Alliance for Women's Health & Prevention

January 13th, 2025

Dr. Wanda Nicholson
Chair, U.S. Preventive Services Task Force
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Nicholson,

The Alliance for Women's Health and Prevention (AWHP) is grateful for the opportunity to comment on the United States Preventive Services Task Force's (USPSTF, or Task Force) draft recommendations for cervical cancer screening.

As a non-profit advocacy organization focused exclusively on women's preventive health across all life stages, we understand the important role the Task Force plays in ensuring access to screening for diseases like cervical cancer. Prevention of disease is critical to the health, quality of life, and longevity of all women and girls, who have demonstrated need for access to early diagnostics and better preventive care. Given that women experience unique health conditions and have differing concerns from their male counterparts, our healthcare system must be responsive to these discrepancies and bolster preventive efforts to preemptively address women and girls' health concerns.

With these values in mind, AWHP wishes to express its support for the draft recommendations for cervical cancer screening and propose slight changes for the final guidelines. **We believe that the final guidelines must maintain an A rating for co-testing, ensuring access to screening options and prioritizing patient-provider choice. Language that references "alternative" methods, suggesting one screening method over another, should be removed from the final guidelines.** Based on our review, there are no USPSTF guidelines that include preferential language. Therefore, the inclusion of this language is a departure from the rating criteria set forth by the Task Force and creates unnecessary confusion among providers, patients, and payers.

Safeguarding access to cervical cancer screening through the Pap and HPV tests will aid in detecting, diagnosing, and treating cervical cancer earlier and more effectively. We thank the Task Force for its important work on this issue and encourage its members to consider the following information in drafting its final recommendations.

Cervical cancer still causes thousands of deaths a year in the U.S., making it a continued women's health priority.

At one point, cervical cancer was one of the leading causes of cancer death among women in the U.S.[1] With the introduction of the Pap test, the most successful screening tool we have in our arsenal to catch cervical abnormalities early, mortality of the cancer has declined by more than 70%.[2] Currently, each year in the U.S., more than 11,000 cases of cervical cancer are diagnosed, and more than 4,000 women die from this nearly preventable disease.[3]

After decades of steady progress, the decline in cervical cancer rates has stalled[4] — and in some communities, incidence rates are on the rise. Among women ages 30-44, cervical cancer incidence rates increased 1.7% each year from 2012 to 2019.[5] Increased incidence rates have also been reported among women in low-income counties, and mortality rates are *increasing* among Black women in low-income counties, even as diagnoses are *decreasing* among this group.[6] Unfortunately, this means cancers are being diagnosed at a later stage, when treatment is more difficult and mortality is therefore more likely.

Plateauing rates of cervical cancer incidence and mortality highlight the urgent need to ensure that patients have access to the most appropriate testing modality as well as reinforce the ongoing need to educate patients about the importance of screening.[7]

Screening is a critical tool for prevention.

Adherence to regular screening is essential for detecting cervical cancer at an early stage, reducing the burden of disease, and saving lives. Despite the effectiveness of screening for cervical cancer in driving the decline of cervical cancer rates, screening uptake has declined in recent years and remains suboptimal.[8]

Women who are under-screened or infrequently screened are at a higher risk of developing cervical cancer compared to those who undergo regular screening.[9] An assessment of USPSTF guideline-concordant cervical cancer screening rates found that adherence to regular cervical cancer screening has decreased over time since intervals have been expanded.[10] Women of all ages were less likely to be up to date with their screening in 2019 compared to 2005.[11] Women 21-29 years of age also had a significantly higher rate of under-screening than women ages 30-65.[12] These gaps must be rectified with the ultimate goal of preventing cervical cancer deaths.

Racial, ethnic, and socioeconomic inequities in screening exacerbate the impact of cervical cancer on minoritized communities.

A woman's race, ethnicity, socioeconomic status, and geographic location all contribute to her likelihood of receiving regular screening.[13,14,15,16] An AWHP-commissioned Ipsos survey of 1,000 women about their experiences with healthcare underscored this disparity: it found that white women were more likely to have received a cervical cancer screening in their lifetime (81%) than Black women (65%), Asian women (66%), and Hispanic women (68%). Further, women who were insured (79%) were more likely to have received a screening than uninsured women (51%), and Medicaid patients were less likely to have received a screening than those with other insurance.[17]

Given these screening disparities, gaps in cervical cancer outcomes persist as well. Black women are more than twice as likely to die of cervical cancer compared to white women,[18] while Hispanic women are 40% more likely to be diagnosed with cervical cancer as compared to white women.[19] In addition, because of delays in screening, Black women are more likely to be diagnosed with advanced cervical cancer than any other racial group, further demonstrating the disproportionate impact cervical cancer has on women from minoritized communities.[20] Unfortunately, this advanced stage diagnosis results in the fact that the 5-year survival rate for

Black patients with cervical cancer is 56%, compared to 67% for white women.[21,22] Generally, the highest rates of stage 4 cervical cancer occur in Black and Hispanic women.[23,24]

Further, LGBTQ+ individuals are less likely to be up to date with screening compared to heterosexual women,[25] and research shows uninsured and low-income women often forgo regular cervical cancer screenings citing affordability concerns.[26] In fact, in 2019, 42% of uninsured women were overdue for their cervical cancer screening, compared to 18% of women with private insurance and 28% of women with public insurance.[27] Finally, the U.S. states with the highest rates of cervical cancer have nearly double the incidence rate of the states with the lowest incidence rates, suggesting that geographic disparities also contribute to screening challenges and poor outcomes.[28]

Now more than ever, we must work to eliminate the disparities in cervical cancer diagnosis and deaths by advancing guidelines that protect access to effective preventive services.

The draft recommendations must maintain the range of screening options, safeguarding access to "co-testing."

Co-testing with Pap and HPV is a widely adopted, preferred, and proven method for cervical cancer screening in the U.S., detecting almost 95% of cervical cancers and over 99% of pre-cancers.[29] In 2018, the USPSTF concluded with high certainty that the benefits of screening every 3 years with cytology alone in women aged 21 to 29 years substantially outweighed the harms.[30] Kaufman et al., which represents the largest retrospective study of cervical cancer screening strategies, demonstrated that 95% of cervical cancer cases were detected by co-testing, while HPV primary screening missed 1 in 5 women with cervical cancer.[31] Cytology also provides ancillary benefits given the potential for detection of other cancers and infectious organisms that can be visualized through a Pap test.[32,33,34]

AWHP strongly believes that the age of screening initiation should remain at 21 (with Pap alone until 29) and should maintain an A rating. Starting at 21 is important because of low vaccination rates and early age of sexual debut in many populations causes these women to be at risk for pre-cancerous lesions that need to be detected and monitored/treated in order to prevent cervical cancer in older age groups — especially given the increase incidence of cervical cancer in younger women and rise in stage 4 cancers.[35,36] Data supports maintaining an A grade for co-testing for women ages 30 to 65 and removing language that prefers HPV primary over co-testing. Simply put, several publications representative of real-world data reflective of the U.S. population demonstrate co-testing misses the fewest cases of cervical cancer and pre-cancer.[37,38,39,40,41,42]

Furthermore, the USPSTF did not include any head-to-head studies comparing HPV primary to co-testing in its evidence review.[43] HPV primary testing has very limited adoption the U.S. (1.4% adoption per the USPSTF's evidence review document).[44] The potential harms of relying solely on a primary hrHPV-based screening approach in the U.S. have not been adequately addressed. However, it is well-established that a significant percentage of CIN3 and cervical cancers test HPV negative, indicating that HPV primary testing may not be sufficient.[45,46,47,48,49,50,51] Further, hrHPV-negative results can occur in as many as 31% of cases of high-grade disease and 20% of cancers.[52,53] Maintaining access to co-testing therefore bolsters the effectiveness of screenings and protects patient outcomes.

HPV self-collection testing is gaining traction as another testing modality, but further evidence is needed before it becomes implemented as a primary method for screening. At this time, we do not believe there is sufficient evidence to warrant an A rating for self-collection. The Task Force should re-grade self-collection and provide a grade that is consistent with the rating criteria set forth by the Task Force (suggest I or C rating).

The FDA approvals currently indicate that self-collected vaginal specimens can be obtained only in a healthcare setting, as an alternative specimen type when cervical sampling is either contraindicated or cervical specimens otherwise cannot be obtained.[54,55,56]

The FDA included language to caution against regularly screened individuals switching from clinician-collected cervical specimens to self-collected vaginal specimens as it could result in missed cervical disease that would have otherwise been detected.[57,58] Currently, there is not enough high-quality data to demonstrate with high certainty that the net benefit of self-collection is substantial. Most studies included in the evidence review did not use an HPV test that is FDA-approved for primary HPV testing or sold in the U.S. Of the 22 studies, only seven utilized an FDA-approved test for self-collection in the U.S.[59]

Early data on HPV self-collection use in other countries has shown lower sensitivity and higher false negative results compared to clinician-collected samples.[60] Data from the Netherlands showed the detection of CIN2+ were lower with self-collected vaginal specimens than clinician collected cervical specimens (OR= 0.76) after adjusting for screening history, other sociodemographic characteristics and follow up. This same trend was observed in women over 35 years who had previously been screened: the odds of identifying a CIN2+ in self-collected samples were lower than in clinician collected (OR = 0.73).[61]

Further, there is a significant concern that in real-world screening, women will not get the necessary follow up after a positive HPV result.[62] Guidance from Community Preventive Services Task Force publications have identified that culturally appropriate messaging directed at target groups with lower than optimal screening rates can be effective at increasing utilization of cervical cancer screening, a strategy which will continue to prove critical as self-collection becomes increasingly common.[63]

While AWHP recognizes the value of self-collection in certain populations, we have concerns about the rating put forth by the Task Force. The available data on self-collection is limited and already shows a loss to follow up. As an organization, we continue to monitor the ongoing trials required by the FDA and the intended use for self-collection and urge the agency to follow suit.

AWHP encourages the Task Force to prioritize patient-provider decision-making and early detection while considering the health equity impacts of their guidance.

AWHP's Ipsos survey underscores how insurance coverage and out-of-pocket costs are critical to how and when women access preventive care. The survey highlights the existing disparities in cervical cancer screenings. Further, it shows that an overwhelming majority of women want the guidelines that determine insurance coverage of preventive services to prioritize affordability, early detection, patient-provider decision making, and health equity impacts:[64]

- 91% say it's important to prioritize ensuring providers can make best choice for patients based on unique needs
- 91% say it's important to prioritize ensuring comprehensive preventive care and screening is affordable
- 90% say it's important to prioritize allowing for the earliest possible detection of disease through the most robust testing
- 90% say it's important to prioritize encouraging conversations between patients and providers and shared decision-making
- 89% say it's important to prioritize removing barriers to care, not make it more difficult for women to get screenings
- 87% say it's important to prioritize ensuring there isn't a negative impact on health equity
- 84% say it's important to prioritize considering the needs and lived experiences of all women by examining the potential impact on different races and populations

Given this evidence, we thank the Task Force for its draft guidelines and encourage the prioritization of comprehensive early detection while considering the health equity impacts of their guidance as the recommendation is finalized. We recognize the need to address access to care for all populations, but we also need to thoughtfully consider the types of screening methods that we are offering and ensure that test offerings for all populations are of the same caliber. As referenced above, education and awareness are absolutely critical to increase screening compliance.

With the range of highly effective screening tools available, cervical cancer is nearly preventable — and it is our duty to work tirelessly toward its eradication. We encourage the Task Force to leverage its key role in this effort.

We thank you for the opportunity to comment on this issue. We would be delighted to hold a meeting should you wish to discuss further or have any questions — please do not hesitate to reach out.

Sincerely,

Millicent Gorham
CEO, Alliance for Women's Health and Prevention

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