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Title Pre-analytical conditions on testing for the genome (DNA) of oncogenic human papillomaviruses in cervical smears

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http://www.has-sante.fr/portail/jcms/c_1264004/fr/conditions-pre-analytiques-de-realisation-de-la-recherche-du-genome-adn-des-papillomavirus-humains-hpv-oncogenes-a-partir-de-frottis-cervico-uterins-rapport-devaluation?xtmc=&xtcr=14

Aim

In France, cervical cytology is used as the principal screening test to detect cervical cancer inasymptomatic women. HAS recommends cervical cytology screening every three years (between 25 and 65 years of age) after 2 annual smears have been normal. According to the ANAES guidelines, if cervical cytology screening reveals an ASC-US1 smear, one of the three possible options2 is to carry out a qualitative test for the genome (DNA) of oncogenic HPVs. This is done using a liquid-based smear and is performed in several stages: sampling, transportation and storage, release of DNA and detection of nucleic acids. Sampling is generally done by a gynaecologist, but also by other healthcare professionals (general practitioner, midwife, etc.). The cells are scraped from the cervix, washed in a liquid solution (storage medium) then sent to the laboratory.

The liquid-based smear can be sampled only for HPV testing, or it can previously have been used for cytology testing. The HPV test is carried out by two healthcare professionals: a biomedical analyst and an anatomical and cellular pathologist (ACP); each of these professions operates within its own regulatory framework. As regards equipment, several storage media and several HPV test kits are marketed and used in France. A particular storage medium is not generally intended to be used with all test kits.

In such a multifactorial setting, there is great potential for error. The aim of this work – which is being done in the context of the assessment of women with atypical squamous cells of undetermined significance (ASCUS), the only indication recommended and reimbursed by National Health Insurance is thus:

- to identify pre-analytical factors likely to distort the results of HPV tests,
- to lay down conditions to be met in the pre-analytical phase of HPV tests.

Conclusions and results

The results of the various analyses cited above and the summarised opinions of the professionals consulted all point to the same conclusions:

- the coordination and sharing of information at all pre-analytical stages between the person who samples the CS (gynaecologist, general practitioner, midwife, etc.) and the person who does the HPV test (biomedical analyst, ACP), wherever and however they practice;
- adherence to the rules of good practice laid down in the Guide for good conduct of biomedical analyses (GBEA)3, which applies to all biomedical analysts and is recommended for ACPs, as regards the identification, storage and transportation of samples;
- adherence to the technical procedures for carrying out the optimal cervical smear (equipment, technique and sampling site);
- adherence to good practice in carrying out the HPV test.

Methods

The assessment method used in this work is based on an analysis of regulatory texts covering the pre-analytical phase, an analysis of good practice guidelines and specific studies, and on the collected views of professionals consulted individually.

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