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Key Considerations on Cervical Cancer Screening & Management

Announcer:
Welcome to ReachMD.

This medical industry feature, titled “Key Considerations on Cervical Cancer Screening and Management” is sponsored by Roche Diagnostics, ‘doing now what patients need next’. This program is intended for physicians.

Here’s your host, Dr. Hector Chapa.

Dr. Chapa:
Evidence that infection with high-risk HPV can increase the risk of cervical cancer continues to grow. That's why the American College of Obstetricians and Gynecologists, the American Cancer Society, and the American Society for Colposcopy and Cervical Pathology have updated their guidelines to help identify patients at risk while reducing unnecessary invasive procedures and over-testing.

This is ReachMD, and I'm Dr. Hector Chapa. Joining me to explore current perspectives on cervical cancer screening and management guidelines is Dr. Linda Ahn, a board-certified OB/GYN with over 20 years of experience in clinical practice, including all aspects of women's health management. Dr. Ahn, thank you for being here today.

Dr. Ahn:
It's my pleasure to be here to discuss cervical cancer screening and management and to introduce recent tests which have been FDA approved to solve some of the unmet needs in the setting.

Dr. Chapa:
I mean, this is such an important and ever-evolving story. So, it's vital that we cover this right now. So Dr. Ahn, having said that and diving right in, what are the current cervical cancer screening guidelines tell us?

Dr. Ahn:
Absolutely. Currently, there are three different cervical screening approaches, Pap cytology, Pap HPV co-testing and primary HPV testing, as shown in this chart from the United States Preventive Service Task Force, or USPSTF. Pap cytology, the oldest screening method, requires testing every three years for women aged 21 to 65 and is still considered acceptable but declining in use, as it has low sensitivity with limitations due to subjective interpretation. On the other hand, increased understanding of HPV as a cause of cervical cancer has led to HPV testing being adopted into the guidelines. Currently, co-testing is the predominant method, and primary HPV screening is the emerging method. Screening for high-risk HPV is recommended in women 30 years and older every five years either in combination with cytology or alone.

In 2020, the American Cancer Society updated their guidelines and now has primary HPV screening for women aged 25 to 65 every five years as the preferred strategy. If primary HPV screening is not available, then individuals aged 25 to 65 can be screened with co-testing every five years or cytology alone every three years.

What's important is that more, recently, in April of 2021, the American College of Obstetricians and Gynecologists joined the American Society of Colposcopy and Cervical Pathology and the Society of Gynecologic Oncology in endorsing the USPSTF screening recommendation of primary HPV screening to be done every five years for women 30 to 65 years of age.

Dr. Chapa:
Now that can't be overstated enough. April of 2021, three professional societies endorsed primary HPV screening. So, Dr. Ahn, having

said that, can you explain in a little bit more detail, primary HPV screening?

Dr. Ahn:
So yeah, we now know that HPV screening is more sensitive than Pap. HPV identifies greater than 90% of CIN 3 or greater disease, while cytology detects approximately 50 to 70%. Primary HPV screening is a method in which a woman is given an HPV test first, and if positive, a triage test is performed for confirmation of abnormal cells. Primary HPV screening places HPV, the most sensitive test, first to identify women at risk, followed by the more specific test, cytology, to identify disease.

So to start, if the HPV test is negative, a woman is considered at very low risk of disease and returns to routine follow-up in five years. On the other hand, a positive HPV 16 or 18 result places a woman at high risk, and she's referred for colposcopy, while a positive result for 12 other high-risk HPV type places her at intermediate risk, which is then reflex to cytology.

The FDA approved primary HPV screening in 2014 based on the outcomes from the ATHENA trial with cobas HPV test, and it has been in the guidelines since 2016.

Dr. Chapa:
All right, Dr. Ahn, now remember, it's very important for us to remember what we're talking about here. There's two things for cervical cancer, there's screening guidelines, and then management guidelines. Now because we've already talked about these updated screening guidelines, Dr. Ahn, how do they fit in into the ASCCP management guidelines?

Dr. Ahn:
So yes, ASCCP revise their guidelines to a risk-based management model. The revisions were motivated by the complexity of the 2012 guidelines, and the queue of soon to be available new tests, such as dual-stain cytology and extended genotyping. HPV is pivotal in the risk estimate of the ASCCP guidelines.

And there are two fundamental concepts of this guideline. The first one being that the longer the HPV infection has been present, the higher the risk of cervical pre cancer and cancer, and second that the management is based on risk and not results. So, this shift from a result to risk-based management may lead to different recommendations determined by a combination of current test results and past history. This results in personalized care and better risk stratification. So, what this looks like for high-risk patients is that there's more intensive management leading to expedited diagnosis and treatment. And for low-risk patients, we can avoid unnecessary procedures, resulting in fewer invasive procedures.

Dr. Chapa:
Alright Dr. Ahn, those are great words. Honestly, that's what it's all about, expedited diagnosis and treatment while avoiding unnecessary procedures.

If you're just tuning in, we're listening to ReachMD, and I'm Dr. Hector Chapa. And I'm speaking with Dr. Linda Ahn about cervical cancer screening and management.

Dr. Ahn, earlier you'd mentioned that ASCCP revised its guidelines to accommodate new available tests. I mean, this is how fast things are moving. So, we want to know more about that. Tell us more about these new available tests.

Dr. Ahn:
Sure. There are currently two tests with regulatory approval, dual-stain cytology and HPV extended genotyping, which are not yet included in the guidelines. Dual-stain cytology is a biomarker-based cytology test that combines two biomarkers P16 and Ki-67 to detect transforming HPV infections. P16 and Ki-67 are mutually exclusive proteins which should not be present together in a normal cervical epithelial cell. The co-expression of both P16 and Ki67 in a cervical epithelial cell indicates cell cycle deregulation and is a hallmark of a transforming persistent HPV infection. The IMPACT trial which led to the FDA approval of P16, Ki-67 dual-stain cytology revealed that dual stain is more sensitive than Pap as a triage of HPV-positive results.

On the other hand, HPV extended genotyping identifies high-risk HPV types beyond HPV 16 and 18 to determine the appropriate follow-up interval, which can range between one to three years.

Dr. Chapa:
So, Dr. Ahn, all this is fascinating. Dual-stain cytology, it's coming. So, what kind of impact is choosing this guideline-supported HPV test have on quality of care?

Dr. Ahn:
Sure. It's beneficial to choose a test that gives you access to every screening app - option such as ASCUS, reflex, Pap, HPV co-testing, and primary HPV screening. This will allow you to effectively triage results so that you can have the information you need to manage

your patients appropriately. Currently, there are only two FDA-approved primary HPV tests available for cervical cancer screening.

Dr. Chapa:
Okay, understood. And so what does an ideal screening and management method actually look like for our patients?

Dr. Ahn:
So, in the case of primary HPV screening, HPV is a highly sensitive test, identifying more than 90% of women at risk. But with most HPV infections being transient, a positive HPV test does not mean that a woman is at risk for cervical pre cancer. And this is why we have to rely on a triage test to identify who is truly at risk to refer for further testing. It is also important to note the significance of genotyping in screening and management strategy. Identification of the highest risk HPV genotype 16 and 18 is critical to defining the patient management strategy. It is also - okay, I'm going to start that over.

It is also important to note the significance of genotyping in the screening and management strategy. Identification of the highest risk HPV genotype 16 and 18 is critical to defining the patient management strategy. While extended genotyping helps to detect other high-risk HPV types, biomarker-based tests like dual-stain cytology, can indicate if the cells are undergoing oncogenic transformation. This information can help with more accurate management decisions and can be made on the first round of testing. This improves specificity over high-risk HPV testing and gives more significant insight for patient care today.

So, the goal of a great triage test is therefore to preserve as much sensitivity from the screening step while adding as much specificity as possible.

Dr. Chapa:
Well, I have to tell you as an OB/GYN, I absolutely love this. I love the progress. I remember where we were with cervical cancer screening with slide Pap smears. And now look where we're going. So that's fascinating.

Now before we close, Dr. Ahn, let me open up the floor to you for some final thoughts. What would you like our listeners to take home as some clinical pearls or as some final messages?

Dr. Ahn:
Yeah, so there are much progress being made in cervical cancer screening. So great strides have been made in our understanding of cervical cancer. But despite the progress we've made, challenges still remain. However, promising new technologies will continuously help evolve our approach. Today, we're in a period of evolution and transition. There are overwhelming evidence demonstrating the efficacy and efficiency of primary HPV screening. And studies have shown that HPV-based cervical cancer screening has superior sensitivity and long-term negative predictive value compared to cytology screening. But due to the transient nature of most HPV infections, an effective triage method is necessary to identify which HPV positive women are truly at risk for disease. As far as we know, new technologies for triage of HPV positive results such as dual-stain cytology and extended genotyping are expected to be incorporated into the ASCCP risk-based management guidelines.

Dr. Chapa:
You know, you said two great words this is part of the evolution and the transition of cervical cancer screening. Primary HPV screening, dual-stain cytology, extended genotyping; I'm very excited because I think we're going to be able to take better care of our patients.

So, with these considerations in mind, I want to thank my guest, Dr. Linda Ahn, for helping us better understand the ever-evolving cervical cancer screening and management guidelines and their overall impact. Dr. Ahn, it was great speaking with you today.

Dr. Ahn:
It was a pleasure. Thank you for having me.

Announcer:
This program was sponsored by Roche Diagnostics 'doing now what patients need next.' If you missed any part of this discussion, visit ReachMD.com/IndustryFeature. This is ReachMD. Be Part of the Knowledge.