Cost-effectiveness analysis of prophylactic lamivudine use in preventing vertical transmission of hepatitis B virus infection

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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.

CRD summary
This study examined the cost-effectiveness of lamivudine, given to mothers to prevent mother-to-child transmission of hepatitis B virus and the long-term effects in neonates, compared with infant immunisation and hepatitis B immunoglobulin. The authors concluded that the addition of lamivudine for mothers with high hepatitis B viraemia might be cost-effective, from a societal perspective in Taiwan. The methods were satisfactory and the results were reported well. The authors’ conclusions seem to reflect the evidence available.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This study examined the cost-effectiveness of the addition of lamivudine, given to mothers to prevent mother-to-child transmission of hepatitis B virus and the long-term effects in neonates, compared with infant immunisation and hepatitis B immunoglobulin.

Interventions
Lamivudine plus usual care was compared with usual care alone, which consisted of universal neonatal vaccination (at zero, one, and six months) and 200 international units of hepatitis B immunoglobulin, given by injection.

Lamivudine 100mg was given once daily in the last month of gestation until delivery, to mothers with high hepatitis B viraemia, defined as a hepatitis B DNA level of 42.5 million copies per mL or positive tests for serum hepatitis B surface antigen (HBsAg) and hepatitis B e antigen (HBeAg).

Location/setting
Taiwan/primary care.

Methods
Analytical approach:
The analysis was based on a decision tree, followed by a Markov model, with one-year cycles until 80 years. The authors stated that the analysis was carried out from a societal perspective.

Effectiveness data:
The clinical effectiveness estimates were primarily from a systematic literature search and meta-analysis, conducted by the authors, which identified and analysed three randomised controlled trials (RCTs) that compared lamivudine versus placebo. The other transition probabilities for the model were from the literature. The main clinical estimate was the relative risk of mother-to-child transmission with versus without lamivudine.

Monetary benefit and utility valuations:
The utility values were identified from the literature by a previous cost-effectiveness study on the prevention of hepatitis B in Asian and Pacific Island adults.

Measure of benefit:
The summary benefit measures were quality-adjusted life-years (QALYs) and the number of hepatitis B infections
averted.

Cost data:
The economic analysis included the costs of vaccination, laboratory testing, drugs, disease treatment, and productivity losses due to early death. The costs were presented as category totals, and were from several sources, including the Bureau of National Health Insurance of Taiwan and published studies. All costs were reported in US $ and the price year was 2008. Costs were discounted at an annual rate of 3%.

Analysis of uncertainty:
Probabilistic sensitivity analysis, with Monte Carlo simulation, was conducted to assess the impact of the overall parameter uncertainty. Beta, gamma, and triangular distributions were used for the clinical inputs and triangular distributions were used for the cost inputs. The results were presented in a scatter plot and a cost-effectiveness acceptability curve.

Results
Compared with no lamivudine treatment, lamivudine was associated with 480 QALYs gained and 46,000 acute infections averted per 200,000 births per year in Taiwan. Lamivudine saved $7.4 million per year.

Lamivudine dominated usual care alone, as it was more effective and less costly.

Probabilistic sensitivity analysis indicated that lamivudine was cost-effective in 94% of simulations, at a willingness-to-pay threshold of $20,000 per QALY gained.

Authors' conclusions
The authors concluded that the addition of lamivudine for mothers with high hepatitis B viraemia might be cost-effective, compared with the usual immunisation and immunoglobulin for infants without lamivudine for mothers, from a societal perspective in Taiwan.

CRD commentary
Interventions:
The interventions were clearly reported. The comparator (universal neonatal vaccination alone) was relevant to the authors' setting and it was the usual practice in Taiwan.

Effectiveness/benefits:
A systematic review of the literature was conducted to identify the primary studies and its methods were reported, including the databases searched and the inclusion and exclusion criteria. A meta-analysis of the identified RCTs was performed to derive the effectiveness evidence. These approaches seem to have been valid and should have included relevant trials, but the authors acknowledged that the efficacy data were from small trials with short follow-up periods. QALYs were an appropriate benefit measure, as hepatitis affects both survival and quality of life. The utility values were from published studies, but limited information was provided. It was unclear if future QALYs were discounted.

Costs:
The categories of costs were relevant to the stated perspective and the sources appear to have been representative of Taiwan. The costs were presented as category totals and not by individual item, but their sources were given, in a table. The unit costs and resource quantities were generally not reported separately, and the exchange rate was not reported, reducing the ability to reproduce the analysis. The generalisability of these cost estimates to other settings was unclear. The price year was reported and future costs were appropriately discounted.

Analysis and results:
The key details of the decision model were reported. An appropriate incremental approach was used to synthesise the costs and benefits of the two strategies. The uncertainty was investigated, using a valid approach, and the methods and results were presented clearly. The authors acknowledged some limitations to their analysis, such as the small numbers of patients in the three RCTs. The results were presented in appropriate graphs.

Concluding remarks:
The methods were satisfactory and the results were reported well. The authors’ conclusions seem to reflect the evidence available.

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