Title	Assessment of laboratory medicine procedures related to the diagnosis and follow-up of hepatitis E
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Aim

The objective of this work is to assess the relevance of the Health Insurance proposals to update the list of procedures involved in the diagnosis and follow-up of viral hepatitis E (detection of RNA and detection of serum antibodies), by specifying their indications and the techniques used. The aim of this work is not to assess the treatment, screening or overall management of this type of hepatitis.

Conclusions

This assessment notes inconsistencies between the data collected for certain points of the assessment, methodological flaws of some publications in the literature review, as well as the poor quality or lack of references upon which these publications have been based. Nevertheless, it can be concluded from this assessment that:

- 1) the detection of HEV RNA, currently done using RT-PCR, plays a role in the management of immunosuppressed patients in the diagnosis of an acute infection, the diagnosis of a chronic infection, and therapeutic monitoring. For the diagnosis, this test is primarily carried out on a blood sample; to monitor the treatment, it is carried out on blood and stool samples. In the case of a chronic infection, persistence of the virus is confirmed for up to six months. To diagnose an acute infection in immunosuppressed patients, the detection of HEV RNA may be carried out in the case of severe symptoms of acute hepatitis, with a suspicion of HEV infection;
- 2) the detection of serum anti-HEV IgM, using an EIA technique, plays a role in the diagnosis of acute infection in immunocompetent and immunosuppressed patients;
- 3) based on the almost unanimous opinion of the professional bodies, the test to detect HEV and that to detect other hepatic viruses may be done at the same time in cases of suspicion of viral hepatitis;
- 4) last, the anti-HEV IgG assay for detecting a past infection cannot be used because none of the data collected indicate its clinical usefulness. Similarly, as regards the use of this testing within the context of an

acute infection, not enough data have been collected to recommend it in this indication.

Methods

The method used involves:

- performance of a critical analysis of the synthetic literature (good practice guidelines, health technological assessment reports, meta-analyses and systematic reviews) identified by a systematic literature search and then selected using specific criteria; thus two systematic reviews and twelve good practice guidelines were selected; in addition, to understand the sometimes differing conclusions of these documents, the references cited to support their conclusions were also analysed;
- collection of the reasoned views of the professional bodies for the specialties involved in the subject (laboratory medicine, infectious diseases, hepatology, recipient and donor) and of the National Centre of reference for hepatitis with enteric transmission.

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