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| <b>Title</b>     | Evaluation of nucleic acid amplification tests (NAATs) for detecting <i>Neisseria gonorrhoeae</i>  |
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| <b>Reference</b> | ISBN number: 978-2-11-139114-7, link to full report in French: <a href="http://www.has-sante.fr/portail/jcms/c_2035591/fr/evaluation-des-tests-d-amplification-des-acides-nucleiques-taan-recherchant-neisseria-gonorrhoeae">http://www.has-sante.fr/portail/jcms/c_2035591/fr/evaluation-des-tests-d-amplification-des-acides-nucleiques-taan-recherchant-neisseria-gonorrhoeae</a> |

## Aim

The objective of this study was to evaluate the benefit of detecting *Neisseria gonorrhoeae* (NG), a pathogen that causes sexually transmitted infections (STIs), by a nucleic acid amplification test (NAAT) in symptomatic patients, asymptomatic patients (screening of persons at risk) and in other clinical situations (post-treatment follow-up, reactive arthritis in adults, investigations of male infertility, suspected conjunctival infection in neonates) with a view to deciding on the reimbursement of NAAT by the French National Health Insurance Fund.

## Conclusions and results

On the basis of all documents examined (21 national guidelines and the auditions of five French professional bodies), our national health agency concludes that NAATs for detecting NG are indicated:

- in symptomatic individuals at the relevant anatomical site(s) (genital  $\pm$  extragenital<sup>1</sup>), in combination with culture (for monitoring antimicrobial susceptibility);
- in asymptomatic individuals<sup>2</sup> at the relevant anatomical site(s) (genital  $\pm$  extragenital), used alone as first-line unless NG infection is highly likely<sup>3</sup>, in which case culture is combined with a NAAT (for monitoring antimicrobial susceptibility);
- in some post-treatment follow-up for symptomatic individuals who responded well or for certain asymptomatic individuals (especially in certain critical situations<sup>4</sup>), as a test of cure after 2 weeks post-treatment;

- in asymptomatic individuals with a history of NG infection, as a test of late reinfection, after 3 to 6 months post-treatment;
- as part of diagnostic investigations in individuals likely to sexually acquired reactive arthritis (genital  $\pm$  extra-genital anatomical sites).

If detection of *Chlamydia trachomatis* (CT) is indicated, the NAATs for detecting NG can be performed simultaneously to the NAATs for detecting CT through the use of a dual NAAT for both CT and NG.

This evaluation also specifies the indications for culture to identify NG (with monitoring of antimicrobial susceptibility), as well as the conditions for better way of using NAATs, in particular the use of a supplementary assay in some cases (cf. HTA report) directed at a different genetic target from that of the first-line assay (if positive).

## Methods

The evaluation comprises an analysis of the consistency between the French national health insurance allegations and position statements of guidelines (identified by a systematic review of guidelines and health technology assessment reports according to explicit selection criteria) and of several professional bodies (French stakeholders).

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<sup>1</sup> Anorectal site and/or pharynx.

<sup>2</sup> Risk factors are sexually active young adolescents and adults (< 25-30 years old), in particular those consulting a genitourinary medicine clinic, other at-risk cohorts (history of STIs, HIV-positive, men who have sex with men), risky sexual behaviour (sexual partner recently infected with NG or with another STIs, prostitution, drug users, multiple sexual partners, unprotected sex), some special populations (people from endemic areas, persons in correctional facilities).

<sup>3</sup> For example, if a patient is believed to have had recent relations with a sexual partner with documented NG infection.

<sup>4</sup> Pregnancy, pharyngeal infection, administration of probabilistic antibiotic that was not recommended and not validated by

antimicrobial susceptibility testing, high risk of early reinfection, multidrug-resistant gonorrhoea, severe infection, or suspicion of incomplete cure by the clinician.