

FDA Advisory Committee recommends the HPV test as the primary screening tool for cervical cancer

➔ The cobas HPV test could replace the Pap smear for cervical cancer screening

Deborah Reale, Managing Editor

The US Food and Drug Administration (FDA) Microbiology Devices Panel of the Medical Devices Advisory Committee has unanimously recommended that the cobas HPV (human papillomavirus) test be used as a first-line primary screening tool in women aged 25 years and older to assess their risk of cervical cancer based on the presence of clinically relevant high-risk HPV DNA. In making this recommendation, the committee concluded that the benefits outweigh the risks of the test, and that the cobas HPV test is safe and effective for the proposed indication.¹

If approved by the FDA, the cobas HPV test would become the “first and only HPV test indicated as the first-line primary screen of cervical cancer in the United States.”² Although the FDA is not required to follow the Advisory Committee’s recommendation, it takes the advice into consideration.

Data behind the recommendation

The Advisory Committee’s recommendation is supported by data from the ATHENA study, which included more than 47,000 women, making it the largest US-based registration study for cervical cancer screening. Data show that when the cobas HPV test was used as the primary test and Pap cytology as a secondary test, significantly more cervical disease was detected than with Pap screening alone.²

“Through technological and scientific advancement, we now have a better screening tool for cervical cancer. Women around the world deserve the best tool to know their

risk and reduce their chances of developing cervical cancer,” said Roland Diggelmann, COO for the Division of Roche Diagnostics, the company that developed and manufactures the test.

How could current practice change as a result of final FDA approval?

The cobas HPV test is currently FDA-approved for co-testing with the Pap smear in women older than age 30 for cervical cancer screening, and for screening patients aged 21 and older with abnormal cervical cytology.

Mark H. Einstein, MD, MS, chair of cervical cancer education efforts of the Foundation for Women’s Cancer and professor of obstetrics and gynecology at Albert Einstein Cancer Center and Montefiore Medical Center in Bronx, New York, says final approval of this test as a primary screening tool would entail significant changes to clinical practice. However, “similar to what happened when co-testing [with the cobas HPV test] was approved, it took time for scientific stakeholding groups to update clinical guidelines, then years before clinicians adopted it into routine practice.”

“Unlike a new prescription, clinical algorithms tend to be ‘hard-wired’ into clinicians heads, and adopting significant change is a process,” Einstein says. “It’s likely that a new cervical cancer screening testing clinical algorithm would be adopted by some clinicians early and by many clinicians over time.” He added that the Society

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of Gynecologic Oncologists and the American Society for Colposcopy and Cervical Pathology have an interim clinical guidance document currently drafted, and those guidelines will be released soon after any decisions by the FDA.

When that time comes (assuming final FDA approval is received), Einstein says, “some clinical settings will be able to start with the more sensitive HPV test. For some patients, this will be followed by genotyping or cytology. This has been shown to be an

effective strategy for homing in on the most at-risk women in a screening population.”

References

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2. FDA Advisory Committee unanimously recommends Roche’s HPV Test as primary screening tool for detection of women at high risk for cervical cancer [media release]. http://www.roche.com/media/media_releases/med-cor-2014-03-13.htm. Published March 13, 2014. Accessed March 14, 2014.

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