Aim

To assess the potential benefit of HPV testing in primary screening of precancerous and cancerous lesions of the cervix.

Results and conclusions

(i) Prevalence and history of cervical cancer: It is the 8th most common cancer in women in France. In 2000, the incidence was 3400 women, with 1000 deaths a year. A relationship has been established between HPV infection and cervical cancer. High-risk HPVs have been identified (types 16 and 18 classified as carcinogens).

(ii) Risk factors: HPV is a sexually transmissible infection. Prevalence decreases after age 30–35. Age is therefore a variable that can be used to select a population for screening. Persistent infection with high-risk HPV is a major risk factor for progression to cancer.

(iii) Disease management: When abnormalities are detected in a cervical smear (CS), a diagnostic and management strategy is implemented. There is no treatment for HPV infection.

(iv) HPV tests: Tests using molecular hybridization (Hybrid Capture 2® (HC2)) or gene amplification (PCR) are available. The HC2 test is simple to use. The design quality of the 11 studies selected in our review was not high (2 cross-sectional studies, only 1 of which was randomised, and 2 cohort studies). The results, however, suggest that the HPV tests are more sensitive and less specific than CS.

(v) Implementation of HPV testing: No studies support using the HPV test instead of CS as a first-line test. The high negative predictive value (99–100%) of the combination “HPV test + CS” could lead to spacing tests out, but the performance of tests repeated at different intervals has not been assessed. Test timing, intervals, and the level of population coverage have to be taken into account in the assessment of the efficacy of a screening programme. The psychological impact of HPV testing has not been assessed. Only the FDA has approved “HC2 + CS” for primary screening; the algorithms for management are based on expert opinion. Three randomised trials and three cohort studies are in progress.

(vi) Economic assessment: There are no French economic studies. No published model supports HPV testing alone and models for “HPV test + CS” are not robust.

(vii) Conclusions: HPV testing instead of a CS is not justified. The medical and economic benefit of “HPV test + CS” has to be reassessed after the results of ongoing studies are available and after a cost-efﬁcacy model has been constructed. HPV testing should be compared with a strategy for optimising the level of cover obtained with CS.

Methods

The assessment was based on WHO criteria. ANAES systematically searched the Medline, Embase and Pascal databases, useful websites, and the grey literature between 1997 and Dec. 2003 for guidelines, French articles, and economic studies. English-language epidemiological and clinical studies were selected for the period 1999 - Dec. 2003 only, as a thorough review had already been carried out in 1999. Studies were selected according to the level of evidence and design quality. The report was submitted to a working group of 16 experts, and then to 23 peer reviewers recruited from the relevant professional societies.
Looking ahead
(i) Current priority: To perform an economic assessment of the situation in France.
(ii) Need to determine algorithms for management, technical conditions for using the tests, quality control procedures and the content of patient information.
(iii) Need to assess the impact on professional practice.