



Society of Gynecologic Oncology

Primary HPV Testing Q&A April 24, 2014

1. Define primary testing and how it differs from how the HPV test is currently being used.

Primary testing means that a test is the first one used to screen or test for a particular condition. In cervical cancer screening, the Pap test is currently the primary test for women under 30. For women over 30, Pap and HPV can be done at the same time for primary screening. Doctors refer to this as a “co-testing”, and it is the preferred method of cervical cancer screening in this age group. The HPV test currently is used mostly in two situations: after a Pap test when the results are inconclusive, and along with a Pap test in women 30 years and older. Primary HPV testing means the HPV test is the first test used when screening for cervical cancer. The test looks for the presence of HPV, the human papillomavirus, including the two types that are responsible for most cervical cancer. If these viruses are present, it may mean that the woman is at risk for developing cervical cancer and may need follow-up monitoring and possibly additional tests such as a Pap.

2. Now that the FDA has approved the HPV test for primary testing, how will the use of the HPV test and the Pap test change? Will the Pap test go away?

First, let me be very clear that the HPV test does not replace the Pap test. FDA approval of the HPV test for primary testing simply means that the FDA considers the HPV test safe and effective when used as the first test in screening for cervical cancer, based on evidence from clinical trials. Approval doesn't mean the HPV test must or should be used first, only that it can be. The FDA does not issue guidelines for the use of a test, and approval of the HPV test does not change current screening recommendations for cervical cancer. No one in medicine would ever predict that any medical test or treatment will never go away, but I can say that the Pap test is not being eliminated with approval of the HPV test for primary screening.

3. How do you think the HPV test should be used?

The HPV test should be used according to current guidelines developed by doctors and researchers involved in screening and treating women for cervical cancer: Those guidelines say it should be used when the results of a Pap test are inconclusive and for screening in women 30 years and older. FDA approval of primary HPV screening means we can use the HPV test first, giving us one more option to help us detect, prevent and treat cervical cancer. SGO is participating in the development of a document to provide guidance to doctors for incorporating the new HPV indication into their current testing, which we expect to be completed soon. This document is intended to serve as interim guidance before new formal guidelines are developed.

4. There's concern that using the HPV test in young women will result in over-testing and over-treatment because it will detect viruses that most likely will never cause a problem. This will not only be more expensive, but could result in needless anxiety for the patient and harm to the cervix that could cause future health problems. How do you respond?

If the test detects the presence of one of the types of HPV that puts a woman at risk of developing cervical cancer, any follow-up tests, such as a Pap, would certainly not be considered over testing. If the HPV test leads to the detection of pre-cancer, we then have the possibility of treating the condition and preventing cancer. This would certainly not be considered over-treatment. On the other hand, a negative HPV test may eliminate the need for other tests, reducing anxiety *and* health care costs. One way to look at this is that you can sometimes do too many tests, but you can never have too many options.

5. A letter opposing the FDA approval, signed by several respected health and women's groups, says that the protocol for primary HPV testing will be to follow a positive test with a colposcopy, which is more expensive and more invasive than a Pap. Is this true?

It is not correct to say colposcopy is the standard follow-up to a positive HPV test. In some cases, a Pap smear is the standard follow up.

6. Do you think it's a conflict of interest for the American Society for Colposcopy and Cervical Pathology to be issuing guidance when it looks like the HPV test will result in more colposcopies?

There's absolutely no reason to think that primary HPV testing will result in more colposcopies. Approval of the test for primary testing is not intended to increase or decrease the number of any tests being performed, but rather to improve the overall performance of cervical cancer screening, and to improve our ability to keep women from getting and dying from cervical cancer. The ASCCP and other women's health organizations like SGO are deeply committed to reducing the global burden of cervical cancer to women and their families. Many of the leaders of these organizations work on a volunteer basis and are motivated to improve care by seeing first-hand the negative effects that can result from the diagnosis and treatment of abnormal pap tests, pre-cancer, and cancer. There is little to no real financial gain for the ASCCP or any provider who would be doing more colposcopy. The goal of screening is to do colposcopy on the right patients, meaning not missing the ones who need it and not doing it on the ones who do not need it.

7. The opposition letter was critical of the studies that the FDA panel based its recommendations on. Can you tell me about the study?

Much of the unanimous vote from the FDA panel was based on the ATHENA trial (Addressing the Need for Advanced HPV Diagnostics). This is the largest HPV screening study conducted in the United States. The study design was carefully vetted with input from numerous experts across the United States and many of these experts are central to our screening guidelines. Preliminary results from the ATHENA trial found that nearly 1 in 7 women who had a normal Pap test and were later found to have a certain type of HPV actually had high-grade cervical disease, or potentially precancerous changes in cervical cells and tissues.

8. Should the HPV test be used in women in their 20s, as Roche wants, since a high percentage will be HPV positive but will be able to fight the virus and will most likely never develop cervical cancer?

This is an excellent question that might need further research. If the FDA approves the test for women in their 20s it's because they believe the data from clinical trials supports this. Many women in their 20s may already have pre-cancers, even if they have a negative Pap. The HPV test will help us identify these women and get them treatment as early as possible.

9. Doesn't the Pap test detect numerous other conditions that the HPV test doesn't, such as various infections and sexually transmitted diseases? Are you concerned that approval of primary HPV testing will minimize the use of the Pap and miss a lot of these conditions?

The primary goal of the Pap test is to find cervical pre-cancers and cancers. Pap testing should not be exclusively used for the detection of other infections including STDs. We have other effective tests for these conditions.

10. Why replace a proven highly successful test with one that's twice as expensive and tests for fewer things?

Although Pap tests have had a tremendous impact on cervical cancer prevention, it does miss a number of pre-cancers and cancers. Having one more way to test for cervical cancer, or for conditions that can lead to cervical cancer, will allow us to do a better job of saving lives and keeping women healthy.

11. What do you want women who read the news about this HPV test approval to understand? What do you want them to do? What should they expect at their next visit to the gynecologist?

I would like women to know that the Pap test is an excellent tool for detecting cervical cancer and pre-cancer and it has saved countless lives. But, like most tests, it's not perfect. The approval of the HPV test is an example of how we are always trying to improve how we detect and treat disease. It's one more test that can be used alone, along with a Pap test or before or after a Pap test. I hope women will talk to their doctors if they have questions about which tests they should have, and how often. I also urge all parents of girls to make sure their daughters are vaccinated against the HPV virus. It's the best way to prevent cervical cancer and other cancers caused by HPV, and it could truly help us eliminate this terrible disease.

12. With the introduction of the HPV vaccine, will we see a day when the Pap and the HPV test will no longer be necessary?

The HPV vaccine is a tremendous breakthrough and if all girls and boys are vaccinated, eventually we could reach the goal of a world without cervical cancer and other cancers caused by HPV. For now, HPV and cervical cancer are still very much with us and we're lucky we have so many testing options to detect them and keep women healthy.