Rapid molecular assays for the diagnosis of sepsis and identification of sepsis causing pathogens

Mundy L, Hiller JE

Record Status
This is a bibliographic record of a published health technology assessment from a member of INAHTA. No evaluation of the quality of this assessment has been made for the HTA database.

Citation

Authors' conclusions
The Prove-it™ assay provides rapid identification of a large number of bacterial species involved in sepsis infection once sepsis has been diagnosed by conventional means. Appropriate changes in patient antimicrobial therapy may take place 18 or more hours earlier than with blood culture, however the number of false negatives and false positives make this technology suitable as only an adjunct to blood culture. Severely ill patients may still be better served waiting for blood culture results, especially as the Prove-it™ assay does not provide any information on the antimicrobial susceptibility of detected pathogens. The SeptiFast assay has pros and cons associated with it as well. On the plus side, the SeptiFast can be used on whole blood while not waiting for the results of blood culture, however the number of pathogens able to be detected by the SeptiFast is reduced in comparison to the Prove-it™ assay. The reported specificity of the SeptiFast assay is high, indicating that it is correctly identifying those patients who do not have sepsis and may be receiving antimicrobial treatment unnecessarily. However, the reasonably low sensitivity indicates that the assay is poor at correctly identifying those patients who do have sepsis, and therefore many patients may not receive antimicrobial treatment if treatment was based on the PCR test alone. Both assays appear to be of value if used in conjunction with blood culture as time to correct therapy is vitally important in the treatment of sepsis. There is a large body of evidence describing the use of rapid molecular tests for either the diagnosis of sepsis or the rapid identification of bacteria involved in sepsis infection. As sepsis is associated with high levels of mortality, there is a clear clinical need to identify the causative agents involved in the infection as rapidly as possible. Rapid molecular tests, used in conjunction with conventional blood culture, may result in changes to patient management, which may be reflected in improved patient outcomes in terms of both mortality and morbidity. HealthPACT action is pending on the determination of whether sufficient evidence exists for conducting a Horizon Scanning Report.

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**Address for correspondence**
Adelaide Health Technology Assessment, University of Adelaide, Discipline of Public Health, School of Population Health and Clinical Practice, Mail Drop DX650545, SA 5005 Adelaide Australia Email: tracy.merlin@adelaide.edu.au

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