February 23, 2016

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 January 2016, CDC added HPV genotyping as an allowable procedure in the Breast and Cervical Cancer Program if performed as guided by the ASCCP Flow Sheets. The Medical Advisory Committee revised the Minimal Clinical Elements based on the updated guidance.

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. Also enclosed are Selected ASCCP Consensus Guidelines on the Management of Women with Abnormal Cervical Cancer Screening Tests and Cancer Precursors © 2013 relevant to the Maryland Breast and Cervical Cancer Program.

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: Courtney Lewis, MPH. Dawn Henninger, RN, MS Local Program Coordinators
    Ken Lin Tai, MD, MPH Holly Harshbarger, RN, BS
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Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Prevention and Control
February 2016

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.

Objectives:
- To assist local BCCPs in evaluating cervical cytology screening interval, results and recommended management.
- To incorporate into the Minimal Clinical Elements the 2012 USPSTF Recommendations for Screening for Cervical Cancer.
- To assure the Minimal Clinical Elements remain in line with the 2001 Bethesda System Terminology for Reporting Results of Cervical Cytology.
- To inform clinicians of these guidelines.

Attachment A: Detection of Cervical Cytologic Abnormalities in the BCCP
- Attachment A1: Screening Interval
- Attachment A2: Program Guidelines
- Attachment A3: Cervical Specimen Collection and Cytology Findings Reported (2001 Bethesda System)

Attachment B: Management of Cervical Cytologic Abnormalities in the BCCP

References:
4. Thomas C. Wright Jr, MD, L. Stewart Massad, MD, Charles J. Dunton, MD, Mark Spitzer, MD, Edward J. Wilkinson, MD, Diane Solomon, MD for the 2006 American Society for


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### Attachment A1

#### Screening Interval

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women ages 40-64</td>
<td>Screen with cytology alone every 3 years or Co-testing with cytology and HPV every 5 years</td>
</tr>
<tr>
<td>Women older than 65 who have had adequate prior screening and are not high risk</td>
<td>Do not screen if adequate prior screening. (See Attachment A2 Program Guidelines #5)</td>
</tr>
<tr>
<td>Women after hysterectomy with removal of the cervix and with history of a high-grade precancerous lesion (CIN 2 or 3) or cervical cancer</td>
<td>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.</td>
</tr>
<tr>
<td>Women after hysterectomy with removal of the cervix and with history of a high-grade precancerous lesion (CIN 2 or 3) or cervical cancer</td>
<td>Women who have had a hysterectomy for CIN disease should undergo cervical cancer screening with cytology alone every three years or co-testing with cytology and HPV every 5 years 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.</td>
</tr>
</tbody>
</table>
1. Program eligibility for the Maryland Breast and Cervical Cancer Program
   a. Women 40 – 64 years old or 65+ without Medicare Part B;
   b. Meets income eligibility of \( \leq 250\% \) of the Federal Poverty Guideline;
   c. Has no health insurance, has no health insurance that covers cervical cancer screening, or has coverage but has not met the deductible for the year; and
   d. Either:
      i. Has an intact cervix (no hysterectomy or supracervical hysterectomy); or
      ii. Has had a hysterectomy for cervical cancer, for CIN 2/3, or for an indication unknown to the woman.

2. Vaginal Pap tests may be performed **only** on women who required a hysterectomy due to cervical cancer or CIN 2/3.
   a. For other indications (symptoms or vaginal lesion), refer the woman to another program for Pap testing or evaluation.
   b. Women who have had a hysterectomy for CIN 2/3 disease should undergo cervical cancer screening every 3 years with cytology alone or co-testing with cytology and HPV every 5 years for 20 years even if screening extends beyond the age of 65.
   c. Women who have had a hysterectomy due to cervical cancer should continue annual screening indefinitely as long as they are in reasonable health.
   d. If the reason for the hysterectomy cannot be documented, she should continue routine screening with Pap testing every 3 years or co-testing every 5 years.

3. The screening interval for average risk women—
   a. Cytology alone every 3 years **OR**
   b. Co-testing with cytology and HPV 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; or
   c. Are HIV-infected.

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.)

6. HPV DNA Testing
   a. Testing for the high-risk HPV panel\(^1\) is reimbursable as a screening test in the Maryland Breast and Cervical Cancer Program (BCCP) if used when co-testing with cytology every 5 years.
   b. Testing for the high-risk HPV 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 Flows titled “Cytology NILM but EC/TZ Absent/Insufficient” and “Management of Women ≥ Age 30, who are Cytology Negative, but HPV Positive”.
   d. Testing for low-risk HPV types is not reimbursable in the Maryland BCCP.

7. If the Pap test is read as “unsatisfactory for evaluation,” Follow the ASCCP algorithm titled "Unsatisfactory Cytology"

8. If the Pap test is read as “Normal. Satisfactory for evaluation; no endocervical cells present,” Follow the ASCCP algorithm titled "Cytology NILM but EC/TZ Absent/Insufficient"

9. 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.

10. Follow ASCCP Flow Sheets (Attachment B) based on Cytologic and Histologic findings.

11. 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. Consultation with the local BCCP public health program is advised before proceeding with further procedures.

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\(^1\) 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.
Maryland Breast and Cervical Cancer Program  
Maryland DHMH, Center for Cancer Prevention and Control  
Attachment A3  

Cervical Specimen Collection and  
Cytology Findings Reported (2001 Bethesda System)  

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 d and #2 a, b, & c 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)  
      i. Organisms (e.g., Trichomonas; fungal org. consistent with Candida; bacterial vaginosis; Actinomyces species; cellular changes consistent with Herpes simplex virus).  
      ii. Other non-neoplastic findings (e.g., Reactive changes/Glandular status post hysterectomy/Atrophy).  
   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).  

Cervical Minimal Elements, February 2016  
6
• 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).

Educational Notes and Suggestions—Women who are pregnant or who still desire pregnancy should have additional consultation beyond these guidelines.
Attachment B—Management of Cervical Cytologic Abnormalities in the BCCP

Selected ASCCP Flow Charts Relevant to the Maryland Breast and Cervical Cancer Program: Cytology and Histology

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The entire set of ASCCP Flow Charts including the charts not included here are available at http://www.asccp.org/consensus.shtml

Charts not included here are:
- Management of Adolescent Women with Either ASC-US or LSIL
- Management of Pregnant Women with LSIL
- Management of Women Ages 21-24 years with Atypical Squamous Cells, Cannot Rule Out ASC-H and HSIL
- Management of Women with No lesion or Biopsy-confirmed CIN I in Women Ages 21-24
- Management of Young Women with Biopsy-confirmed CIN 2,3 in Special Circumstances
Unsatisfactory Cytology

- HPV unknown (any age)
- HPV negative (age ≥30)
- HPV positive (age ≥30)

Repeat Cytology after 2-4 months

- Abnormal
  - Manage per ASCCP Guideline
- Negative
  - Routine screening (HPV-/unknown)
    or Cotesting @ 1 year (HPV+)
- Unsatisfactory
  - Colposcopy
Cytology NILM* but EC/TZ Absent/Insufficient

Ages 21-29+

- HPV negative
  - HPV testing (Preferred)
  - Routine screening

- HPV unknown
  - Repeat cytology in 3 years (Acceptable)

Age ≥30 years

- HPV positive
  - HPV testing
  - Cytology + HPV test in 1 year
  - Genotyping
  - Manage per ASCCP Guideline

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

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

- **Repeat Cotesting**
  - @ 1 year
  - Acceptable
  - Cytology Negative and HPV Negative
  - Repeat cotesting @ 3 years

- **HPV DNA Typing**
  - Acceptable
  - ≥ASC or HPV positive
  - HPV 16 or 18 Positive
  - HPV 16 and 18 Negative
  - Repeat Cotesting @ 1 year

  - Colposcopy
    - Manage per ASCCP Guideline

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

- **Repeat Cytology** @ 1 year Acceptable
  - Negative
  - > ASC
    - Routine Screening*

- **HPV Testing** Preferred
  - HPV Positive
    - HPV Positive (managed the same as women with LSIL)
  - HPV Negative
    - Repeat Cotesting @ 3 years

- **Colposcopy**
  - Endocervical sampling preferred in women with no lesions, and those with inadequate colposcopy; it is acceptable for others

*Management options may vary if the woman is pregnant or ages 21-24.
*Cytology at 3 year intervals

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

**LSIL with negative HPV test**
- Preferred
  - Repeat Cotesting @ 1 year
    - Cytology Negative and HPV Negative
      - Repeat Cotesting @ 3 years

**LSIL with no HPV test**
- Acceptable
  - Colposcopy
    - Non-pregnant and no lesion identified
    - Inadequate colposcopic examination
    - Adequate colposcopy and lesion identified
      - No CIN2,3
        - Manage per ASCCP Guideline
      - CIN2,3
        - Manage per ASCCP Guideline

**LSIL with positive HPV test**
- Endocervical sampling “preferred”
  - Endocervical sampling “preferred”
  - Endocervical sampling “acceptable”

* Management options may vary if the woman is ages 21-24 years (see text)
Management of Women with Atypical Squamous Cells: Cannot Exclude High-grade SIL (ASC-H)*

Colposcopy
Regardless of HPV status

CIN2,3

Manage per ASCCP Guideline

No CIN2,3

Manage per ASCCP Guideline

* Management options may vary if the woman is ages 21-24.
Management of Women with High-grade Squamous Intraepithelial Lesions (HSIL)*

Immediate Loop Electrosurgical Excision*  Or  Colposcopy (with endocervical assessment)

No CIN2,3  CIN2,3

Manage per ASCCP Guideline

* Management options may vary if the woman is pregnant, postmenopausal, or ages 21-24
* Not if patient is pregnant or ages 21-24
Initial Workup of Women with Atypical Glandular Cells (AGC)

All subcategories (except atypical endometrial cells)

» Colposcopy (with endocervical sampling) and Endometrial sampling (if ≥ 35 yrs or at risk for endometrial neoplasia*)

Atypical Endometrial Cells

» Endometrial and Endocervical Sampling

No Endometrial Pathology

» Colposcopy

*Includes unexplained vaginal bleeding or conditions suggesting chronic anovulation.
**Subsequent Management of Women with Atypical Glandular Cells (AGC)**

**Initial Cytology is AGC - NOS**
- **No CIN2+, AIS or Cancer**
  - Cotest at 12 & 24 months
    - Both negative
      - Cotest 3 years later
    - Any abnormality
      - Colposcopy

**Initial Cytology is AGC (favor neoplasia) or AIS**
- **CIN2+ but no Glandular Neoplasia**
  - Manage per ASCCP Guideline
    - Any abnormality
      - Colposcopy
- **No Invasive Disease**
  - Diagnostic Excisional Procedure
    - *Should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred.*
Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by "Lesser Abnormalities"*

Follow-up without Treatment

- Cotesting at 12 months
- HPV(-) and Cytology Negative
- Age appropriate retesting 3 years later
- Cytology negative +/- HPV(-)

≥ ASC or HPV(+)
- Colposcopy

No CIN
- Manage per ASCCP Guideline

CIN2,3
- If persists for at least 2 years
- Follow-up or Treatment †

CIN1
- Follow-up or Treatment †

* "Lesser abnormalities" include ASC-US or LSIL Cytology, HPV 16+ or 18+, and persistent HPV

∞ Management options may vary if the woman is pregnant or ages 21-24.

+ Cytology if age <30 years, cotesting if age ≥30 years

† Either ablative or excisional methods. Excision preferred if colposcopy inadequate, positive ECC, or previously treated.
Management of Women with No Lesion or Biopsy-confirmed Cervical Intraepithelial Neoplasia — Grade 1 (CIN1) Preceded by ASC-H or HSIL Cytology

Cotesting at 12 and 24 months*  Or  Diagnostic Excision Procedure*  Or  Review of cytological, histological, and colposcopic findings

↓  ↓  ↓
HPV(-) and HPV(+) or Any cytology abnormality except HSIL HSIL at either visit

Age-specific Retesting in 3 years*  Colposcopy

*Only if colposcopy was adequate and endocervical sampling is negative
^ Except in special populations (may include pregnant women and those ages 21-24)
* Cytology if age <30, cotesting if age ≥30 years

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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

1If 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.

Adequate Colposcopy

Either Excision† or Ablation of T-zone*

Cotesting at 12 and 24 months

2x Negative Results

Repeat cotesting in 3 years

Routine screening

Inadequate Colposcopy or Recurrent CIN2,3 or Endocervical sampling is CIN2,3

Diagnostic Excisional Procedure†

Any test abnormal

Colposcopy With endocervical sampling

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

**Hysterectomy — Preferred**

**Conservative Management**
Acceptable if future fertility desired

Margins Involved or ECC Positive

- **Re-excision Recommended**
- **Re-evaluation**
  @ 6 months — acceptable

Margins Negative

- **Long-term Follow-up**

* Using a combination of cotesting and colposcopy with endocervical sampling

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

Low Grade Squamous Intraepithelial Lesion (LSIL)* → Manage like CIN1

High Grade Squamous Intraepithelial Lesion (HSIL)* → Manage like CIN2,3

*Histopathology Results only.

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