CERVICAL CYTOLOGY SCREENING AND MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY

I. INTRODUCTION

The Maryland Department of Health and Mental Hygiene's Family Planning and Reproductive Health Program requires all delegate agencies to initiate cervical cytology screening protocols that are consistent with current national professional organization standards. Delegate agencies site Medical Directors must ensure providers follow guidelines issued by the American College of Obstetrics and Gynecology (ACOG).

For the follow-up of abnormal cervical cytology results, the Family Planning and Reproductive Health Program requires that delegate agencies follow the American Society for Colposcopy and Cervical Pathology's (ASCCP) 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. ASCCP Guidelines are referenced in this document and may be found at http://www.asccp.org.

II. CERVICAL CYTOLOGY SCREENING RECOMMENDATIONS

A. General screening recommendations:
   1. Cervical cytology using either Liquid-Based Cytology or Conventional (slide) Pap Test (and high-risk HPV co-testing as appropriate) is the standard screening test for cervical cancer and precancerous cervical lesions.
   2. Cervical cytology cancer screening should be initiated per age-specific recommendations (as outlined below). A woman may need other reproductive healthcare such as contraceptive initiation and STI screening at an earlier age. Cervical cytology is not a prerequisite to the provision of these services.
   3. A pelvic exam (speculum and bimanual) should be performed at the same time as the Pap test and is only required every three to 5 years (unless medically indicated more frequently).
   4. For Chlamydia STI screening and testing (when a pelvic exam is not indicated) CDC guidelines recommends the use of urine testing or vaginal self swab instead of a pelvic exam and endocervical sample, if available.
   5. All recommendations for "HPV testing" refer to high-risk HPV testing (HR-HPV). Low-risk HPV testing has no utility and should not be done.
      a. In select circumstances, "genotyping" of HPV (for strains 16/18 or 16 alone) may be useful for further triage after a diagnosis of a positive HR-HPV. See ASCCP guidelines for details.

B. Age-based screening recommendations:
   1. For the purpose of these guidelines an ADOLESCENT is defined as an individual 20 years of age or younger.
   2. Pelvic exams (speculum and bimanual) on females 13-20 years of age are no longer required unless medically indicated (i.e., symptoms or conditions related to sexually transmitted disease, vaginitis, abnormal vaginal bleeding, amenorrhea, pelvic pain, foreign body or pelvic mass).
   3. Screening for cervical cancer should begin at age 21.
   4. Adolescents must be able to obtain appropriate preventative health care, including, but not limited to, an assessment of health risks, counseling for pregnancy and sexually transmitted

infection (STI) prevention, contraception, and treatment of STI's; even if they do not need a Pap smear.

5. Adolescents and young women who have received the HPV vaccine should continue cervical cancer screening according to the current recommendations.
6. Clinical breast exam should begin at age 21 and be performed at least every 3 years until age 40, and then should occur annually.

C. Recommendations for Cervical Cancer Screening:

In November 2012, ACOG released a Practice Bulletin revising cervical cancer screening recommendations. This Practice Bulletin incorporates new screening recommendations from the American Cancer Society, ASCCP and the American Society for Clinical Pathology.

These guidelines assume patients adhere to recommendations for testing and treatment. All practice management should be tailored to individual patient care.

The ASCCP and ACOG guidelines, including recommendation for spacing of pap smears, are for women with normal immune status and who are at average risk for development of cervical cancer. Women at high risk for cervical neoplasia should be screened using alternate guidelines. These women include those with:

- HIV
- Immune compromise (eg: solid organ transplant patients)
- DES exposure in-utero
- History of cervical cancer

Age to Begin	Screening Exam	Screening Interval
Age 21-29	Conventional Pap Test *OR* Liquid Based Cytology (LBC)	Every three years
Age 30- 65*	Conventional Pap Test only *OR* Liquid Based Cytology only *OR* Liquid Based Cytology with HR-HPV co-testing *(preferred)*	Every three years. *OR* Every five years Frequency should be individualized using clinical judgment
Age > 65	No screening necessary	Only applies for immunocompetent women without a history of CIN 2-3, AIS or cervical cancer within the last 20 years

* High-Risk Human Papillomavirus testing as an adjunct to cervical cytology testing may be used for cervical cancer screening in women 30 years of age or older. HR-HPV co-testing should not be performed for women <30 during routine screening. HR-HPV testing is still appropriate for

patients aged 21-29 to triage ASCUS pap smear results. For abnormal results, follow-up guidelines may be found on http://www.asccp.org. HR-HPV testing is not a funded Title X family planning test, however, sites can opt to use their funds to pay for this test.

D. Contraindications for Pap Screening:
Visible cervical mass with bleeding
These patients should be immediately referred for colposcopy / biopsy.

E. Conditions that may increase risk of inadequate sample:
1. Heavy menstrual bleeding. To improve quality of sample, the cervix can be lightly wiped with a cotton swab stick. The use of liquid-based cytology greatly decreases the risk of a specimen being obscured by blood.
2. Women less than 6-8 weeks post-partum (vaginal delivery) or 6-8 weeks post-abortion. If appropriate, post-partum/post-abortion pap smears should be conducted at 6 weeks post-partum/post-abortion, but if necessary, can be done earlier with the knowledge that inflammatory results are more common in a postpartum pap smear done at less than 6-8 weeks postpartum. Post partum status should not be a reason to delay follow-up of abnormal on abnormal cervical cancer screening.

NOTE: Pap testing should not be deferred if vaginal discharge or signs and symptoms of vaginal infection are present.

III. CLIENT INFORMATION/EDUCATION

A. Regular cervical cancer screening (Pap test) is viewed as an important component of routine preventive care. Screening (via patient history) and testing for sexually transmitted infections, if indicated, should occur at the annual visit even if cervical cancer screening is not done.
B. Discuss the importance of cervical cancer screening which includes:
1. Frequency of cervical cancer screening is based on recommendations from a nationally recognized professional organization**,** a woman's age and her Pap test history.
2. Cervical cancer screening test is a Pap test**.** (Frequency of Pap testing is dependent on previous Pap test results)
3. Possible need for testing for HPV or other STI's
C. Discuss limitations of screening procedures
1. Normal results on a screening exam do not necessarily indicate absence of disease.
2. No screening test is 100% accurate; therefore, some cases of the disease may be unavoidably missed.
3. Normal results never rule out the later development of the disease, which is why regular screening is so strongly recommended.
4. The detection of an abnormality does not mean the abnormality is cancerous. Only some women with abnormal screening results will, after further evaluation, be diagnosed with disease.

IV. ADDITIONAL CONSIDERATIONS AND MANAGEMENT OF WOMEN WITH SPECIAL CONDITIONS

A. Special Considerations:

1. Women with a histologically-confirmed HSIL (CIN 2 or CIN 3), whether or not they receive treatment - continue cervical cancer screening on a regular basis, for 20 years following diagnosis or treatment of HSIL.
2. Women who are HIV+, immunocompromised, or had *in utero* DES exposure – should have ANNUAL cervical cancer screening regardless of the testing method.
    a. Women with HIV should be screened twice the year after diagnosis, and then annually.
3. For patients with unsatisfactory cytology and HPV unknown (or untested), cytology should be repeated in 2-4 months. With unsatisfactory cytology where HPV is known to be positive, the patient should receive a colposcopy.
4. If pap results are normal, but no endocervical component is identified, recommendations are determined by patient age.
    a. Age 21-29 – continue routine screening (q 3 years)
    b. Age ≥30 – HPV testing preferred
        i. if HPV negative, continue routine screening (q 5 years)
        ii. if HPV positive, perform genotyping (follow guidelines if HPV 16/18 positive) or perform cytology with HPV testing in 1 year
        iii. If HPV unknown, repeat cytology in 3 years
5. Women who have had a total hysterectomy (cervix removed) who are immunocompetent and who have not had a history of CIN 2 or CIN 3 should not receive further pap smears.
6. Pregnant women: per the ASCCP pregnant women are given special consideration. See guidelines for details at http://www.asccp.org.
    a. ASCUS: manage as non-pregnant women; may defer colposcopy to 6 weeks postpartum
    b. LSIL: Immediate colposcopy preferred; may defer until 6 weeks postpartum
    c. HSIL or ASC-H: manage as non-pregnant women

    For ALL pregnant women undergoing colposcopy: Endocervical curettage (ECC) is contraindicated, and biopsies should be performed only in select circumstances.
7. Invasive cancer is the only indication for treatment during pregnancy.

B. Provision of Screening and Diagnostic Services for Family Planning Women with Abnormal Pap Tests
1. Women <40 years of age seen in a delegate agency family planning clinic site who have an abnormal Pap test result requiring follow-up for the abnormality can be referred to the Maryland Breast and Cervical Cancer Diagnosis and Treatment Program for diagnostic a treatment services if they meet the program eligibility criteria. For more information about the program eligibility requirements visit the Breast and Cervical Cancer Diagnosis and Treatment (BCCDT) Program website at http://fha.maryland.gov/cancer/bccdt_home.cfm or call 410-767-6787 or 1-800-477-9774.
2. HPV testing should be discussed and recommended to the client.

V. MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY RESULTS

A. Follow-up Process for Abnormal Pap Test Results must be established:
1. Delegate agencies must develop and implement a tracking system that will notify women of cervical screening results and follow-up diagnostic testing that is required.
2. A method of contacting women without violating their confidentiality must be established at the first visit.
3. All women with an abnormal pap must be notified within 2 weeks of obtaining the Pap

test.

4. If the pap results are HSIL, AGC, Squamous CC, or AIS, a regular letter and a certified letter should be sent to the client.
5. Documentation must be maintained in the medical record of all phone calls and letters to clients.
6. Colposcopy should be completed within 90 days of performing the pap test, therefore, it is recommended that follow-up be initiated as quickly as possible.
7. High Risk Type-HPV testing should be used for follow-up of ASC-US pap is used to determine management for either referral for colposcopy or return to routine screening.

B. Clinical Management of Pap Testing Results
   1. ABNORMAL pelvic examination (abnormal gross appearance of cervix), NORMAL Pap test
      a. Notify the patient of the results of her pelvic examination and its potential implication(s). This information should include:
         i. The nature of the suspected disease and differentiation between a cervical lesion or other pelvic abnormality (ovarian mass) and implications for coverage by BCCDTP, etc.
         ii. Refer immediately for colposcopy with biopsy as indicated. Do not rely on cervical cytology results alone.
      b. Notify the patient's primary provider (if any).
         i. The physical exam findings and screening test results
         ii. BCCDTP role/action taken
   2. UNSATISFACTORY cervical cytology specimen
      a. A pap smear is considered unsatisfactory if it does not have adequate squamous cellularity, is not preserved and/or fixated correctly, or if there are significant obscuring elements such as blood or inflammatory elements.
         b. For patients with unsatisfactory cytology and HPV unknown (or untested), cytology should be repeated in 2-4 months.
         c. If unsatisfactory cytology where HPV is known to be positive, the patient should receive a colposcopy.
   3. NO ENDOCERVICAL COMPONENT: If pap results are normal, but no endocervical component is identified, recommendations are determined by patient age.
         a. Age 21-29 – continue routine screening (q 3 years)
         b. Age ≥30 – HPV testing preferred
            i. if HPV negative, continue routine screening (q 5 years)
            ii. if HPV positive, perform genotyping (follow guidelines if HPV 16/18 positive) or perform cytology with HPV testing in 1 year
            iii. If HPV unknown, repeat cytology in 3 years
   4. ABNORMAL cervical cytology report
      a. Notify the patient of the results of the Pap test and its implications as soon as possible but within 6 weeks of receipt of abnormal findings, including:
         i. Specifics regarding the results
         ii. Clarification that many cervical lesions are not cancerous, but rather precancerous lesions which require follow-up but that may spontaneously resolve and/or are treatable
         iii. The need for further testing for definitive diagnosis before treatment
         iv. Treatment options available, benefits and risks of each
      b. Refer/arrange for repeat Pap test and/or diagnostic work-up and treatment based on Pap test results.

VI. FOLLOW-UP OF ABNORMAL CYTOLOGY RESULTS

The website http://www.asccp.org contains algorithms for:

A. Unsatisfactory cytology
B. Normal cytology with absent cervical cytology
C. Normal cytology with HPV positive test
D. Management of ASCUS, LSIL, ASC-H, HSIL, AGC
E. Management of CIN 1 after "lesser abnormalities"
F. Management of CIN 1 after ASC-H / HSIL
G. Management of CIN 2, 3
H. Management of AIS
I. Management of *young women* (21-24) with ASCUS, LSIL, ASC-H, HSIL
J. Management of *young women* (21-24) with no lesion or CIN 1; CIN 2, 3
K. Management of *pregnant women* with LSIL

VII. ADDITIONAL INFORMATION

Indications for referral to a qualified colposcopist:

A. Women age 20 and under requiring treatment for CIN2/3 (if using the ACS screening recommendations).
B. Pregnant women with HSIL cytology.
C. Women with a significant cervical lesion in which immediate biopsy may be indicated.
D. Women desiring fertility who, after excisional treatment, have recurrent or persistent cervical dysplasia.
E. Women who have had two "unsatisfactory for evaluation" tests 2-4 months apart.
F. Women with AGC (Abnormal Glandular Cells) or AIS (Adenocarcinoma in situ) on cytology. Management follows the algorithm found at http://www.asccp.org.
G. Women with any gynecologic cancer should be referred to a Gynecologic Oncologist.

REFERENCE

1. American College of Obstetricians and Gynecologists--Obstetrics & Gynecology, Practice Bulletin #131 "Screening for Cervical Cancer". November, 2012
2. Massad LS, et al., "2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors", J Lower Genital Tract Dis 17(5), S1-S27, 2013.

LISTING OF ASCCP ALGORITHMS

To access algorithms, please go to: http://www.asccp.org.

1. Unsatisfactory Cytology
2. Cytology NILM but EC/TZ Absent / Insufficient
3. Management of Women ≥30 who are Cytology Negative but HPV Positive
4. Management of Women with ASCUS on Cytology
5. Management of Women Ages 21-24 with ASCUS or LSIL
6. Management of Women with LSIL
7. Management of Pregnant Women with LSIL
8. Management of Women with ASC-H
9. Management of Women Ages 21-24 with ASC-H and HSIL
10. Management of Women with HSIL
11. Initial Workup of Women with AGC
12. Subsequent Management of Women with AGC
13. Management of Women with No Lesion or Biopsy-confirmed CIN 1 Preceded by "Lesser Abnormalities"
14. Management of Women with No Lesion or Biopsy-confirmed CIN 1 Preceded by ASC-H or HSIL Cytology
15. Management of Women Ages 21-24 with No Lesion or Biopsy-confirmed CIN 1
16. Management of Women with Biopsy-confirmed CIN 2, 3
17. Management of Young Women with Biopsy-confirmed CIN 2, 3 in Special Circumstances
18. Management of AIS during a Diagnostic Excisional Procedure
19. Interim Guidance for Managing Reports using LAST Histopathology Diagnoses