March 31, 2009

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. 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), and the American Cancer Society.

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 BCCP.

In 2007, the American Society for Colposcopy and Cervical Pathology published the “2006 Consensus Guidelines for the Management of Women with Abnormal Cervical Cancer Screening Tests,”¹ and the “2006 Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia or Adenocarcinoma in situ.”² The Medical Advisory Committee revised the Minimal Clinical Elements based on these new consensus guidelines.

Some of the major changes include:

- Discontinues the use of intra-vaginal estrogen therapy for post-menopausal women with atrophy and either LSIL or ASC-US prior to repeating the cervical cytology;

- Allows HPV/DNA test at 12 months for follow-up after specific, designated procedures per the ASCCP guidelines;

- Expands management guidelines for women with biopsy confirmed cervical intraepithelial Neoplasia grades 2/3 (CIN 2/3).

Enclosed are the revised “Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis.”

We appreciate your cooperation in using these 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 Diane Dwyer, M.D., Medical Director of the Center for Cancer Surveillance and Control (CCSC) at (410) 767-5088 or ddwyer@dhmh.state.md.us.

Sincerely,

[Signature]
Stanley Watkins, M.D.
Chairman, Medical Advisory Committee
Maryland Breast and Cervical Cancer Program

Enclosure

cc: Donna Gugel, M.H.S., Director, CCSC
    Diane Dwyer, M.D., Medical Director, CCSC
    Courtney Lewis, M.P.H., Program Manager, BCCP
    Julia Mitchner, M.A.S., R.N., Nurse Program Consultant, BCCP
    Local BCCP Coordinators
Minimal Clinical Elements for Cervical Cancer Detection and Diagnosis
Maryland Breast and Cervical Cancer Program
Maryland DHMH, Center for Cancer Surveillance and Control
March 2009

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 results and recommended management
- 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
- To incorporate into the Minimal Clinical Elements the 2006 American Society for Colposcopy and Cervical Pathology (ASCCP) Consensus Guidelines for the Management of Women with Cervical Intraepithelial Neoplasia and Cervical Cytological Abnormalities

Attachment A. Detection and Management of Cervical Cytologic Abnormalities in the BCCP


References:
Members of the Cervical Cancer Subcommittee of the BCCP Medical Advisory Committee

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Cervical Minimal Clinical Elements, March 2009
Attachment A

Detection and Management of Cervical Cytologic Abnormalities in the Breast and Cervical Cancer Program

Cervical Cancer Minimal Clinical Elements

A. Maryland Breast and Cervical Cancer Program (BCCP) Program Guidance

1. A woman is eligible for cervical cancer screening (Pap testing) with liquid-based or conventional cervical cytology (See B. and C, below) in the BCCP if she:
   a. Is 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 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 are documented to have required a hysterectomy due to cervical cancer or CIN 2/3.
   a. For other indications (symptoms or vaginal lesion), refer woman to another program for Pap testing or evaluation.

3. The screening interval for average risk women with negative Pap tests is
   a. For liquid-based cervical cytology: every two years until a woman has 3 consecutive negative cervical cancer screening tests documented within a 60-month period, then provide one test every three years.
   b. For conventional cervical cytology: every year until a woman has 3 consecutive negative cervical cancer screening tests documented within a 60-month period, then provide one test every three years.

4. HPV DNA Testing
   a. HPV DNA testing is not reimbursable as a screening test in the BCCP.
   b. HPV DNA testing is reimbursable if performed as guided by ASCCP Flow Sheets in the management of abnormal cytology/histology, for example:
      1. as a follow-up test to an ASC-US result (See Attachment B, ASCCP Flow, Page 7 of 16); or
      2. for surveillance at 12 months following LSIL without evidence of CIN on colposcopy-directed biopsy (See Attachment B, ASCCP Flow, Page 9 of 16).
   c. Only HPV DNA testing for high-risk genotypes is reimbursable.

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5. If the Pap test is read as “unsatisfactory for evaluation,”
   a. If the woman had prior Negative Pap test results, repeat Pap test in 4 months.
   b. If the woman had (one or more) prior Abnormal Pap test results, repeat the Pap test in 4 months.

6. If the Pap test on a premenopausal woman is read as “Normal. Satisfactory for evaluation; no endocervical cells present,”
   a. If the woman had prior Negative Pap tests for the prior 2-3 tests, then return for repeat Pap test in 12 months.
   b. If the woman did not have a history of several prior Negative Pap tests, then return for repeat Pap test in 4 months.

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 a gynecologic oncologist to routine screening (e.g., after five 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 B) based on Cytologic and Histologic findings.

9. Only pay for procedures recommended in the ASCCP Flow Sheets based on the Cytologic or Histologic findings. Additional or alternative procedures are usually not paid for by the BCCP. Consultation with the local BCCP public health program is advised before approving procedures for payment.

B. Cervical Cytology

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 A. 1, and 2. above, BCCP Program Guidance)
   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 (see A. 1, and 2, above, BCCP Program Guidance)
C. Cervical Cytology Findings Reported (2001 Bethesda System)*

1. **Specimen Type**
   a. Conventional (Pap test)
   b. Liquid Based cytology

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)
         • 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 a woman > 40yrs of age)
      ii. Other Malignant Neoplasms (specify)

D. Educational Notes and Suggestions

1. Women who are pregnant or who still desire pregnancy should have additional consultation beyond these guidelines.
Attachment B

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

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2006, 2007

Footnotes in the charts may refer to text or special situations further clarified in these references:


The entire set of ASCCP Flow Charts including the charts not included here is 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 Adolescent Women (20 Years and Younger) with HSIL
- Use of HPV DNA Testing as an Adjunct to Cytology for Cervical Cancer Screening in Women 30 Years and Older
- Management of Adolescent Women (20 Years and Younger) with CIN-1
- Management of Adolescent and Younger Women with a Histological Diagnosis of CIN 2,3

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

- Repeat Cytology @ 6 & 12 mos
  - Both Tests Negative → Routine Screening
  - ≥ ASC (on either result) → 2 ASC or HPV (+) → Repeat Colposcopy

- HPV DNA Testing*
  - Preferred if liquid-based cytology or co-collection available
  - HPV Positive* (managed in same manner as women with LSIL) → Manage per ASCCP Guideline
  - HPV Negative → Repeat Cytology @ 12 mos

Colposcopy
Endocervical sampling preferred in women with no lesions, and those with unsatisfactory colposcopy

- HPV Unknown
  - Repeat Cytology @ 12 mos

- HPV Positive*
  - ≥ ASC or HPV (+) → Repeat Colposcopy
  - Negative → Routine Screening @ 12 mos
Management options may vary if the woman is pregnant, postmenopausal or an adolescent - (see text, below)

Note: The management of LSIL in Postmenopausal women is essentially the same as the management of ASC-US:

“Postmenopausal women: Acceptable options for the management of postmenopausal women with LSIL include "reflex" HPV DNA testing, repeat cytological testing at 6 and 12 months, and colposcopy.
If the HPV DNA test is negative or CIN is not identified at colposcopy, repeat cytology in 12 months is recommended.
If either the HPV DNA test is positive or the repeat cytology is ASC-US or greater, colposcopy is recommended.
If 2 consecutive repeat cytologic tests are negative for intraepithelial lesion or malignancy, return to routine cytologic screening is recommended.”
Management of Women with High-grade Squamous Intraepithelial Lesion (HSIL) *

Immediate Loop Electrosurgical Excision†

OR

Colposcopic Examination (with endocervical assessment)

NO CIN 2,3

Satisfactory Colposcopy

All three approaches are acceptable

CIN 2,3

Unsatisfactory Colposcopy

Diagnostic Excisional Procedure†

Observation with Colposcopy & Cytology @ 6 mo intervals for 1 year

Diagnostic Excisional Procedure†

Review Material^ Change in Diagnosis

Manage per ASCCP Guideline

+) Not if patient is pregnant or an adolescent

^) Includes referral cytology, colposcopic findings, and all biopsies

* Management options may vary if the woman is pregnant, postmenopausal, or an adolescent
Initial Workup of Women with Atypical Glandular Cells (AGC)

All Subcategories (except atypical endometrial cells)

Colposcopy (with endocervical sampling) AND HPV DNA Testing AND Endometrial Sampling (if > 35 yrs or at risk for endometrial neoplasia*)

Atypical Endometrial Cells

Endometrial AND Endocervical Sampling

NO Endometrial Pathology

Colposcopy

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Subsequent Management of Women with Atypical Glandular Cells (AGC)

**Initial Pap of AGC - NOS**

- **NO CIN AND NO Glandular Neoplasia**
  - HPV Status Unknown
    - Repeat Cytology
      - @ 6 mos intervals for four times
  - HPV (-)
    - Repeat Cytology and HPV DNA Testing
      - @ 12 mos if HPV (-), @ 6 mos if HPV (+)
    - ≥ ASC or HPV (+)
      - Colposcopy
    - BOTH Tests Negative
      - Routine Screening
  - HPV (+)

- **CIN but NO Glandular Neoplasia**
  - Manage per ASCCP Guideline

**Initial Pap of AGC (favor neoplasia) or AIS**

- **NO Invasive Disease**
  - Diagnostic Excisional Procedure
    - Should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred.
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia Grade 1 (CIN 1) Preceded by ASC-US, ASC-H or LSIL Cytology

Follow-up Without Treatment

Cytology every 6-12 mos OR HPV Testing^ every 12 mos

2x Cytology Negative OR HPV (-) Once

Routine Cytological Screening

≥ ASC or HPV (+)

Colposcopy

NO CIN

CIN 2,3

Manage per ASCCP Guideline

CIN 1

If Persists for AT LEAST 2 yrs 13 of 16 Follow-up OR Treatment *

^ Test only for high-risk (oncogenic) types of HPV
* Either ablative and excisional methods. Excision preferred if colposcopy unsatisfactory, ECC is positive, or patient previously treated.
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - Grade 1 (CIN 1) Preceded by HSIL or AGC-NOS Cytology

There are 3 Acceptable Options

Diagnostic Excisional Procedure ^

OR

Review of All Findings †

OR

Observation with Colposcopy & Cytology *
@ 6 mos intervals for 1 year

2X Negative Results
HSIL at either 6 or 12 mos

Routine Cytological Screening

Diagnostic Excisional Procedure

Change in Diagnosis

Manage per ASCCP Guideline for Changed Diagnosis

No Change

EITHER Observation OR Diagnostic Excisional Procedure

^ Except in special populations
† Includes referral cytology, colposcopic findings, and all biopsies
* Provided colposcopy is satisfactory and endocervical sampling is negative. If not, diagnostic excisional procedure.
Management of Women with a Histological Diagnosis of Cervical Intraepithelial Neoplasia - (CIN 2,3) *

Satisfactory Colposcopy

Either Excision or Ablation of T-zone *

Cytology @ 6 mos intervals
OR Cytology & Colposcopy @ 6 mos intervals

2X Negative Results
Routine Screening for at least 20 years

≥ ASC (any repeat cytology)

Colposcopy with endocervical sampling

Unsatisfactory Colposcopy OR Recurrent CIN 2,3

Diagnostic Excisional Procedure *

HPV DNA Testing performed @ 6-12 mos after treatment

HPV Positive (for high-risk types)
Routine Screening for at least 20 years
HPV Negative (for high-risk types)

Acceptable Follow-up Approaches Post-treatment

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* Management options will vary in special circumstances

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

- **Hysterectomy - Preferred**
- **Conservative Management** Acceptable if future fertility desired

  - **Margins Involved OR ECC Positive**
    - Re-excision Recommended
  - **Margins Negative**
    - Re-evaluation* @ 6 mos - Acceptable
    - Long-term Follow-up

* Using a combination of cytology, HPV testing, and colposcopy with endocervical sampling

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