

Changing a national cervical cancer screening program: Randomized implementation of primary HPV testing in Norway

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Background: Cytology is an efficient method of reducing cervical cancer incidence, and has resulted in a substantial reduction in cervical cancer across the world. However, cytology does not detect all precancerous cervical lesions. In women above 35, testing for high risk types of human papilloma virus (hrHPV) may be a more efficient method in detecting high-risk lesions and preventing cervical cancer. The challenge is how to change a well functioning national screening program from cytology to HPV testing. Such a major change should be implemented gradually, and in a fashion that ensures evaluation of the change. Ideally, the change should be implemented in a randomized fashion.

Hypothesis: Randomized implementation of a new method in a national screening program is possible.

Methods: On February 1st, 2015, a 3-year randomized implementation of hrHPV testing in primary screening was implemented in four Norwegian counties, covering about 1 million people. Half of the women aged 34-69 receive cytology and half hrHPV test as their primary screening test. Which test each woman gets is determined by her birth day; women born on even days receive HPV testing, those born on odd days receive cytology. All centers use the same DNA-based test (testing for 14 oncogenic types), the same biobank solutions, and similar quality assurance protocols. All cytology, HPV and histology results are reported to the Cancer Registry of Norway for administration and surveillance.

Results: There were some differences in HPV positivity rates between the laboratories in the first part of the implementation, but such differences diminished with time. After almost one year of the implementation, overall HPV positivity rate is 6.7%. The positivity rate declines as a function of age with a weak increase in prevalence after 58 years. Reflex cytology in triage of hrHPV positives indicate approximately 50% abnormalities. This leads to referral to colposcopy and biopsy of 2.7% of the women in the HPV group, compared to 1.2% in the cytology group.

Conclusion: Careful preparation has translated to a smooth transition from cytology to HPV testing. Gradual and randomized implementation alleviates workload increase for the colposcopy and pathology services, and allows comparison of screening algorithm outcomes.