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
State Laboratory of Public Health

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
www.ncdhhs.gov
N.C. DHHS is an equal opportunity employer and provider.

275 copies of this public document were printed at a cost of _____ or _____ per copy. 09/13.
This document is also available on the web at http://bcccp.ncdhhs.gov/

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

Pat McCrory
Governor

Aldona Z. Wos, M.D.
Ambassador (Ret.)
Secretary DHHS

Daniel Staley
Acting Division Director

MEMORANDUM

To: Local Health Directors
Attention: Nursing Directors/Supervisors

From: Robin G. Cummings, M.D.
Acting State Health Director

Date: September 30, 2013

Subject: Revised Edition (September 2013)
Cervical Screening Manual: A Guide for Health Departments and Providers

Enclosed is the revised edition (dated September 2013) of North Carolina's Cervical Screening Manual: A Guide for Health Departments and Providers. Please replace the previous manual (dated July 2008) with this edition.

Numerous professional organizations and references were consulted to assure that current standards and guidance on the care of patients with abnormal Pap tests were considered for this revision. Some of these included the following:

- American Cancer Society (ACS)
- U.S. Preventive Services Task Force (USPSTF)
- American College of Obstetricians and Gynecologists (ACOG)
- 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors

Revisions were made by the Division of Public Health through a collaborative effort of the Chronic Disease and Injury Section, the Women's and Children's Health Section and the State Laboratory. 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 or revise 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
State Laboratory of Public Health

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

Members of the Revision Committee:
Dianah C. Bradshaw, PhD, RN, Breast and Cervical Cancer Control Program
Vicki W. Deem, MLS, MPA, RN, Breast and Cervical Cancer Control Program
Pat Cannon Fowler, MPA, BSN, RN, Breast and Cervical Cancer Control Program
Cheryl Kovar, PhD, RN, CNS, Women's and Children's Health Section
Marjorie Lavender, BS, SCT(ASCP), State Laboratory of Public Health

Reviewers for the Guide:
Sydney P. Atkinson, MSW, Family Planning and Reproductive Health Unit Manager, Women's Health Branch
Les G. Burke, MD, Medical Director, Cancer Cytology, State Laboratory of Public Health
Isa Cheren, MD, Medical Consultant, Women's Health Branch, Women's and Children's Health Section
Kathy Dail, RN, MEd, Technical Assistance & Training Program Manager, Communicable Disease Branch · Epidemiology Section
Debi Nelson, MAEd, Branch Head, Cancer Prevention and Control Branch
Ruth Petersen, MD, MPH, Chief, Chronic Disease and Injury Section

Supported by funding from:
North Carolina Cancer Prevention and Control Branch/Breast and Cervical Cancer Control Program, Chronic Disease and Injury Section
Women's Health Branch, Women's and Children's Health Section

Cervical Screening Manual

A Guide for Health Departments and Providers

Table of Contents

Divider – Overview

Overview

The incidence of cervical cancer has decreased significantly since the 1940s in large part because of early detection efforts via the Papanicolaou (Pap) test. This cytologic staining procedure of cells from the uterine cervix is primarily for detection and diagnosis of cervical cancer and certain pre-malignant conditions. Since its introduction in 1948, the Pap test is credited with saving tens of thousands of women's lives and decreasing deaths from cervical cancer by more than 70 percent. Still, the American Cancer Society estimates 12,340 new cases of cervical cancer and 4,030 cervical cancer deaths nationwide for 2013. (American Cancer Society)

Detection and treatment of pre-cancerous cervical lesions identified by a Pap test can prevent cervical cancer from developing. Even when cancer has already developed, a Pap test 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 2013 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 Pap tests are used. These references can be found in Appendix E.

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

> *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.
>
> *2013 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.

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 their clinical providers and their 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, Women's Health Branch and the State Laboratory of Public Health recommend this Guide to develop local policy.

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 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

---

1. REPORTING OF PAP TEST RESULTS

THE BETHESDA SYSTEM 2001

The Bethesda System 2001 (TBS 2001) updates the standard terminology for reporting Pap test findings. It has been the standard of reporting in North Carolina since October 1, 2002.[7] See Appendix A for a summary of reporting categories.

The major features of the system are the following:

- Specimen adequacy is reported as either "Satisfactory" or "Unsatisfactory" for interpretation. The former category of "Satisfactory but Limited by…" was eliminated. The Bethesda 2001 system further divides the unsatisfactory category into two sections:
  (1) Unsatisfactory rejected
  (2) Unsatisfactory examined (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 category of Negative for Intraepithelial Lesion or Malignancy replaces the earlier category of Within Normal Limits. Specific other findings may also be listed, including:
  (1) Evidence of infection with specific organisms, or
  (2) Endometrial cells present in a woman over 40.
- The category of Benign Cellular Changes was eliminated. It is now included as a descriptor only in the category of Negative for Intraepithelial Lesion or Malignancy.
- The finding of ASC (atypical squamous cells) is divided into two sub-categories:
  (1) ASC-US (atypical squamous cells of undetermined origin)
  (2) ASC-H (atypical squamous cells, cannot exclude high-grade lesion)

- LSIL (low-grade squamous intraepithelial lesion) is unchanged. It encompasses HPV changes and mild dysplasia (CIN I).
- HSIL (high-grade squamous intraepithelial lesion) is unchanged. It encompasses moderate and severe dysplasia and carcinoma *in situ* (CIN II, CIN III, and CIS).
- Squamous cell carcinoma remains unchanged.
- The category of AGC (atypical glandular cells) now divides atypical glandular cells by subtype. Atypical Glandular Cells (AGC) are reported as:

  (1) Atypical glandular cells

  (2) Atypical glandular cells, favor neoplasia
- Adenocarcinoma *in situ* and adenocarcinoma are also reported under Atypical Glandular Cells[9]

---

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). In March 2013, 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 (Massad, and et al, 526).

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) (Saslow, and et al, 153).

- **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**, if cytology alone is used, screen every three years or if screened with cytology and HPV co-test, screen every five years. Annual screening should not be performed.

MATERNAL HEALTH PATIENTS

Cervical cytology as indicated according to ACOG, ACS/ASCCP/ASCP and USPSTF guidelines. 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 as indicated according to ACOG/ACS/ASCCP/ASCP/USPSTF guidelines.

STI CLINIC PATIENTS

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

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 with normal cervical cytology tests and are not otherwise at high risk for cervical cancer.

ACS/ASCCP/ASCP: 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 (Saslow, and et al, 162).

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).

ACOG: For women over 65 years of age, no screening is necessary after adequate negative prior screening results. For women with a history of CIN2, CIN3 or adenocarcinoma *in situ*, screening should continue for a total of 20 years after spontaneous regression or appropriate management of such disease, even if it extends the screening past age 65 years (ACOG, 1229).

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 (Saslow, and et al*,* 163, 162).

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 with cytology alone every 3 years for the 20 years after the initial post treatment surveillance period is recommended (ACOG, 1229-1230).

USPSTF: The USPSTF recommends against routine cervical cytology screening in women who have had a total hysterectomy for benign disease (USPSTF)

NC BCCCP: Screening should be discontinued in women who have had a hysterectomy for benign reasons. See Appendix C for specifics of the policy.

---

3. 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.

CERVICAL CYTOLOGY COLLECTION TECHNIQUE

A good cytology test specimen samples cells from the squamocolumnar junction (transformation 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 2001 REPORTING

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

1. *Satisfactory for evaluation.* These specimens are of good quality and they usually contain some endocervical cells. However, the narrative portion of the report may describe some quality concerns such as:
   a. Absence of endocervical 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. *Unsatisfactory rejected.* 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. *Unsatisfactory examined.* The cytologist attempted to evaluate these specimens, 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

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.

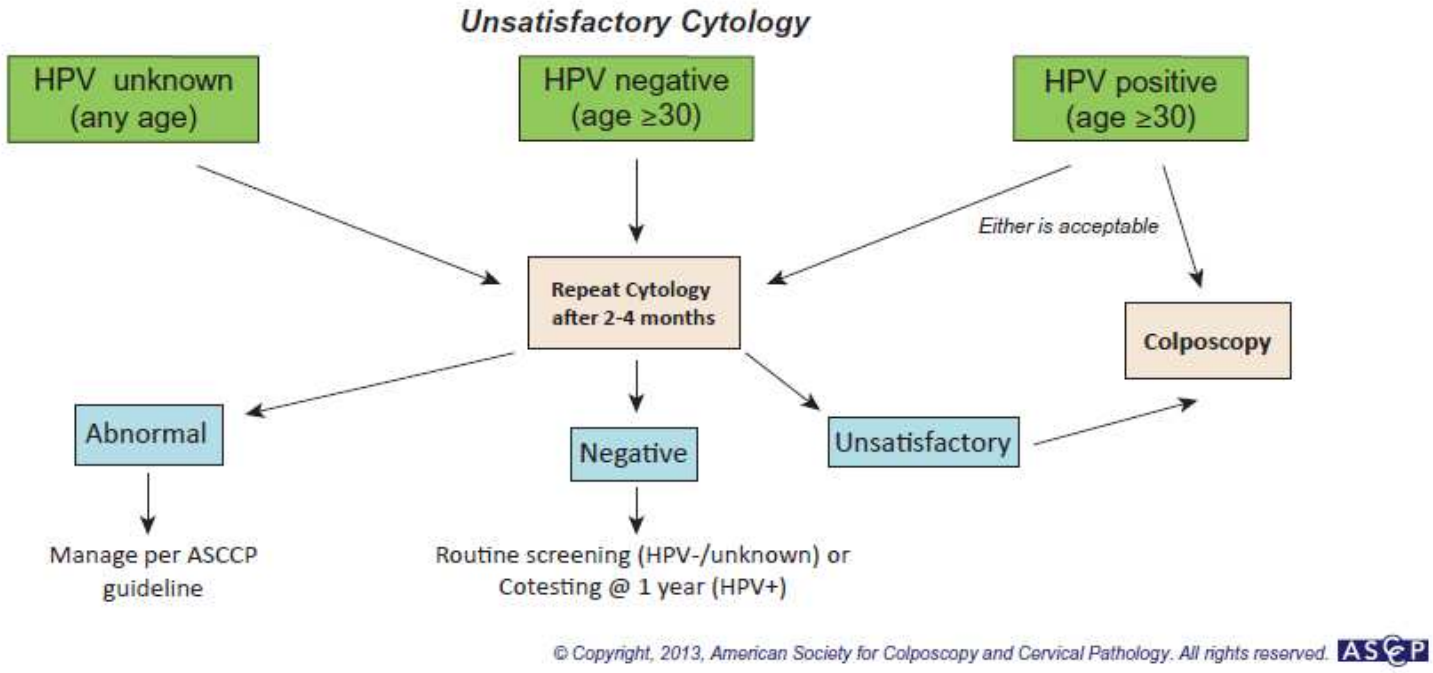
The presence of the endocervical component (endocervical cells and/or metaplastic cells and/or cervical mucus with endocervical cells) in the cytology test indicates that the squamocolumnar junction (transformation zone) has been sampled. The endocervical component should be present in the test collected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



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

1A. NEGATIVE FOR INTRAPETHELIAL 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 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 5 for RECOMMENDED SCREENING INTERVALS.

[*] Algorithm is based on American Cancer Society Recommendations for screening intervals for women at average risk for cervical cancer. Women who are at high risk should continue to be screened annually. High-risk women are those who:

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

****** 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.

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:

- Infection, changes or organisms consistent with
  (1) Trichomonas vaginalis
  (2) Candida species
  (3) Herpes simplex virus
  (4) Actinomyces
  (5) Bacterial vaginosis
- Other non-neoplastic findings, such as endometrial cells present in a woman over 40 years old.
- Reactive cellular changes, such as those associated with:
  (1) Inflammation or repair (including hyperkeratosis)
  (2) Radiation
  (3) Intrauterine contraceptive
  (4) Atrophy

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.

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

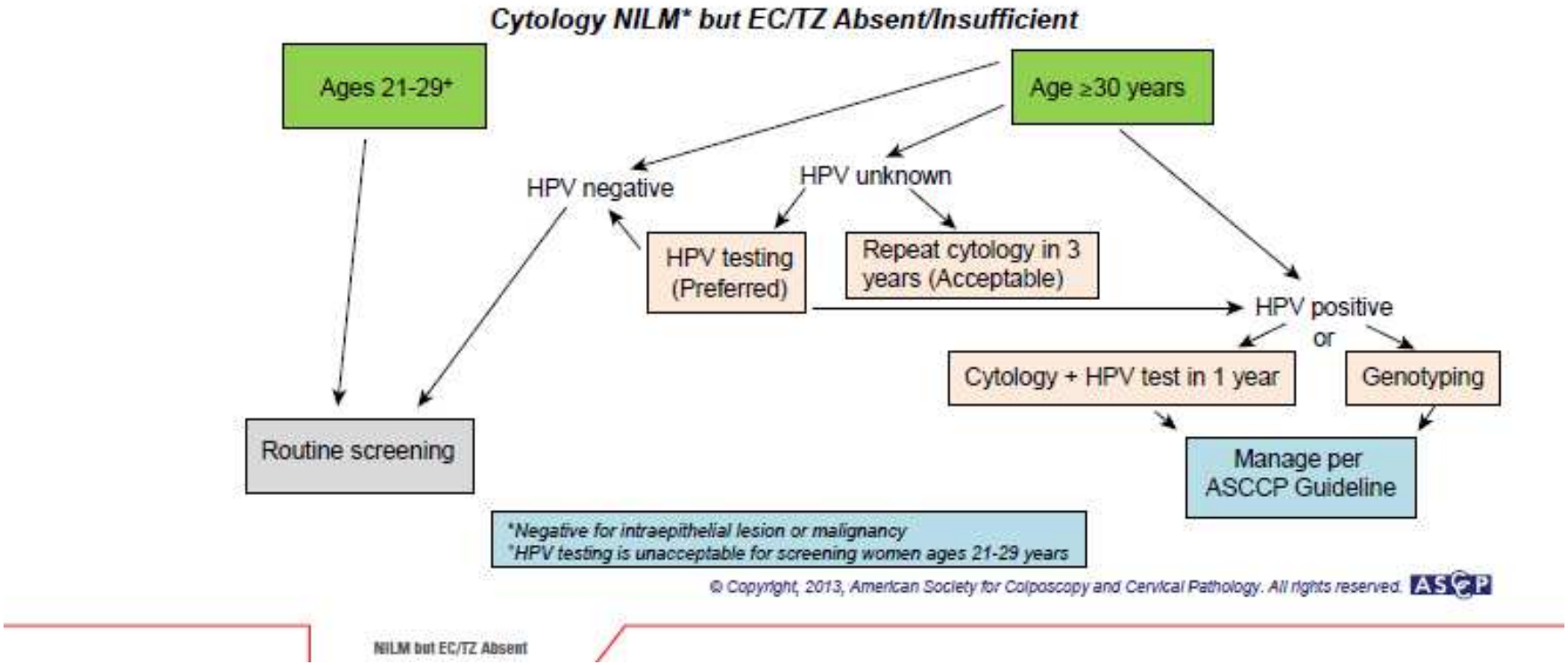
Notify the patient of normal cytology test results according to local policy if age 21-29 years. For women age 30 years and older with cytology reported as negative, advise according to clinical management described below. Instruct your patient regarding the importance of returning for a cytology test 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 both tests in 1 year is acceptable.

Refer to ASCCP Published Algorithms

Cytology NILM but EC/TZ Absent/Insufficient

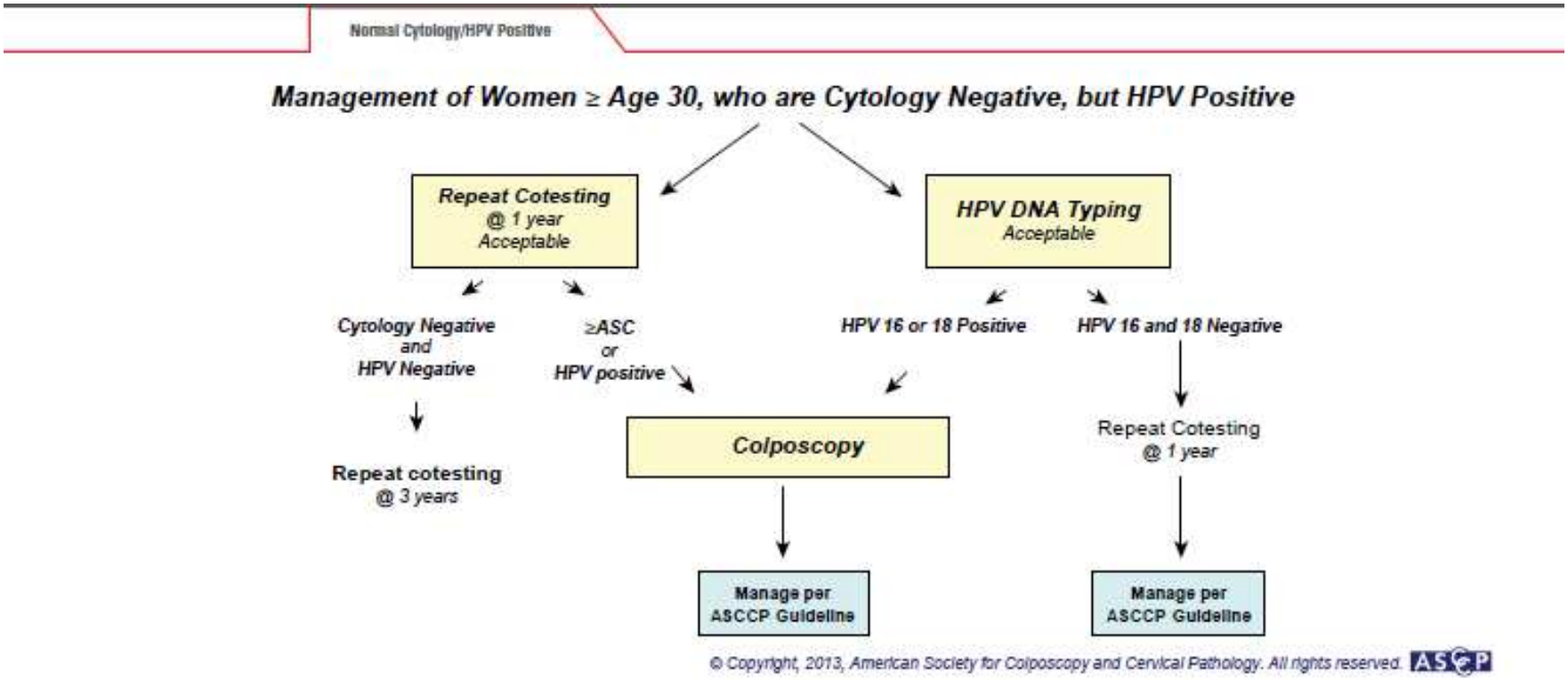


2. Management of Women age 30 and older who are Cytology Negative but HPV Positive

For women 30 years of age and older with HPV-positive but cytology negative co-testing, repeat co-testing at 1 year. At the 1 year co-test, if the HPV test is positive or cytology is ASC-US or worse, colposcopy is recommended. If the 1 year repeat co-test is HPV-negative and cytology negative, repeat co-testing in 3 years.

Refer to ASCCP Published Algorithms

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



Reprinted from the Journal of Lower Genital Tract Disease Volume 17, Number 5, with the permission of ASCCP @ American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.

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, and et al*,* S9-S11).

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 1 year. If negative, return to cytology testing at 3 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 3 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 1 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 3 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 1 year, co-testing is preferred but cytology is acceptable.

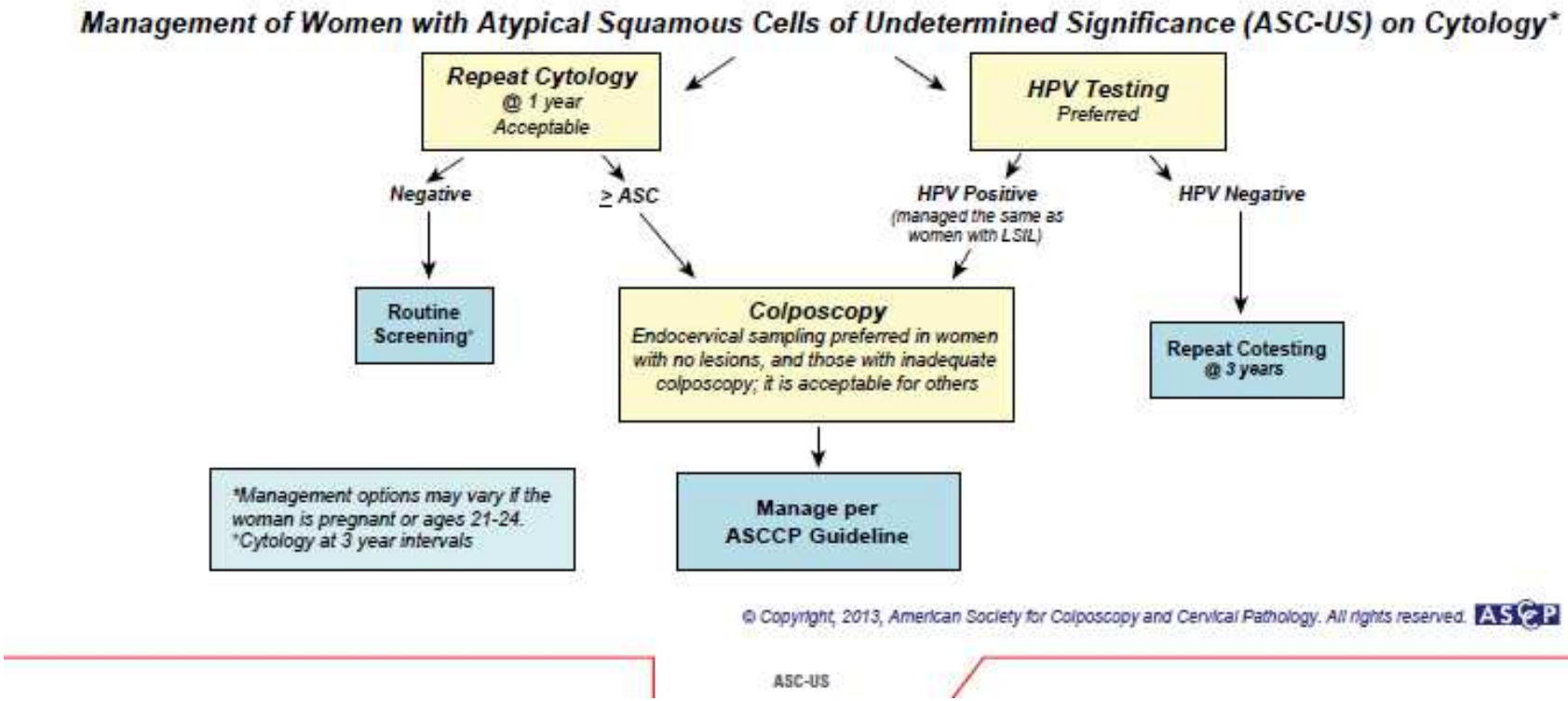
Pregnant women. Pregnant women with ASC-US should be managed in the same manner as non-pregnant women with ASC-US, with the exception that deferring colposcopy until 6 weeks postpartum is acceptable.

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

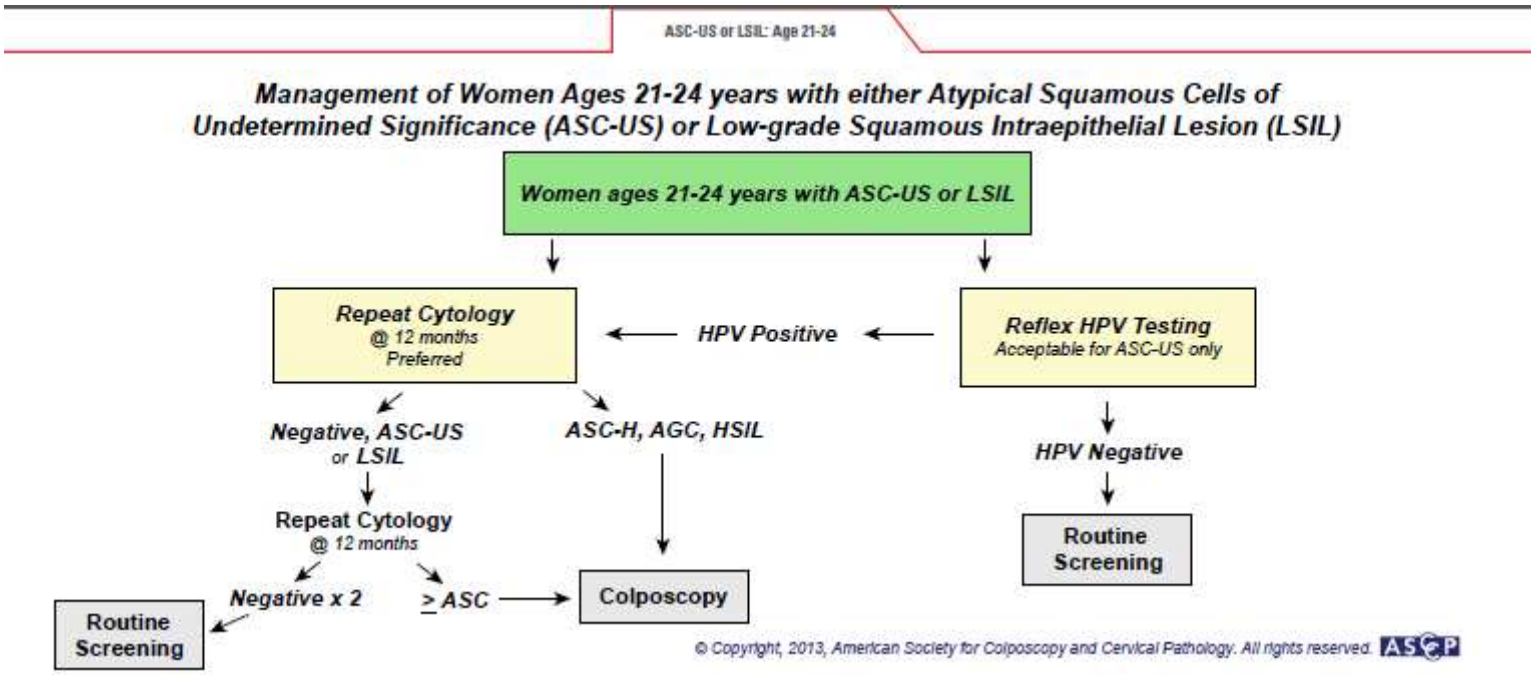
Refer to ASCCP Published Algorithms

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)



Reprinted from the Journal of Lower Genital Tract Disease Volume 17, Number 5, with the permission of ASCCP @ American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.



Reprinted from the Journal of Lower Genital Tract Disease Volume 17, Number 5, with the permission of ASCCP @ American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.

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 1 year is preferred, but colposcopy is acceptable. If repeat co-testing at 1 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 1 year is HPV negative and cytology negative, repeat co-testing after an additional 3 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. A DHHS computer-generated Pap Test Follow up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow up (See Section III "Instruction for Form Usage" on the DHHS 1011.) A DHHS 1011(Cancer Screening Follow up Report) will be sent to the health care provider agency when the cytology result is a second consecutive atypia, HPV, or more significant findings/changes.

SPECIAL POPULATIONS

Women age 21-24 years. For women with LSIL who are age 21-24 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, and et al, S16-S20).

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 6 month intervals 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 1 year, repeat biopsy is recommended. After two consecutive negative cytology results, an additional co-test

1 year later is recommended. If the additional co-test is negative, then repeat co-testing in 3 years is recommended. Colposcopy is recommended if either the 2-year or 5-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.

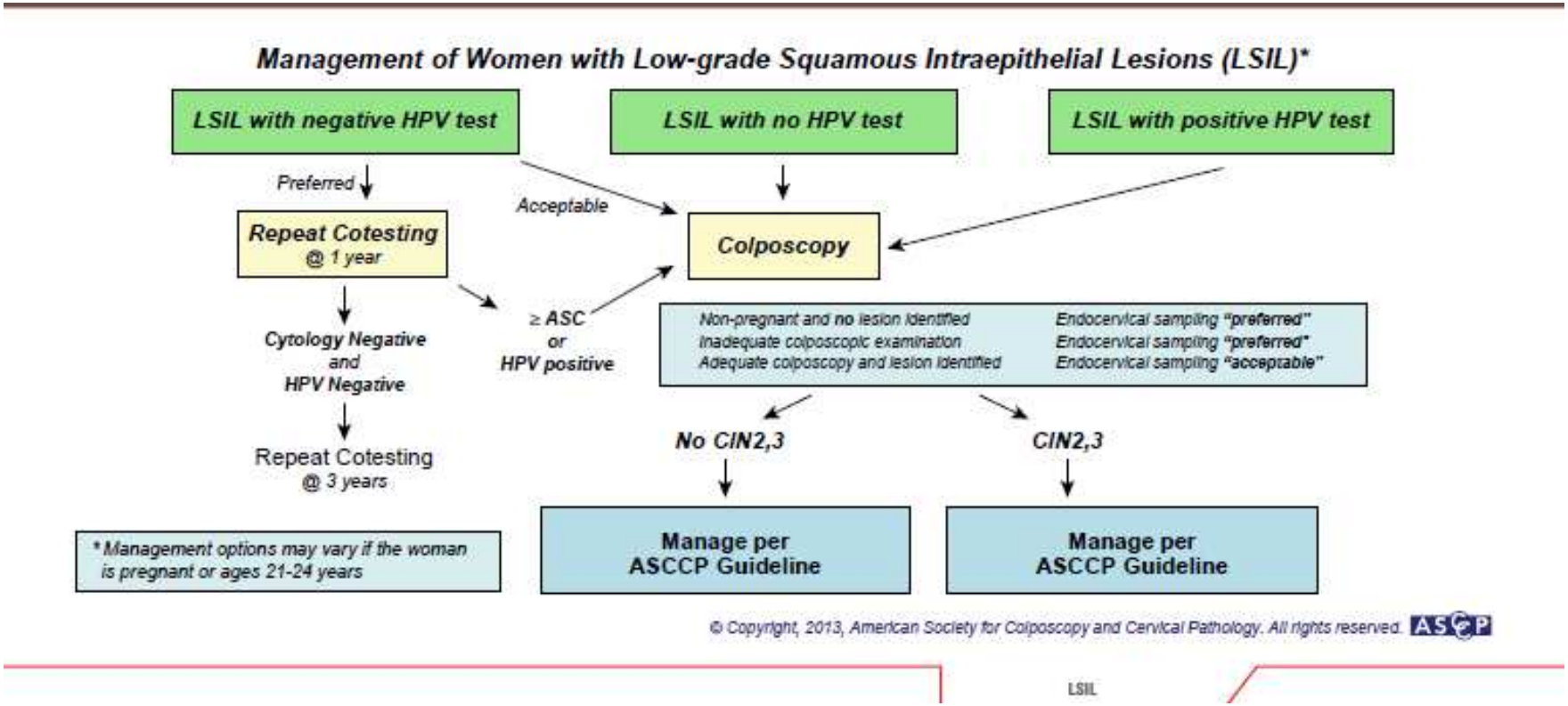
Pregnant women. In the absence of invasive disease or advanced pregnancy, additional colposcopic and cytologic examinations are acceptable in pregnant women with CIN 2, CIN 3, or CIN 2,3 at intervals no more frequent than every 12 weeks. Repeat biopsy is recommended only if the appearance of the lesion worsens or if cytology suggests invasive cancer. Deferring reevaluation until at least 6 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 6 weeks postpartum.

Refer to ASCCP Published Algorithms

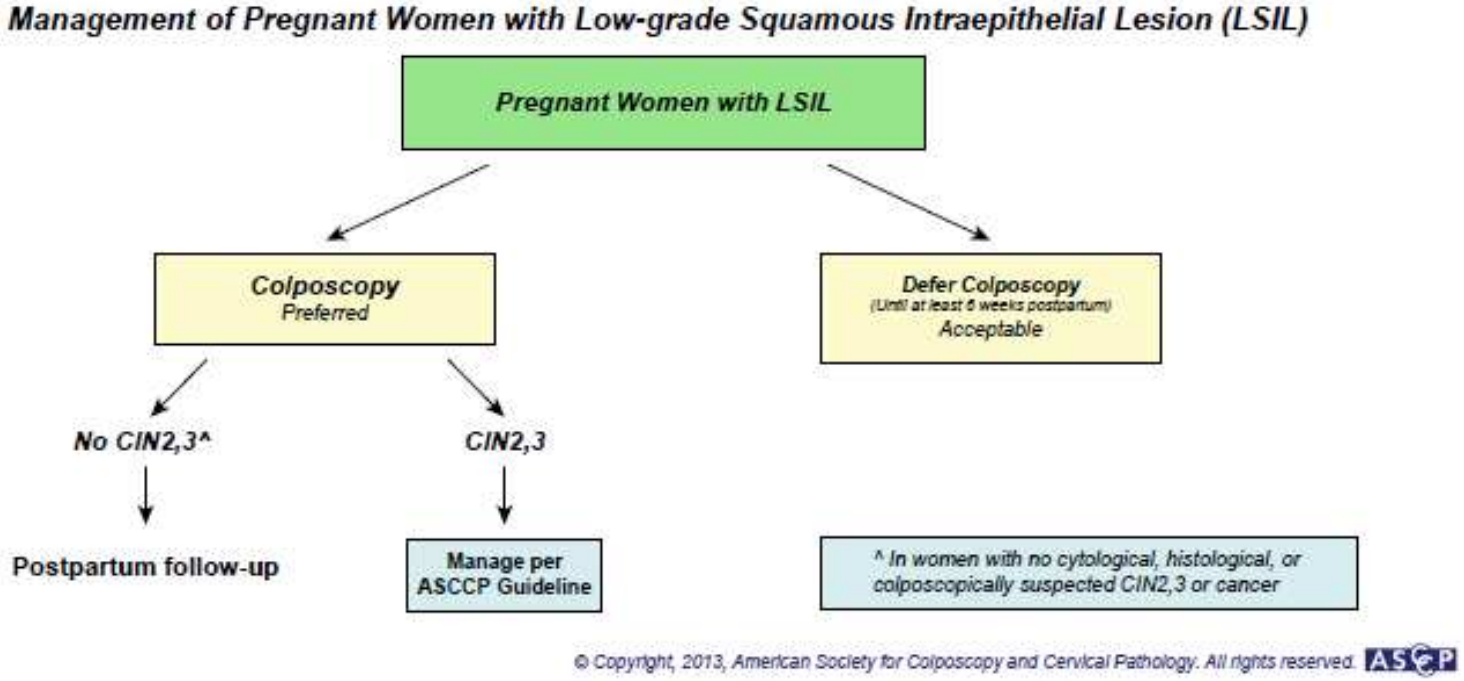
Management of Women with Low-grade Squamous Intraepithelial Lesion (LSIL)

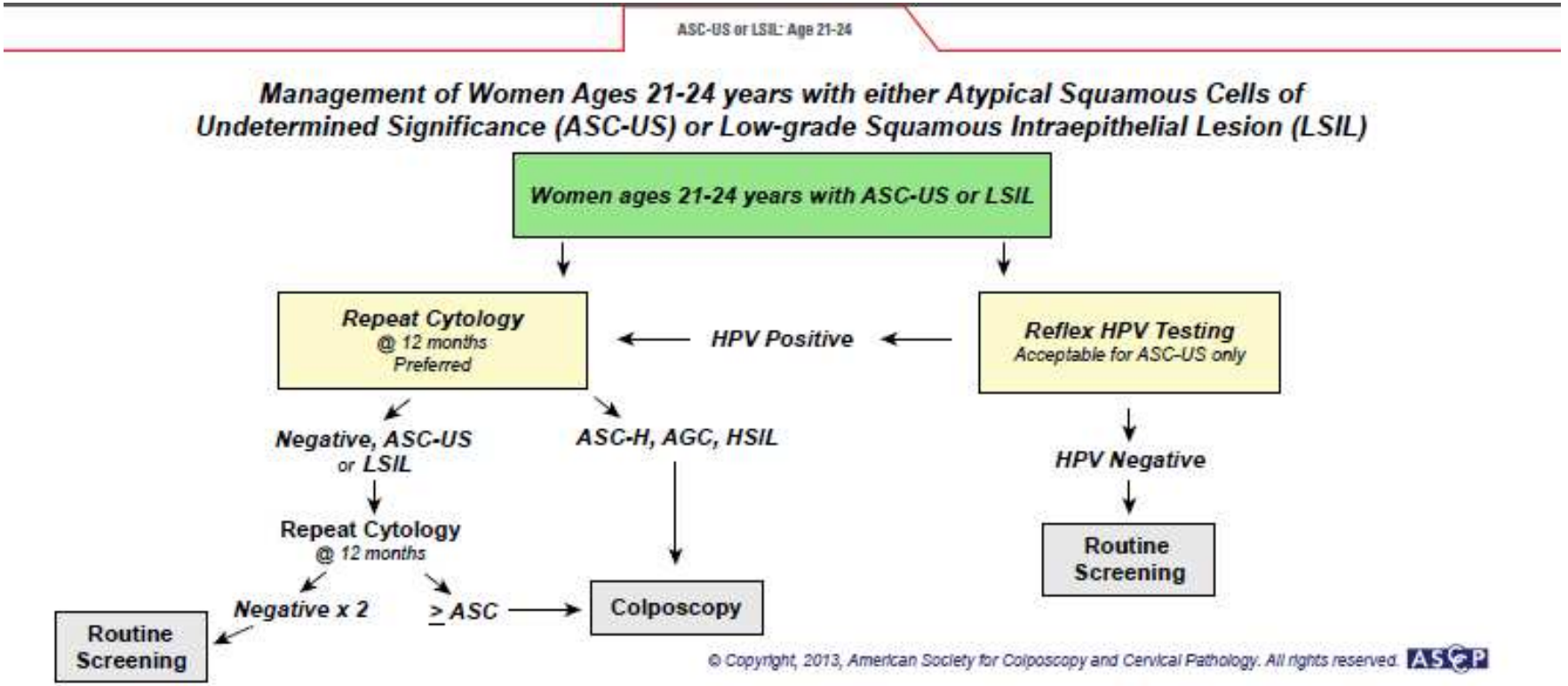
Management of Pregnant Women with Low-grade Squamous Intraepithelial Lesion (LSIL)

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



Reprinted from the Journal of Lower Genital Tract Disease Volume 17, Number 5, with the permission of ASCCP @ American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.





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. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up (See Section III "Instruction for Form Usage" on the DHHS 1011).

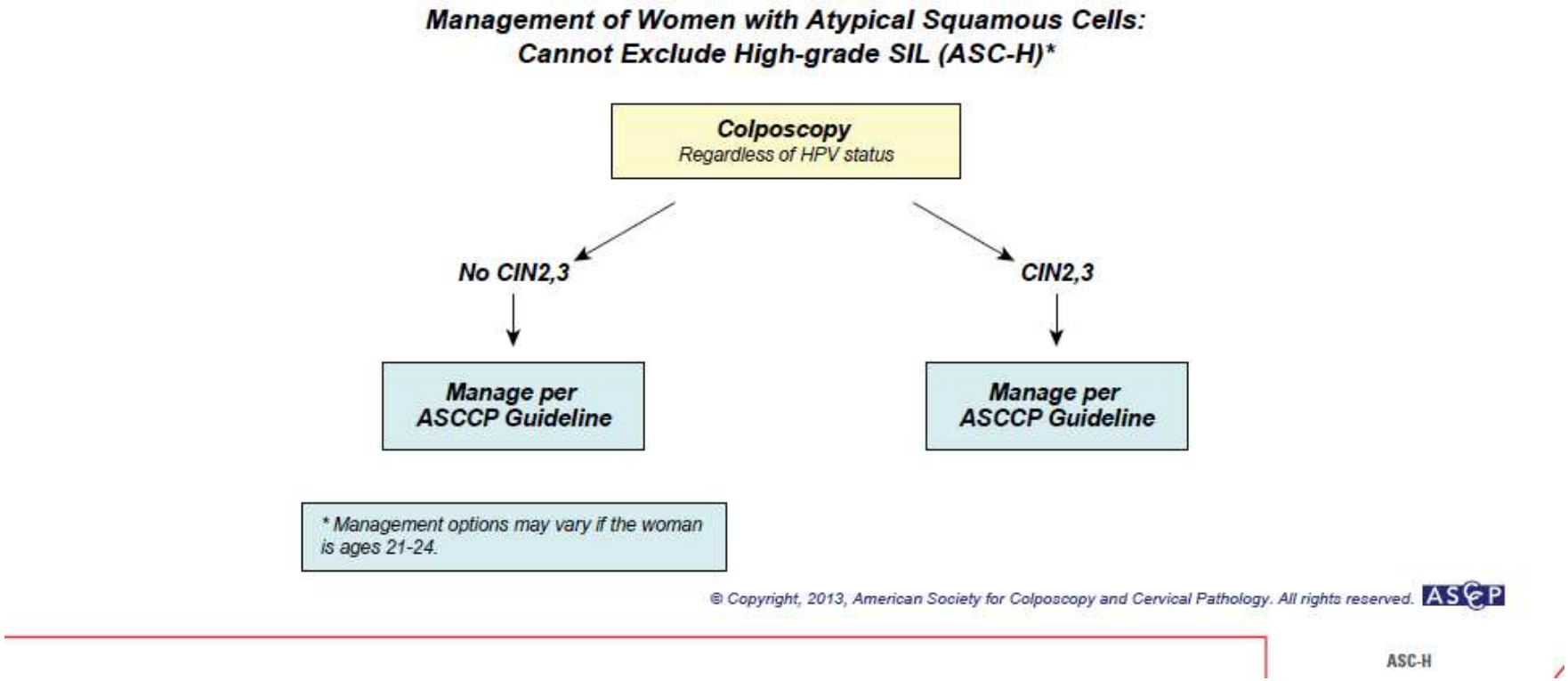
SPECIAL POPULATIONS

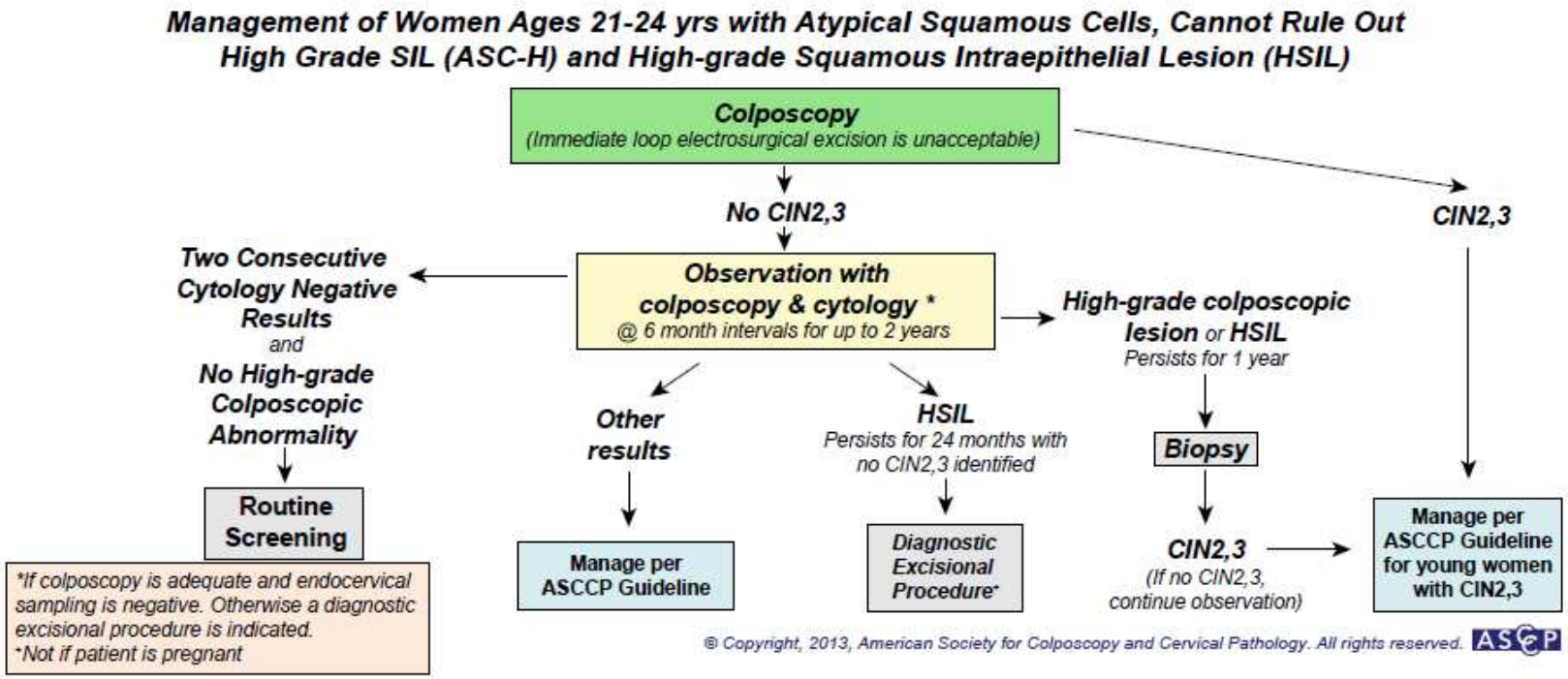
Women age 21-24 years. Colposcopy is recommended. Further management should follow guidelines for women age 21-24 years with HSIL.

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)





6. HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESION (HSIL)

HSIL is a serious finding. Approximately 60% 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, and et al).

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 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. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See Section III "Instruction for Form Usage" on the DHHS 1011.)
- The State Lab gives notification of HSIL Pap results. 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:

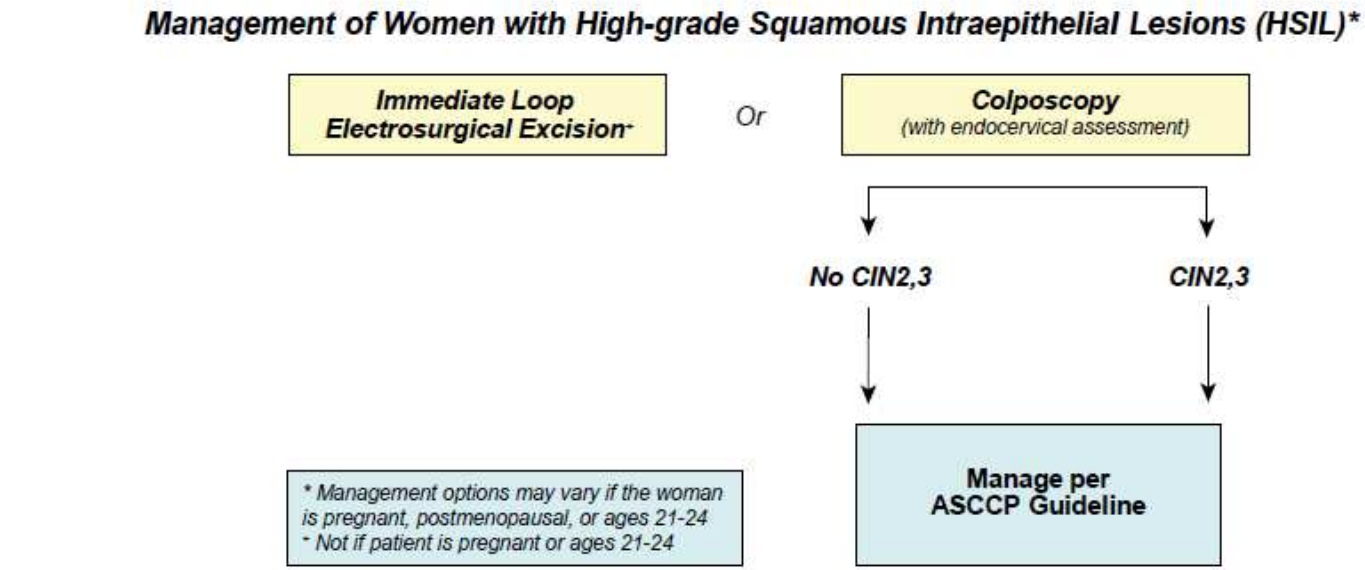
- **Colposcopy of women who are pregnant should be conducted by clinicians who are experienced in the evaluation of colposcopic changes associated with pregnancy**

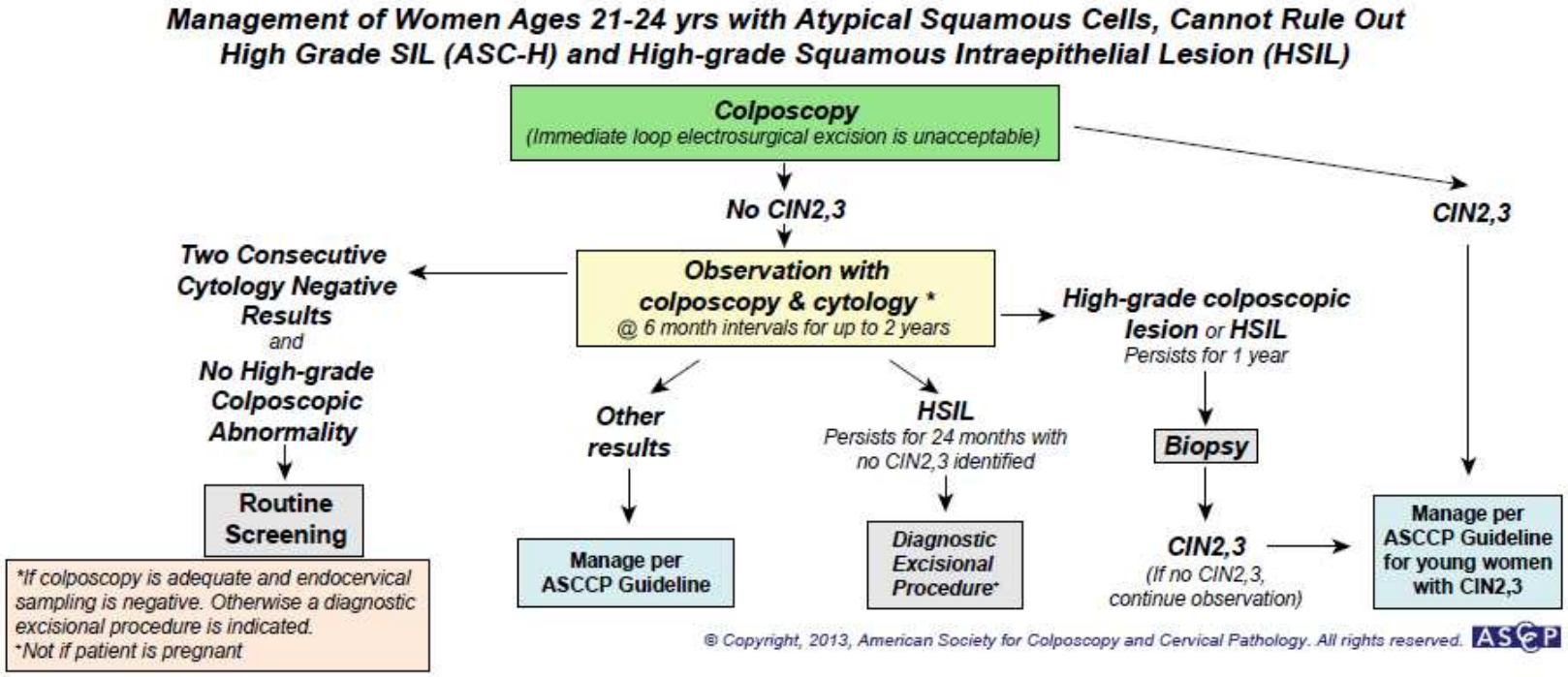
- Biopsy of lesions suspicious for high-grade disease or cancer is preferred. Biopsy of other lesions is acceptable.
- Endocervical curettage (ECC) is unacceptable in pregnant women
- Unsatisfactory colposcopy should be repeated in 6-12 weeks
- Unless invasive cancer is identified, treatment (including 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)





7. SQUAMOUS CELL CARCINOMA

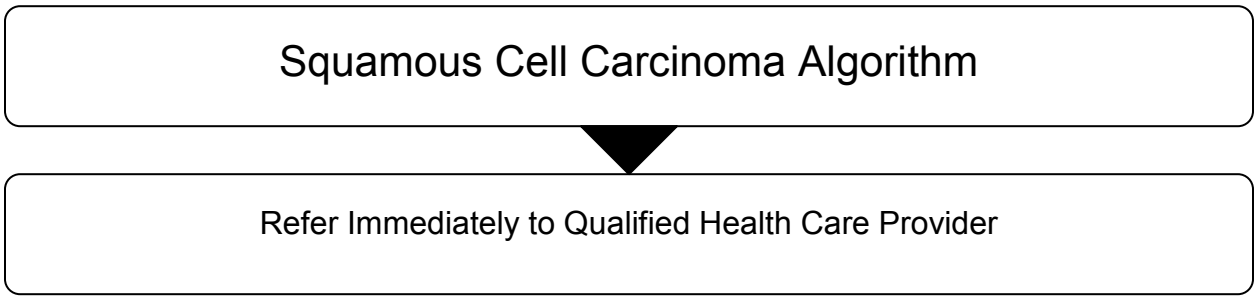
Squamous cell carcinoma is a serious finding on a cervical cytology test. It is regarded as strongly suspicious for malignancy.

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 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. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See Section III "Instruction for Form Usage" on the DHHS 1011.)
- Treatment and follow-up is 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 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. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See Section III "Instruction for Form Usage" on the DHHS 1011.)

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.

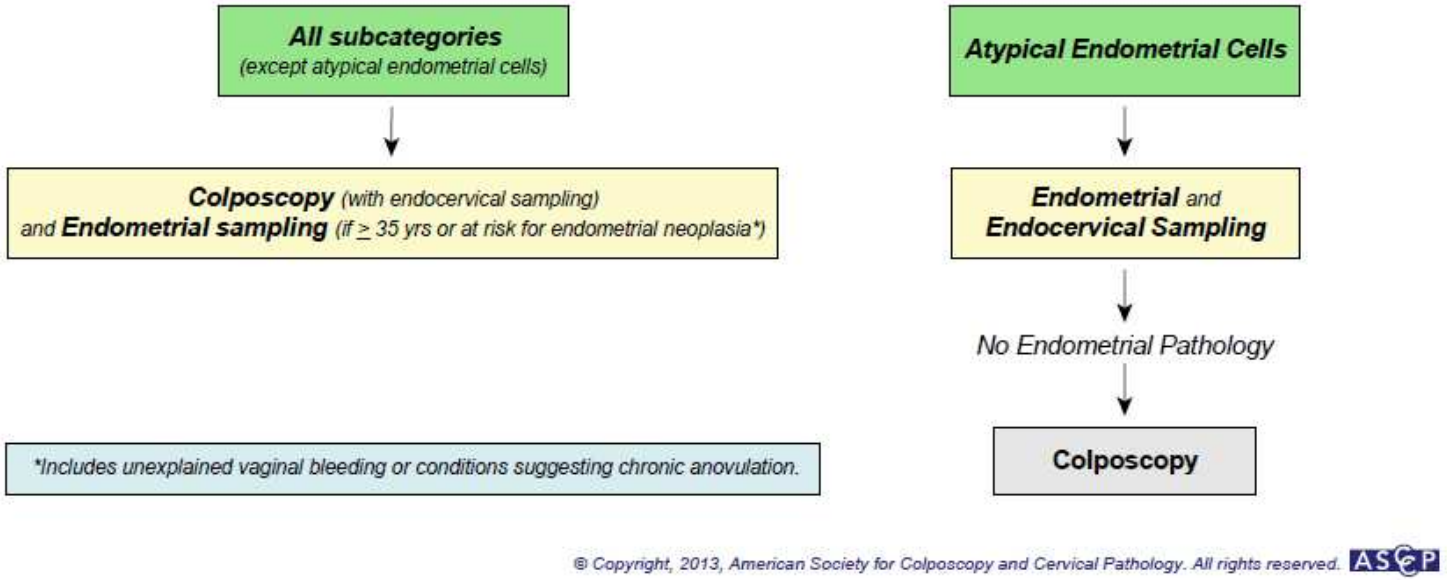
Refer to ASCCP Published Algorithms

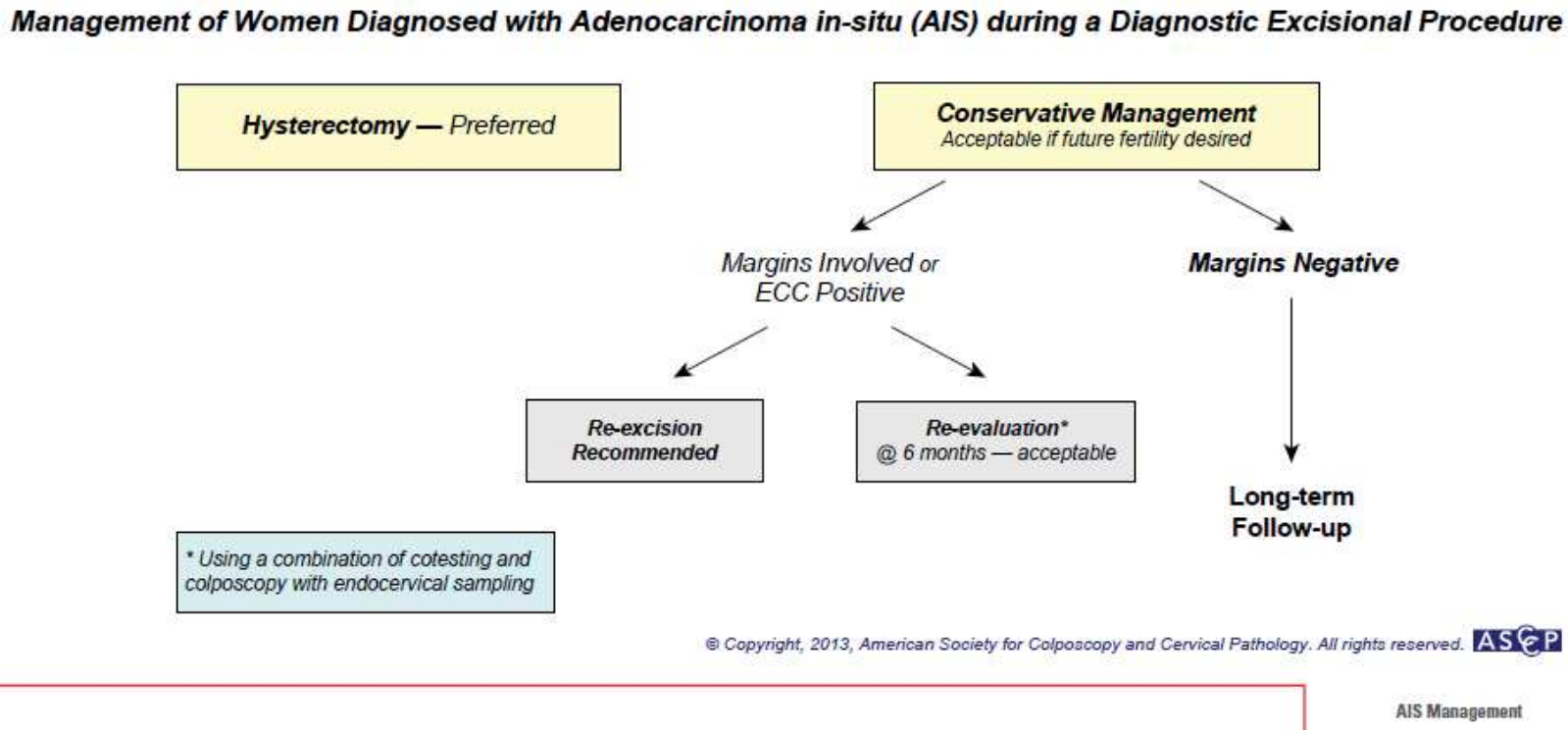
Initial Workup of Women with Atypical Glandular Cells (AGC)

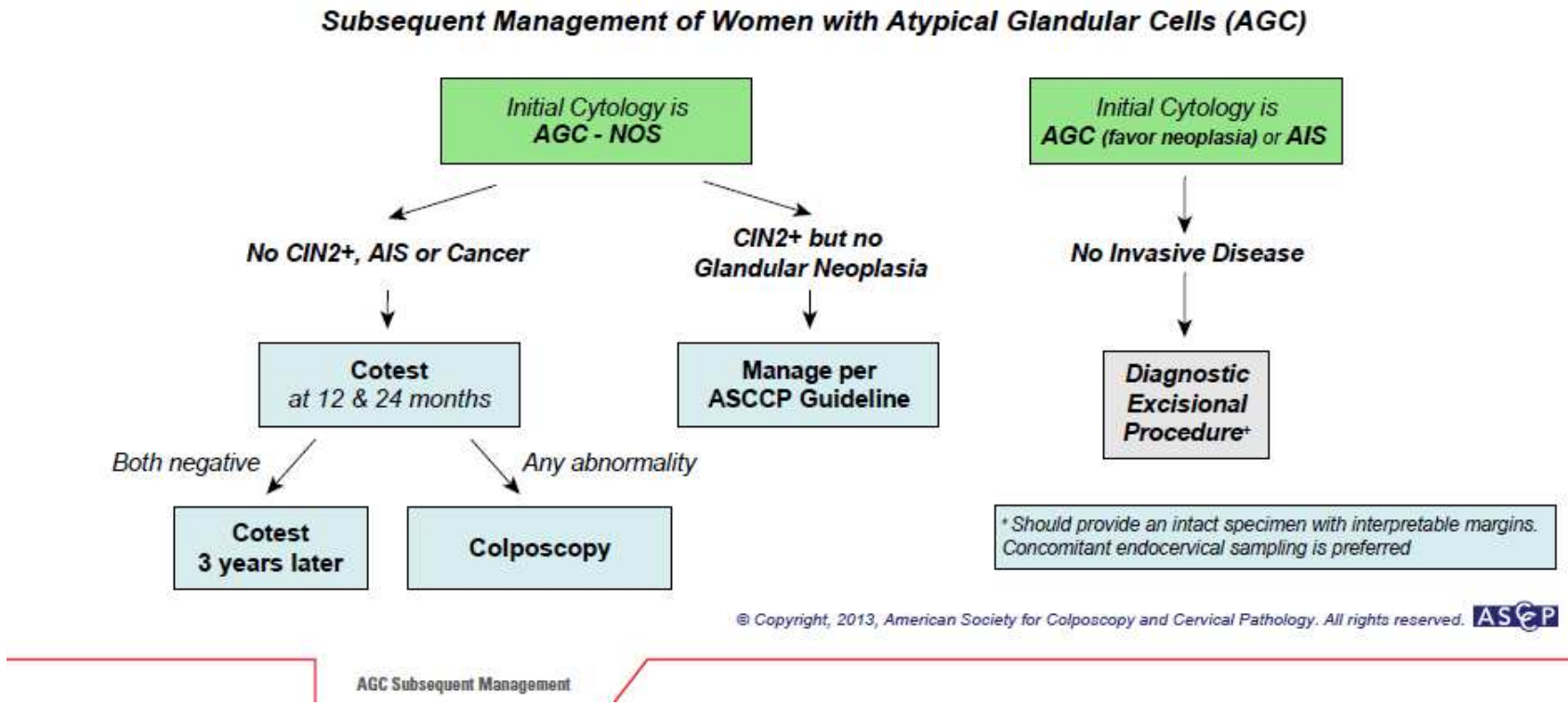
Management of Women Diagnosed with Adenocarcinoma-In-Situ (AIS) During a Diagnostic Excisional Procedure

Subsequent Management of Women with Atypical Glandular Cells (AGC)

AGC







9. OTHER MALIGNANT NEOPLASMS

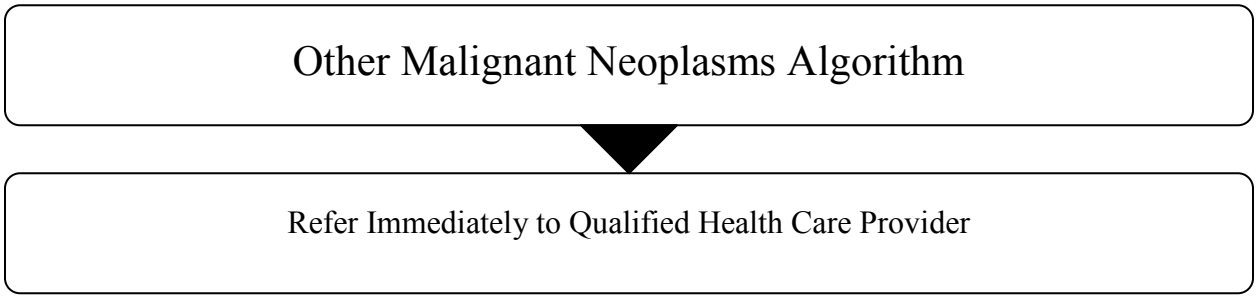
Cytologic evaluation sometimes discovers metastatic lesions such as ovarian, gastrointestinal, melanoma, etc. In these cases, the lab will report the findings as “other malignant neoplasms.”

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 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. A DHHS computer-generated Pap Test Follow-up Form (DHHS 1011) will be sent to the health care provider agency for those patients needing follow-up. (See Section III "Instruction for Form Usage" on the DHHS 1011.)
- Treatment and follow-up is individualized as directed by the QHCP.



DO NOT REPEAT PAP TEST. REFER PATIENT.

C. OTHER FINDINGS ON CERVICAL CYTOLOGY TEST REPORTS AND DEFINITIONS

1. **Reparative changes** - Changes seen when injured tissue attempts to re-establish its structure and function as it existed prior to injury. The injury can be due to causes such as radiotherapy, hysterectomy, cautery, biopsy, severe cervicitis, infection or inflammation. Repair is accompanied by varying degrees of inflammation.

2. **High estrogen level for age** - An increase in estrogen produces a cytologic pattern of maturation of squamous epithelium. Estrogen increase is especially evident in postmenopausal patients and women on hormone replacement therapy. Elevated estrogen effect is reported only on postmenopausal patients, based on the menstrual history and age as noted on DHHS Form 1010.

   NOTE: "High estrogen level for age" is a finding that is determined from a vaginal scrape sample ONLY. Women with a finding of "high estrogen level for age" who are not on hormone replacement therapy should be referred to QHCP.

3. **Hyperkeratosis** (leukoplakia, white patches) - Indicates that a large number of anucleated squamous cells are present in the Pap test. Hyperkeratosis is often diagnostic of benign leukoplakia or a reaction to a chronic irritation as seen in uterine prolapse, inflammation, or chemical or physical trauma to the cervical mucosa. On rare occasions, hyperkeratosis may overlie a significant lesion or dysplastic condition. Hyperkeratosis may exist alone or in combination with parakeratosis.

4. **Parakeratosis** - Parakeratosis is a protective surface reaction of the squamous epithelium. It is characterized by the formation of multiple layers of compact miniature squamous cells with pyknotic nuclei. Parakeratosis may overlie and mask a significant epithelial abnormality such as dysplasia.

5. **Focal reactive changes** -This finding is not clinically significant. No special follow-up is required and the woman should be screened at regular intervals.

6. **Endometrial cells present in a woman over 40** - If patient is premenopausal, this is not clinically significant. If she is postmenopausal, refer to QHCP for further evaluation.

7. **Sexually Transmitted diseases** - 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*.

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.

When considering the order of collecting specimens: The cervical cytology test can be collected any time after the cervix has been cleaned. 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. **Please note:** 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

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, and definitely not when she is menstruating.

C. EQUIPMENT

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

- Good lighting (gooseneck lamp) must be available
- Specula

- Plastic spatula
- Endocervical brush (Do not use in pregnant women.)
- Vial of PreservCyt solution for *ThinPrep* Pap test
- Test tubes with normal saline (saline replaced every 30 days)
- Cotton applicators (large and small)
- N.C. State Laboratory of Public Health Pap Test Screening Form (DHHS Form 1010) or Reference Lab Forms
- Individual zip lock bag
- Mailing container for bagged *ThinPrep* vials or container from Reference Lab

D. PROCEDURE FOR *THINPREP* TESTING

1. Vial of PreservCyt 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.

   Complete Pap test screening form (DHHS Form 1010). Follow instructions on back of form. **All requested information is vital**. It is essential that the patient's correct name, both last and first, is on BOTH the DHHS Form 1010 and the vial. Please indicate previous or maiden name in spaces provided below the Social Security number. The DHHS patient identification number (Social Security Number) **must** be on the form for correct identification. The **Medicaid Number**, if applicable, **must** be on the DHHS Form 1010 for billing purposes; therefore, **it is imperative** that Medicaid numbers are submitted to the laboratory. 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. Ensure that the patient has emptied 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. (Recommend double gloving.) 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 on perineal body to relax muscles.

c. Tell patient that speculum is about to be inserted and ask her to relax pelvic floor muscles.

d. Gently insert closed speculum at 45-degree 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 *ThinPrep* Pap Test Sample**

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

a. TO COLLECT THE SAMPLE FROM THE ECTOCERVIX

(1) Select contoured end of plastic spatula and rotate 360^{o} around entire ectocervix while maintaining tight contact with ectocervical surface. Remove spatula.

(2) Rinse contoured end of plastic spatula in vial of PreservCyt (*ThinPrep)* 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 PreservCyt (*ThinPrep)* solution **ten (10)** times while pushing it against the wall of the vial. Swirl the brush vigorously to further release material. After swirling the brush in the vial ten times, use the spatula to push any remaining material from the brush. Discard the spatula and the brush.

c. To close the vial for shipping:
Tighten the PreservCyt 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. Have endocervical brush and spatula in hand.

c. If squamocolumnar junction **cannot** be identified: place elongated edge of spatula into cervical os, press firmly and rotate 360^{o}, OR

d. If squamocolumnar junction is identified on the ectocervix, obtain sample using the regular end of the spatula.

e. 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.)

f. Lubricant jellies should not be used to lubricate the speculum. Water is sufficient lubricant.

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

h. 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.

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

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

k. 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 *ThinPrep* Pap Test Samples/Specimens**

Refer to State Lab Web site (http://slph.ncpublichealth.com/) for detailed instructions.

a. Make sure that PreservCyt vial is labeled with patient's last and first names.

b. Make sure that DHHS Form 1010 (Pap Test Screening Form) is completed. Indicate any name changes from previous submissions in the spaces provided.

c. Place up to 15 PreservCyt vials (with enough absorbent material to absorb leaks) in a zip-lock plastic bag.

d. Place plastic bag(s) and form(s) in a heavy corrugated cardboard box. Place the forms in the box in a separate bag or envelope. If more than one bag of vials is included, label the bags and forms as bag 1, bag 2, etc. Boxes containing 51 vials or more must have a flammable label attached to the box. Attach a peach-color State Laboratory **Cytology Mailer Label** on the box and send to the State Laboratory via state courier mail service or U.S. Postal Service.

PROCEDURE NOTES

- Have readied a vial of PreservCyt (*ThinPrep*) Solution labeled with patient's name, last name and first name.
- Be sure Expiration Date on the PreservCyt is current. The State Laboratory **will not test samples when the expiration date has passed.** The sample/specimen will be returned to the health care provider agency. The State Laboratory **will not refund** health care provider agencies for expired vials.
- Do not hold specimens in the lab for extended periods. Ship specimens to the SLPH several times each week. FDA regulations require that the *ThinPrep* 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.

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 PreservCyt Solution
   c. Bloody specimens
   d. Inflammation
   e. Presence of organisms

2. The most common reasons for unsatisfactory: rejected specimens are:
   a. No name on vial
   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. No patient ID number
    b. Failure to indicate patient name change
    c. The patient history is incomplete
    d. There is no return address of provider
    e. No patient name on form
    f. Writing is illegible on form
    g. The patient's name on the vial and the form do not match
    h. Two vials are sent with one form

Divider – 3. Cancer Screening Follow-up DHHS Form 1011

CANCER SCREENING FOLLOW-UP DHHS FORM 1011

PURPOSE:

- To provide the State Laboratory of Public Health (SLPH) with diagnostic and tissue study data on Pap tests submitted to the Cancer Cytology Unit where abnormal cytological or clinical findings have been reported
- To comply with the Clinical Laboratory Improvement Amendments of 2004 (CLIA '04) regulations
- As an integral part of the Laboratory's Quality Assessment Program. Laboratory quality is dependent on biopsy correlation.

Cytology Laboratory Initiated Form

The DHHS 1011 (Cytology Screening Follow-up Form) accompanies the State Laboratory of Public Health Cancer Cytology Pap test report when the following cytological findings are present:

- ASC-H (atypical squamous cells- cannot exclude HSIL)
- ASC-US (atypical squamous cells- undetermined significance). NOTE: The SLPH will be changing this so that only those ASC-US cases that are positive for high risk HPV DNA will need to have a DHHS 1011 form completed.
- LSIL (low grade squamous intraepithelial lesion)
- HSIL (Moderate and/or severe squamous intraepithelial lesion, CIS)
- AIS (adenocarcinoma *in situ*)
- Malignancy

Health Care Provider Agency Initiated Form

Under certain circumstances and for some patients who have abnormal cervical conditions detected on clinical exam, the health care provider agency initiates the DHHS 1011. To provide the DHHS essential follow-up data for cytological evaluation, please request a DHHS 1011 from the Cancer Cytology Unit (919-733-7146) when:

- Previous Pap test findings were negative; however, physical findings or surgery indicate a lesion.
- The clinician returns the Referral DHHS Form 2734 with abnormal tissue findings.
- Patient was referred for further follow-up because of clinical findings.
- Refer to Quality Assurance Recommendations on page 49 for other referral and follow-up guidance.

Instructions for completing the DHHS Form 1011

Tissue Studies Completed

- Retain the DHHS 1011 in the patient's chart until diagnostic tests are completed.
- Circle the methods and diagnosis when results are returned from the physician or attach a copy of the physician's report to the DHHS 1011 and return. Do not circle methods unless they are actually completed.
- A copy of the Referral Form 2734 may be attached when the tissue report is not available.

No Tissue Studies Planned

- Circle "No Tissue Studies Planned".
- If patient is to be re-Papped at a later date please note this.
- Also note if patient has been lost to follow-up.
- Enter the date of the repeat Pap and name of examining cytology lab if one is obtained.

Important Note

A copy of a lost Form 1011 can be obtained by notifying the Cancer Cytology Laboratory at the address or telephone number below:

Cancer Cytology Laboratory
State Laboratory of Public Health
Post Office Box 28047
Raleigh, NC 27611-8047
Telephone (919) 733-7146

Tracking the Form 1011

The **Form 1011 Not Returned Report** is no longer available on the State Lab's web site (http://slph.ncpublichealth.com/).

To check on a returned 1011 please contact the Cancer Cytology Laboratory. Provide patient's name, date of birth, and recent pap report accession number as well as where information is to be called or sent.

Importance of Returned DHHS Form 1011

- CLIA '04 requires that all cytology labs collect correlation statistics on biopsy results versus HSIL Pap test reports and also monitor the percentage of HSIL Pap reports that have a returned tissue follow-up report.
- The slides are reviewed when negative biopsy results are received on an abnormal Pap or positive biopsy results on a negative Pap.
- Many of the slides are used for continuing education purposes after biopsy correlation is confirmed. Patient confidentiality is maintained on all specimens used in continuing education studies.

Divider – 4. 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.

Five 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. Track referrals to make sure that patients have actually received follow-up

Each clinic might have a different mechanism for ensuring that all of 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 RNs must have policies and procedures in place for assuring competency and documentation of competency for each nurse performing clinical exams. Policies should be reviewed at least annually and revised as needed.

The following elements are 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 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. For those agencies sending Pap tests to the State Laboratory for Public Health, include instructions on completing and submitting the DHHS 1011 form in the follow up plan.

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
    - Results requiring no intervention require patient notification. The report is initialed and filed in the medical record
    - Results requiring follow-up are reviewed, the patient is notified, and the plan of care is determined based on this manual, local policy, and consultation with the medical advisor
    - The plan of care and notification of the patient are documented in the medical record
    - 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

    Tracking Systems Remind the Staff to:

    - Document all patient contacts
    - See test and examinations ordered and compare to tests with no results
    - Review patients with incomplete interval follow-up (monthly, quarterly, etc.)
    - Develop procedures to overcome patient-related barriers to follow-up, for example, telephone reminders, mailing reminders
    - Attempt to contact patients three times to assure that patients are receiving treatment
    - Use Certified Mail on the third attempt to notify patients

5. **Internal quality assurance:** Periodically (at least annually), chart audits should be performed to track the percent of women with abnormal results who receive definitive diagnostic and therapeutic procedures. Documentation of findings and corrective action must be on file.

B. CERVICAL CYTOLOGY SERVICES EVALUATION CHECKLIST

Methodology

What is the Pap method being provided?

- ☐ *ThinPrep*
- ☐ *SurePath*
- ☐ Conventional

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 01
- ☐ Bethesda
- ☐ 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?

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 status of a specimen be checked or a report 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 ASCP certified? 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 – 5. Appendices

Divider – Appendix A

STATE LABORATORY BETHESDA REPORTING SYSTEM

Cancer Cytology Unit
Bethesda 2001 Pap Test Reporting Categories and Descriptions of Cellular Changes

Specimen Adequacy:

SATISFACTORY FOR EVALUATION: (describe presence or absence of endocervical/transformation zone and any other qualifying indicators)

UNSATISFACTORY:
Specimen Examined: (inadequate cellular component or other quality statement)
Specimen Rejected: (specimen unlabeled, name on vial and form do not match, etc.)

Cytologic Findings Suggest:

Negative for Intraepithelial Lesion or Malignancy
(Reparative, inflammatory and reactive changes will be indicated under this heading.)

ORGANISMS:
Organisms morphologically consistent with Trichomonas Vaginalis
Fungal organisms morphologically consistent with Candida species
Cellular changes associated with Herpes Simplex Virus
Bacteria morphologically consistent with Actinomyces

Other Findings:
Endometrial cells in a patient over the age of 40.

Epithelial Cell Abnormalities

- Squamous
- ASC-US: atypical squamous cells- undetermined significance
- ASC-H: atypical squamous cells- favor high grade squamous intraepithelial lesion
- LSIL: low grade intraepithelial lesion encompassing mild dysplasia and HPV
- HSIL: high grade intraepithelial lesion encompassing CIS, moderate and severe dysplasia
- Squamous Cell Carcinoma

Glandular

Atypical:
- Endocervical cells
- Endometrial cells
- Glandular cells

Atypical:
- Endocervical cells, favor neoplasia

Glandular cells, favor neoplasia

Endocervical Adenocarcinoma *in situ*

Adenocarcinoma:
- Endocervical
- Endometrial
- Extrauterine

Not otherwise specified (NOS)

- Other Malignant Neoplasms: (specify)

Educational notes and comments--examples:

- Suggest short-term vaginal estrogen therapy and repeat
- Suggest treatment of inflammation and repeat
- Please obtain specimen at mid-cycle for optimal results
- Hyperkeratosis may mask a more serious condition
- Suggest treatment of inflammation and colposcopy
- Glandular cells, cytologically benign, in a post hysterectomy patient
- Suggest colposcopy/biopsy/ECC if clinically appropriate
- Shift in flora suggestive of bacterial vaginosis

Reflex High-Risk HPV DNA Testing

The HPV Test

The NCSLPH, in order to align our testing with the new Consensus Guidelines published in March 2012 (http://www.asccp.org/consensus/cytological.shtml) and to allow the health departments/clinician/patient more control of the testing decision making, will offer the following options on the Pap test requisition form:

- Pap test only
- Pap plus HPV if ASC-US (reflex HPV)
- Pap plus HPV (co-testing)

The NCSLPH tests for HPV using the Cervista® HPV HR test. This assay detects several of the high risk genotypes (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), but does not distinguish among them. The reports simply will indicate that high risk genotypes either were detected or were not detected in the patient's sample.

The Process

NCSLPH receives ThinPrep® vials from local health departments and processes them daily. Cytotechnologists review all prepared slides and record their results following a tightly controlled quality assurance process. All slides with abnormal results are reviewed and approved by an on-site cytopathologist. After the ASC-US result is confirmed by the pathologist, the remaining patient sample in the ThinPrep® vial will be transferred from Cancer Cytology to Virology/Serology-Bacterial STD for subsequent HPV testing. A preliminary report is sent to the health care provider with the ASC-US diagnosis with HPV testing pending. The final laboratory report will include both pathology and HPV results on the Cancer Cytology form.

Turnaround Time (TAT)

NCSLPH will perform HPV testing approximately twice a week in order to maximize efficiency when performing this lengthy procedure. Because HPV testing will only be performed after the final pathology report is received, the effect on TAT is expected to be a delay of no more than two to three days than is currently observed for abnormal reports.

Unsatisfactory Samples

Apart from the routine reasons a sample is deemed unsatisfactory for testing (questionable patient or sample identification, missing test requisition, overtly bloody sample), there may be reasons a sample is unsatisfactory for HPV testing, such as having insufficient quantities of remaining ThinPrep® sample required to perform the reflex test. If NCSLPH is unable to perform the test for this reason, a comment will be included in the report.

Our goal is to consistently produce high quality, accurate and timely tests results. In the case of HPV testing, providing information to health care providers about the presence

or absence of high risk genotypes allows for better patient management when following up ASC-US results.

HPV DNA Testing

HPV high risk: negative

- HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 not detected
- Low likelihood of underlying CIN 2-3 or cancer
- Results are not intended to prevent women from proceeding to colposcopy

HPV high risk: positive

- HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68 detected
- Low but increased likelihood that underlying high grade CIN will be detected at colposcopy

HPV high risk: unsatisfactory

QNS-Quantity of specimen left in ThinPrep® vial not sufficient for HPV testing

If you have any technical questions about the HPV test, please call Virology/Serology at 919-733-7544 and ask for Myra Brinson or Mary Noel Dodd. For any technical questions about Pap testing, please call Cancer Cytology at 919-733-7146 and ask for Les Burke or Aubrey Wiggins. (Zimmerman)

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 mailed 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 voice mail. Since HIPAA regulations prevent leaving patient identifiers on voice mail, 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 or the report may be downloaded from the State Lab web site (http://slph.ncpublichealth.com/) immediately.

The State Lab issues Critical Value notification for the following Pap reports:

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

In an effort to provide more timely notification of critical values and amended reports, the Cancer Cytology Unit at the N.C. State Laboratory of Public Health is formatting an e-mail list of nurse supervisors in the local health departments. The e-mail notice of a Critical Value report will contain only the lab accession number to ensure HIPAA compliance. The report and additional patient information may be accessed from the N.C. State Laboratory web site (http://slph.ncpublichealth.com/) or by contacting the Cancer Cytology Unit at 919-733-7146. An e-mail return receipt will document the confirmation of the critical value notice.

On the following survey, please list the name, phone number and e-mail address of the nurse supervisor and another contact that would be responsible for forwarding the Pap report information to the appropriate clinic supervisor so that receipt of the report is tracked.

Please complete the attached survey and fax to:

Cancer Cytology Unit
Clerical Supervisor
919-715-0171

If you have any questions, please contact the Cancer Cytology Unit at 919-733-7146. Thank you for taking the time to complete this survey and working with us to improve the timeliness of your reports.

Survey for Pap Report Notification 2013

Facility: _____

Address: _____

_____

_____

Primary Contact:

Nurse Supervisor: _____

E-Mail Address: _____

Phone Number: _____

Additional Contact:

Name: _____

E-Mail Address: _____

Phone Number: _____

Divider – Appendix C

Cervical Cancer Screening Policies

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

CERVICAL CANCER SCREENING POLICY

Effective July 2012

Introduction:

In 2011, 107 North Carolina women died of preventable cervical cancer (State Center for Health Statistics). 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. The incidence of cervical cancer has decreased significantly in the years since World War II, in large part because of early detection efforts using the Pap test. When cervical cancer is detected early, the likelihood of survival is almost 100 percent with timely and appropriate diagnostic follow-up and treatment.

In March 2012, 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 July 2012. Revised program guidance for NBCCEDP grantees was published in October 2012 (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), effective retroactively to July 2012, are as follows:

Eligible Women:

- Women between the ages of 21 and 64 years of age, with an intact cervix, are eligible to enroll in the NC BCCCP, provided their family income is at or below 250% of the current federal poverty level. Women between the ages of 40 and 64 may be screened using federal BCCCP dollars. Women between the ages of 21 and 39 may be screened using state BCCCP dollars.
- 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 39 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 Never or Rarely Screened:

- At least twenty percent of all clients newly enrolled for cervical cancer screening should be women who have never been screened for cervical cancer or who have not been screened for cervical cancer in the past 5 years.

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

- The NC BCCCP funds may be used to reimburse cervical cancer screening following the 2012 United States Prevention Services Task Force (USPSTF) recommendations. NC BCCCP funds can be used for reimbursement of cervical cancer screening among women age 21 to 64 years old, regardless of sexual activity.
    - 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 or co-testing with the combination of Pap testing with human papilloma virus (HPV) testing every 5 years. Grantees must make both cervical cancer screening options (i.e., Pap testing every 3 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 64 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 64 for most women; at age 65 it is assumed she is eligible for a Medicare-funded cervical cytology. If a woman over 64 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 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.

- 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 without documentation regarding the reason for the hysterectomy or that no neoplasia or cancer was identified, NC BCCCP funds can be used to reimburse for cervical cancer screening. 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. The presence of a cervix can be determined with a physical examination. NC BCCCP funds CAN be used to reimburse for an initial examination (i.e., 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 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. The specific cervical cancer screening method must be indicated in the HIS data, so that the number of liquid-based tests can be distinguished from the number of conventional Pap tests performed. This will provide a means by which the test-specific diagnostic outcomes can be compared.

Use of Automated Screening Technologies for Quality Assurance:

- NC BCCCP funds may not be used to reimburse automated technologies when they are used as a secondary assessment of Pap testing for quality assurance purposes. These quality assurance costs are included in the pricing of tests and are paid by the cytopathology laboratories.

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.
- 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:

- High Risk HPV DNA testing is a reimbursable procedure when used for screening with Pap testing (i.e., cotesting) and for follow-up of abnormal Pap results as per American Society for Colposcopy and Cervical Pathology (ASCCP) algorithms. Providers should specify the high-risk HPV DNA panel. Reimbursement for low-risk HPV DNA panel and HPV genotyping is not permitted.

Reimbursement of Other Services:

- NC BCCCP funds may not be used to pay for any cervical diagnostic or treatment services not included on the NC BCCCP services fee schedule (e.g., LEEP, conization, etc.) unless prior authorization is obtained.
- NC BCCCP funds may not be used to reimburse for a repeat Pap test which is performed simultaneously with colposcopy or colposcopy with biopsy, unless more than four months have passed since the initial Pap test was performed.

Divider – Appendix D

Procedure for Referral, Evaluation, Treatment (Colposcopy Providers)

List of Qualified Health Care Providers (QHCP)

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.

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).

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. Once you obtain results, complete the "Cancer Screening Follow-up Report" (DHHS Form 1011).

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 assist in facilitating transportation if necessary.

Partial List of Qualified Health Care Providers

Provider	Sub-Contractor	Phone
Anson Co HD	Pinehurst Women's Clinic- Dr. J. Puleo 70 Memorial Dr., Pinehurst, NC	910-295-4342
Beaufort Co HD	Washington Women's Care 1204 Brown St, Washington, NC	252-946-6455
	Obstetrics and Gynecology of Washington 1210 Brown St., Washington, NC	252-946-6544
Albemarle Health Serv.	Carolina Surgical Associates	
Carteret Co. HD	Carteret Surgical Assoc. PA 3714 Guardian Ave., Morehead City, NC	252-247-2101
	Darryl C. Falls, MD 1508 Arendell St., Morehead, City, NC	252-726-7374
	Carteret OB/GYN Assoc. 3511 John Platt Dr., Morehead City, NC	252-247-4297
	Carteret Women's Health Ctr. 302 Penny Ln., Morehead City, NC	252-726-8016
	Way Surgical Associates, PA 210 Penny Ln. Morehead City, NC	252-247-4769
Craven Co HD	Eastern Carolina Women's Center 801 McCarthy Blvd, New Bern, NC	252-633-3942
	Leo Jenkins Cancer Center 600 Moye Blvd, Greenville, NC	252-744-1888
Goshen Medical Center	Duplin General Hospital 401 N. Main St., Kenansville, NC	910-296-0941

Provider	Sub-Contractor	Phone
	Sampson Regional Medical Center 606 Beaman St., Clinton, NC	910-592-8511
	Wayne Memorial Hospital 2700 Wayne Memorial Drive, Goldsboro	910-736-1110
Granville-Vance District	Center for Women's Health	
Hertford County Public Health Authority	Premier Women's Health Professionals Women's Care of Ahoskie 606 S Academy St., Ahoskie, NC	252-209-3614
	Roanoke Chowan Women's Center 214 E. Church St., Ahoskie, NC	252-332-6111
	ECU Physicians* 2160 Herbert Court, Greenville, NC	252-744-3850
Lincoln County HD	Lincoln Center for Women's Health* 1460 E. Gaston St., Lincolnton, NC	704-735-2134
	Lincoln OB-GYN* 275 Highway 16 N, Denver, NC	704-732-3346
Mecklenburg County HD	Carolinas Medical Center Myers Park & Health Department	
MTW District	Leo Jenkins Cancer Center 600 Moye Blvd, Greenville, NC	252-744-1888
	Tarheel Surgical 310 S McCaskey Rd., Williamston, NC	252-799-3006
Northampton	Women's Health Specialties	
	Halifax Pathology	
	Smith Church OB/GYN 244 Smith Church Rd., Roanoke Rapids	252-535-4343

Provider	Sub-Contractor	Phone
Rural Health Group	Women's Health Specialist	
Stanly County HD	Carolinas Women's Health Center 929 N. 2nd St # 201, Albemarle, NC	704-985-1799
	All are providing clinical services under BCCCP guidelines.	

Divider – Appendix E

Works Cited

1. American Cancer Society, "Estimated Number of New Cancer Cases and Deaths by Sex, US, 2013.". American Cancer Society, 2013 Web. 20 Jun 2013. <http://www.cancer.org/acs/groups/content/@epidemiologysurveilance/documents/document/acspc-037124.pdf>.
2. ACOG Practice Bulletin. Screening for cervical cancer. *Obstetrics & Gynecology 120*(5), 1222-1233.
3. ASCCP, *Updated Consensus Guidelines for Managing Abnormal Cervical Cancer Screening Tests and Cancer Precursors*. American Society for Colposcopy and Cervical Pathology, 21 March 2013. Web. 17 Jul 2013. <http://www.asccp.org/Portals/9/docs/ASCCP Updated Guidelines Algorithms 6.3.13.pdf>.
4. CDC. "Genital HPV Infection - Fact Sheet." *Sexually Transmitted Diseases (STDs)*. Centers for Disease Control and Prevention, 18 Mar 2013. Web. 17 Jul 2013. <http://www.cdc.gov/std/HPV/STDFact-HPV.htm>..
5. Code of Federal Regulations, Title 42 – Public Health, Part 493 Laboratory Requirements, Subpart K—Quality System for Nonwaived Testing, Section 1241 Standard: Test Request. http://www.gpo.gov/fdsys/pkg/CFR-2003-title42-vol3/xml/CFR-2003-title42-vol3-part493.xml#seqnum493.1241
6. *Improving the Quality of Clinician Pap Smear Technique and Management, Client Pap Smear Education, and Evaluation of Pap Smear Laboratory Testing: Resource Guide for Title X Family Planning Projects.* September 2003. U.S. Department of Health and Human Services.
7. Massad, L.S., Einstein, M.H., Huh, W.K., Katki, H.A., Kinney, W.K., et al (2013). 2012 Updated consensus guidelines for the management of abnormal cervical cancer screening tests and cancer precursors. *Journal of Lower Genital Tract Disease, 17*(5), S1-S27.
8. National Breast and Cervical Cancer Early Detection Program. *NBCCEDP Program Guidance Manual*. Book 2. October 2012. Pages 10-12.
9. Saslow, D., Solomon, D., Lawson, H.W., Killackey, M., Kulasingam, S.L et al. (2012). 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. *Journal of Lower Genital Tract Disease, 16*(3),
10. *Screening for Cervical Cancer*, Topic Page. April 2012. U.S. Preventive Services Task Force. http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm
11. State Center for Health Statistics. *Cancer Mortality Rates by Sex*. 12 Feb 2013. Web. <http://www.schs.state.nc.us/schs/CCR/mort2011s.pdf>

12. CDC. "Genital HPV Infection - Fact Sheet." *Sexually Transmitted Diseases (STDs)*. Centers for Disease Control and Prevention, 18 Mar 2013. Web. 17 Jul 2013. <http://www.cdc.gov/std/HPV/STDFact-HPV.htm>..
13. Zimmerman, Scott J. Ph.D., Director of the State Laboratory of Public Health. "Memo."29 Jun 2013.

Divider – Appendix F

Breast and Cervical Cancer Medicaid (BCCM)

NORTH CAROLINA BREAST AND CERVICAL CANCER CONTROL PROGRAM

NCBCCCP

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

Women must FIRST be eligible for NCBCCCP

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.
- Patients must be referred to the local NCBCCCP prior to diagnosis to be eligible for Breast and Cervical Cancer Medicaid.

There are several ways you can enroll an eligible patient in NCBCCCP by-

1. *PREFERRED METHOD:* Refer patient to local NCBCCCP for screening as soon as she presents with or without complaints.
2. Refer patient to local NCBCCCP when there is an abnormal screening or diagnostic test result, but **before** cancer is diagnosed.
3. Provide preliminary screening test (CBE, screening and/or diagnostic mammogram, Pap test, colposcopy, etc.) with referral.

Final diagnostic testing will be done through NCBCCCP with NCBCCCP funds.

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

For more information, contact the North Carolina Breast and Cervical Cancer Program (NCBCCCP) 919-707-5300

North Carolina Cancer Prevention and Control Branch

Rev. 2013-08-28

Divider – Appendix G

Cervical Screening Manual Evaluation Form

We appreciate your comments or suggestions about this manual. Your suggestions will help us continue to make the Pap Screening Manual as useful as possible.

Complete and fax to Professional Development, NC Breast and Cervical Cancer Control Program, (919) 870-4812.

Date: _____

Name: _____

Organization: _____

1. How much of this manual did you read?

   ☐ All of it ☐ Most of it ☐ Only a little of it

2. How useful was this manual in developing your cervical screening policies?

3. Please circle the number that indicates how useful each section of the manual was:

Low			**High**	
1	2	3	4	**Introductory pages and table of contents**
1	2	3	4	**Section. 1** – Patient Management and Follow Up of Cervical Cytology Results
1	2	3	4	**Section 1** - Algorithms
1	2	3	4	**Section 2** – Procedure for Obtaining a Pap Test
1	2	3	4	**Section 3** – Cancer Screening Follow Up DHHS Form 1011
1	2	3	4	**Section 4** – Quality Assurance Recommendations
1	2	3	4	**Appendix A** – State Lab Bethesda Reporting System
1	2	3	4	**Appendix B** – Critical Value Notification
1	2	3	4	**Appendix C** – NC BCCCP Cervical Cancer Screening Policies
1	2	3	4	**Appendix D** – Qualified Health Care Providers for Evaluation and Treatment of Dysplasia
1	2	3	4	**Appendix E** – References and Resources

4. For your background and experience, please tell us if you thought this manual was:

   ☐ Too difficult ☐ Too basic ☐ Just right

5. How can this manual be improved?

6. Do you have suggestions for other program manuals?

7. Do you have any other comments you would like to share?