Gregory N. Sossaman, MD, MASCP
ASCP President

October 31st, 2025

To: Health Resources and Services Administration (HRSA)

From: The American Society for Clinical Pathology

The American Society for Clinical Pathology (ASCP) is a professional association encompassing 100,000 pathologists and laboratory professionals, including those specialized in cervical cancer screening and diagnosis. Founded in 1922, ASCP provides programs in education, certification and advocacy on behalf of patients, pathologists, and laboratory professionals.

Re: Response to the draft recommendations for the HRSA-supported Women's Preventive Services Initiative Guidelines relating to screening for Cervical Cancer

Dear Members of the Health Resources and Services Administration,

We appreciate the opportunity to comment on the proposed updates to the HRSA-supported Women's Preventive Services Initiative (WPSI) Guidelines for cervical cancer screening.

As a patient-centric organization, ASCP has several concerns about the recommendations as written. The WPSI guidelines suggest patient- or self-collected specimens be considered equivalent or even superior to clinician-collected specimens. There is little or no research to support this equivalence. While HPV self (or home) – collection presents potential future benefits for select patient populations, there is not enough robust data to demonstrate with certainty that the net benefit of self-collection is substantial. Therefore, there is insufficient data to recommend self-collection over clinician-collected specimens; there are also concerns regarding access to routine healthcare for underserved populations if self-collection is promoted over clinician-collected.

ASCP recommends self-collection be restricted to asymptomatic individuals of average-risk and recommends screening every 3 years (as opposed to 5) for self-collected samples until more long-term data are available. For individuals in the surveillance setting with an abnormal screening history, self-collected HPV specimens should not be considered equivalent to clinician-collected specimens.

Since the preventive services and screenings set forth in the HRSA-supported WPSI guidelines are required to be covered without cost-sharing by certain group health plans and health insurance issuers, we are concerned that certain screening tests (primary HPV, hrHPV) are being emphasized while others are considered "alternative" or "non-preferred".

There is documented evidence of low availability among US laboratories of the necessary testing platforms for primary HPV screening. Specifically, according to a study published in the Journal of the American Society of Cytopathology, "Despite national guideline recommendations, primary HPV screening remains underutilized, and

our findings highlight a gap between recommendations and real-world practice. Poor institutional adoption is centered around reluctance to change without demonstrated evidence in the enduring guidelines for extended genotyping."[1] Conversely, the recently-issued US Preventive Services Task Force (USPSTF) cervical cancer screening guideline presents three options as *equivalent* recommendations (maintains Grade A designation and therefore coverage under the ACA): (hrHPV only, cytology only, or co-testing) whereas the WPSI guideline implies that hrHPV testing is preferred.

ASCP is concerned about the transition period during which laboratories may lack the necessary infrastructure to offer primary HPV testing. Further, the USPSTF guideline was developed by experts over many years and has robust data behind its recommendation, where the WPSI offers little scientific evidence to bolster the claim that primary HPV is "preferred".

Provider preference for co-testing is well documented, and adoption of primary HPV testing in the United States remains low. Therefore, ASCP is concerned that real-world practice does not accurately reflect current guidelines. For example, 2023 survey data showed that 3% of clinicians reported using primary HPV testing for eligible patients, and only 50% were willing to adopt it as the preferred cervical cancer screening method.[2] Additionally, another 2023 survey found that more providers believe co-testing is the most effective screening method for women ages 30-65 compared with HPV primary or cytology alone.[3]

ASCP recommends that WPSI remove the "preferred" designation for the hrHPV option and adopt the USPSTF draft recommendation regarding the three equivalent options.

Finally, the draft guidelines do not adequately (and prominently) specify that HPV testing platforms utilized for primary screening of clinician- and patient-collected specimens should be FDA-approved/cleared for those specific indications.

ASCP recommends primary HPV screening of clinician and self-collected specimens should be performed only with testing platform(s) that are FDA-approved or cleared for those specific indications. The draft recommendations should make this statement prominently, so this requirement is made clear to all ordering clinicians and testing laboratories.

ASCP appreciates the opportunity to provide feedback and urges HRSA to consider these recommendations to ensure patient-centric cervical cancer screening guidelines that are evidence-based, practical, and aligned with current clinical practice.

Sincerely,

Gregory M. Sossaman, MD, MASCP
President, ASCP

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ASCP President

References:

1. Maharjan, Melissa Randolph, Ben Shuler, Tieying Hou, Sheila Segura, Low Uptake of Primary HPV Screening: One-Year Experience with the BD Onclarity™ Assay. Journal of the American Society of Cytopathology, Volume 14, Issue 5, 2025, Page S40, ISSN 2213-2945,https://doi.org/10.1016/j.jasc.2025.07.063.

2. Rodriguez NM, et al. Clinician practices, knowledge, and attitudes regarding primary human papillomavirus testing for cervical cancer screening: A mixed-methods study in Indiana. Prev Med Rep. 2022 Nov 30;31:102070.

3. Kruse GR, et al. Provider beliefs in effectiveness and recommendations for primary HPV testing in 3 health-care systems. JNCI Cancer Spectr. 2023 Jan 3;7(1)