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New USPSTF Cervical Cancer Screening *Draft* Recommendations Would Put Lives at Risk

The USPSTF (United States Preventive Services Task Force) ***draft*** recommendations[1]:

UNCHANGED

Pap-Alone: Grade A
Interval = 3 years; Ages 21-65

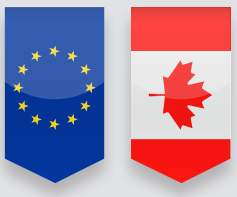
NOW EXCLUDED

Co-Testing: Pap+HPV
(Previous Grade A recommendation)

NOW INCLUDED

HPV-Alone*: Grade A
Interval = 5 years; Ages 30-65

USPSTF Analysis Did Not Consider Current US Medical Practice



USPSTF relied heavily on data from Europe and Canada.[2]

USPSTF ANALYSIS	CHALLENGES
⚠ Did **not** take into account **HPV negative** cervical cancers.[2]	Data from US clinical practice has shown, 1-in-5 cervical **cancers missed with HPV-Alone* screening**.[3]
⚠ 5 of 7 studies evaluated used **conventional cytology**.[2]	**Less than 5%** of US market uses conventional cytology – which **reduces performance** of co-testing in analysis.[4]
⚠ HPV tests used **did not** have **FDA approval** for HPV-Alone* screening.[2]	US guidelines and clinical practice emphasize the **importance** of **FDA-approved** testing.[5,6]
⚠ **All studies** used HPV **DNA** testing.[2]	**Co-testing with mRNA** is the most **widely used** screening strategy in the US – specificity would have been improved.[7,8]
⚠ **Did not use genotyping** as part of co-testing.[2]	Inclusion would have led to **immediate treatment** of 16/18+ results and may **improve model performance**.
⚠ Despite inferior sensitivity inputs **HPV-Alone*** showed decreased **mortality rates** vs. co-testing.[2]	**Co-testing** detects **more pre-cancer and cancer** than either test alone, proven by data from real-world US clinical practice.[3,9-13]

*Recent **HRSA** recommendations and **ACOG** guidelines **include Co-Testing** for women age 30 to 65 as the **preferred screening strategy** for cervical cancer.*[5,6]

TAKE ACTION BY
OCTOBER 9, 2017

Visit **ProtectPapPlusHPV.com**
to learn more and urge USPSTF to reconsider.

Pap+HPV Together

* A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.

References:
1. U.S. Preventive Services Task Force. Draft Recommendation Statement, Cervical Cancer: Screening. https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/cervical-cancer-screening2. Published September 2017. Accessed September 14, 2017. **2.** U.S. Preventive Services Task Force. Draft Evidence Review: Cervical Cancer: Screening. https://www.uspreventiveservicestaskforce.org/Page/Document/draft-evidence-review/cervical-cancer-screening2. Published September 2017. Accessed September 14, 2017. **3.** Blatt AJ, et al. Comparison of cervical cancer screening results among 256,648 women in multiple clinical practices. Cancer Cytopathol. 2015;123(5):282-288. doi:10.1002/cncy.21544. (Study included ThinPrep, SurePath, Hybrid Capture 2 Assay). **4.** Laboratory Economics. The U.S. Anatomic Pathology Market: Forecast & Trends 2016. Poughkeepsie, NY: Laboratory Economics; 2016. **5.** The American Congress of Obstetricians and Gynecologists. Practice Bulletin Number 168: Cervical Cancer Screening and Prevention. Obstet Gynecol. 2016;128(4):e111-e130. **6.** Women's Preventive Services Initiative. Recommendations for preventive services for women: final report to the U.S. Department of Health and Human Services, Health Resources & Services Administration. Washington, DC: American College of Obstetricians and Gynecologists; 2016. **7.** Hologic, Inc. Data on file. **8.** Aptima HPV Assay [package insert, AW-12820 Rev.001], San Diego, CA; Hologic, Inc., 2015. **9.** Zhou H, et al. Clinical performance of the Food and Drug Administration-Approved high-risk HPV test for the detection of high-grade cervicovaginal lesions. Cancer Cytopathol. 2016;124(5):317-23. doi:10.1002/cncy.21687. (Study included cobas HPV test, SurePath, ThinPrep). **10.** Katki HA, Kinney WK, Fetterman B, et al. Cervical cancer risk for women undergoing concurrent testing for human papillomavirus and cervical cytology: a population-based study in routine clinical practice. Lancet Oncol. 2011;12(7):663-72. PMID: 21684207. http://dx.doi.org/10.1016/S1470-2045(11)70145-0. **11.** Gage JC, Hunt WC, Schiffman M, et al. Similar risk patters after cervical screening in two large U.S. populations. Cervical Dysplasia. 2016;128(6):1248-57. **12.** Gage JC, Schiffman M, Katki HA, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. J Natl Cancer Inst. 2014;106(8). PMID: 25038467. http://dx.doi.org/10.1093/jnci/dju153. Accessed September 13, 2017. **13.** Katki HA, Schiffman M, Castle PE, et al. Five-year risks of CIN 3+ and cervical cancer among women who test Pap-negative but are HPV-positive. J Low Genit Tract Dis. 2013;17(5 Suppl 1):S56-63.