



MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

March 25, 2019

Maryland Breast & Cervical
Cancer Program Medical
Advisory Committee

Cervical Cancer Subcommittee

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Dear Maryland Breast and Cervical Cancer Program Provider:

Thank you for providing cervical cancer screening for uninsured or underinsured women aged 40 – 64 enrolled in the Maryland Breast and Cervical Cancer Program (BCCP). The Maryland BCCP is a grantee of the National Breast and Cervical Cancer Early Detection Program, funded by the Centers for Disease Control and Prevention (CDC). The policies of the national program are based on evidence in scientific literature and recommendations from national organizations such as the American Society for Colposcopy and Cervical Pathology (ASCCP), United States Preventive Services Task Force (USPSTF) and the American Cancer Society (ACS).

In October 2018, The Centers for Disease Control and Prevention (CDC) allowed Primary (high-risk) hrHPV screening every 5 years for women 30-64 years as a reimbursable procedure in the Breast and Cervical Cancer Program. In addition, to align and leverage cervical cancer screening funds awarded to the state of Maryland, age eligibility for cervical cancer screening in the program has been expanded to include women 21-39 years old.

We are pleased to enclose the revised “Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis” developed by the Medical Advisory Committee for the BCCP to serve as guidelines for the screening and management of women receiving cervical cancer screening through the Breast and Cervical Cancer Program. Included in the MCEs is the recommended Primary hrHPV screening algorithm as a guide for follow-up to an abnormal primary hrHPV screening exam as printed in the Journal of Lower Genital Tract Disease, volume 19, number 2, April 2015.

We appreciate your cooperation in using the new guidelines. If you have any questions regarding the new “Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis” for the Maryland BCCP, please contact Ken Lin Tai, M.D., M.P.H., Medical Director for the Center for Cancer Prevention and Control (CCPC) at 410-767-2036 or kenlin.tai@maryland.gov.

Sincerely,

Stanley Watkins, M.D.
Chairman, Medical Advisory Committee

Maryland Breast and Cervical Cancer Program

Enclosure

Cc: Ken Lin Tai, MD, MPH

Teresa Small, RN, BS

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JoAnn Johnston, RN, BSN

Local BCC Program Coordinators

Maryland Department of Health, Center for Cancer Prevention and Control
Maryland Breast and Cervical Cancer Program
Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
February 2016, Updated March 2019

Goal: The goal of the Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis is to provide clients of the Maryland Breast and Cervical Cancer Program (BCCP) with optimal, up-to-date screening for cervical cancer and management of findings.

Objective: To provide clinical guidelines for cervical cancer screening and diagnostic testing including the management of abnormal results.

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- Management of Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2 and 3 (CIN2,3)
- Management of Young Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2,3 (CIN2,3) in Special Circumstances
- Management of Women Diagnosed with Adenocarcinoma in-situ (AIS) during a Diagnostic Excisional Procedure
- Interim Guidance for Managing Reports using the Lower Anogenital Squamous Terminology (LAST) Histopathology Diagnosis

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Detection of Cervical Cytologic Abnormalities

I. Screening Interval

Population	Recommendation
Women ages 21-29	Screen with cytology alone every 3 years
Women ages 30-64	Screen with cytology alone every 3 years; or Co-testing with cytology and (high-risk) hrHPV every 5 years; or hrHPV alone every 5 years
Women older than 65 who have had adequate prior screening and are not high-risk	Do not screen if adequate prior screening. (See Section II, Program Guidelines #5, page 4)
Women after hysterectomy with removal of the cervix and with no history of a high-grade precancerous lesion (CIN 2 or 3) or cervical cancer	Do not screen women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.
Women after hysterectomy with removal of the cervix and with history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer	Women who have who have a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3), should undergo routine cervical cancer screening for 20 years even if it goes past the age of 65. Women who have had cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.

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II. Program Guidelines

1. Program eligibility for the Maryland Breast and Cervical Cancer Program:
 - a. Women 21-64 years of age without Medicare Part B **and** women 65 years of age and over (without Medicare Part B) who have not had adequate screening as described in #5 below; **AND**
 - b. Either:
 - i. Has an intact cervix (no hysterectomy or supracervical hysterectomy); **OR**
 - ii. Has had a hysterectomy with a history of cervical cancer, high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3), or for an indication and/or history unknown to the woman.
2. Vaginal Pap tests may be performed **only** on women who have had a hysterectomy with a history of cervical cancer or a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3).
 - a. For other indications (symptoms or vaginal lesion), refer the woman to another program for evaluation.
 - b. Women who have had a hysterectomy and a history of a high-grade precancerous lesion (i.e., cervical intraepithelial neoplasia [CIN] grade 2 or 3) should undergo routine cervical cancer screening for 20 years, even if screening extends beyond the age of 65.
 - c. Women who have had a hysterectomy and a history of cervical cancer should undergo annual cervical cancer screening indefinitely as long as they are in reasonable health.
 - d. If the woman had a hysterectomy and her cervical cancer screening history cannot be documented, she should continue routine screening.
3. The screening interval for average risk women:
 - a. Cytology alone every 3 years **OR**
 - b. Co-testing with cytology and hrHPV every 5 years; **OR**
 - c. Primary hrHPV alone every 5 years.
4. Women who are considered high-risk may need more intensive (i.e. annual) screening. This pertains to women who:
 - a. Were exposed in utero to diethylstilbestrol (DES);
 - b. Are immunocompromised;
 - c. Are HIV-infected; or
 - d. Have a history of cervical cancer (with or without a cervix).
5. Women age 65+ who have had adequate prior cervical cancer screening and are not otherwise at high-risk for cervical cancer should not be tested. (Adequate prior screening is defined as 3 consecutive negative cytology results or 2 consecutive negative HPV results within 10 years before cessation of screening, with the most recent test occurring within 5 years.)

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6. High-risk (hr)HPV Testing
 - a. Testing for the *hrHPV panel*¹ is reimbursable as a screening test in the Maryland Breast and Cervical Cancer Program (BCCP) if used alone every 5 years or when co-testing with cytology every 5 years.
 - b. Testing for the *hrHPV panel* is reimbursable if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology.
 - c. Testing for *HPV genotyping*² (e.g. HPV 16/18) is reimbursable in the Maryland BCCP, if performed as guided by the ASCCP Flow Sheets in the management of abnormal cytology/histology.
 - d. Testing for low-risk HPV types is **not** reimbursable in the Maryland BCCP.

7. If a patient has a history of cervical cancer *without* hysterectomy (e.g., radiation, implant, conization)
 - a. If the woman is being released from gynecologic oncologist to routine screening (e.g., after 5 years of follow-up post diagnosis), obtain and review medical history of Pap test results to know what will be expected on the Pap tests in the BCCP (e.g., endocervical cells or not).
 - b. If the woman has no medical records, refer first (before testing in the BCCP) to a gynecologic oncologist for consultation on appropriate Pap testing and test result interpretation.

8. Follow ASCCP Flow Sheets (Attachment A) based on Cytologic and Histologic findings.

9. Only procedures recommended in the ASCCP Flow Sheets based on the Cytologic or Histologic findings will be paid. Additional or alternative procedures are usually not paid for by the BCCP. Providers should consult with the local BCCP program about coverage for payment of procedures before proceeding with further procedures.

10. Special Situations:
 - a. Screening recommendations should be evaluated for women who have comorbidities that would make the harms of screening outweigh the benefits (i.e., diagnosed cancer for which she is being treated, significant cardiovascular disease, etc...)
 - b. Routine screening options are recommended for average-risk women. Women at high-risk may benefit from one screening option versus another.
 - c. Women who are pregnant or who still desire pregnancy should have additional consultation beyond these guidelines.

¹ The high-risk (oncogenic) HPV panel includes types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 without differentiation of the individual type.

² Genotyping detects the presence or absence of specific high-risk HPV types (e.g. 16 and 18) only.

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III. Cervical Specimen Collection and Cytology Findings

1. Specimen Collection
 - a. Collection of conventional Pap smear
 - i. A sample of the ectocervix is collected with a spatula rotating 360 degrees at least once around the cervix.
 - ii. A sample of the endocervix is collected preferably with a cytobrush rotating at least 90 degrees.
 - iii. If no cervix present, a sample of the vaginal cuff only is collected (see BCCP Program Guidelines #1 b, ii and #2 a, b, c, & d above).
 - b. Collection of liquid-based cervical cytology
 - i. A gynecologic sample is collected using a broom-type or cytobrush/spatula cervical sampling device and then rinsed into the collection medium following directions of the manufacturer.
2. Specimen Adequacy
 - a. Satisfactory for evaluation (note presence or absence of endocervical/transformation zone component).
 - b. Unsatisfactory for evaluation because of... (specify reason).
 - i. Specimen rejected/not processed (specify reason).
 - ii. Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (specify reason).
3. Results
 - a. Negative for Intraepithelial Lesion or Malignancy (reporting non-neoplastic findings is optional)
 - b. Epithelial Cell Abnormalities
 - i. Squamous Cell
 - ASC-US (atypical squamous cells of undetermined significance).
 - ASC-H (atypical squamous cells-cannot exclude high grade squamous intraepithelial lesion [HSIL]).
 - LSIL (low grade squamous intraepithelial lesion—includes Human Papilloma Virus [HPV]/ mild dysplasia/CIN 1).
 - HSIL (high grade squamous intraepithelial lesion—includes mod. and severe dysplasia, CIS; CIN-2 & CIN-3).
 - Squamous cell carcinoma
 - ii. Glandular Cell
 - Atypical glandular cells (AGC) specify endocervical, endometrial, or not otherwise specified (NOS).
 - Atypical glandular cells, favor neoplastic (specify endocervical, or NOS).
 - Endocervical adenocarcinoma in situ (AIS).
 - Adenocarcinoma (all types).
 - c. Other
 - i. Endometrial cells (in women > 40 years of age).
 - ii. Other Malignant Neoplasms (specify).

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References:

- Solomon D, Davey D, Kurman, R, et al. for the Forum Group Members and the Bethesda 2001 Workshop. The 2001 Bethesda System: Terminology for Reporting Results of Cervical Cytology. *JAMA*. 2002;287: 2114-9.
- Saslow, D, Solomon, D, Lawson, HW, et al. “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” *Am J Clin Pathol* 2012;137:516-542.
- *JAMA*, 2018;320(7):674-686.doi:10.1001/jama.2018.10897

Cervical Cancer Medical Advisory Committee:

The following members participated in the formulation of the Minimal Clinical Elements:

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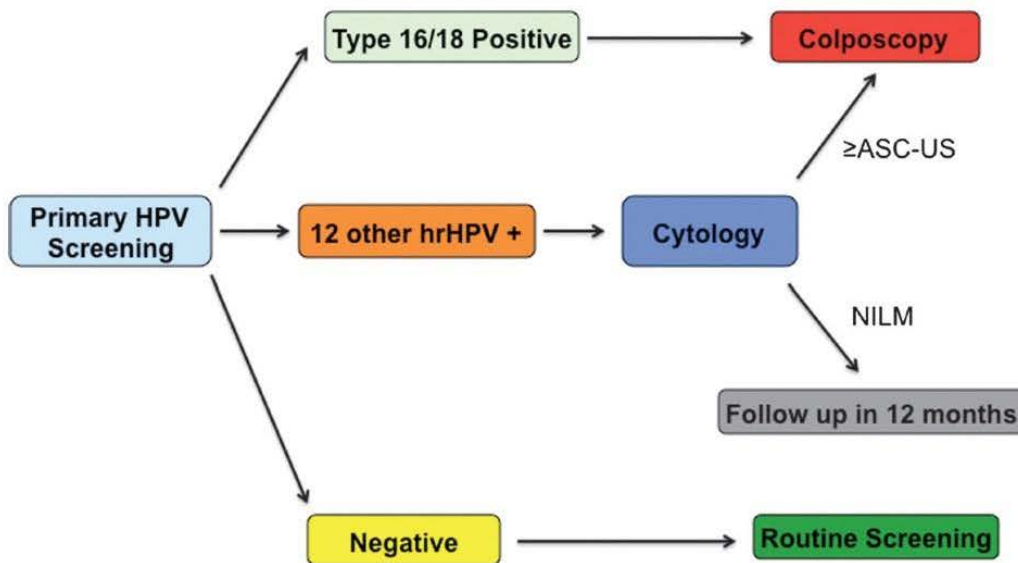
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Attachment A

Management of Primary hrHPV Testing

Reprinted from *JAMA*. 2018;320(7):706-714. doi:10.1001/jama.2017.19872 © 2018 American Medical Association



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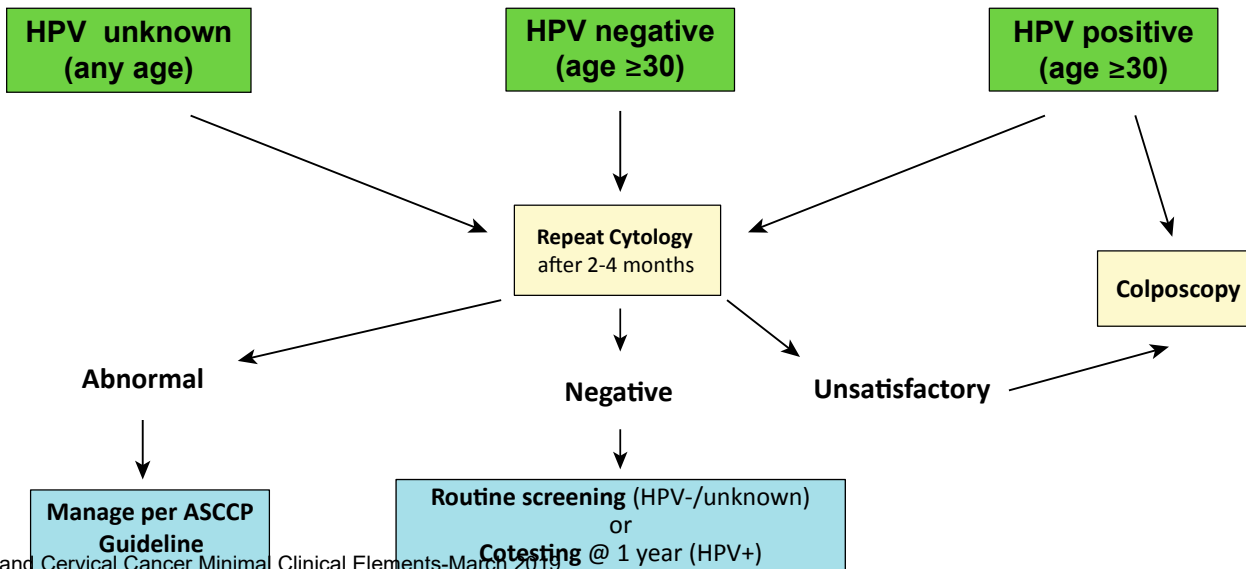
Management of Cervical Cytologic Abnormalities:
ASCCP Flow Charts

Attachment B:

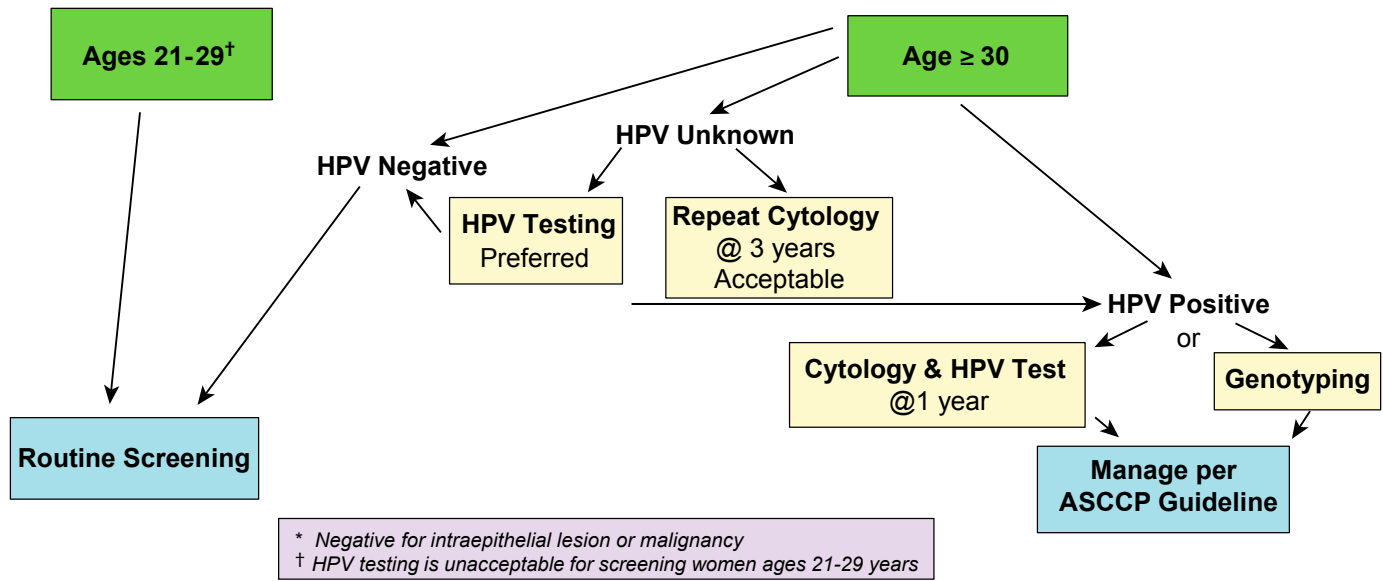
Reprinted from *The Journal of Lower Genital Tract Disease* Volume 17, Number 5, with the permission of ASCCP ©American Society for Colposcopy and Cervical Pathology 2013. No copies of the algorithms may be made without the prior consent of ASCCP.

The entire set of ASCCP Flow Charts are available at <http://www.asccp.org/consensus.shtml>

Unsatisfactory Cytology

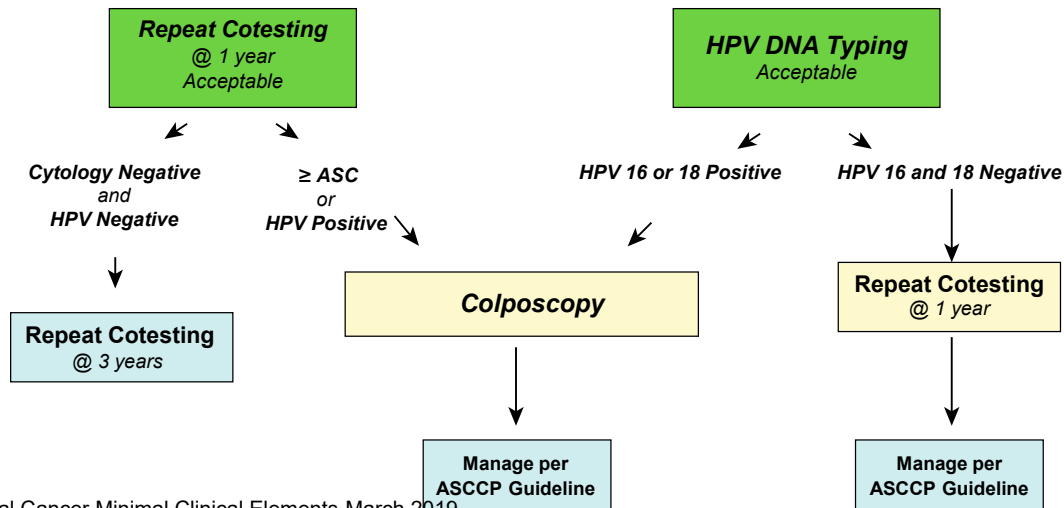


Cytology NILM* but EC/TZ Absent/Insufficient

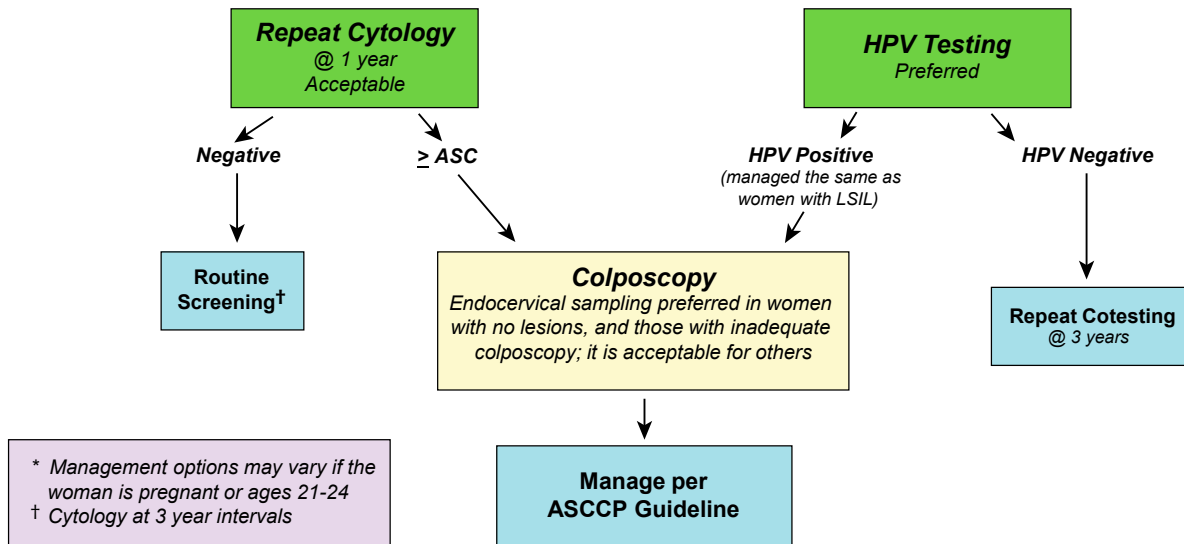


* Negative for intraepithelial lesion or malignancy
 † HPV testing is unacceptable for screening women ages 21-29 years

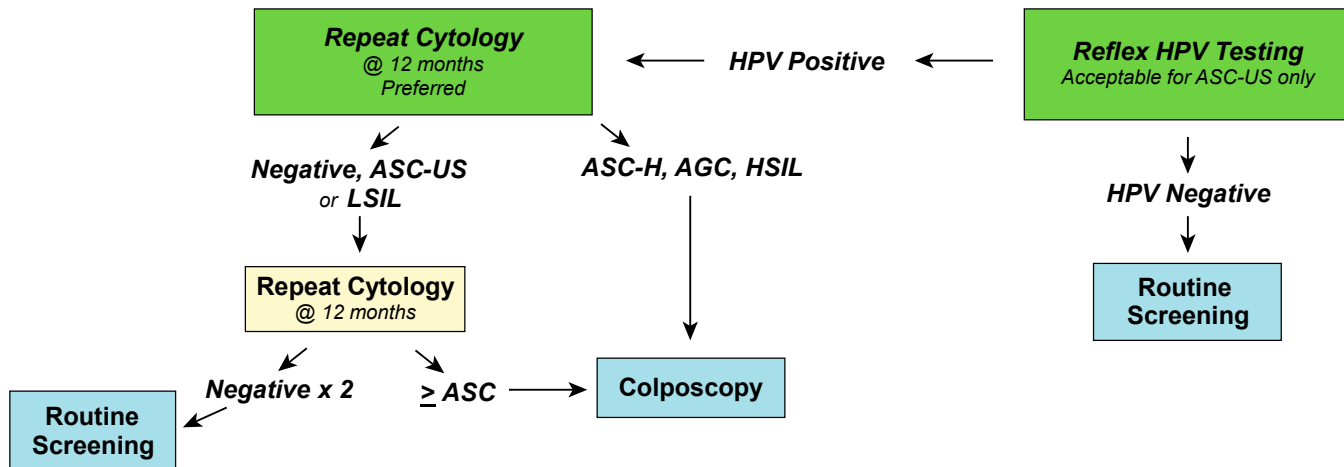
Management of Women \geq Age 30, who are Cytology Negative, but HPV Positive



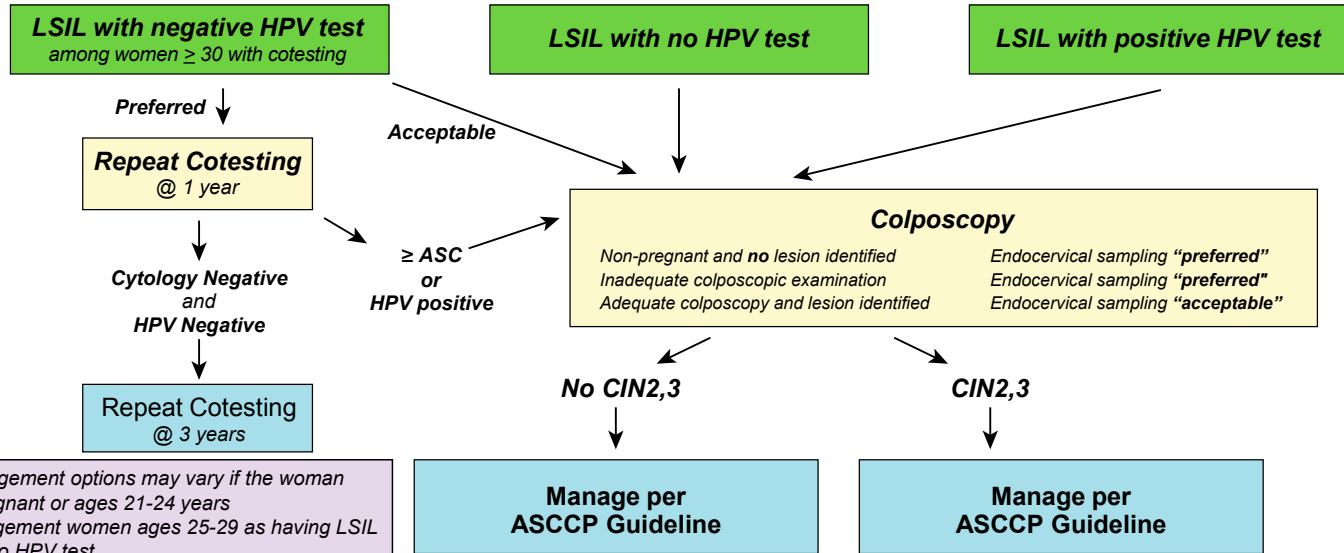
Management of Women with Atypical Squamous Cells of Undetermined Significance (ASC-US) on Cytology*



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



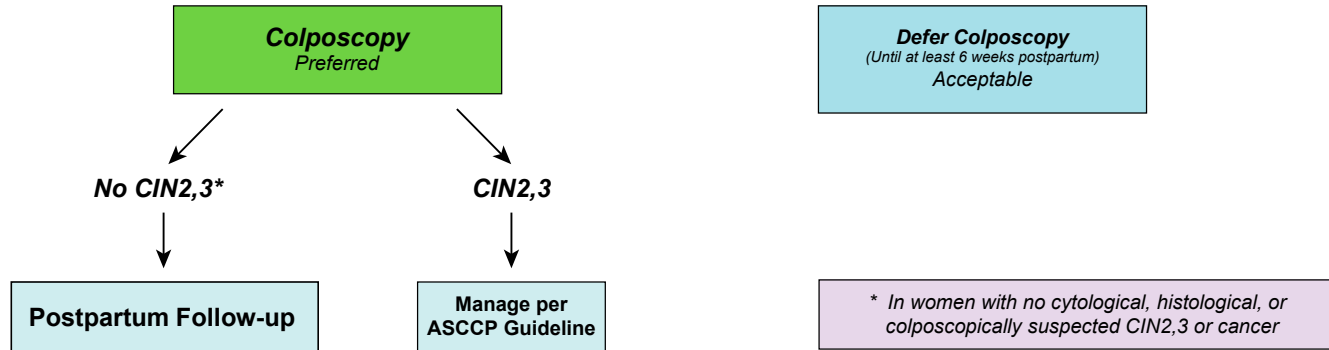
Management of Women with Low-grade Squamous Intraepithelial Lesions (LSIL)*†



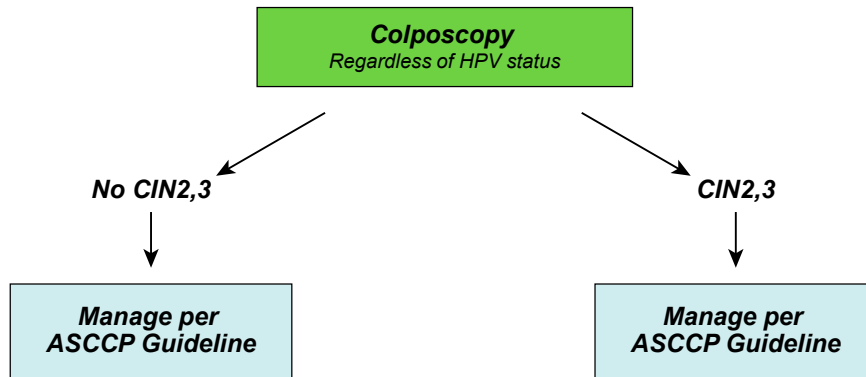
* Management options may vary if the woman is pregnant or ages 21-24 years

† Management women ages 25-29 as having LSIL with no HPV test

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

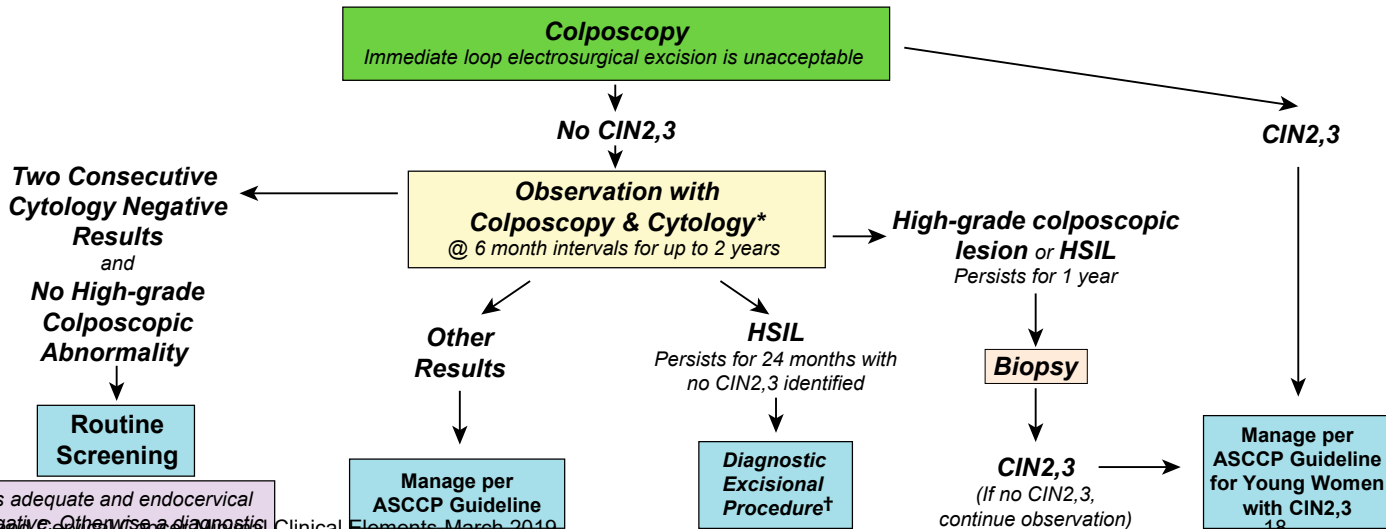


Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)*



** Management options may vary if the woman is ages 21-24*

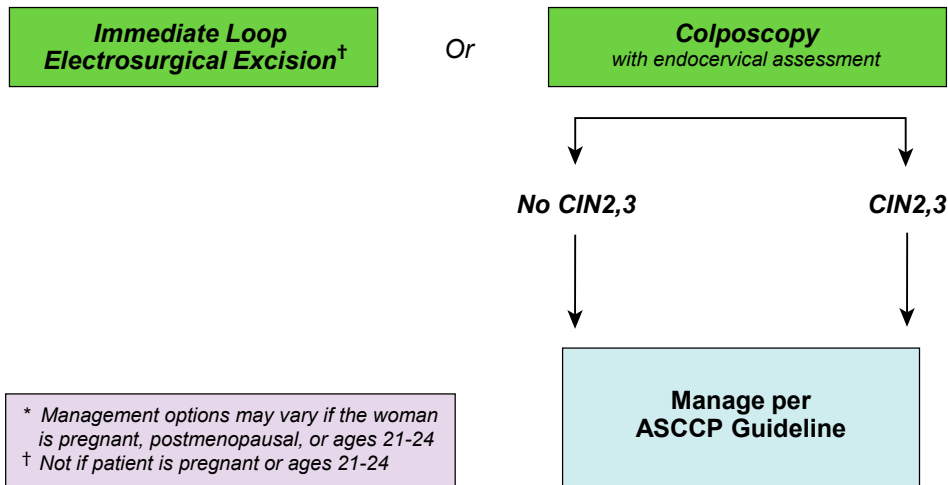
Management of Women Ages 21-24 yrs with Atypical Squamous Cells, Cannot Rule Out High Grade SIL (ASC-H) and High-grade Squamous Intraepithelial Lesion (HSIL)



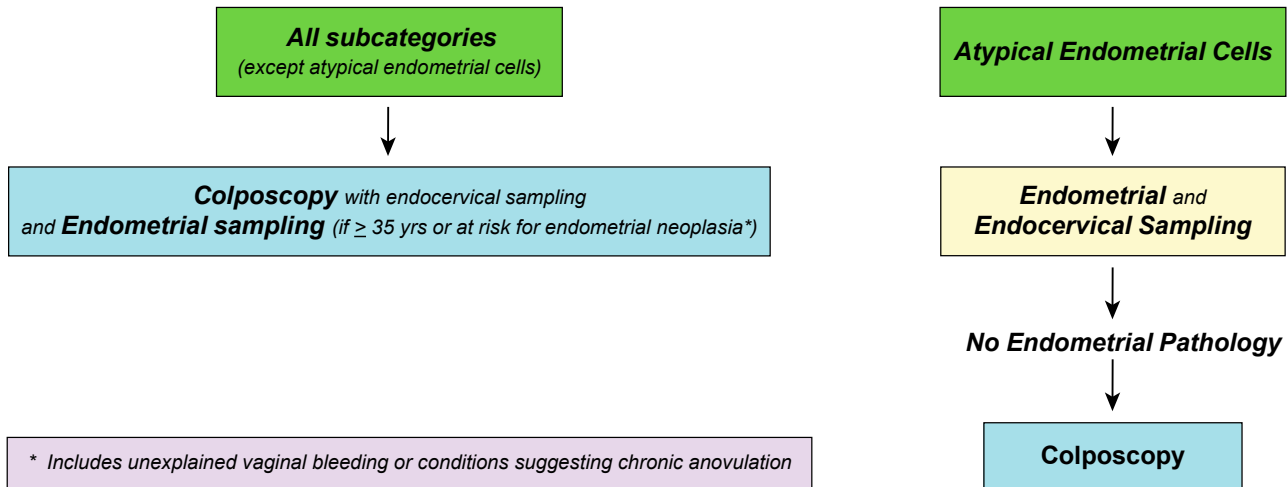
* If colposcopy is adequate and endocervical sampling is negative. Otherwise a diagnostic excisional procedure is indicated.

† Not if patient is pregnant

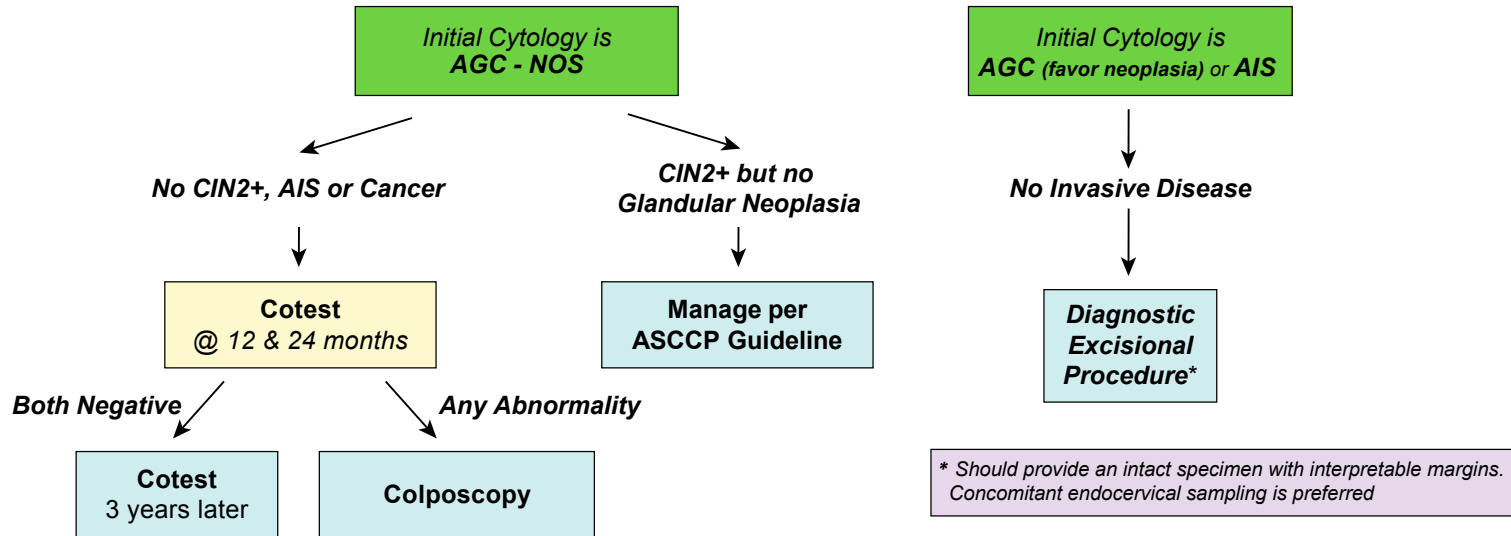
Management of Women with High-grade Squamous Intraepithelial Lesions (HSIL)*



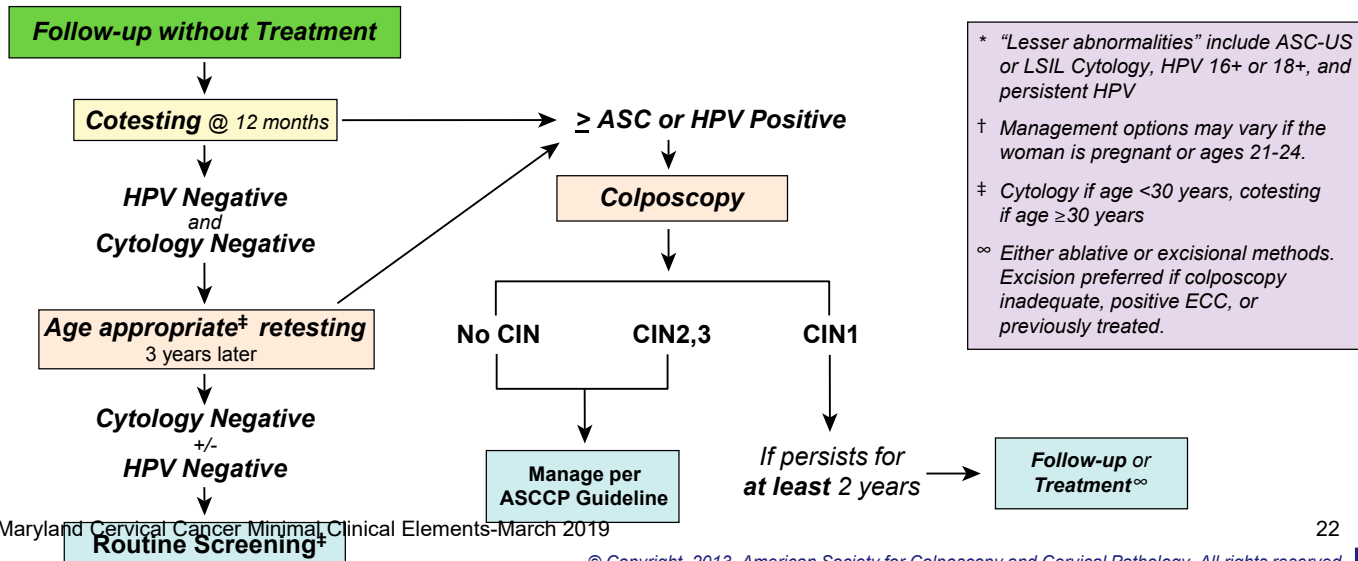
Initial Workup of Women with Atypical Glandular Cells (AGC)



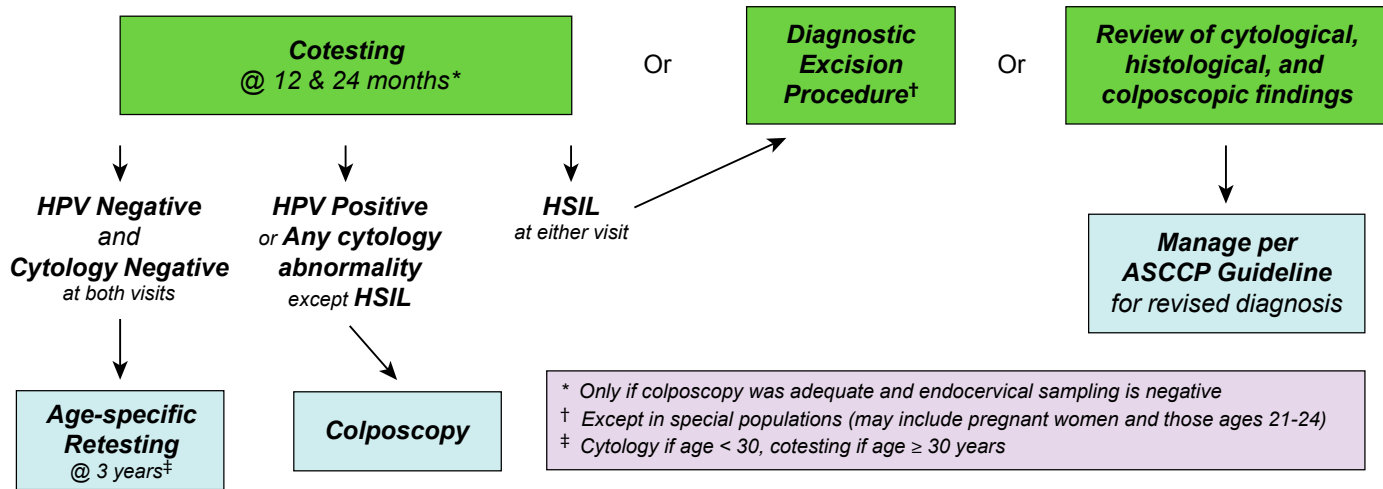
Subsequent Management of Women with Atypical Glandular Cells (AGC)



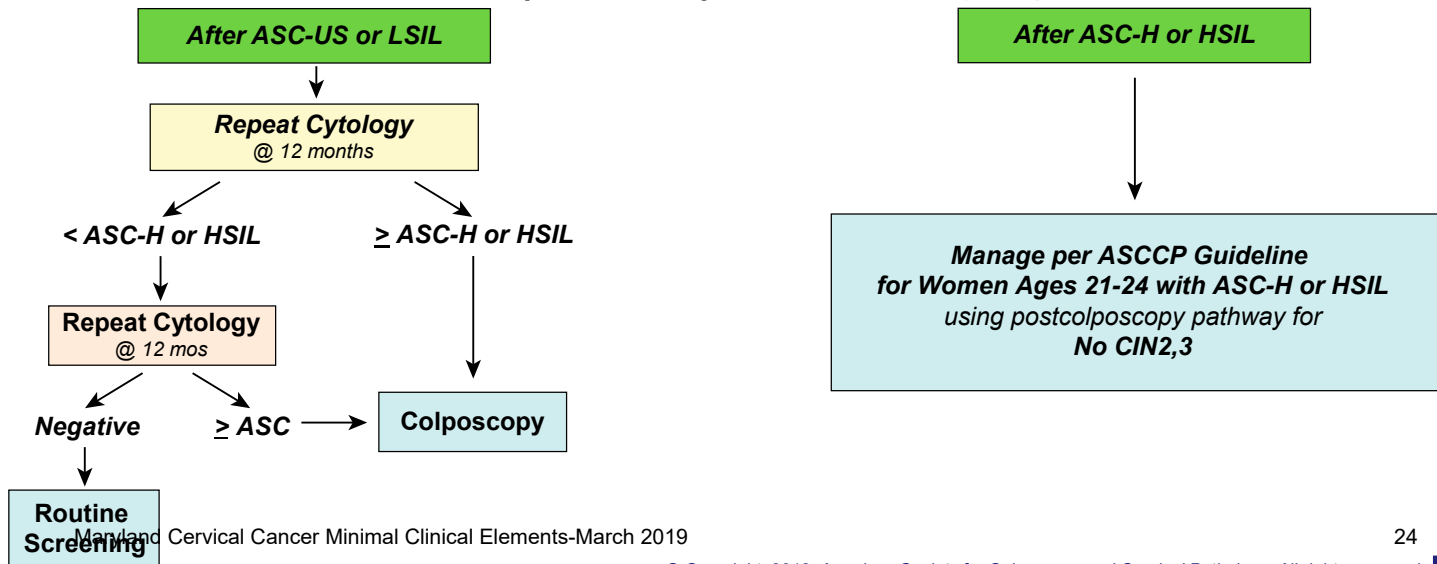
Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by “Lesser Abnormalities” *†



Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by ASC-H or HSIL Cytology



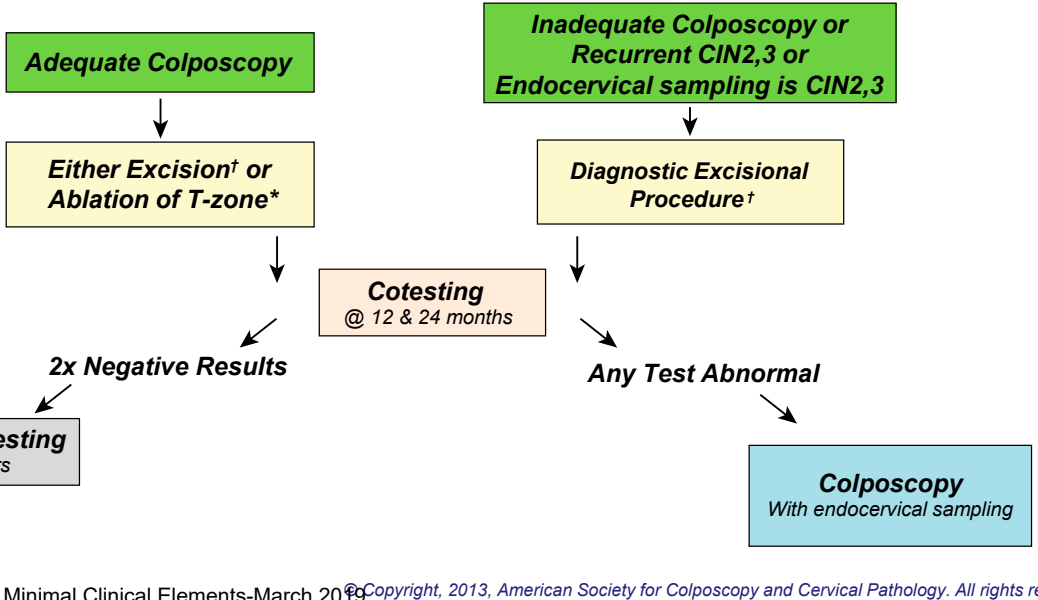
Management of Women Ages 21-24 with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1)



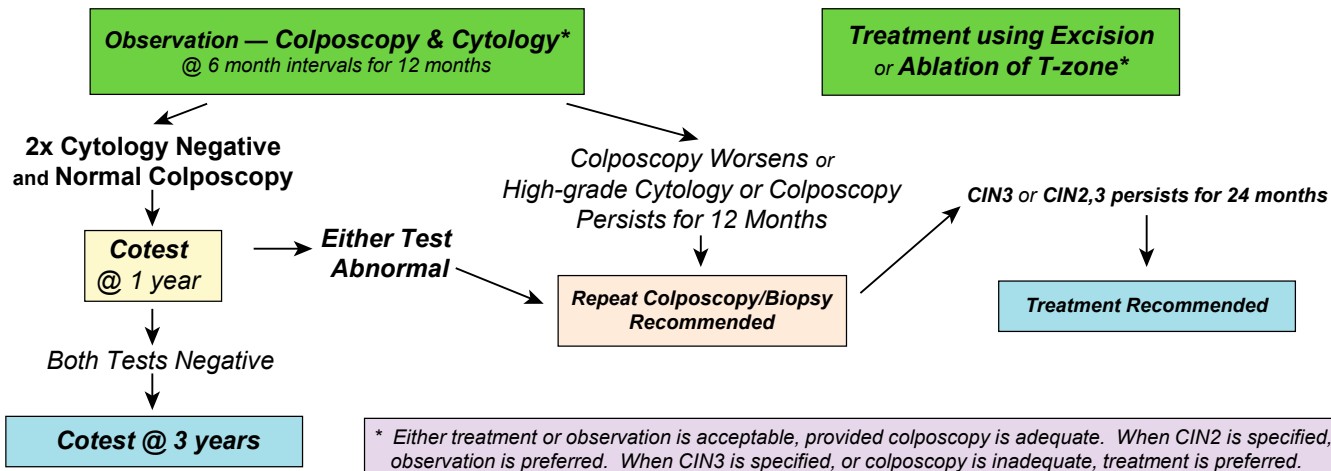
Management of Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2 and 3 (CIN2,3)*

* Management options will vary in special circumstances or if the woman is pregnant or ages 21-24

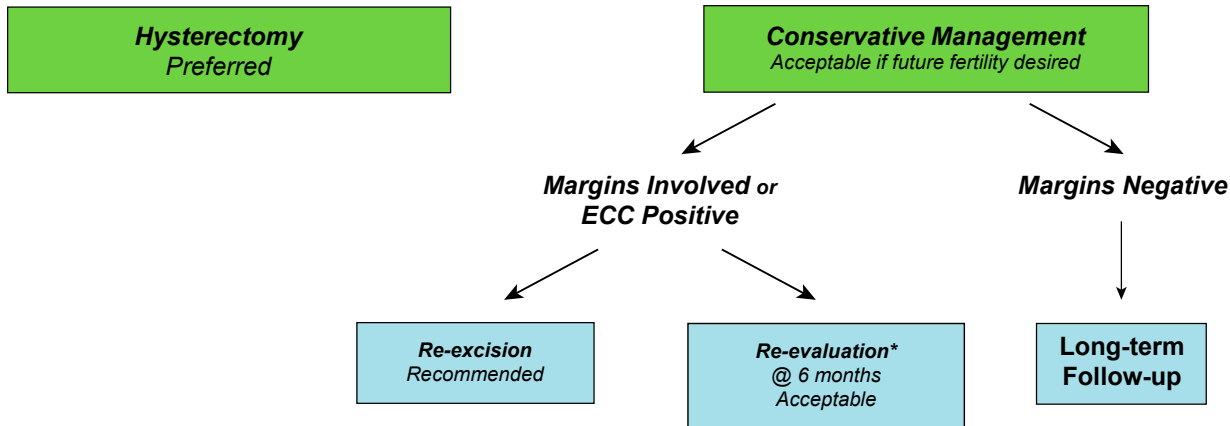
† If CIN2,3 is identified at the margins of an excisional procedure or post-procedure ECC, cytology and ECC at 4-6mo is preferred, but repeat excision is acceptable and hysterectomy is acceptable if re-excision is not feasible.



Management of Young Women with Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 2,3 (CIN2,3) in Special Circumstances*



Management of Women Diagnosed with Adenocarcinoma in-situ (AIS) during a Diagnostic Excisional Procedure



* Using a combination of cotesting and colposcopy with endocervical sampling

Interim Guidance for Managing Reports using the Lower Anogenital Squamous Terminology (LAST) Histopathology Diagnoses

