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ReachMD

www.reachmd.com
info@reachmd.com
(866) 423-7849

A Review of Risk in Cervical Cancer: An Analysis of the ASCCP Guidelines & NCI Risk Matrix

Announcer:
Welcome to ReachMD.

This medical industry feature, titled “A Review of Risk in Cervical Cancer: An Analysis of the ASCCP Guidelines & NCI Risk Matrix” is sponsored by BD.

Here’s Dr. Jeffery Andrews.

Dr. Andrews:
The current ASCCP Risk Based Management Consensus Guideline for abnormal cervical cancer screening tests and cancer precursors is a risk-based guideline that utilizes an electronic application that connects to a risk matrix and calculator, housed at the National Cancer Institute.

The NCI Risk Matrix Calculator is primarily based on the Kaiser-Permanente Northern California Data. NCI also used the BD Onclarity Clinical Trial, the New Mexico HPV and Pap Repository Data, CDC’s National Breast and Cervical Cancer Early Detection Program, Athena Trial Data, and the Mississippi Strides Trial Data. For mixed genotyping infections, the NCI considered genotyping results as a categorical variable with the following hierarchical levels: Type 16 positive first, LSIL Type 18 positive, LSIL Type 31, followed by 3358, LSIL 52, LSIL 45 and finally 35, 39, 51, 56, 59, 66, or 68.

The Risk Matrix utilizes past history, current HPV genotype and current cytology interpretation, if done. To first calculate an immediate risk estimate for CIN3 or worse. If that risk is above 4%, then colposcopy is recommended. If the immediate risk is less than 4% than the five-year risk of CIN3 or worse is estimated, and that risk determines the interval until follow-up testing.

That clinical guideline is called an Enduring Guideline and can be continuously updated if new evidence is approved by updating the evidence reports and the electronic app.

BD Onclarity extended genotyping was approved by the FDA in July of 2020. The value of extended genotyping for cervical cancer screening and triage has been reported from large clinical studies since 2015. Three systematic reviews and meta-analysis of extended genotyping were published in 2019 to 2020. On April 1st, 2022, the ASCCP announced that extended genotyping had been approved for the first update of the Enduring Guideline. The NCI Risk Matrix already contains the extended genotyping data.

The change for the clinician user will be the capability to enter HPV genotype results for all of the reported genotypes instead of the current 16, 18, 45 only. The recommendation outputs of the guideline app will also not change: colposcopy, or interval retest, or five-year rescreen. The Risk Matrix calculations will be more stratified and provide more precise and personalized recommendations. For example, HPV 31 has similar CIN3+ risk as HPV 18, and the risk estimate is likely to result in a recommendation for colposcopy, depending on other risk factors. As another example, the CIN3+ risk with genotypes 56, 59, or 66, when cytology is ASCUS, could be low enough for a longer interval than the recommended retest.

The ASCCP recommended only using FDA approved HPV assays. The only two HPV assays approved for primary HPV screening are BD Onclarity and Roche Cobas. BD Onclarity is the only HPV assay with FDA approval for extended genotyping. The BD Onclarity HPV assay is processed on the BD Viper LT or the BD Core Instrument, depending on the volume of testing in that lab.

When introducing risk-based guidelines and discussing extended genotyping, ASCCP emphasized equal management for equal risk, the safety of primary HPV negative result, safer, more immediate diagnosis for women at risk, and reduction of unnecessary

colposcopies for women at lower risk.

With the FDA approval and inclusion in clinical risk-based guidelines, BD can now offer laboratories, clinicians, and patients access to critical information and screening for cervical cancer in the United States.

Our goal is to continue the global fight towards eliminating diseases and associated deaths due to cervical cancer with our comprehensive diagnostic solutions.

Thank you.

Announcer:
This program was sponsored by BD. If you missed any part of this discussion or to find others in this series, visit ReachMD.com/medical-industry-feature. This is ReachMD. Be Part of the Knowledge.