

## Sensitivity and specificity of the human papillomavirus identification test



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**To the Editor:** When the sensitivity of a test such as the Pap smear is determined, both positive and negative results should be submitted to the gold standard of histology.<sup>1</sup> If this is not done, the sensitivity will be unrealistically high.<sup>1,2</sup> The human papillomavirus (HPV) test has not been adequately investigated in this way. In this letter I report a preliminary study in which the HPV test was evaluated against histology in all cases.

In a prospective analytical study, 241 consecutive women in a primary health care clinic were tested with the HPV test and the Pap smear. A cervical punch biopsy for histological examination was done on all patients after 5% acetic acid application. The biopsy specimen was taken either from an acetowhite area or the most convenient area on the cervix (usually the 12 or 6 o'clock position). The cytological and histological examinations were done by the local teaching hospital's laboratories, while the HPV tests were analysed by means of PCR amplification by the Digene Corporation in Gaithersburg, Maryland, USA.

The median age of the 241 women was 34 years (range 27 - 52 years), and the median parity was 3 (0 - 6).

The Pap smear results were 81.5% negative and 18.5% positive. Among the positive findings were 12 cases of atypical squamous cells of undetermined significance

(5.2%), 28 low-grade squamous intraepithelial lesions (12%), 1 high-grade squamous intraepithelial lesion (0.4%) and 2 cases of cancer (0.9%). The HPV test was positive in 47.8% of cases and negative in 52.2%, while the biopsies were positive in 23.9% of cases (condyloma, cervical intraepithelial lesion and cancer).

The sensitivity of the HPV test was 75.6% (95% confidence interval (CI) 61.3 - 85.8%) and the specificity 60.4% (95% CI 52.4 - 67.9%). The sensitivity of the Pap smear was 48.9% (95% CI 33.7 - 60.6%) and its specificity was 88.9% (95% CI 83.6 - 93.4%).

The HPV test therefore has a higher sensitivity but a lower specificity than the Pap smear. It is an expensive test and also requires a high level of technical expertise to perform, making it unsuitable for resource-constrained countries in its present form. On the other hand, liquid-based cytological testing has a similar sensitivity and a higher specificity and is much less costly.<sup>3</sup>

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