

The Case for PAP-HPV Co-testing: A Conservative Approach is Warranted and More

Philip T Valente*

Department of Pathology, The University of Texas Health Science Center, USA

*Corresponding author: Philip T Valente, Professor of Pathology, Department of pathology, The University of Texas Health Science Center, San Antonio, Texas 78229 USA, Tel: 210-567-4134; Fax: 210-567-2478; E-mail: VALENTEP@uthscsa.edu

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Editorial

The Pap test has been the most successful screening method for the prevention of cervical cancer with a seventy per cent decrease in its death rate since 1950. This is in the face of the sexual revolution of the 1960's occasioned in part by the introduction of the birth control pill in 1960. The subsequent change in sexual mores and increased promiscuity should have resulted in an increased incidence and death rate from cervical cancer. In fact the detection of cervical intraepithelial neoplasia (CIN) increased dramatically and its subsequent treatment resulted in successful cancer prevention.

In recent years, the limitations of the Pap test have been recognized and HPV testing, first as reflex testing for ASCUS and then as a cotesting method in women over 30 have been advocated. On April 24, 2014, the FDA approved the Roche Cobas HPV test for primary screening, largely based on the ATHENA trial [1]. The conclusion was that HPV testing was better at selecting women who were ultimately found to have CIN3⁺. This approach, it was claimed, would result in fewer unnecessary colposcopic examinations. Many in the cytology community were critical of this decision and pointed out methodological flaws in the ATHENA study as well as the lack of experience with primary HPV screening in routine clinical practice [2].

A recent study of cervical cancer screening among 256,648 women has supported the superiority of Pap HPV cotesting [3]. Of the 526 cancers detected, HPV testing alone would have missed 18.6% and cytology alone 12.2%. Although this study involved Digene Hybrid Capture and not the Roche Cobas test, there were a surprising number of HPV negative cancers, especially among adenocarcinoma. Although more sophisticated HPV analysis might reveal some of the tumors to be HPV related, false negative HPV tests are sufficiently common to undermine its role as a primary testing method. The practice implications of these recent studies is that cotesting is the more sensitive approach overall.

Beyond these issues, this controversy is reflective of a recent trend in laboratory medicine. When new technologies are developed, there is often a rush to implement a more expensive test for a somewhat limited increased patient benefit, but with great benefit to venture capital investors. The original benefit of the conventional Pap smear was its low cost and the ease of screening large populations. Thin layer technology has improved screening practice both by clearing an obscuring background and drying artifact and providing a platform for HPV and other STD testing. Automated screening adds additional costs which are balanced by increased "through put" by

cytotechnologists under commercial pressure to increase profits. In recent years even cytotechnologists and pathologists have even invested in these new biotech companies, clearly a potential conflict of interest.

Much of this is done in the name of decreasing health care costs and the morbidity of unnecessary colposcopy. While these are desirable goals, cotesting remains the most sensitive screening approach at the present time and is likely to remain so until an HPV vaccine covering all oncogenic types is developed.

What is lost in this discussion is the fact that the best way to increase early detection of cervical precancer and cancer in the United States is the extension of the simple Pap test to those women at high risk in underserved populations. While it is appropriate to increase the sensitivity of any cancer screening test, twenty per cent of American women are not being screened at all! The increase of the age of initial screening to 25 across the board ignores the fact that invasive cancer does occur in women in their early 20s in high risk populations. Similarly, the increase in the screening interval from one to three or even five years assumes universal health care where all women are covered and reliably followed as in the United Kingdom and the Netherlands. In underserved US populations coverage is often haphazard and the abolition of the annual Pap test will probably mean that women are screened less often than even three years. Although Obamacare has greatly reduced the number of the uninsured, true universal health care remains elusive in the US. It is sad that there is so much investment in refining screening methods for the insured while high risk uninsured women are not screened. Federal regulators and health care policy makers need to keep their eye on the prize which is the health and welfare of the all American women.

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