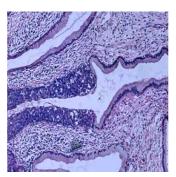


New Cervical Cancer Screening Guidance: Using HPV Test Alone



The Society of Gynecologic Oncology (SGO) and the American Society for Colposcopy and Cervical Pathology (ASCCP) have issued a new interim guidance for cervical cancer screening that recommends the use of a human papillomavirus (HPV) test alone as the primary screen to find cervical cancer or its precursors. At present, such screening is done with either cytology (the Pap smear) alone or co-testing with cytology and HPV testing.

Under the new guidance, the Pap smear, which dates back more than 80 years, would still be used for follow-up tests if an HPV test is positive. The Pap smear will still be used for primary screening of women under age 25. The new guidance is published simultaneously in the journals *Gynecologic Oncology, Obstetrics & Gynecology*, and the *Journal of Lower Genital Tract Disease* under the title "Use of Primary High Risk Human Papillomavirus Testing for Cervical Cancer Screening: Interim Clinical Guidance."

The need for guidance about using the HPV test was prompted last April when the U.S. Food and Drug Administration (FDA) approved one existing HPV test for use in primary cervical cancer screening. The cobas® HPV test detects DNA from 14 high-risk HPV types, including types 16 and 18, which are responsible for 70 percent of cervical cancers.

"Although FDA approval is critically important for introducing a new screening test or algorithm, providers ultimately rely on guidance or guidelines to help them make the best decisions for their patients and want to understand advantages, disadvantages and unknowns associated with a new screening approach," said Warner K. Huh, MD, Division Director and Professor in the Division of Gynecologic Oncology at the University of Alabama, Birmingham. Dr. Huh is a spokesperson for the SGO and lead author of the interim guidance report.

The new interim guidance will help clinicians determine how best to integrate primary HPV testing into the care of their patients until several medical organisations update their evidence-based guidelines for cervical cancer screening.

Cervical cytology or the Pap test can detect abnormal cells in the cervix that could be pre-cancerous; follow-up and management leads to prevention of invasive cancer. Its widespread use in the United States is credited with significantly reducing both the occurrence of and deaths from cervical cancer.

As scientists and researchers learned about the role HPV plays in the development of cervical cancer, tests to detect the virus were developed and used in conjunction with cytology. Today, many studies indicate that HPV testing may be more effective than cytology alone in detecting cervical pre-cancer.

"Our review of the data indicates that primary HPV testing misses less pre-cancer and cancer than cytology alone. The guidance panel felt that primary HPV screening can be considered as an option for women being screened for cervical cancer," Dr. Huh pointed out.

Amongst the key recommendations in the new guidance are:

- Women under age 25 should continue to follow current guidelines that recommend cytology alone beginning at age 21.
- Primary HPV testing can be considered for women starting at age 25.
- Women with a negative primary HPV test result should not be retested again for three years. This is the same screening interval recommended under current guidelines for a normal cytology test result.
- An HPV test positive for HPV 16 and 18, two types associated with a higher risk of future disease, should be followed with colposcopy, a
 test that allows the doctor to examine the cervix under illumination and magnification.
- · A test that is positive for HPV types other than 16 and 18 should be followed by reflex cytology testing.

In developing the new guidance, the SGO-ASCCP panel reviewed 11 studies, including "Primary Cervical Cancer Screening with Human Papillomavirus: End of Study Results from the ATHENA Study Using HPV as the First-Line Screening Test." also published Jan. 8 in Gynecologic Oncology. The ATHENA study, also published in Gynecologic Oncology, showed that primary HPV screening is an effective screening strategy in women 25 years and older.

According to the panel, "While there continue to be numerous practical and research questions, primary HPV testing has the potential to further reduce morbidity and mortality of cervical cancer in the U.S. However, what is most important is that women need to be screened with any strategy, as many women in the U.S. with cervical cancer are either unscreened or underscreened."

From the patient's point of view, the experience of getting an HPV test will be the same as getting a Pap smear. The difference is how the sample will be screened: Instead of a technician looking for abnormal cells (Pap), the HPV sample is put into an automated machine to detect HPV DNA.

"We will continue to work to find the best way to combine screening tools with other prevention efforts like HPV vaccines, for the early detection and treatment of cervical cancer", said ASCCP's Chief Medical Officer Herschel Lawson, MD. "The most important message for providers and the community is that women should be screened for cervical cancer. Screening saves lives."

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