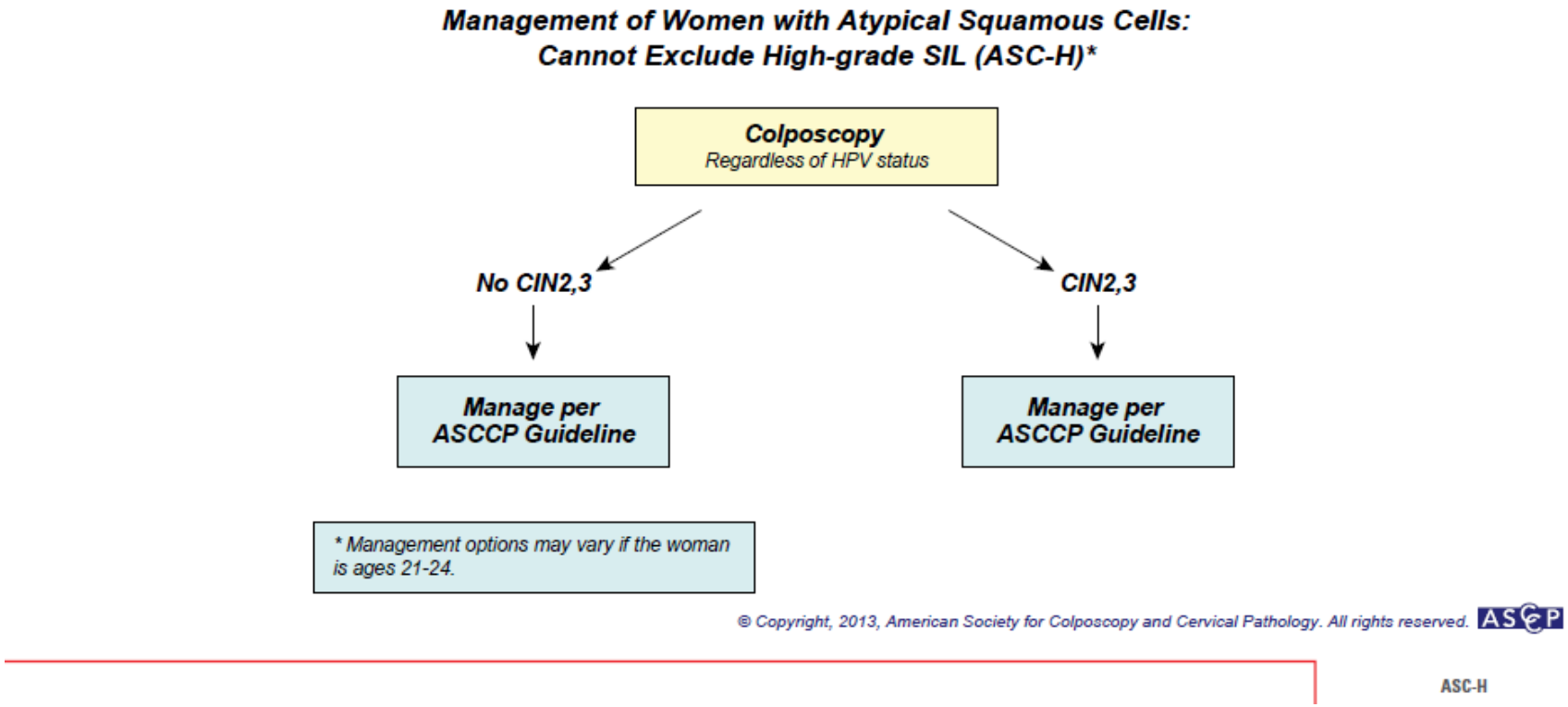
SPECIAL POPULATIONS

Women age 21-24 years. Colposcopy is recommended. Further management should follow guidelines for women age 21-24 years with HSIL.

Refer to ASCCP Published Algorithms

Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)

Management of Women ages 21-24 years with Atypical Squamous Cells: Cannot Rule Out High Grade SIL (ASC-H) and High-grade Squamous Intraepithelial Lesion (HSIL)



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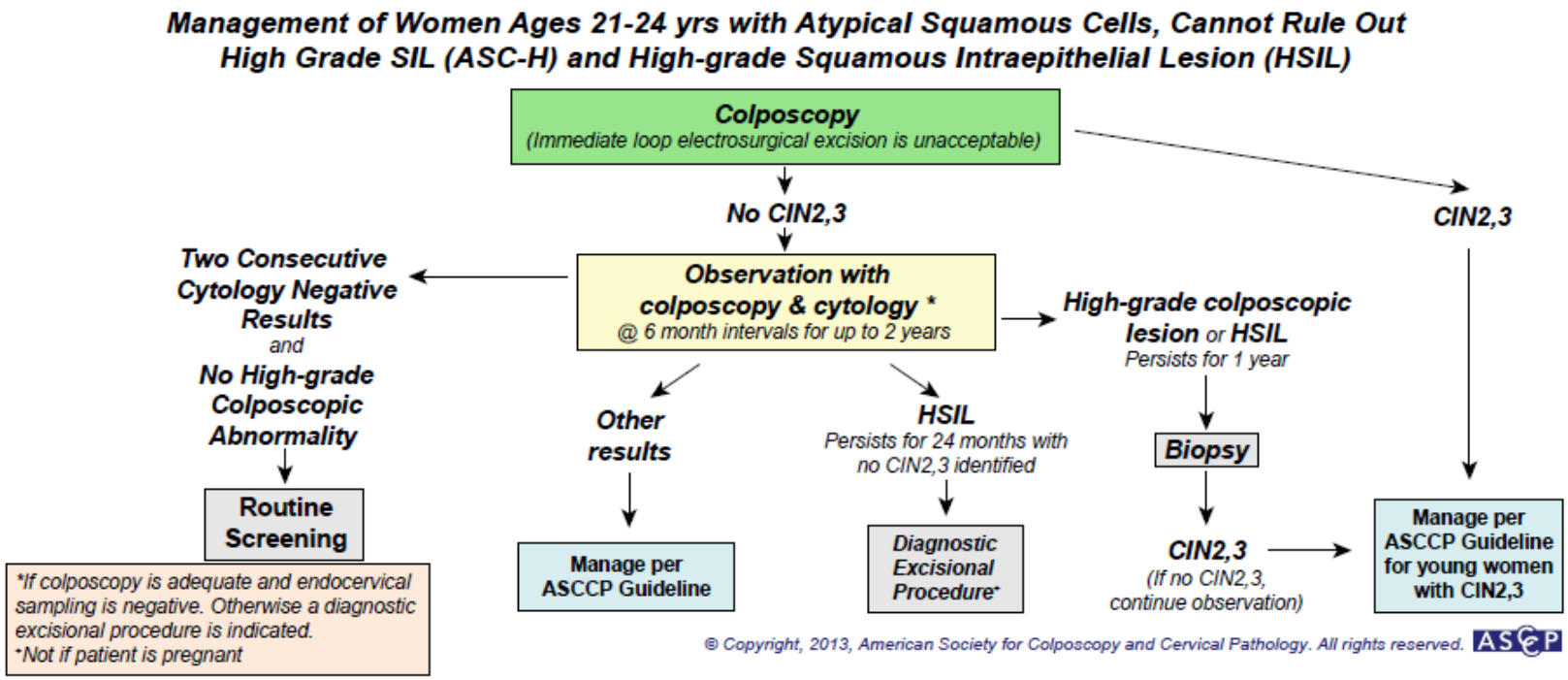

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6. HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION (HSIL)

HSIL is a serious finding. Approximately 60% to 75% of women with an HSIL cervical cytology test will have a biopsy-confirmed CIN 2+ at colposcopy. Cervical cancer is found at colposcopy in some 2% of women with HSIL, although risk rises with age and is low among women age 21-24 years, even with follow up (Massad et al., 2013; Creasman, 2012).

PATIENT NOTIFICATION AND EDUCATION

Notify the patient and counsel regarding the seriousness of the test report and seek prompt medical care. Document your actions. Additional evaluation is necessary.

CLINICAL MANAGEMENT

HSIL should always be referred for colposcopy, diagnosis and treatment. **DO NOT REPEAT PAP TEST; REFER PATIENT.**

- Refer the patient to a Qualified Health Care Provider (QHCP) for medical follow-up for colposcopy and treatment. Since patients with this test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment.
- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal screening results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); Follow-up appointment information (date, follow-up provider, and follow-up location); Date the referral was made; and results of all referrals, including the report from the follow-up provider.
- Patient navigation is required for all HSIL results. See page 61.
- CLIA has indicated this is a critical value report. See Appendix B for instructions.
- Treatment and follow-up is individualized, as directed by the QHCP

Note: If colposcopy was not completed, the patient should be advised about the necessity of this procedure.

SPECIAL POPULATIONS

Women Age 21-24 years. For women age 21-24 years with HSIL, colposcopy is recommended. Immediate treatment (i.e., see and treat) is unacceptable. When CIN 2+ is not identified histologically, observation for up to 24 months using both colposcopy and cytology at 6-month intervals is recommended, provided the colposcopic examination is adequate and endocervical assessment is negative for CIN1. If CIN2,

CIN3, or CIN2,3 is identified histologically, management according to the 2012 consensus guideline for the management of young women with CIN2, CIN3, or CIN 2,3 is recommended.

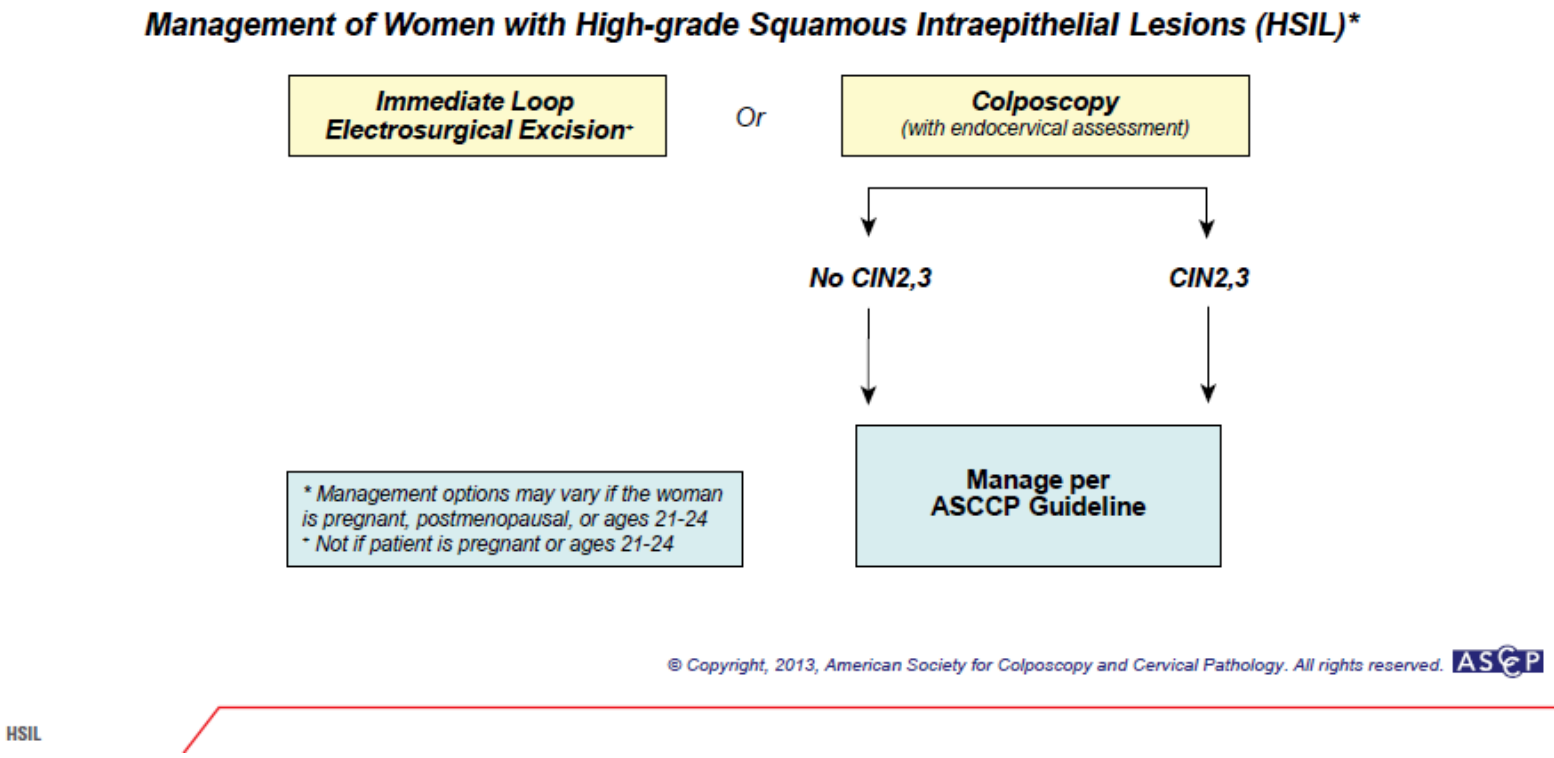
Pregnant Women:

- **Colposcopy of women who are pregnant should be conducted by clinicians who are experienced in the evaluation of colposcopic changes associated with pregnancy**
- Biopsy of lesions suspicious for high-grade disease or cancer is preferred. Biopsy of other lesions is acceptable.
- Endocervical curettage (ECC) is unacceptable in pregnant women
- Unsatisfactory colposcopy should be repeated in 6-12 weeks
- Unless invasive cancer is identified, treatment (including LEEP) is unacceptable
- Re-evaluation should be completed after six weeks postpartum

Refer to ASCCP Published Algorithms

Management of Women with High-Grade Squamous Intraepithelial Lesion (HSIL)

Management of Women ages 21-24 years with Atypical Squamous Cells: Cannot Rule Out High Grade SIL (ASC-H) and High-grade Squamous Intraepithelial Lesion (HSIL)



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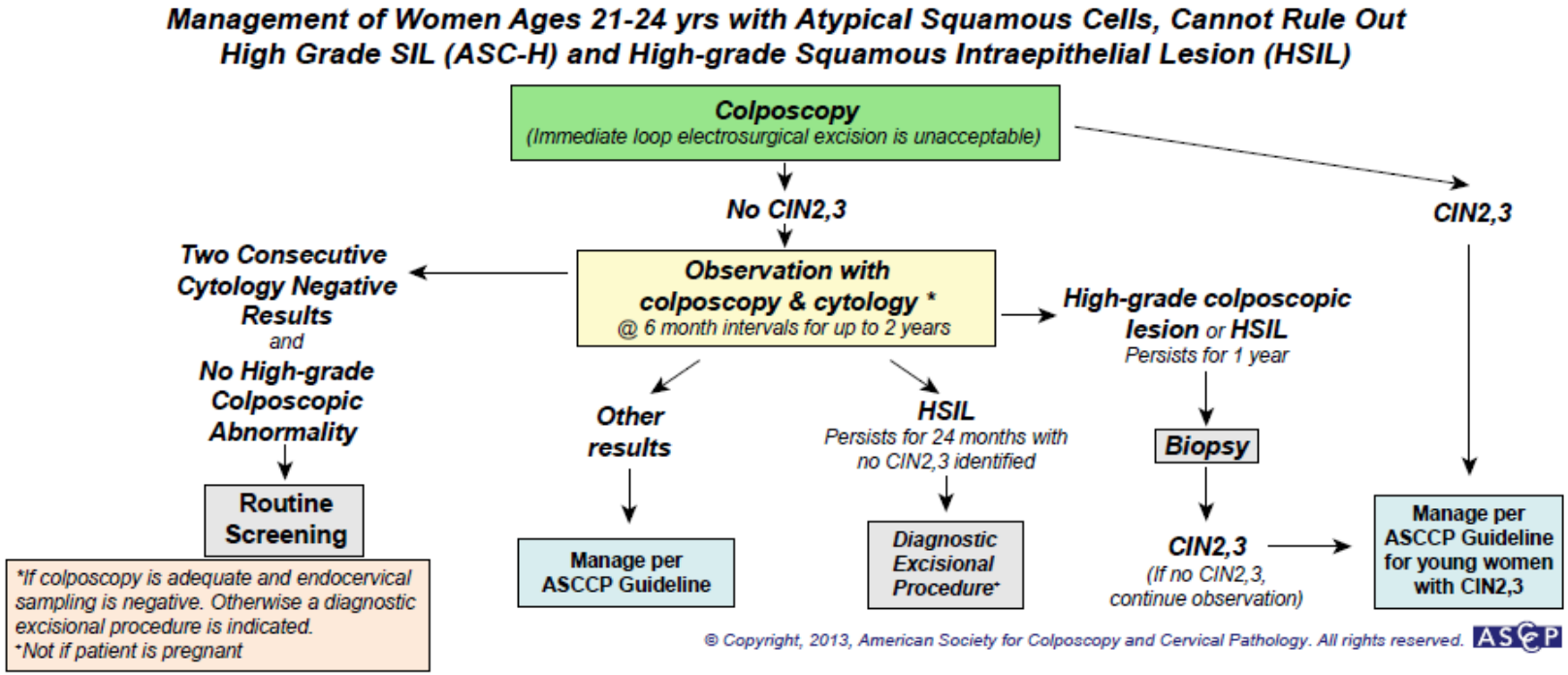

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7. SQUAMOUS CELL CARCINOMA

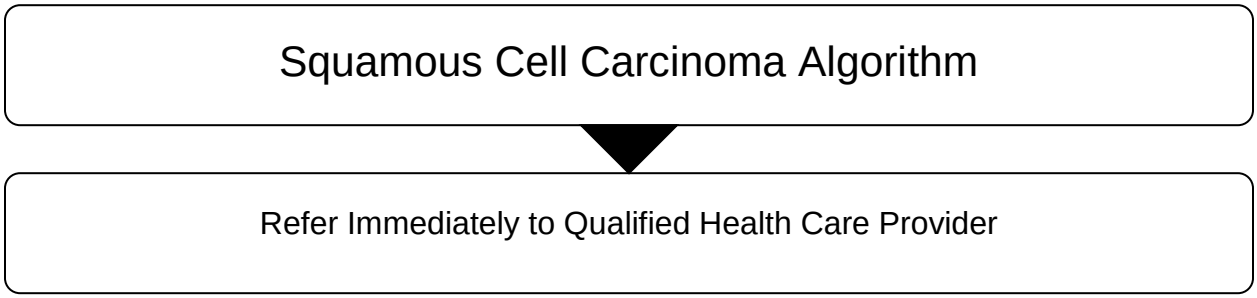
Squamous cell carcinoma is a serious finding on a cervical cytology test. It is regarded as strongly suspicious for malignancy.

PATIENT NOTIFICATION AND EDUCATION

Notify and counsel the patient regarding the seriousness of the cytology test report and the need for immediate medical care. Document your actions. Additional evaluation is necessary.

CLINICAL MANAGEMENT

- Squamous cell carcinoma is a serious finding on a cytology test. It is regarded as strongly suspicious for malignancy and warrants a pathologic diagnosis. This requires a tissue sample, which is usually obtained through colposcopy with directed biopsy or LEEP.
- **IMMEDIATE** referral must be made for medical follow-up to a Qualified Health Care Provider (QHCP).
- Since patients with this test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment.
- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal Pap test results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); Follow-up appointment information (date, follow-up provider, and follow-up location); Date the referral was made; and results of all referrals, including the report from the follow-up provider.
- Patient navigation is required for all SCC results. See page 61.
- Treatment and follow-up are individualized, as directed by the QHCP.



DO NOT REPEAT PAP TEST. REFER PATIENT.

8. ATYPICAL GLANDULAR CELLS (AGC) INCLUDING ADENOCARCINOMA *IN SITU* (AIS)

Glandular neoplasia is more difficult to diagnose than squamous neoplasia. Atypical glandular cells (endocervical or endometrial) may be described by the cervical cytology report as any of the following:

- Atypical glandular cells
- Endocervical adenocarcinoma
- Endocervical adenocarcinoma *in situ*
- Endometrial adenocarcinoma
- Extrauterine adenocarcinoma
- Adenocarcinoma, NOS

PATIENT NOTIFICATION AND EDUCATION

Notify and counsel the patient regarding the seriousness of the test report and the need for immediate medical care. Document your actions. **Additional evaluation is necessary.**

CLINICAL MANAGEMENT

- Refer the patient to a Qualified Health Care Provider (QHCP) for medical follow-up for colposcopy and/or endometrial evaluation.
- Since patients with this test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment.
- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal Pap test results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); Follow-up appointment information (date, follow-up provider, and follow-up location); Date the referral was made; and results of all referrals, including the report from the follow-up provider.
- Patient navigation is required for all AGC results. See page 61.

AGC OR CYTOLOGIC AIS IN SPECIAL POPULATIONS

Pregnant Women. The initial evaluation of AGC in pregnant women should be identical to that of nonpregnant women except that endocervical curettage and endometrial biopsy are unacceptable.

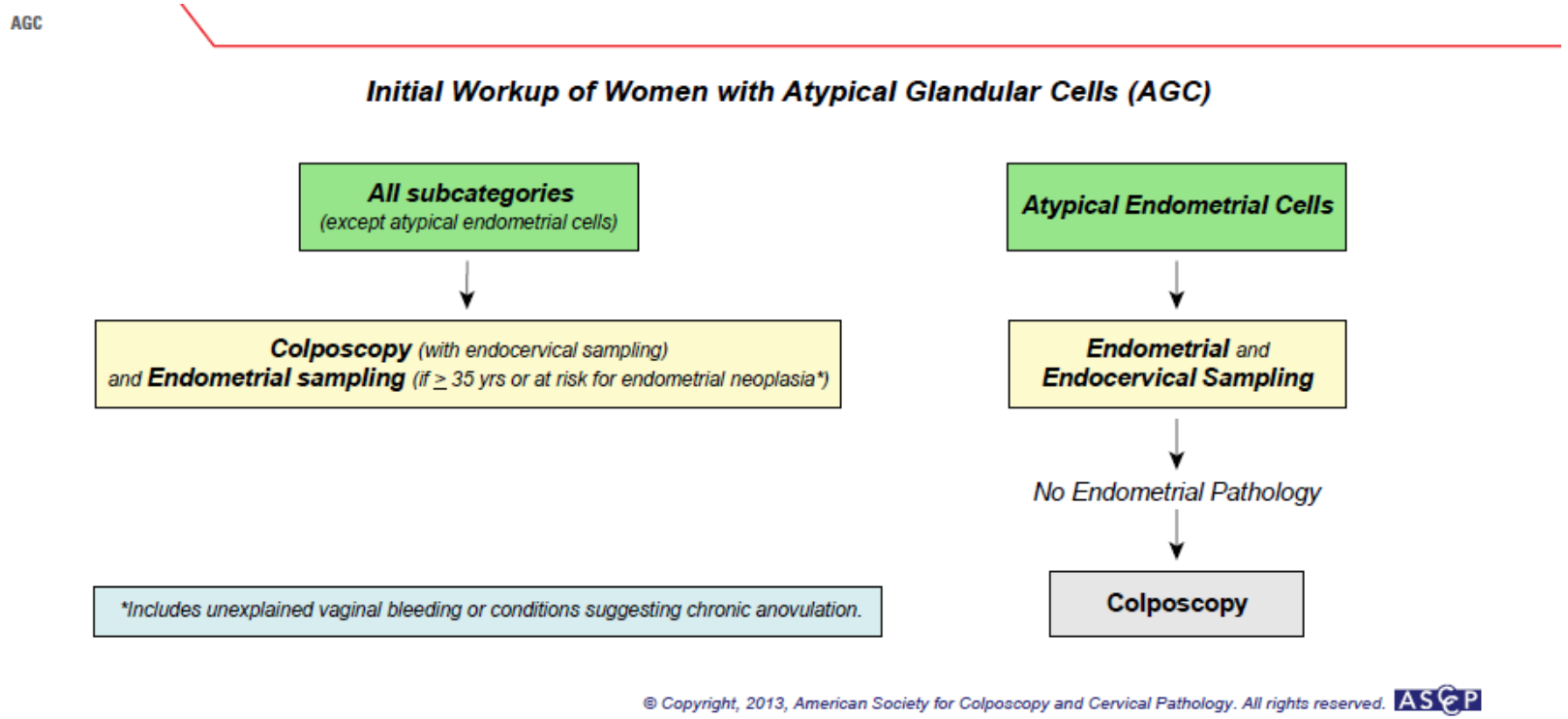
Women Age 21-24 years. It is recommended that ASCCP guidelines for management of AGC be followed for all women, including those age 21-24 years.

Refer to ASCCP Published Algorithms

Initial Workup of Women with Atypical Glandular Cells (AGC)

Management of Women Diagnosed with Adenocarcinoma-In-Situ (AIS) During a Diagnostic Excisional Procedure

Subsequent Management of Women with Atypical Glandular Cells (AGC)



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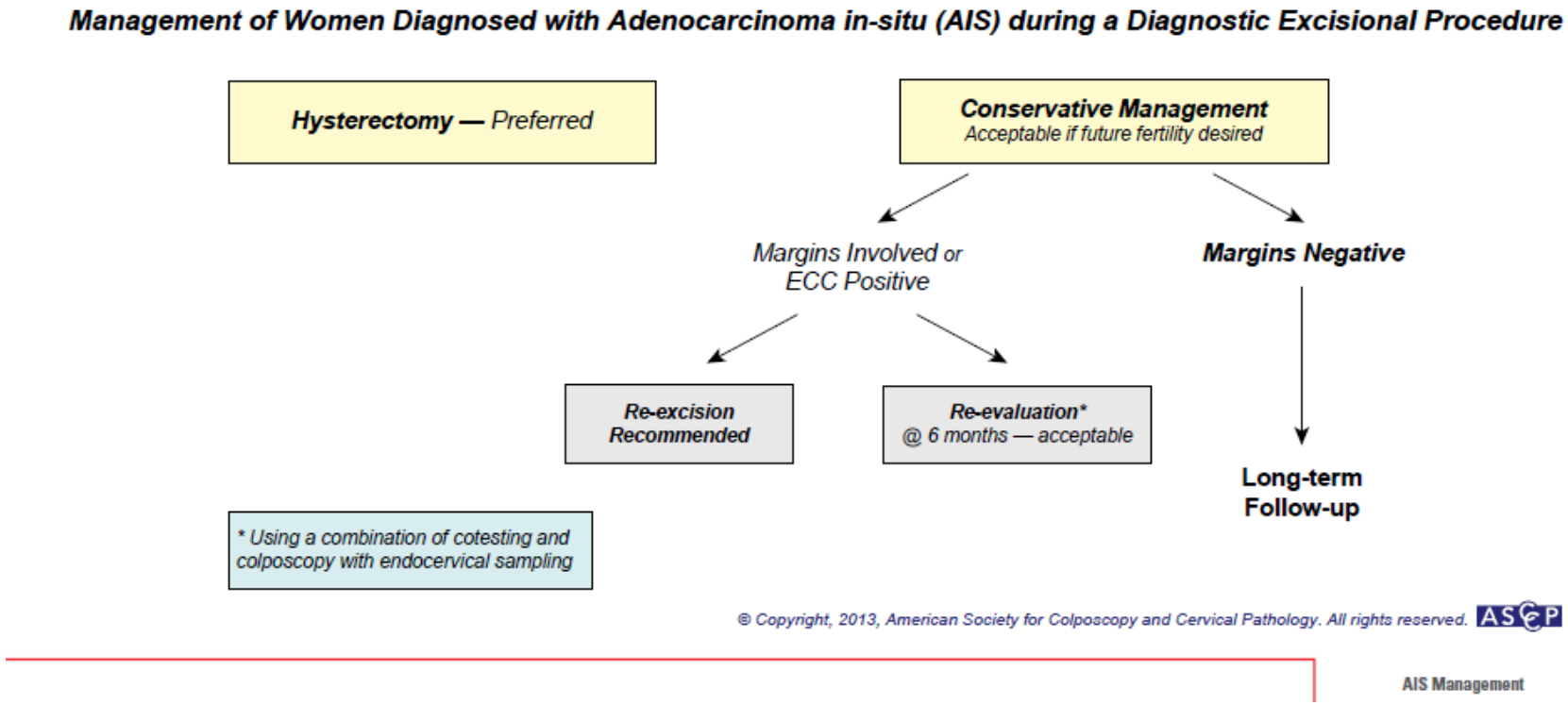

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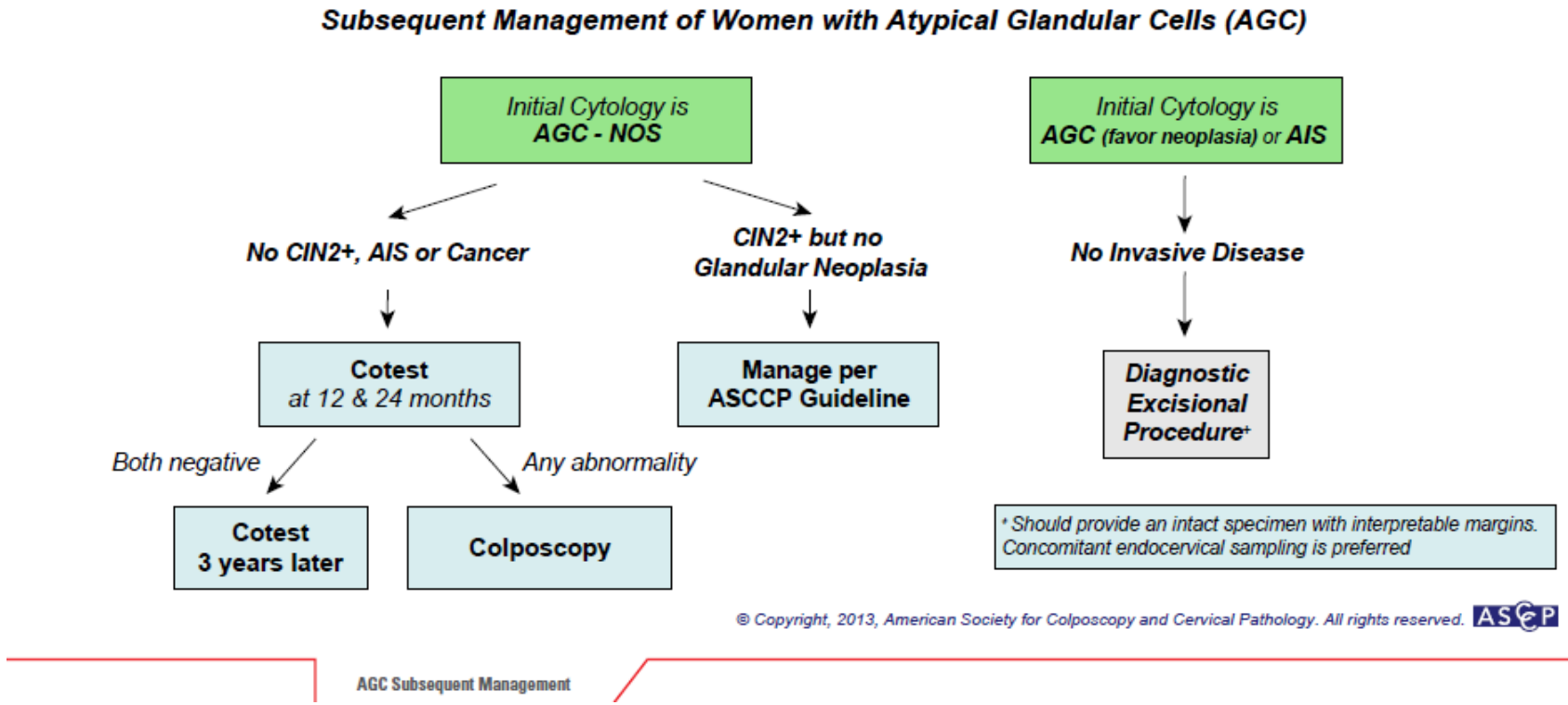

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9. OTHER MALIGNANT NEOPLASMS

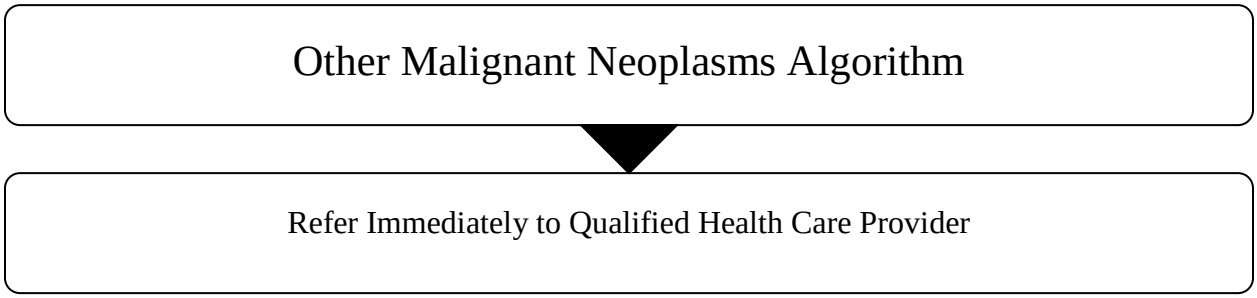
Cytologic evaluation sometimes discovers metastatic lesions such as ovarian, gastrointestinal, melanoma, etc. In these cases, the lab will report the findings as "other malignant neoplasms."

PATIENT NOTIFICATION AND EDUCATION

Notify and counsel the patient regarding the seriousness of the cytology test report and the need for immediate medical care. Document your actions. Additional evaluation is necessary.

CLINICAL MANAGEMENT

- IMMEDIATE referral must be made for medical follow-up to a Qualified Health Care Provider (QHCP).
- Since patients with this test finding all require colposcopy, the health care provider agency should assure that referral is for colposcopic evaluation and treatment.
- At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record. For all abnormal Pap test results, the following information shall be documented in the patient's medical record: Patient contact information (number and date of attempts made to follow-up); follow-up appointment information (date, follow-up provider, and follow-up location); date the referral was made; and results of all referrals, including the report from the follow-up provider.
- Patient navigation is required for all other malignant neoplasms results. See page 61.
- Treatment and follow-up is individualized as directed by the QHCP.



DO NOT REPEAT PAP TEST. REFER PATIENT.

C. Nonneoplastic Cellular Variations

1. Squamous Metaplasia- Cells which show a range of cytoplasmic differentiation from immature parabasal-like cells to those that approximate the appearance of differentiated intermediate/ superficial cells. The mean nuclear area is larger than that of the intermediate cell and similar to the parabasal cell. The process of metaplasia represents the replacement of one type of epithelium (endocervical) with another (squamous) as a protective response. Squamous metaplastic cells can exhibit a spectrum of morphology from relatively undifferentiated small round cells to highly differentiated intermediate/ superficial squamous cells. In metaplasia, stimuli such as infection, inflammation, or other type of trauma cause an alteration in the pathway of development of new cells replacing those lost by wear and tear. The newly generated cells become progressively more differentiated along the squamous pathway in response to the noxious stimulus.

2. Keratotic Cellular Changes- Normally, the cervix is nonkeratinizing, stratified squamous epithelium. Keratotic changes usually occur as a protective reactive phenomenon or in association with human papillomavirus (HPV)- induced cell changes. Both of these processes lead to hypermaturation of the native squamous epithelium, more closely approximating the normal appearance of skin. Keratotic changes can be considered a second-order protective reaction for subepithelial tissues with metaplasia being the first-order reaction. “Keratosis”, “hyperkeratosis”, “parakeratosis”, and “dyskeratosis” are descriptive terms for keratotic cellular changes which have been used inconsistently in the past. These terms are not specifically listed in Bethesda terminology due to a lack of consensus definitions. They are included parenthetically for clarification only. Although some cytologists may choose to include such terms to describe a morphologic feature that may correlate with leukoplakia on colposcopy, they should not be used as an interpretive category in cytology reports.

    a. Typical Parakeratosis- Miniature superficial squamous cells with dense orangeophilic or eosinophilic cytoplasm. Cells may be seen in isolation, in sheets, or in whorls; cell shape may be round, oval, polygonal, or spindle shaped.

    b. Hyperkeratosis- Anucleate but otherwise unremarkable mature polygonal squamous cells, often associated with mature squamous cells showing keratohyaline granules. Empty spaces or “ghost nuclei” may be noted. The Bethesda classification and interpretation of keratonic changes depends on the nuclear alterations present. Miniature squamous cells with small pyknotic nuclei and orangeophilic to eosinophilic cytoplasm (“parakeratosis”) are a nonneoplastic reactive cellular change. Single cells or cell clusters that demonstrate pleomorphism of nuclear shape and/or increased nuclear size and/or chromasia (“atypical parakeratosis”, “dyskeratosis”, or “pleomorphic parakeratosis”) are representative of an epithelial cell abnormality. Such findings should be categorized as atypical squamous cells (ASC) or as a squamous intraepithelial

lesion (SIL), depending on the degree of cellular abnormality identified. Anucleate, but otherwise unremarkable mature, squamous cells ("hyperkeratosis") constitute a nonneoplastic cellular change. When extensive hyperkeratosis is present, an underlying neoplastic or nonneoplastic process may be associated and should be considered when evaluating such cytologic preparations. Thick plaques of pleomorphic anucleate squamous cells with irregular contours may rarely be the only clue to an underlying squamous cell carcinoma. Similar to parakeratosis, hyperkeratosis alone does not constitute a specific interpretive category.

c. Tubal Metaplasia- A metaplastic phenomenon in which the normal endocervical epithelium is replaced by an epithelium that recapitulates that of the normal fallopian tube. This metaplastic epithelium includes several cell types (ciliated cells, peg cells, and goblet cells). Tubal metaplasia is a frequent finding in the upper endocervical canal/ lower uterine segment. Tubal metaplasia is among the most common benign processes to be misinterpreted as endocervical atypia or neoplasia. This is due to the tendency toward enlarged nuclei, crowded nuclei, and nuclear stratification. However, terminal bars and cilia establish a benign interpretation.

d. Atrophy- Normal aging phenomenon associated with a lack of hormonal stimulation that leads to thinned epithelium consisting of only immature basal/ parabasal cells. Atrophic changes are due to decreased hormonal support of epithelial tissues. The degree of atrophic change is highly variable, reflecting the differing levels of hormonal support that may be present. Cytomorphology can range from intermediate cell predominant to parabasal predominant to deeply atrophic (atrophic vaginitis) patterns in postmenopausal women. These differences may reflect alternate sources of endogenous estrogen or the presence of exogenous estrogenic substances. Reporting of atrophic changes is variable and poorly reproducible. Atypical cellular changes associated with atrophy warrant an interpretation of atypical squamous cells (ASC). A patient is more likely to have significant disease in face of a history of previous cervical abnormality or a prior positive high-risk HPV test. Atrophy may coexist with dysplasia or neoplasia. Atrophic changes may also be seen for weeks after parturition and other situations where estrogen and progesterone levels have decreased. In postmenopausal and postpartum states, multinucleated histiocytes (or giant cells) are found in cervical samples associated with chronic inflammatory processes.

e. Pregnancy-Related Cellular Changes- During pregnancy, a variety of epithelial and non-epithelial cell changes can be identified in cervical cytology specimens. These changes can be misinterpreted as representing neoplastic abnormalities.

f. Hormonal Changes- The altered hormonal stimulation in pregnancy leads to incomplete maturation of the squamous epithelium resulting in an intermediate cell- dominant pattern. In association with this pattern, a particular appearance of the intermediate squamous cell showing prominent glycogen with a flattened "boat-like" appearance is common. This appearance is referred to as "navicular"

cells. When progesterone secretion is prolonged (as in pregnancy), the navicular cells have greatly thickened borders and form dense clusters.

i. Decidua- Present in pregnancy and during the postpartum period. These cells are derived from hormonally stimulated endocervical or endometrial stroma.

ii. Cytotrophoblast- Derived from the placenta in late pregnancy and in the postpartum period. Rarely, they can be present for months after delivery. Cytotrophoblast are rarely identified as such. They may resemble small squamous metaplastic or endometrial cells, as well as high-grade squamous intraepithelial lesion cells. When recognized, the background often has either findings of exodus or other elements of pregnancy which give a clue to the identity.

iii. Syncytiotrophoblast- Derived from fusion of cytotrophoblastic cells. They can be identified in cervical cytology specimens in late pregnancy and postpartum periods. They can rarely be present for months after delivery.

iv. Arias-Stella Reaction- A benign process which involves glandular epithelial cells (either endocervical or endometrial) and is found in association with pregnancy or occasionally in nonpregnant hormonally stimulated individuals (Nayar et al., 2015)

Note: The changes seen in pregnancy can be misinterpreted as being of preneoplastic or neoplastic origin, primarily because they may show concerning nuclear features. It is important to be aware of the patient's pregnant or postpartum status to avoid overinterpretation of these findings (Nayar et al., 2015).

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OTHER NONNEOPLASTIC FINDINGS ON CERVICAL CYTOLOGY TEST REPORTS AND DEFINITIONS

1. **Reactive/ Reparative Cellular Changes** – Reactive cellular changes which are associated with inflammation, physical or chemical trauma, radiation, IUD irritation, or other nonspecific causes (Nayar et al., 2015).

2. **Reactive Cellular Changes Associated with Inflammation (Includes Typical Repair)**- Reparative changes may involve mature squamous, squamous metaplastic, or columnar epithelium. Cognizance of criteria for reactive/ reparative changes is important for stratifying the boundaries between Negative for Intraepithelial Lesion or Malignancy (NILM) and epithelial abnormalities. Reactive and reparative processes can show wide variation in nuclear area. In some instances, the nuclear size may fall into the range noted in SIL or cancer. When a combination of anisonucleosis irregularities in chromatin distribution, nuclear contour irregularities, or variation in size and shape of nucleoli are present (features of so-called atypical repair), the differential widens to include not only reactive conditions but also squamous intraepithelial lesions and invasive cancers. When present such changes may be better categorized as

"atypical glandular cells" (AGC) or "atypical squamous cells" (ASC-US or ASC-H) (Nayar et al., 2015).

3. **Lymphocytic (Follicular) Cervicitis**- A form of chronic cervicitis that results in the formation of mature lymphoid follicles in the sub-epithelium of the cervix. These sub-epithelium lymphocytes may be sampled in the course of obtaining a cervical specimen (Nayar et al., 2015).

4. **Reactive Cellular Changes Associated with Radiation**- The effects of ionizing radiation on cells can lead to cytologic features which may be mistaken for neoplastic or preneoplastic conditions. Acute radiation-induced changes, consisting of degenerated blood, bizarre cell forms, and cellular debris, generally resolve within 6 months following therapy. However, in some patients, chronic radiation-induced cellular changes may persist indefinitely. Certain chemotherapeutic agents may produce changes in cervical epithelial cells similar to those seen with acute and chronic radiation effects. It is important to note that bona fide squamous intraepithelial lesions in patients who have received pelvic radiation therapy will appear identical to such lesions in non-radiated patients. Care must be taken to not overinterpret specimens from radiated patients, especially in the face of perceived low-grade lesions associated with degenerated cells. Also, pelvic examinations and colposcopic procedures are more difficult in an irradiated pelvis which can complicate management (Nayar et al., 2015).

5. **Reactive Cellular Changes Associated with Intrauterine Contraceptive Device**- Reactive glandular cell clusters occasionally seen in women with intrauterine devices (IUD) may represent either endometrial or endocervical columnar cells exfoliated as a result of chronic irritation by the IUD device. Cells associated with the presence of an IUD may persist for several months after removal of the device. The characteristic changes fall into two distinct patterns: IUD-associated cells may resemble clusters of cells derived from adenocarcinoma of the endometrium, fallopian tube, or ovary when present as three-dimensional clusters; IUD-associated cells mimic a high-grade squamous intraepithelial lesion when present as single atypical cells. If there is any doubt as to the significance of the cellular abnormalities, the cytopathologist should consider recommending removal of the IUD followed by repeat cervical cytology sampling (Nayar et al., 2015).

6. **Glandular Cells Status Post Hysterectomy-** Occasionally benign-appearing glandular cells can be present in cervical cytology specimens from women who have undergone prior hysterectomy. While the origin of these benign cells may be obscure, the morphology should not be of concern for neoplasia. There are a number of explanations for this phenomenon to include the existence of glandular rests adjacent to vaginal mucosa, development of adenosis after trauma, mucinous or goblet cell metaplasia in response to atrophy, or prolapse of the remaining fallopian tube after simple hysterectomy. Following supracervical hysterectomy, benign endocervical-type glandular cells should be expected. The

most important task is to exclude adenocarcinoma, especially if the hysterectomy was performed for glandular neoplasia. If not atypical, post hysterectomy glandular cells have no clinical significance and reporting them is optional since they do not change the management (Nayar et al., 2015).

7. **Endometrial cells present in a woman over 45** - If patient is premenopausal, this is not clinically significant. If she is postmenopausal, refer to QHCP for further evaluation.
8. **Sexually Transmitted diseases** - STD's cannot reliably be diagnosed by Pap tests. Any STD identified on the Pap test should be confirmed by additional testing. Consult the current version of the *North Carolina Sexually Transmitted Diseases Public Health Program Manual* and current recommendations regarding sexually transmitted diseases from the *Centers for Disease Control and Prevention, Clinical Practice and Treatment Guidelines*.

Please refer to the NC Department of Public Health Sexually Transmitted Disease Branch Manual for specific details on STD Examination and wet mount instructions at the link below:

http://epi.publichealth.nc.gov/cd/lhds/manuals/std/toc.html

Please refer to the NC Department of Public Health Sexually Transmitted Disease Branch for guidelines on the treatment of sexually transmitted diseases at the link below which were updated in May 2013. These guidelines for the treatment of persons who have or are at risk for sexually transmitted diseases (STDs).

https://www.cdc.gov/std/tg2015/default.htm

Note: The wet mount specimen is taken from the vaginal vault and not the cervix, so it shouldn't normally matter if the pap or the wet mount is completed first, but in the case of manipulation of the cervix which may lead to bleeding, the clinician may want to collect the wet mount specimen first to decrease the risk of contaminating the wet mount specimen with blood which may make it hard to visualize microscopically.

From Wet Mount:

Trichomonas vaginallis: On wet mount, *Trichomonas vaginalis* is seen as pear-shaped, oval, or round cyanophilic organism ranging in area from 15 to 30 µm2. The nucleus is pale, vesicular, and eccentrically located. Eosinophilic cytoplasmic granules are often evident and sometimes flagella are observed. Leptothrix may be seen in association with T. vaginalis. Associated background changes include mature squamous cells with small perinuclear halos (trich change) and 3-dimensional clusters of neutrophils or polyballs. In liquid-based preparations, organisms tend to be smaller due to fixation in the solution and rounding. Nuclei and cytoplasmic eosinophilic granules are often better visualized. Flagella may be better preserved and therefore identified more readily. Occasional kite-shaped forms may be seen especially in SurePath preparations. In conventional smears, it is common to have increased neutrophilic infiltrate and flagella are less often identifiable (Nayar et al., 2015). Trichomonas PCR testing is available and can be used as a confirmatory test if needed.

Bacterial Vaginosis and Bacterial Vaginitis- Bacterial vaginosis has been associated with pelvic inflammatory disease, preterm birth, postoperative gynecologic infections, and abnormal cervical cytology. Consultation with clinical services is suggested before routinely reporting findings of vaginitis/ vaginosis so as to tailor reports to meet clinical needs (Nayar et al., 2015). Bacterial Vaginosis should be diagnosed via Amsel's criteria if using wet mount. Transitional flora can only be diagnosed via gram staining (for example, pap smear) with Nugent's criteria. Amsel's criteria is diagnosed by at least 3 of the four criteria: 1) Thin, homogenous vaginal discharge; 2) Vaginal pH >4.5; 3) Positive whiff test (positive amine odor when a solution of 10% KCl is added); 4) At least 20% clue cells. Modified Amsel's has been used which is to have 2/3 criteria.

Candida Cells - Budding yeast and/or psuedohyphae, sometimes spanning many cells and are eosinophilic to gray brown on the Papanicolaou stain. Pseudohyphae formed by cytoplasmic extension of budding yeasts, lack true septations but show complete constrictions along their length that indicate the formation of new cells. Fragmented leukocyte nuclei and groups of squamous epithelial cells speared by pseudohyphae and held together in a rouleaux are often seen. *Candida glabrata* shows small uniform, round budding yeast forms surrounded by clear halos on Papanicolaou stain. Unlike other Candida species, it does not form pseudohyphae in vivo or in culture (Nayar et al., 2015).

Divider – 2. Procedure for Obtaining a Cervical Cytology Test

PROCEDURE FOR OBTAINING A CERVICAL CYTOLOGY TEST

A. PURPOSE

It is important to remember that a cervical cytology test is a screening test, and as such it is intended to be used in an asymptomatic population. Symptoms that may be due to neoplasia should be completely evaluated. A cervical cytology test in this situation is not appropriate management. In the presence of frank bleeding, the cytology test should not be obtained. If there is suspicion that the patient's bleeding may be due to a neoplastic process, the patient should be referred for prompt, complete evaluation (Huh et al., 2015).

When considering the order of collecting specimens: The cervical cytology test is normally collected without cleaning of the cervix except in cases of copious discharge. In the case of copious discharge, a dry cotton tip can be utilized in order to visualize the os of the cervix. If too much cleaning is done, this could alter the sensitivity of the Pap test. Normally, the test should be performed first, before any testing is undertaken for gonorrhea or chlamydia infection. Collect gonorrhea, chlamydia and cytology specimens according to local protocol using review of patient symptoms and clinic requirements. Liquid-based cytology systems allow testing for cytology, HPV, gonorrhea, chlamydia and trichomonas from a single specimen.

Note 1: The wet mount specimen is taken from the vaginal vault and not the cervix, so it shouldn't normally matter if the pap or the wet mount is completed first, but in the case of manipulation of the cervix which may lead to bleeding, the clinician may want to collect the wet mount specimen first to decrease the risk of contaminating the wet mount specimen with blood which may make it hard to visualize microscopically.

Note 2: Collecting any other test(s) sample(s) before collecting the cytology test may remove cells diagnostic for cancer and its precursor lesions and may cause false negative cervical cytology test results.

B. PREPARATION OF THE PATIENT

If newer generation Pap tests are utilized, the following may not be a concern. However, depending on the availability of the provider to access the newer generation Pap tests, the following may be considered: At the time the appointment is made for an examination which includes a cervical cytology test, the patient should be advised that the likelihood of getting a higher quality test is increased by putting **nothing** in the vagina for 48 hours prior to the exam. This includes:

- No intercourse
- No tampons
- No douching

- No vaginal medications or lubricants
- No vaginal contraceptive

In addition to the above recommendations, if possible, the patient should be tested as close to 2 weeks after the first day of her last menstrual period, so as to schedule when the patient is not menstruating. If the appointment falls at a time the patient is menstruating, this should not be seen as a reason to reschedule an appointment, unless it is the patient's preference.

C. EQUIPMENT

A clinic room set up for a female pelvic exam, including the following:

- Good lighting (gooseneck lamp) must be available
- Specula
- Broom (preferred) or Plastic spatula
- Endocervical brush (Do not use in pregnant women.)
- Vial of preservative solution for liquid base Pap test
- Test tubes with normal saline (saline replaced every 30 days)
- Cotton applicators (large and small)
- Reference Lab Forms
- Individual zip lock bag
- Mailing container for vials or container from Reference Lab

D. PROCEDURE FOR PRESERVATIVE SOLUTION TESTING

1. Vial of preservative solution may be labeled **before** the test is taken. Print patient's last name and then first name on vial. Make sure name is legible. A computer-generated name label may be used (preferred). Place computer printed or hand-written label **horizontally** around the vial the uncovered portion of the vial remains uncovered and toward the top of the vial, so the vial's expiration date remains viewable. This positioning will allow the depth of liquid in the vial to be viewed and allow a place for a bar code to be added sometime in the future.

   Certain elements, for pap smears, are required by federal CLIA 04 regulations such as the patient's last menstrual period, and documentation of whether the patient had a previous abnormal report, treatment, or biopsy. Other elements (e.g., IUC use, hysterectomy, BCP or Depo-Provera use, etc.) are important in the evaluation of any cellular changes.

2. Offer the patient an opportunity to empty her bladder. Give patient a gown with instructions for wearing. Assist patient onto the examining table.
3. Assist patient to lithotomy position, drape and adjust light.
4. Put on gloves. Proceed at relaxed pace and explain each step of procedure to patient.
5. Insert the speculum
    a. Place one or two fingers just inside or at introitus.
    b. Press down gently on perineal body to relax muscles unless patient is uncomfortable with this procedure.
    c. Tell patient that speculum is about to be inserted and ask her to relax pelvic floor muscles.
    d. Gently insert closed speculum at a slight angle downward as you withdraw fingers.
    e. Hold bills at oblique angle and direct speculum toward posterior wall.
    f. With handle, rotate bills to horizontal position maintaining downward angle and pressure posteriorly.
    g. Insert speculum fully, and direct bills accordingly.
    h. If unable to locate cervix, pull back on speculum slightly and redirect bills anteriorly; cervix will usually become visible.
    i. Lock bills when cervix becomes visible.
6. **Obtain the Pap Test Sample**

    Collect samples for the liquid-based Pap test from **both ecto- and endocervix**.

    a. TO COLLECT THE SAMPLE FROM THE ECTOCERVIX

        (1) Select broom and rotate 5 times maintaining contact with the ectocervical surface **or** select the contoured end of plastic spatula and rotate 360º around entire ectocervix while maintaining tight contact with ectocervical surface. Remove spatula.

        (2) If using a broom, the tip is slipped off and left in the solution. If using plastic spatula, rinse contoured end of plastic spatula in vial of preservative solution by swirling vigorously **ten (10)** times. Leave the spatula in the vial while collecting the endocervical sample. (Step 2.)

        It is **most** important that an adequate sample be taken from the squamocolumnar junction, also called the transformation zone. The location of the squamocolumnar junction can be identified by a change in color and texture between the squamous and columnar epithelia. The squamous epithelium appears as pale pink, shiny and smooth. The columnar epithelium appears reddish with a granular surface.

b. To collect a sample from the endocervix

   (1) Insert the cytobrush device into the endocervix only until the bottom-most bristles are exposed. Slowly rotate one-fourth to one-half turn in one direction. Remove brush. **Do not over-rotate. Additional rotation may cause bleeding and contaminate specimen**.

   (2) Rinse the cytobrush in the preservative solution while pushing it against the wall of the vial. Break off the cytobrush and leave in the solution**.**

c. To close the vial for shipping:
Tighten the preservative vial cap so that the **torque line** on the cap **meets** the **torque line** on the vial.

d. **Make sure** that the vial is properly labeled with the patient's name, **last name and first name.** Make sure the name on the **vial matches** the name on the **form**.

7. **Special Considerations for Pap Test Collection:**

   a. Do not use endocervical brush in pregnant women.

   b. For the patient who has had a hysterectomy, use regular tip of plastic spatula to scrape the area of the vaginal cuff. (Refer to page 7 to determine if your patient who has had a hysterectomy should have a screening cervical cytology test (Huh et al., 2015).

   c. Remove excess mucus or other discharge present before taking sample. This should be gently removed with ring forceps holding a folded gauze pad.

   d. Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry 2x2 piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry proctoswab or scopette.

   e. The cervix should not be cleaned by washing with saline or it may result in a relatively acellular specimen.

   f. The sample should be obtained before the application of acetic acid.

   g. If you also have STD samples to collect, the order of testing is not important and should be based upon the primary purpose for the visit.

8. **Packaging and Shipping of Pap Test Samples/Specimens**

   Refer to reference lab instructions for detailed instructions.

   a. Make sure that preservative vial is labeled with two patient identifiers including the patient's last and first names and preferably date of birth.

   b. Follow lab procedures as specified by your laboratory to make sure all information is provided to the reference laboratory.

c. Follow packaging and shipping instructions provided by the reference laboratory.

PROCEDURE NOTES

- Have readied a vial of preservative solution labeled with two patient identifiers.
- Be sure Expiration Date on the preservative solution is current. The laboratory **will not test samples when the expiration date has passed.**
- Do not hold specimens in the lab for extended periods. Ship specimens to the lab frequently to avoid specimen rejection. FDA regulations require that the Pap slide must be prepared within three weeks of collection.
- Improved patient preparation or clinician technique may correct the cause of the unsatisfactory or partially obscured Pap. Refer to your lab for procedure notes.

E. UNSATISFACTORY CYTOLOGICAL SPECIMENS

Unsatisfactory cytological specimens fall into two categories:

- Unsatisfactory: examined
- Unsatisfactory: rejected

1. The most common reasons for unsatisfactory: examined samples/specimens are:
   a. Insufficient number of cells
   b. Failure to properly rinse collection devices in vial of preservative solution
   c. Bloody specimens
   d. Inflammation
   e. Presence of organisms

2. The most common reasons for unsatisfactory or rejected specimens are:
   a. Vial not labeled with at least two patient identifiers.
   b. Illegible handwriting or stamped name
   c. Name on vial does not match name on form
   d. Specimen collected after expiration date of vial
   e. Two vials with same patient's name and two forms with two different names.
   f. Slide breakage or leakage of liquid specimens

3. The most common errors in usage of form are:
   a. Incomplete patient information
   b. Failure to indicate patient name change
   c. The patient history is incomplete

d. There is no return address of provider
e. Writing is illegible on form
f. The patient's name on the vial and the form do not match
g. Two vials are sent with one form

Divider – 3. Quality Assurance Recommendations

Quality Assurance Recommendations

A. QUALITY ASSURANCE RECOMMENDATIONS FOR CERVICAL CANCER SCREENING

For a cervical cancer screening to be effective, health care providers need to have systems in place to ensure that any abnormalities detected by clinical pelvic exam or Pap test are appropriately followed up. Notify patients with abnormal test results promptly. Track patients who need additional diagnostic or treatment to assure they get proper follow-up care (NBCCEDP, 2017).

Six key steps are necessary for managing the results of cervical cancer screening:

1. Track Pap test and any diagnostic tests until results are obtained
2. Follow requirements for patient notification. At least three attempts must be made to locate and inform the patient of **abnormal screening results**. The last attempt must be by certified letter. Written documentation of all attempts must be included in the medical record.
3. Document that notification has occurred
4. Refer patients with any abnormalities on clinical pelvic exam or Pap test for appropriate follow up
5. Patient Navigation for abnormal test results (NBCCEDP, 2017).
6. Track referrals to make sure that patients have actually received follow-up

   Tracking systems remind staff to:

   - Document all patient contacts
   - See tests and examinations ordered and compare to tests with no results
   - Review patients with incomplete interval follow-ups (monthly, quarterly, etc.)
   - Develop procedures and implement evidence-based interventions to overcome patient-related barriers to follow-up, for example telephone or mailing reminders.
   - If patients with abnormal results cannot be reached on the first attempt, make at least 3 attempts to locate patient before determining the patient is lost to follow-up.

Each clinic might have a different mechanism for ensuring that all these steps have occurred, but all clinics should all have written guidelines, standards, and policies for management of cervical cancer screening. Written policies must be accessible to staff. This manual contains recommendations that should be considered in the development of local policies. Agencies providing Pap screening by Enhanced Role Registered Nurses (ERRNs) must have policies and procedures in place for assuring competency and documentation of competency for each ERRN performing clinical exams. Policies should be reviewed at least annually and revised as needed.

Elements Integral to a Good Follow-Up System

1. **Designation of a responsible person**: The person designated as having responsibility for follow-up of cervical cancer screening should be a nurse or provider who has knowledge of cervical cancer screening programs and familiarity with guidelines regarding follow-up of patients with abnormal Pap test results.
2. **A referral plan:** The referral plan will contain written procedures for referring patients with abnormal findings, including referral resources, the process of referring, and the preparation of eligibility forms, if applicable. All education and counseling protocols should be included, along with a list of educational materials used to assist the patient in understanding the abnormal test result or any additional diagnostic tests that may be done.
3. **A follow up-plan:** The follow up plan will contain written procedures that ensure the patient was referred to a provider, needed services were provided, and results of the referral returned to the agency.
4. **A tracking system**: Clinical management of patient is improved with a tracking system. Tickler files, computerized databases or handwritten logs are common methods of tracking patients. The system alerts staff of patients' status, especially abnormal cervical screening, and provides a simple tool for follow-up. Any tracking system must be checked at predetermined intervals to ensure follow-up is completed. The following is a suggested general process for cervical screening tracking:
    - All cervical cytology tests ordered are logged into a tracking system.
    - When results are received by the agency, the person responsible for follow-up reviews the reports.
    - Patients should be notified of all results including those with no abnormal findings. The report is signed off and stored in the medical record.
    - Results requiring follow-up are reviewed, the patient is notified, and the Patient Navigation process begins. The plan of care is determined based on this manual, local policy, and consultation with the agency medical advisor.
    - When further assistance is needed to determine the plan of care, providers/ agencies may consult NC BCCCP Nurse Consultants or Women's Health Nurse Consultants, depending on which program is appropriate.
    - Medical record documentation will include patient notification, any patient navigation services, plan of care, and all follow-up information.
    - The nurse responsible for patient follow-up enters information in the tracking system and monitors the progress of the patient until follow up is complete.

Internal quality assurance: Periodically (at least annually), chart audits should be performed to ensure all program requirements are being met. Documentation of findings and any corrective actions must be on file (NBCCEDP, 2017).

B. Patient Navigation Recommendations

Patient Navigation: For purposes of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP), Patient Navigation is defined as, "Individualized assistance offered to clients to help overcome health care system barriers and facilitate timely access to quality screening and/or diagnostics as well as initiation of treatment services for women who are diagnosed with cancer." Women in need of screening shall receive assessment of the need for patient navigation and assistance to access screening services (NBCCEDP, 2017). Patients often face significant barriers to accessing and completing cancer screening and diagnostics. Patient Navigation is a strategy aimed at reducing disparities by assisting patients to overcome these barriers.

Required Patient Navigation Activities- Patient Navigation services vary based on individual patient needs. At a minimum, patient navigation services will include the following activities:

1. A written assessment of the patient's barriers to cancer screening, diagnostic services, and initiation of cancer treatment.
2. Client education and support.
3. Resolution of client barriers (i.e. transportation, translation services).
4. Client tracking and follow-up to monitor progress in completing screening, diagnostic testing, and initiating cancer treatment.
5. Given the centrality of the patient-navigator relationship, patient navigation must include a minimum of two, but preferably more contacts with the patient.
6. Collection of data to evaluate the primary outcomes of patient navigation: patient adherence to cancer screening, diagnostic testing, and treatment initiation. Patients lost to follow-up should also be tracked.

Priority Populations for Patient Navigation

Navigation is an individual intervention, intensive in nature, and potentially costly. Priority should be given to patients who would not complete the screening process without it. Patient Navigation services is provided to patients enrolled in the NCCCEDP as well as those who have other resources (such as insurance) to pay for screening and diagnostic services. Women who receive navigation should either be enrolled in NBCCEDP programs or have low incomes. Documentation of Patient Navigation must be completed.

Terminating Patient Navigation

Depending on screening and diagnostic outcomes, patient navigation services are terminated when a patient (1) completes screening and has a normal result; (2) completes diagnostic testing and has a normal result; or (3) initiates cancer treatment or refuses cancer treatment. When a patient concludes her cancer treatment and has been released by her treating physician to return to a routine screening schedule, patient navigation services resume.

C. CHECKLIST FOR LABORATORY CONTRACT

Methodology

What is the Pap method being provided?

- ☐ Liquid based
- ☐ Conventional

What types of HPV testing are provided?

- ☐ High-risk type
- ☐ Types 16 and 18 only
- ☐ Cobas HPV test

Is reflex HPV testing provided if Pap result is ASC-US? ☐ Yes ☐ No

What are the dysplasia and ASC-US rates for each method used and the lab's overall rates? _____

What is the reporting format used?

- ☐ Bethesda 2014
- ☐ Other (specify) _____

Cost

What is the current cost per test? _____

How long is the current price guaranteed? _____

How often does the price of testing increase? _____

Are billing invoices clear and correct? ☐ Yes ☐ No

Service

What is the turnaround time? _____

Is consultation available for reporting and follow-up guidelines? ☐ Yes ☐ No

Are statistical reports provided with the number of tests submitted, breakdown of results in each reporting and specimen adequacy category, and a report of follow-up of abnormal results? ☐ Yes ☐ No

Is it easy to contact lab personnel and get answers or resolutions to problems? ☐ Yes ☐ No

Can the status of a specimen be checked, or can a report be downloaded from the Internet? ☐ Yes ☐ No

Quality

What is the correlation rate of biopsy to Pap report? _____

How many slides are cytotechnologists required to read per day? _____

How many cytotechnologists are employed? Are all cytotechnologists _____

Average years of experience of cytotechnologist staff? _____

What is the frequency of staff turnover? _____

What is the average slide per day per cytotechnologist? _____

Are all slides screened during regular working hours? _____

Is overtime mandatory for cytotechnologists? _____

What percentage of work is screened after hours? _____

Is all work done at one site? _____

What percentage of negative slides is rescreened? _____

Are the cytotechnologists responsible for performing this rescreening in addition to the daily requirement of first screens? _____

What Proficiency Testing Program is used and what has the performance history been for the lab and individual cytotechnologists? _____

What type of competency assessment is done for cytotechnologists? _____

Ask for a copy of the Cytology Laboratory Quality Assessment Plan.

Is an automated screening device used for screening? ☐ Yes ☐ No

If yes, does a cytotechnologist still review every slide? ☐ Yes ☐ No

Ask for an organizational chart showing chain of command and certification of each level.

Is an ASCP certified cytotechnologist in charge of the cytopreparation area?
☐ Yes ☐ No

How many years of experience does this person have? _____

Must these duties be performed in addition to screening slides? ☐ Yes ☐ No

If so, how many slides per day does this person average? _____

Are any off-label procedures being used in the processing of gynecologic slides?
☐ Yes ☐ No

How many staff pathologists review Pap slides? _____

What percentage of slides received does a pathologist review? _____

Is there any pending litigation concerning Pap reporting? ☐ Yes ☐ No

Has the lab been involved in prior litigation of any kind related to Pap screening services? _____

Ask for certificates of accreditation (CAP, CLIA, JCAH, etc.) and accreditation inspection reports.

References

Ask for customer references. _____

Using the questions listed above as a guide, are customers satisfied with:

- ☐ Methodology
- ☐ Cost
- ☐ Service
- ☐ Quality

Divider – 4. Appendices

Divider – Appendix A

2014 BETHESDA SYSTEM FOR REPORTING CERVICAL CYTOLOGY

Specimen Type:

Indicate conventional smear (Pap smear) vs. liquid-based preparation vs. other

Specimen Adequacy:

Satisfactory for evaluation (describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g., partially obscuring blood, inflammation, etc.)

Unsatisfactory for evaluation (specify reason)
-Specimen rejected/ not processed (specify reason)
-Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (specify reason)

General Categorization

- Negative for Intraepithelial Lesion or Malignancy
- Other: See Interpretation/ Result (e.g. endometrial cells in a woman $\geq$ 45 years of age)
- Epithelial Cell Abnormality: See Interpretation/ Result (specify 'squamous' or 'glandular' as appropriate)

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)

NON-NEOPLASTIC FINDINGS (optional to report; list not inclusive)

- Non-neoplastic cellular variations
  - Squamous metaplasia
  - Keratonic changes
  - Tubal metaplasia
  - Atrophy
  - Pregnancy-associated changes
- Reactive cellular changes associated with:
  - Inflammation (includes typical repair)
    - Lymphocytic (follicular) cervicitis
  - Radiation
  - Intrauterine contraceptive device (IUD)
- Glandular cells status post hysterectomy

ORGANISMS

- *Trichomonas vaginalis*
- Fungal organisms morphologically consistent with *Candida spp.*
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with *Actinomyces spp*.
- Cellular changes consistent with herpes simplex virus
- Cellular changes consistent with cytomegalovirus

OTHER

- Endometrial cells (in a woman ≥ 45 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 1)
- High-grade squamous intraepithelial lesion (HSIL)
  (encompassing: moderate and severe dysplasia, CIS; CIN 2 and CIN 3)
  -with features suspicious for invasion (if invasion is suspected)
- Squamous cell carcinoma

GLANDULAR CELL

- Atypical
  -endocervical cells (NOS or specify in comments)
  -endometrial cells (NOS or specify in comments)
  -glandular cells (NOS or specify in comments)

- Atypical
  -endocervical cells, favor neoplastic
  -glandular cells, favor neolplastic

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

OTHER MALIGNANT NEOPLASMS: (specify)

ADJUNCTIVE TESTING

Provide a brief description of the test method(s) and report the result so that it is easily understood by the clinician.

COMPUTER-ASSISTED INTERPRETATION OF CERVICAL CYTOLOGY

If case examined by an automated device, specify device and result.

EDUCATIONAL NOTES AND COMMENTS APPENDED TO CYTOLOGY REPORTS (optional)

Suggestions should be concise and consistent with clinical follow-up guidelines published by professional organizations (references to relevant publications may be included) (Nayar et.al, 2015).

Divider – Appendix B

CRITICAL VALUE NOTIFICATION

Critical Value Pap Reports

CLIA requires notification to a nurse of all Pap reports containing critical values. This alerts the submitter that a critical value report has been sent and that its receipt should be tracked to avoid a lost critical value report. The lab must have confirmation that the critical value report was received by the submitter when the notice is left on voicemail. The nurse must call or email the lab to verify receipt of the message and to get the patient's name and the cytodiagnosis.

The lab should be notified if the report is not received within a few days

The lab issues Critical Value notification for the following Pap reports:

- High-grade intraepithelial lesions (HSIL)
- Cancer
- Herpes in pregnancy
- Amended report

Divider – Appendix C

NC BCCCP Cancer Screening Policies

1. NC BCCCP Eligibility for Family Planning Patients

NORTH CAROLINA BREAST & CERVICAL CANCER CONTROL PROGRAM (NC BCCCP)

07/01/2017
Effective Immediately

Introduction:

The North Carolina Breast and Cervical Cancer Control Program is required by law to be the payer of last resort for women enrolled in the program. (Public Law 101-354, 42 U.S.C. § 300n [d]) As a result, NC BCCCP is unable to provide screening services that may be provided by the Family Planning (Title X) program.

Impact on local agencies:

Because Family Planning provides a clinical breast exam and Pap test for eligible women, NC BCCCP funds should not be used to pay for these services if the woman is eligible for or enrolled in family planning.

However, Family Planning may not be able to cover all expenses related to a screening cycle. In those cases, NC BCCCP funds may be able to help.

> Local BCCCP agencies should develop a policy and standing orders regarding situations in which they will accept a Family Planning patient for diagnostic work up in order to balance service to women in need with the goal of protecting BCCCP funds for the BCCCP priority population. Policies must be approved by the agencies' BCCCP Nurse Consultants.

Situations in which NC BCCCP may be used to help:

Breast circumstances

- Women between the ages of 50 and 64 may have a screening mammogram provided through NC BCCCP, using Federal BCCCP funds. These women will count toward Federal screening targets. The local agency is eligible to be reimbursed $255 of Federal funds for this patient.
- Women between the ages of 40 and 49 may have a screening mammogram provided through NC BCCCP, using State BCCCP funds. These women will count

toward State screening targets. The local agency is eligible to be reimbursed $255 of State funds for this patient.

- Women between the ages of 35 and 39 who present with an abnormal clinical breast examination may qualify for a mammogram and/or diagnostic workup through NC BCCCP. This will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $255 for this patient.
- If women between the ages of 21 and 34 years of age present with an abnormal clinical breast examination, they *may* qualify for a BCCCP-funded ultrasound and/or diagnostic workup. These women will count toward NC BCCCP service targets. Because this woman has been served by the local agency, the local agency is eligible to be reimbursed $255 for this patient.

Cervical circumstances

- Women between the ages of 21 and 64 who have a Family Planning Pap result of HSIL or worse may have a diagnostic workup provided through NC BCCCP. These women will count toward Federal service targets. The local agency is eligible to be reimbursed $255 of Federal funds for this patient because this patient has been served. Serving this patient through BCCCP will enable her to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if she meets other eligibility requirements and has a diagnosis of CIN 2 or worse.
- Women between the ages of 30 and 64 who have a Family Planning Pap result of ASC-H or LSIL may have a diagnostic workup provided through NC BCCCP. These women will count toward NC BCCCP service targets. The local agency is eligible to be reimbursed $255 of BCCCP funds for this patient because this patient has been served. Serving this patient through BCCCP will enable her to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if she meets other eligibility requirements and has a diagnosis of CIN 2 or worse; however, the likelihood of CIN disease in these patients is relatively low.
- Women between the ages of 21 and 29 who have a Family Planning Pap result of ASC-H or LSIL may have a diagnostic workup provided through NC BCCCP. These women will count toward BCCCP service targets. The local agency is eligible to be reimbursed $255 of BCCCP funds because this patient has been served. Serving this patient through BCCCP will enable her to qualify for Breast and Cervical Cancer Medicaid to pay for treatment if she meets other eligibility requirements and has a diagnosis of CIN 2 or worse; however, the likelihood of CIN disease in these patients is low and may not be the best use of BCCCP funding.

Date written: April 8, 2015 Approved by: _____
NC BCCCP Medical Advisor

Date revised: July 21, 2017 _____
NC BCCCP Program Director

2. CERVICAL CANCER SCREENING POLICY

NORTH CAROLINA BREAST & CERVICAL CANCER CONTROL PROGRAM (NC BCCCP)

Effective December 15, 2018

Introduction:

The primary focus of cervical cancer screening is to identify and treat pre-cancerous cervical lesions and detect and treat cervical cancer at an early stage. When cervical cancer is detected early, the likelihood of survival is almost 100 percent with timely and appropriate diagnostic follow-up and treatment.

In August 2018, new Pap screening guidelines were released jointly by the United States Preventive Services Task Force (USPTF), American Cancer Society (ACS) and American College of Obstetricians and Gynecologist (ACOG). Subsequently, Centers for Disease Control and Prevention adopted these guidelines for National Breast and Cervical Cancer Early Detection grantees, effective August 24, 2018. Revised program guidance for NBCCEDP grantees was published in August 2018 (National Breast and Cervical Cancer Early Detection Program).

Consistent with these recommendations, the cervical cancer screening policies for the North Carolina Breast and Cervical Cancer Control Program (NC BCCCP) are as follows:

Eligible Women:

- NC BCCCP reimburses for cervical cancer screening and diagnostic services provided to women between the ages of 21 and 64 years of age, who are at or below 250% of the current federal poverty level and have no other source of health care reimbursement such as medical insurance. Women between the ages of 21 and 64 may be screened using federal BCCCP dollars. Women between the ages of 21 and 64 may be screened using state BCCCP dollars. The priority population includes women who have never been screened (defined by CDC as not screened in 10 years or more). Recruitment efforts should be concentrated on the priority population.
- Women covered by Medicare-Part B and/or Medicaid are not eligible to enroll in the NC BCCCP. Women who are enrolled in and receiving services under Title X (Family Planning) are not eligible to have Pap tests reimbursed using NC BCCCP funds.
- Women between the ages of 21 and 64 are eligible to enroll in the NC BCCCP for diagnostic work-up of abnormal Pap results, provided their family income is at or below 250% of the current federal poverty level. Federal BCCCP dollars may be used to pay for the diagnostic workup.

NC BCCCP Cervical Screening Services Priorities:

Increasing Screening for NC BCCCP-Eligible Women Who Have Never Been Screened:

- At least twenty percent of all clients enrolled for cervical cancer screening should be women who have never been screened for cervical cancer (have not been screened for 10 years or more).

Cervical Cancer Screening for Women 21 to 64 Years of Age:

The NC BCCCP funds may be used to reimburse for Pap testing alone every three years for average risk women aged 21- 29 years and for Pap testing alone every 3 years, screening with the high risk HPV test alone (primary HPV testing) every 5 years, or co-testing with the combination of Pap testing and with human papilloma virus (HPV) testing every 5 years for women aged 30- 64 years. Women should talk to their clinician to choose which strategy is right for them. The Task Force continues to recommend against screening in women younger than 21 years and in women older than 65 years who have had adequate prior screening.

  - Women age 21 to 29 years — NC BCCCP funds can be used to reimburse for Pap testing alone every 3 years.
  - Women age 30 to 64 years — NC BCCCP funds can be used to reimburse for Pap testing alone every 3 years, screening with the high-risk HrHPV test alone (primary HPV testing) every 5 years, or co-testing with the combination of Pap testing with human papilloma virus (HPV) testing every 5 years. Grantees must make all three cervical cancer screening options (i.e., Pap testing every 3 years, screening with the high-risk HrHPV test alone (primary HPV testing) every 5 years, and Pap testing with HPV testing every 5 years) available.

- NC BCCCP funds can be used for annual cervical cancer screening among women who are considered high-risk (e.g., in-utero DES exposure, immunocompromised such as HIV infection, or history of cervical cancer).
- NC BCCCP funds cannot be used to reimburse for cervical cancer screening in women under the age of 21.

Cervical Cancer Screening for Women Over 65 Years of Age:

- Cervical cancer screening is not recommended for women older than age 65 who have had adequate screening and are not high-risk. NC BCCCP eligibility continues only through age 65 for most women; at age 65 it is assumed she is eligible for a Medicare-funded cervical cytology. If a woman over 65 needs to be screened and is eligible to receive Medicare benefits, but is not enrolled, she should be encouraged to enroll. Women enrolled in Medicare Part B are not eligible for the NC BCCCP clinical services. Women who are eligible for Medicare Part B but have low incomes (up to 250% of the federal poverty level) and cannot pay the premium to enroll in Medicare Part B are eligible to receive services through the NC BCCCP.

Cervical Cancer Screening for Women at High Risk:

- Women who are at high-risk for cervical cancer need to be screened more frequently than average-risk women. This includes women with HIV infection, who have had an organ transplantation, who may be immunocompromised from another health condition, or who had DES exposure in utero.
- In general, women under the age of 30 should undergo annual Pap testing and women age 30 years and older should have co-testing every three years or annual Pap testing.

Cervical Cancer Screening Following Hysterectomy or Other Treatment for Cervical Neoplasia or Cancer:

- NC BCCCP funds CANNOT be used to reimburse for cervical cancer screening in women with total hysterectomies (i.e., those without a cervix), unless the hysterectomy was performed because of cervical neoplasia (precursors to cervical cancer) or invasive cervical cancer.
- When a woman concludes her cancer treatment, has been released by her treating physician to return to a schedule of routine screening, and continues to meet NC BCCCP eligibility requirements, she may return to the program and receive all its services.
- For women with a history of cervical neoplasia or *in situ* disease, NC BCCCP funds can be used to reimburse for routine cervical cancer screening for 20 years post treatment, even if it extends screening past age 65.
- For women with a history of invasive cervical cancer, NC BCCCP funds can be used to reimburse for cervical cancer screening indefinitely as long as they are in good health.
- For women whom the reason for the hysterectomy or final diagnosis of no neoplasia or invasive cancer cannot be documented, NC BCCCP can be used to reimburse for cervical cancer surveillance. For these women, cervical cancer screening should continue until there is a 10-year history of negative screening results, including the documentation that the Pap tests were technically satisfactory.
- If it is unknown if the cervix was removed at the time of the hysterectomy, a physical examination can be done to determine if the cervix is present. NC BCCCP funds <u>can</u> be used to reimburse for an initial examination (i.e. office visit for a pelvic examination to determine if a woman has a cervix).
- NC BCCCP funds may not be used to pay for follow-up pelvic exams in the absence of a Pap test.
- Women who have had a **supracervical hysterectomy** remain eligible for cervical cancer screening under the NC BCCCP.

Policy on Liquid-Based Cytology (LBC) Technologies for Primary Cervical Cancer Screening:

- Programs may reimburse for conventional or liquid-based cervical cytology for primary cervical cancer screening, up to the allowable Medicare rate. The screening interval is the same for both the use of liquid-based tests and the conventional Pap tests.

Managing Women with Abnormal Cervical Cancer Screening Results:

- The management of women whose cervical cancer screening tests yield abnormal results shall be in accordance with current standards of care as described in the Cervical Screening Manual. These standards rely on a body of scientific literature that is constantly growing and changing.
- To arrive at a definitive diagnosis for a woman with an abnormal cervical cancer screening test, programs may use NC BCCCP funds to reimburse colposcopy, colposcopy-directed biopsy, endocervical curettage, and, in unusual cases, diagnostic excisional procedures (such as LEEP and cold-knife excisions), as well as associated pathology. Excisional procedures require prior authorization by a NC BCCCP nurse consultant.

Reimbursement of HPV DNA Testing:

- HPV DNA testing is reimbursable when used for screening or follow-up of abnormal Pap results as per American Society for Colposcopy and Cervical Pathology (ASCCP) algorithms. HPV genotyping is reimbursable when used for follow-up of abnormal cervical cancer screening results as per ASCCP algorithms.

Reimbursement of Other Services:

- NC BCCCP funds may not be used to pay for any cervical diagnostic services not included on the NC BCCCP services fee schedule (e.g., LEEP, conization, etc.) unless prior authorization is obtained.
- NC BCCCP funds cannot be used to pay for treatment.

Adequacy of Follow-Up for Women with Abnormal Screening Results:

- Public Law 101-354 requires programs to take all appropriate measures to ensure the provision of necessary follow-up services required by women who have abnormal screening results and whose clinical services are paid for in whole or in part by NC BCCCP funds. A woman whose cervical cancer screening was abnormal or suspicious must receive appropriate diagnostic procedures to arrive at a final diagnosis. Women with a diagnosis of cervical cancer must be referred for appropriate treatment. Referrals should be made to the NC Breast and Cervical Medicaid (BCCM) program.

Divider – Appendix D

Procedure for Referral, Evaluation, Treatment (Colposcopy Providers)

List of Qualified Health Care Providers (QHCP)

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1. Procedure for Referring Patients Referral/Eligibility Requirements

Definition

Qualified Health Care Providers (QHCPs) provide outpatient services for the evaluation of an abnormal Pap test via colposcopy, and for the treatment of local cervical lesions via cryosurgery, laser conization, electrocautery or LEEP, or cold knife conization (CKC). They may also provide outpatient services for evaluation and treatment of non-cervical gynecologic dysplasia (vaginal and vulvar lesions) identified by physical examination, cytology, or biopsy (NC BCCCP, 2018-19).

A. Procedure

1. Health care provider (i.e., local health care provider agency) referral to a QHCP
    a. Referral is made to the QHCP for those patients with a Pap test result that is:
        (1) Second consecutive Pap test reported as Atypical Squamous Cells of Undetermined Significance (ASC-US); or
        (2) Single Pap test reported as Atypical Squamous Cells of Undetermined Significance (ASC-US) and a positive test for high-risk HPV DNA; or
        (3) Single Pap test reported as Atypical Squamous Cells: Cannot Exclude High-grade Squamous Intraepithelial Lesion (ASC-H); or
        (4) Single Pap test reported as Atypical Glandular Cells (AGC); or
        (5) Single Pap test reported as Low-grade Squamous Intraepithelial Lesion (LSIL); or
        (6) Single Pap test reported as High-grade Squamous Intraepithelial Lesion (HSIL) or Carcinoma.
    b. Referral is made to the QHCP for those patients with lesions of the vagina or vulva identified during physical exam that are suspicious for dysplasia or malignancy. (NOTE: if you notice any lesions that appear chancroid or suggestive of syphilis, please refer the patient immediately to STD services.)
    c. Each patient has the right to choose to be referred to a QHCP who can provide a colposcopic examination.

d. Each patient served by a QHCP is expected to pay for services through medical insurance, Medicaid, or self-pay. Limited diagnostic services for eligible patients may be paid by North Carolina's Breast and Cervical Cancer Control Program (NCBCCCP, 2018- 19).

e. Referrals are made by the health care provider via telephone to the QHCP near the patient's residence or of the patient's choice.

2. Track and document the outcome of your referral.

3. Document the results in the patient's medical record and complete the Patient Navigation documentation per format (NBCCEDP, 2017).

B. Patient Education

The patient should be given instructions along with counseling when the appointment is made for the QHCP. The following points should be stressed prior to appointment:

1. Do not douche, use intravaginal medications or tampons, lubricants, have intercourse, or use vaginal contraceptives for at least 48-72 hours prior to appointment.

2. When scheduling the appointment, suggest that the patient select a day not likely to be during her menstrual period.

3. Determine if patient has transportation needs and/ or other barriers and assist in facilitating transportation or removing other barriers if necessary. Complete Patient Navigation assessment and care plan if applicable. See page 61 for Patient Navigation policy (NBCCEDP, 2017).

2. Partial List of Qualified Health Care Providers Who Provide Colposcopies

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Alamance Regional Medical Center	Encompass Women's Care 1248 Huffman Mill Road Suite 101 Burlington, NC 27215 Westside Ob/Gyn 1091 Kirkpatrick Road Burlington, NC 27215	336-538-0089 336-538-1880
Albemarle Health Services	Pasquotank Health Department (serves Albemarle Regional Health Services Counties) 711 Roanoke Ave. Elizabeth City, NC 27907	252-338-4449
Anson County Health Department	Anson County Health Department Wadesboro, NC 28170	704-694-5188
Appalachian District Health Department: Ashe, Allegany and Watauga County Health Departments	Mount Jefferson Family Medicine 200 Hosp. Ave. #3 Jefferson NC 28640 Harmony Center for Women 381 Deerfield Rd Boone, NC 28607	336-846-7433 828-268-8970

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Avery, Mitchell and Yancey County (Toe River District)	Harmony Center for Women 381 Deerfield Road Boone NC 28607 Mission Community Obstetrics and Gynecology 125 Hospital Road Spruce Pine, NC 28777	828-268-8970 Fax: 828-262-1587 828-766-3001 Fax: 828-766-3787
Beaufort Co HD	Vidant Women's Care1204 Brown St, Washington, NC Obstetrics and Gynecology of Washington 1210 Brown St., Washington, NC	252-975-1188
Bladen County Health Department	Women's Health Specialist 300 East McKay Street Elizabethtown NC 28337 Dr. Aycock Columbus County Health Department 304 Jefferson Street Whiteville, NC 28472	910-862-6672 Fax: 910-862-6674 910-640-6615
Blue Ridge Health Care System	Blue Ridge Health Care System: 2579 Chimney Rock Road, Hendersonville NC 28792 709 North Justice Street, Hendersonville, NC 28791	828-692-4289 Fax: 828-692-4396

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Brunswick County HD	Novant OBGYN Physicians Brunswick County Department of Health Bolivia, NC	910-253-2250
Buncombe County HD	MAHEC OB/GYN 119 Hendersonville Rd Asheville NC 28803 Western NC Community Health Services (WNCCHS) 257 Biltmore Ave Asheville, NC 28801	828-771-5500 828-285-0622
Cabarrus Health Alliance	Cabarrus County Health Alliance 300 Mooresville Rd. Kannapolis, NC 28081 (CHA patients only)	704-920-1000
Carolina Family Health Centers	Carolina Family Health Centers, Inc 303 East Green Street Wilson, NC 27893	252 243-9800 Ext: 232 Fax: 252-243-1233
Carteret Co. HD	Carteret OB/GYN Associates 3511 John Pratt Drive Morehead City, NC 28557	252-247-4297
Catawba County Health Department	Catawba County Health Department Melinda Daves, MD 3070 11th Avenue Drive SE Hickory, NC 28602	828-695-5800 Fax: 828-695-4410
Cherokee County Health Department	Dr. Larry Holder and Dr. Pushpa Phillips Murphy Group Practice OB/GYN 75 Medical Park Lane Suite D Murphy, NC 28906	828-837-1332

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Clay County Health Department	Dr. Larry Holder and Dr. Pushpa Phillips Murphy Group Practice OB/GYN 75 Medical Park Lane Suite D Murphy, NC 28906 Union General Women's Health 123 Weaver Road Blairsville, GA 30512	828-837-1332 706-835-2222
Cleveland County Health Department	Cleveland County Health Department 200 South Post Road Shelby, NC 28150	980-484-5100
Columbus County Health Department	Dr. Susan Aycock Columbus County Health Department 304 Jefferson Street Whiteville, NC 28472 Baldwin Woods OB/GYN 627 Jefferson Street Whiteville, NC. 28472 Women's Life Center/ Southeastern Health 800 Oakridge Boulevard Lumberton, NC 28358	910-640-6615 910-642-3294 Fax: 910-640-1110 910-738-2454 Fax: 910-671-9303
Cone Health Cancer Center	Center for Women's Healthcare at Women's Hospital 801 Green Valley Road Greensboro, NC 27408	336-832-4777
Cumberland County Health Department	Cape Fear Valley OB/GYN, 1341 Walter Reed Road Fayetteville, NC 28304	910-615-3500

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Craven County Health Department	Eastern Carolina Women's Center 801 McCarthy Blvd, New Bern, NC Leo Jenkins Cancer Center600 Moye Blvd, Greenville, NC	252-633-3942 252-744-2900
Dare County Health Department	Outer Banks Women's Care 4810 S Croatan Hwy Suite 100 Nags Head, NC 27959	252-261-4885 Fax: 252-441-2641
Davie County Health Department	Dr. Takashi Hirata Novant Health Hillsdale Medical Associates 121 Medical Drive Advance, NC 27006	336-998-9060 Fax: 336-998-9061
Durham County Health Department	Duke Cervix Clinic 40 Duke Medicine Circle Clinic 1J Durham, NC 27710 Durham County Department of Public Health Colposcopy Clinic located in the Family Planning Clinic (2nd Floor) 414 East Main Street Durham, NC 27701	919-684-2471 919-560-7631
Edgecombe County Health Department	Vidant Women's Care 2704 N Main Street Tarboro, NC 27886	252-823-6333

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Forsythe County Health Department	Wake Forest Baptist Medical Center Downtown Health Plaza 1200 MLK Junior Drive Winston Salem, NC 27101	336-713-9800
Gaston County Health Department	Gaston Health Center 991 W. Hudson Blvd Gastonia, NC 28052	704-853-5079
Goshen Medical Center	Goshen Medical Center 444 SW Center Street, Faison, NC 28341	910-296-0787
	Goshen Medical Center 603 East College Street Warsaw, NC 28398	910-267-0421
	Goshen Medical Center 212 Duplin Street Kenansville, NC 28349	910-296-0787 910-296-0790
	UNC Chapel Hill GYN-ONC 101 Manning Drive Chapel Hill, NC 27514	919-966-1194
	Goshen Medical Center 104 Lakeview Drive Trenton, NC 28585	252-448-4321
	Goshen Medical New River 1200 Hargett Street Jacksonville, NC 28540	910-219-1082

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Graham County Health Department	Dogwood Wellness 377 Macktown Rd, Sylva, NC 28779 MAHEC OBGYN 119 Hendersonville Rd, Asheville, NC 28803 Murphy OBGYN 75 Medical Park Ln # D · Murphy, NC 28906 Harris Women's 70 The Village Overlook, Sylva, NC 28779	828-771-5500 828-771-5500 828-837-1332 828-631-8913
Granville-Vance District	Rural Health Group Family and Women's Health Dr. Kelly Lynn Pieh-Holder 1381 Medical Center Drive, Roanoke Rapids, NC 27870 Rural Health Group at Henderson Dr. Modjulie Moore 100 Parkview Drive West, Henderson, NC 27536	252-535-1414 252-438-3549
Green County HD	ECU OB/Gyn Clinic 600 Moye Boulevard, Greenville, NC.	252-744-2350
Haywood County Health Department	Haywood Women's Medical Center, 35 Facility Drive Clyde NC 28721 MAHEC OB/ GYN 119 Hendersonville Road Asheville NC 28803	828 452-5042 828-771-5500

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Henderson County Health Department	Henderson County Department of Public Health 1200 Spartanburg Highway Suite 100 Hendersonville, NC 28792	828-692-4223
Hertford County Public Health Authority	Premier Women's Health Professionals Women's Care of Ahoskie 606 South Academy Street Ahoskie, NC Roanoke- Chowan Women's Center 120 Health Center Drive Ahoskie, NC	252-209-3614 252-209-0237
High Point Regional Health System	UNC Regional Physicians OB/GYN 400 North Elm Street High Point NC 27262	336-878-6530
Hoke County Health Department	Hoke OB GYN clinic 300 Medical Pavilion Dr #250, Raeford, NC 28376	910-904-8035
Jackson County Health Department	Jackson County Department of Public Health 538 Scotts Creek Rd. Sylva, NC 28779	828-587-8228 Fax- 828-587-8295
Johnston County Health Department	Johnston County Health Department Women's Health Clinic 517 N. Brightleaf Blvd Smithfield, NC 27577 UNC Women's Hospital Dysplasia Clinic 101 Manning Drive Chapel Hill, NC 27517	919-989-5200 Fax: 984-974-8613

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Lee County Health Department	UNC-CH Hospital Dysplasia Clinic 101 Manning Drive Chapel Hill, NC 27517	Fax: 984-974-8613
Lenoir County Health Department	Women's Healthcare of Eastern Carolina 103 Airport Road Kinston, NC 28501 Wayne Women's Clinic 102 Handley Park Court Goldsboro, NC 27534	252-477-1001 919-734-3344
Lincoln Community Health Center	Lincoln Community Health Center Duke Providers 1301 Fayetteville Street Durham, NC 27707	919-956-4034
Lincoln County Health Department	Lincoln Center for Women's Health 1460 E. Gaston St., Lincolnton, NC Lincoln OB-GYN275 Highway 16 N, Denver, NC	704-735-2134 704-732-3346
Macon County Health Department	Macon County Public Health 1830 Lakeside Drive Franklin, NC 28734 (MHD patients only)	828-349-2509
Madison County Health Department	Madison County Health Department 493 Medical Park Drive Marshall, NC 28753 MAHEC OBGYN 119 Hendersonville Rd. Asheville, NC 28803	828-649-3531 828-771-5475

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Martin- Tyrrell- Washington District	Leo Jenkins Cancer Center600 Moye Blvd, Greenville, NC Tarheel Surgical 310 S McCaskey Rd., Williamston, NC	252-744-1888 252-799-3006
Mecklenburg County Health Department	Carolinas Medical Center Myers Park Clinic 1350 South King Drive Charlotte, NC 28207 MCHD 2845 Beatties Ford Road Northwest Campus Charlotte, NC 28216	704-446-1600 704-336-6500
MedNorth	MedNorth Health Facility 925 North 4th Street Wilmington, NC 28401	910-343-0270
Nash County Health Department	Nash OB-GYN Associates 200 Nash Medical Arts Mall Rocky Mount, NC 27804	252-443-5941
New Hanover County Health Department	New Hanover County Health Department 2029 South 17th Street, Wilmington, NC 28401	910-798-6500
Northampton County Health Department	Women's Health Specialties OBGYN 63 Office Park Drive, Roanoke Rapids NC 27870 Smith Church OB/GYN 244 Smith Church Rd., Roanoke Rapids, NC 27870	252-535-4343 252-535-1800

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Orange County Health Department	Orange County Health Department, 300 W. Tryon Street, Hillsborough, NC 27278 UNC Department of Obstetrics & Gynecology – Gynecologic Oncology 101 Manning Drive, Chapel Hill, NC 27514	919-245-2400. 984-974-7822
Pender County Health Department	Pender County Health Department 803 S. Walker Street Burgaw, NC 28425	910-259-1230
Randolph Health Care	The Women's Clinic at Women's Hospital of Greensboro, 801 Green Valley Rd. Greensboro, NC 27408	336-832-4777 Fax: 336-832-4779
Richmond County Health Department	First Health OB/GYN Dr. Mohamed Ibrahim 921 South Long Drive Suite 205 Rockingham, NC 28379	910-417-3477
Robeson Healthcare Corporation (RHCC)	Southeastern Women's Healthcare 4300 Fayetteville Road, Lumberton, NC 28358	910-608-3078 Fax: 910-608-3079
Rockingham County Health Department	Rockingham County Department of Health & Human Services 371 NC Hwy 65 Wentworth, NC 27375	336-342-8141

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Rural Health Group	Rural Health Group Family and Women's Health Provider – Dr. Kelly Lynn-Pieh Holder 1381 Medical Center Drive, Roanoke Rapids, NC 27870	252-535-1414
	Rural Health Group at Henderson Provider – Dr. Modjulie Moore 100 Parkview Drive West, Henderson, NC 27536	252-438-3549
Rutherford/ Polk McDowell (RPM) Health Departments	Rutherford OB/GYN Associates, PA 466 NC 108 Hwy Rutherfordton, NC 28139	828-287-7383
	Mission Women's Care McDowell 472 Rankin Dr. Marion, NC 28752	828-659-5700
	Blue Ridge Health Services 2579 Chimney Rock Rd, Hendersonville, NC 28792	828-692-4289 Fax: 828-692-4396
Sampson County Health Department	Goshen Medical Center-Warsaw 603 East College St Warsaw, NC 28398	910-293-3900
Southeastern Medical Center/ Gibson Cancer Center	Southeastern Women's Healthcare Clinic Debra Beasley FNP and Dr. McKinley 4300 Fayetteville Rd, Lumberton, NC 28358	910-608-3078
	Rozier Jr John C MD 295 W 27th St Lumberton, NC 28358	910-739-5550

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Stanly County Health Department	Women's Health Specialist Carolinas Women's Health Center 929 N. 2nd St # 201, Albemarle, NC	704-985-1799
Stokes County Health Department	Health Care Access 515 North Cleveland Ave. Winston Salem, NC 27101 Downtown Health Plaza 1200 Martin Luther King Jr. Drive Winston Salem, NC 27101 Lyndhurst GYN 111 Hanestown Court, Suite 151 Winston Salem, NC 27103 Women's Health Centre 522 S. Van Buren Rd. Eden, NC 27288	336-723-6565 336-713-9800 336-765-9350 336-627-1117
Surry County Health Department	Northern Medical Group OB/GYN 510 S. South Street Mt. Airy, NC 27030	336-786-4522 Fax: 336-789-3025
Swain County Health Department	Harris Women's Care 70 The Village Overlook Sylva, N.C. 28779 Dogwood Wellness 377 Macktown Road Sylva, N.C. 28779	828-631-8913 828-586-6262
Transylvania County Health Department	Transylvania Women's Care 87 Medical Park Dr Ste B Brevard, NC 28712	828-884-8860
Tsalagi Public Health/ Cherokee Women's Wellness Center	Cherokee Indian Hospital Authority 1 Hospital Rd. Cherokee NC 28719	828-497-9163

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Union County Health Department	Atrium Health (CMC) Women's Institute 1025 Morehead Medical Dr. Suite 500 Charlotte N.C. 28204 Union OB- GYN 1550 Faulk St. Suite 2100 Monroe NC 28110 Centro Medico Latino Clinic 1661 Walkup Ave. Monroe NC, 28110	704-355-3149 704-289-2553 704-333-0465
Wake County Health Department	Wake County Government Health Promotion and Chronic Disease Prevention Section 10 Sunnybrook Rd. Raleigh NC 27610 Wake Med Colposcopy Clinic Andrews Building 3000 New Bern Avenue Raleigh, NC 27610	919-212-9310 Fax: 919-250-3059 919-350-8000 919-350-7670
Wayne County Health Department	Wayne Women's Clinic 102 Handley Park Court Goldsboro, NC 27534	919-734-3344
Wilson County Health Department	ECU-Brody Outpatient 600 Moye Blvd. Greenville, NC 27834 Wilson OBGYN 2500 Horton Blvd. Wilson, NC 27893	252-744-2350 252-206-1000

Provider	Sub-contractor/ In-house provider operating under NC BCCCP Guidelines	Phone Number
Yadkin County Human Services Agency	Downtown Health Plaza 1200 MLK Jr. Drive Winston-Salem, NC 27101 Lyndhurst Gynecologic Associates - Winston-Salem 111 Hanestown Court, Suite 151 Winston-Salem, North Carolina 27103	336-713-9800 336-765-9350 Fax**:** 336-760-4255

Divider – Appendix E

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Divider – Appendix F

North Carolina Breast and Cervical Cancer Control Program (N.C. BCCCP)

Breast and Cervical Cancer Medicaid (BCCM)

Do you have patients who would benefit from Medicaid to pay for their breast and cervical cancer treatment?

Women must FIRST be eligible for N.C. BCCCP.

Eligibility includes:

- Women who are below 250% of the Federal Poverty Guidelines, are uninsured or under-insured, and are not covered by Medicare Part B or another federally-funded program.*
- Patients must be referred to the local N.C. BCCCP ***prior to*** diagnosis to be eligible for Breast and Cervical Cancer Medicaid.
- Additional eligibility criteria may apply for BCCM.

There are two ways you can enroll an eligible patient in N.C. BCCCP:

1. *PREFERRED METHOD:* Refer your patient to the local N.C. BCCCP for screening as soon as she presents with or without complaints.
2. With the consent of the local N.C. BCCCP provider, refer a patient who has an abnormal clinical breast exam, mammogram and/or cervical cancer screening test result to the local N.C. BCCCP for diagnostic testing ***before*** cancer is diagnosed.

Final diagnostic testing ***must*** be provided through N.C. BCCCP for the patient to be eligible for BCCM.

Physicians Be Aware: A patient referred by a non-BCCCP provider must be referred and enrolled in BCCCP prior to being diagnosed with breast or cervical cancer to be eligible for BCCM.

*Women with Be Smart family planning Medicaid may be eligible for some limited services through N.C. B.C.C.C.P.

For more information, contact N.C. BCCCP
919-707-5300 ● https://bcccp.ncdhhs.gov/

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www.ncdhhs.nc.gov | http://publichealth.nc.gov
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