Comparison of the COBAS TaqMan HBV test with the COBAS Amplicor Monitor Test for measurement of hepatitis B virus DNA in serum

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Two alternative tests for the measurement of hepatitis B virus (HBV) DNA in serum were examined. One was the COBAS TaqMan HBV test (TaqMan test) and the other was the COBAS Amplicor HBV Monitor Test (Amplicor test).

The TaqMan test used 500 microL of specimen, 700 microL of wash buffer and 75 microL of elution buffer. Centrifugation was carried out at 4,600g.

Both tests used reference plasma established by the Eurohep Pathology Group with a HBV DNA concentration ranging from 2.7 x10^1 to 2.7 x10^8 copies/mL for standardisation.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with chronic hepatitis B who were followed up regularly at 3 to 6 month intervals at the Hepatitis Clinic, Queen Mary Hospital, University of Hong Kong, Hong Kong.

Setting
The setting was a hospital. The economic study was carried out in Hong Kong.

Dates to which data relate
The dates to which the effectiveness and cost data referred were not reported.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing appears to have been performed on the same patient sample as that used for the effectiveness analysis.

Study sample
No power calculations were performed in the clinical analysis. Blood samples were collected from 50 chronic hepatitis patients. All of them tested positive for hepatitis B surface antigen for at least two consecutive follow-ups. They were
all negative for antibodies to hepatitis A, C and D viruses. None of these patients had received any antiviral treatment at the time of recruitment for this study.

**Study design**
This was a diagnostic study of alternative test methods that was carried out at a single centre. The two alternative tests were tested on the same patient group.

**Analysis of effectiveness**
The outcomes assessed in the effectiveness analysis were the dynamic ranges when using the Eurohep international reference plasma, the correlation between HBV DNA values measured by assays and Eurohep standard values, and the sensitivity of the assays. The baseline characteristics of the patients providing serum samples were reported, but the authors did not state whether or not they were statistically comparable.

**Effectiveness results**
The TaqMan test could detect seven (2.7 x 10^2 to 2.7 x 10^8 copies/mL) of eight dilutions of the reference plasma, while the Amplicor test could detect three of them (2.7 x 10^3 to 2.7 x 10^5 copies/mL).

Out of 50 human HBV serum samples, 17 were detected by both the TaqMan and Amplicor tests.

Thirty samples were detected by the TaqMan test but not by the Amplicor test.

No samples were reported to have been detected by the Amplicor test but not by the TaqMan test.

**Clinical conclusions**
The TaqMan Test was found to be accurate, reproducible, sensitive and rapid, with a wide dynamic range.

**Measure of benefits used in the economic analysis**
No summary measure of benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

**Direct costs**
The quantity/cost boundary of the economic analysis was not reported. The direct costs considered in the analysis were those for the TaqMan and Amplicor test. Such costs covered consumables and the DNA extraction. The unit costs, which were reported, appear to have been derived from the setting of the diagnostic study. Discounting was not performed as it was irrelevant. The price year was not reported.

**Statistical analysis of costs**
It appears that the costs have been treated deterministically.

**Indirect Costs**
No indirect costs were reported.

**Currency**
US dollars ($).
Sensitivity analysis
No sensitivity analyses were reported.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The TaqMan test cost $148 and the Amplicor test cost $126.

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach undertaken.

Authors' conclusions
Measuring hepatitis B virus (HBV) DNA solely by the TaqMan test was much more cost-effective in both hepatitis B e antigen (HBeAg)-positive and antibody-to-HBeAg-positive patients than with other strategies.

CRD COMMENTARY - Selection of comparators
The use of the Amplicor test as the comparator was justified on the grounds that it had represented current practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The comparative design seems to have been appropriate for the study question. Both tests were performed on all samples and the results from all samples were reported. The study did not report the sensitivities of the tests, nor did it investigate the specificities of the tests. The authors did not provide evidence that the sample was representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The study was, in effect, a cost-consequences analysis.

Validity of estimate of costs
The perspective adopted in the study was unclear. Only the costs relating to the test packages were included in the economic analysis. The unit costs were provided, whereas the resource quantities were not. The authors also did not report the dates to which the cost data referred, the sources of the cost data, or the price year. These factors introduce uncertainty into the reliability of the conclusions and will hinder reflation exercises in other settings.

Other issues
The authors did not compare their findings with those from other studies. The generalisability of the study to other settings does not appear to have been addressed. The study referred to HBV patients and this was reflected in the authors' conclusions. Thus, the conclusions of the study reflected the scope of the analysis.

Implications of the study
The authors recommend the TaqMan Test for clinical monitoring of HBV DNA levels in patients with chronic hepatitis B.