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## New Modeling Analysis Shows Screening for Cervical Cancer with Pap+HPV Together™



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### Co-testing could prevent more cases of invasive cervical cancer and cost the health care system less money over time, study shows

Researchers presented a new clinical-economic modeling analysis this week showing that screening for cervical cancer with Pap+HPV Together™ (co-testing) using the Aptima® HPV assay (an mRNA-based HPV test) and the Aptima HPV 16 18/45 Genotype assay could cost the health care system less money and prevent more cases of invasive cervical cancer than screening with HPV alone\* using a DNA-based test.

Study results were presented in poster form as part of the International Society For Pharmacoeconomics and Outcomes Research (ISPOR) 18th Annual European Congress in Milan.

Researchers from the University of Southern California and Truven Health Analytics performed clinical-economic modeling analyses of screening with the Aptima HPV assays in combination with the ThinPrep® Pap test, and compared these results to screening with HPV alone using a DNA-based test with HPV 16/18 genotyping and reflex cytology.

"This study demonstrates that eliminating the Pap test as part of frontline screening would not reduce health care costs, despite what some in the medical community have argued," said lead author Juan Felix, MD, Chief of Cytopathology, Los Angeles County + University of Southern California Medical Center. "In fact, it's just the opposite. Co-testing, specifically with an mRNA-based HPV assay, would be more clinically effective and cost less money overall to the health care system than screening with a DNA-based HPV test alone."

#### Study Design and Results

The study simulated the lifetime effects of screening women for cervical cancer every three years from ages 30 to 70 using each screening strategy. These results were then projected to the current U.S. population.

The model predicted that compared to screening with HPV alone\* with a DNA-based test, screening with Pap+HPV Together using the ThinPrep Pap test and Aptima HPV assays could, over the next 40 years<sup>1</sup>:

- Prevent nearly 150,000 cases of invasive cervical cancer.
- Save approximately \$4 billion in health care costs, based on a \$39 difference for each 30-year-old woman modeled in the study.

These predictions were based on the estimate that screening with HPV alone\* could lead to 79 cases of invasive cervical cancer per 10,000 women, compared to 58 cases per 10,000 women when screening with Pap+HPV Together. This represents a potential 37% increase in cervical cancer cases, which contributed to increased treatment costs in the study.

The new model complements results published earlier this year from the largest retrospective, real-world study of cervical cancer screening strategies to date (the Quest study),<sup>2</sup> which found that nearly one in five women with cervical cancer (18.6%) could be missed by screening with HPV alone\*. In addition, the new cost-modeling study reinforces that screening with Pap+HPV Together is the preferred method for women ages 30 to 65, as recommended by consensus guidelines.<sup>3</sup>

"The more research we do, the stronger the case becomes for keeping Pap+HPV Together as the preferred screening method for cervical cancer," said Edward Evantash, MD, Medical Director and Vice President of Medical Affairs for Hologic. "Pap+HPV Together provides superior protection against cervical cancer, and now is shown to be cost-effective, for women over 30. As leaders in women's health, we believe every woman is worth this protection."

The authors note that the study results depended on the underlying performance of the Pap and HPV tests modeled in the analysis as measured by sensitivity (the true positive rate) and specificity (the rate of avoiding false positives). In addition, the study used sensitivity estimates for liquid-based cytology using image-guided technology, the current standard of care.

While the Aptima HPV assay and DNA-based HPV tests both assess the presence of high-risk HPV infection, the Aptima HPV assay also detects the activity of HPV infection, identifying those infections that are most likely to lead to cervical disease.<sup>4</sup> As such, screening with the Aptima HPV assay reduces the rate of false positives,<sup>4</sup> which was a significant factor in the difference in cost savings in the new study. Conversely, screening for cervical cancer using a DNA-based HPV test is associated with a higher rate of false positives,<sup>4</sup> which can lead to unnecessary follow-up and referral of women to colposcopy. This ultimately causes additional physical and emotional burden on women and increases health care costs.<sup>4,5</sup>

## References

1. Felix, J., et al. Presented in poster form at ISPOR 18th Annual European Congress, Milan, Italy, Nov. 7-11, 2015.
2. Blatt et al., Cancer Cytopathology. April 2015. (Study included ThinPrep Pap Test, SurePath Pap Test, Hybrid Capture 2 assay)
3. Saslow et al., Journal of Lower Genital Tract Disease. November 2012.
4. Aptima HPV Assay [package insert, AW-12820 Rev.001], San Diego, CA; Hologic, Inc., 2015. (Data in PI included ThinPrep Pap Test, Aptima HPV assay, Hybrid Capture 2 assay)
5. Sawaya G, Kuppermann M, Identifying a "range of reasonable options" for cervical cancer screening. Obstet Gynec, 2015;125:308-310.

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