Trial watch

SPECIFICITY, SENSITIVITY AND COST

The Papanicolaou (Pap) smear is commonly used to screen for cervical cancer and since its introduction in organized screening programmes in resource-rich countries it has been successful in dramatically reducing the incidence of cervical cancer. However, the sensitivity of the Pap smear is low and so testing for DNA of the causal agent of cervical cancer, human papillomavirus (HPV), either as an alternative or in conjunction with a Pap smear, is being investigated.

Mayrand *et al.* report the results of the first screening round of the Canadian Cervical Cancer Screening Trial, in which over 10,000 women aged 30 to 69 years were randomly assigned to receive either a Pap smear or an HPV DNA test approved by the US Food and Drug Administration to screen for high-grade cervical intraepithelial neoplasia. Women with positive test results underwent colposcopy and biopsy, as did a random sample of women who tested negative. The sensitivity of HPV testing was 94.6%, whereas that of Pap testing was 55.4%. The specificity was 94.1% for HPV testing and 96.8% for Pap smears. Previous concern that HPV testing is less specific than Pap smears was not supported by this study. The authors believe that a shift from cellular to viral tests, coupled with education and vaccination, will contribute to more efficient control of cervical cancer.

In the second study reported in the *New England Journal of Medicine*, over 12,000 women aged 32 to 38 years were randomly assigned to receive either an HPV test plus a Pap smear or, as a control, a Pap test alone. Women who tested positive underwent colposcopy and biopsy, as did a random sample of women in the control group. The HPV test that was used is a sensitive one that is not widely available. The proportion of women in the HPV test plus Pap smear group who were found to have grade 2 or 3 lesions or cancer was 51% greater than the proportion of control women who were found to have such lesions. In subsequent screenings, the proportion of women in the intervention group who were diagnosed with grade 2 or 3 lesions or cancer was 42% less. So, the addition of an HPV test to this group of women reduces the incidence of grade 2 or 3 lesions or cancer detected by subsequent screening.

To make HPV DNA testing accessible to all, a rapid, simple, accurate and affordable test must be developed.

ORIGINAL RESEARCH PAPERS Mayrand, M.-H. *et al.* Human papillomavirus DNA versus Papanicolaou screening tests for cervical cancer. *N. Engl. J. Med.* **357**, 1579–1588 (2007) | Naucler, P. *et al.* Human papillomavirus and Papanicolaou tests to screen for cervical cancer. *N. Engl. J. Med.* **357**, 1589–1597 (2007)