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Title Update of laboratory medicine procedures related to the diagnosis of invasive candidiasis

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Aim

Following the assessment request made by the Caisse nationale d'assurance maladie des travailleurs salariés (CNAMTS [National Health Insurance fund for salaried workers]) for review of procedures listed in the Nomenclature of Procedures in Laboratory Medicine (NABM), this work focused on assessing the proposed changes to the wording for laboratory diagnosis of candidiasis. This request concerns only screening for anti-Candida serum antibodies and soluble antigens, and does not deal with mycological identification procedures.

Conclusions and results

The data collected in the evidence report (literature and positions of professionals) are consistent with the CNAMTS' request to change the wording of the laboratory medicine procedures concerning laboratory diagnosis of candidiasis.

The anti-Candida serum antibodies tested for are primarily anti-mannan [anti-Mn] antibodies; little mention was made in the literature of other anti-Candida antibodies targeting antigenic mixtures. The soluble antigens are represented by Mn and β-(1,3)-D-glucane [BG].

Analysis of the literature and the positions of stakeholders made it possible to confirm that testing for these serum markers is used in the strategy for diagnosing invasive candidiasis (candidaemia, invasive candidiasis associated or not with candidaemia, chronic disseminated candidiasis), pending the results of mycological identification in at-risk populations (haematology-oncology, intensive care, etc.) and that testing for these serum markers is carried out in blood only (serum or plasma).

Concerning anti-Candida antibodies testing, the data collected primarily concern the anti-Mn antibody; screening for this antibody is associated with screening for the Mn antigen in order to enhance the diagnostic performance. The technique used is an ELISA-type immunoenzymatic method, which does not require a confirmatory examination using another technique.

Concerning soluble antigen testing, screening for BG, a pan-fungal marker, is carried out by means of a technique using a colorimetric assay based on an enzymatic reaction, which does not require a confirmatory examination using another technique.

Interpretation of the results is always as a complement to the clinical data of the patient and the results of the additional examinations. However, the use strategy (time of assay, follow-up methods, frequency of sample collections) has not yet been established, in particular due to lack of evidence.

Methods

The assessment method consisted of:

- an analysis of the summary literature on laboratory diagnosis of invasive candidiasis by screening for soluble antigens, (β-(1,3)-D-glucane [BG] and mannane [Mn]) and anti-Candida serum antibodies (primarily anti-Mn antibodies), i.e. 14 guidelines from learned societies, a consensus of experts, six meta-analyses and ten general reviews;
- the collection of the reasoned opinion of learned societies, asked as stakeholders, i.e. the National Professional Councils for anaesthesia and intensive care, intensive care medicine, laboratory medicine and haematology; the French Transplantation Society; and the National Reference Centre for Invasive Mycoses and Antifungals (CNRMA);
- a summary of these items in an evidence report submitted directly to the HAS Board for validation.

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