Title:	Hepatitis B virus DNA testing
Agency:	Medical Services Advisory Committee (MSAC) MDP 106 Commonwealth Department of Health and Ageing GPO Box 9849 Canberra ACT 2601 http://www.msac.gov.au
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Aim

To evaluate the safety, effectiveness and cost-effectiveness of hepatitis B virus (HBV) DNA testing for patient assessment before antiviral therapy and to monitor patients regardless of their antiviral therapy status.

Methods

A systematic review of the clinical literature was conducted for HBV DNA testing.

Results and conclusions

Safety

Safety issues were negligible because HBV DNA testing specimens are collected using standard blood collection methods.

Effectiveness

Available direct evidence indicated that HBV DNA testing alters patient management with benefits for short term health outcomes among lamivudine treated patients. Diagnostic accuracy evidence concerning patients not undergoing antiviral therapy indicated that HBV DNA testing enabled differentiation between inactive HBeAg negative carriers and HBeAg negative active chronic hepatitis B patients. Elevated HBV DNA levels in HBeAg negative patients were predictive of HBeAg reversion. Diagnostic accuracy evidence indicated that HBV DNA testing can predict patient response to lamivudine or interferon therapies. HBV DNA testing can predict sustained response among responders and HbeAg seroconversion or resistance to lamivudine. Linked evidence indicated that serum HBV DNA levels can predict long term health outcomes and show treatment efficacy.

Cost-effectiveness

Evidence was insufficient to assess potential economic benefits of HBV DNA testing on long term health outcomes. The forecast total annual demand for the considered patient groups was about 20,000 HBV DNA tests expected to cost $2.5 to $2.7 m.

Recommendation

MSAC recommended supporting public funding for hepatitis B assay use for patients with chronic hepatitis B; the number of assays for pre-treatment assessment or for monitoring patients not receiving antiviral therapy to be restricted to one assay during a 12 month period. The number of assays for patients receiving antiviral therapy is restricted to four assays during a 12 month period. The Minister for Health and Ageing endorsed this recommendation on 4 June 2007.