INAHTA Brief

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Title Modification of the nomenclature of procedures in laboratory medicine for research into *Treponema pallidum* (bacteria responsible for syphilis)

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Aim

This concerns a request from the Union nationale des caisses d'assurance maladie (UNCAM) [Association of Health Insurance Funds] sent in June 2014 and included in the 2015 HAS work programme. UNCAM wishes to modify the Nomenclature of Procedures in Laboratory Medicine (NABM) for research into *Treponema pallidum* (bacteria responsible for syphilis).

A new algorithm replacing the current algorithm was proposed by UNCAM together with CNR-Syphilis [Centre National de Référence de la Syphilis - National Syphilis Reference Centre].

The algorithm currently in force in the Nomenclature of Procedures in Laboratory Medicine requires the completion of a treponemal test (TT) and a non treponemal test (NTT) as part of a screening process. They are manual tests and are a tedious job.

The algorithm proposed in the request aims primarily to replace the systematic combination of a TT and a NTT with a single treponemal total Ig test using a method that can be reproduced and automated; it uses ELISA (*Enzyme-Linked ImmunoSorbent Assay*) techniques or related ones such as the EIA (*Enzyme ImmunoAssays*) or the CMIA (*Chemiluminescent Magnetic microparticle ImmunoAssay*); these tests, as well as being very sensitive, have a number of practical advantages related to automation.

The concern of the request was therefore to ensure that the proposed change was not going to cause a decline in quality in detection that would lead to disregarding cases of infected patients (appearance of false negatives based on a single automated TT).

Results

Synthetic literature analysis
Four good practice recommendations and one technology appraisal report were included for the final synthetic literature analysis.

The strategy of performing an automatable treponemal test as a first step only and then continuing with a NTT in the event of positivity is cited in all the recommendations analysed as being a reliable and efficient strategy for screen syphilis.

Some recommendations advocate this strategy among the strategies to consider as first-line therapy, others cite it as being one of the possible alternatives.

All the recommendations point to the advantages of automatable immunoenzymatic tests (particularly the saving of time and the reduction of risk of error associated with interpreting the result).

Analyses of field experiences
Overall, the experiences collected (CNQ [Contrôle National de Qualité - national quality control] syphilis by ANSM, CNR Syphilis, Biomnis study, the strategy used for the qualification of blood donation) concerning the performance of an automatic TT, of an immunoenzymatic, even high-speed automation haemagglutination type as the sole first-line test have not resulted in undiagnosed syphilis.

Conclusions

Overall, all the data collected and analysed are consistent and support the proposal of modification put forward by UNCAM and CNR-Syphilis. HAS therefore recommends this proposal of modification of the Nomenclature of Procedures in Laboratory Medicine consisting of changing the algorithm in force by immediately replacing the systematic combination of a TT and an NTT with a single total Ig TT using a method that can be reproduced and automated, of an immunoenzymatic type (ELISA technique or related ones such as the EIA or the CMIA), which will be confirmed by a quantitative NTT in the event of positivity.

Methods

The assessment method validated by the board consisted of:

- the performance of an analysis of the consistency between the content of the request and the conclusions of the good practice recommendations and technology appraisal reports identified by exhaustive research;
- the collection of some field experiences:
  - data collected by the Agence nationale de sécurité du médicament et des produits de santé (ANSM) [French National Agency for Medicines and Health Products Safety] whilst performing their quality controls,

- statistics from some medical laboratories with experience in automatable TTs,
- strategies adopted for the qualification of blood donations in France.

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