Release of the 2020 American Cancer Society Cervical Cancer Screening Guidelines

On July 30th, the American Cancer Society (ACS) released its updated guidelines for "Cervical Cancer Screening for Individuals at Average Risk". The guidelines are found at:

Guideline: https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21628
Patient Page: https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21629

The guidelines recommend that individuals with a cervix institute cervical cancer screening at age 25 years and undergo primary HPV testing every 5 years through age 65 as the preferred screening method. Co-testing (HPV testing in combination with cytology) every 5 years or cytology alone every 3 years are acceptable options if primary HPV testing is not available.

The American Society of Cytopathology (ASC) is a member of the Cytopathology Education and Technology Consortium (CETC), a federation of pathology professional societies dedicated to diagnostic excellence and patient-centered care in cytopathology and cervical cancer screening. The ASC, through its member cytopathology leaders and its collaborative efforts within the CETC, previously commented on the 2017 draft screening guidelines of the United States Preventative Services Task Force (USPSTF)[(1)], in addition to participating in the development of the 2019 American Society for Colposcopy and Cervical Pathology (ASCCP) Risk-Based Management Consensus Guidelines.[(2)] Several CETC member societies also provided comments to the draft ACS guidelines earlier this year.

The ASC remains committed to retaining the use of co-testing and cytology for optimal cervical cancer screening and precancer detection in the opportunistic screening environment in the U.S. and supports appropriate reimbursement for this testing. The final ACS guidelines do address CETC concerns that only HPV testing platforms approved for primary screening be used for that purpose, in addition to referring providers to appropriate ASCCP management guidelines for women with abnormal screening tests.

However, the ASC remains concerned about several other issues, summarized below:

1. Issues Regarding Supporting Data for Primary HPV Screening and Specific Considerations for Cervical Cancer Prevention in the United States

Cervical cancer screening in the U.S. is not performed through an organized national system. Many women are under-screened (or unscreened) with U.S. HPV vaccination rates still lower than other developed countries. Thus, women in the U.S. have less primary and secondary prevention of cervical cancer than countries with organized preventive services who have adopted primary HPV screening.

Studies from the CDC [(3)] show women of lower socioeconomic status are at higher risk of not being screened, along with several minority groups. If cervical cytology is no longer covered by insurers, the existing disparities in preventive services for women in the U.S. are likely to increase.

2. Availability of FDA Approved HPV Testing Methodology, Genotyping and False Negative Results

Most laboratories in the U.S. still do not offer primary HPV screening on FDA approved platforms.[(4)] HPV genotyping, which is a suggested modality for triage of a positive primary HPV test, is also not widely available. Before considering the option of primary HPV screening, clinicians should inquire which HPV testing platform(s) and FDA-approved testing options are offered by their respective laboratories. This is critical since several current HPV tests do not provide an internal specimen adequacy control which ensures that cervical epithelial cells have been sampled. There is a risk of false negative HPV results without the added morphologic control offered by cytology testing if such HPV tests were being offered as a primary HPV screening test.

3. HPV Negative Cervical Cancers and HPV Negative High-Grade Intraepithelial Lesions

A number of studies have found that 9-10% of invasive cancers will test negative for HPV by commercially available tests [5-7] and that 8.3-14% of HSIL cases may also be negative for high-risk HPV.[8-9] Delayed diagnoses could then result in higher stage tumors due to the longer (5-year) screening intervals after negative HPV results.[10] The addition of cytology will add sensitivity as women diagnosed with cervical cancer may be more likely to be detected by liquid-based cytology than a positive HPV test. [11]

Due to the documentation of HPV-negative carcinomas as well as high grade lesions (HSIL/AIS), women should have a morphological examination (Pap test) at some time in their screening history and should not be screened solely with HPV tests. This is especially important for older women with an uncertain screening history or with any clinical symptoms.

4. State of Colposcopy Practice in the U.S.

Colposcopy is an imperfect tool with no formal training or minimum competency requirement to qualify to perform the procedure in the United States. Recent efforts have been made by the ASCCP to develop recommendations for standards in colposcopy practice, however they are not required or enforced.[12] With additional referrals, colposcopy services could be overwhelmed, with patients lost to follow-up or having significant disease processes missed by their initial colposcopy procedures.

5. Acceptability by Physicians, Laboratorians and Patient Compliance

Even after the last set of screening guidelines in 2012 [13], 5-year screening intervals are uncommonly practiced in the U.S.[14-16] It is unlikely that either physicians or patients will be compliant with HPV-only screening every 5 years, especially in a transition period.

In summary, to avoid an increase in cervical cancer cases, the CETC stresses that regular screening is required with methodologies that provide an optimal balance between sensitivity and specificity and remain readily accessible and affordable for all women. The U.S. should continue to focus efforts on increasing primary prevention by vaccination, with improved availability and follow up in preventive services. Most cases of cervical cancer in this country are secondary to a failure of access to screening rather than a failure of the screening methodologies.

Representatives from the CETC have recently published suggestions for cervical cancer screening and management pertinent to laboratories.[2] The CETC is currently in the process of developing a **Frequently Asked Questions (FAQs)** list to include its recommendations for issues commonly raised with respect to laboratory testing related to cervical cancer prevention. We are committed to provide the most appropriate testing for our clinical colleagues and the patients we serve.

Selected References:

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12. *Wentzensen N, Massad LS, Mayeaux EJ Jr, et al. Evidence-based consensus recommendations for colposcopy practice for cervical cancer prevention in the United States. J of Lower Gen Tract Dis 2017;21(4):216-222.*

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