A cost-effectiveness analysis of different therapies in patients with chronic hepatitis B in Italy

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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 tenofovir, lamivudine, adefovir, entecavir, telbivudine, or pegylated interferon, as first-line treatments for hepatitis B virus infection in adult patients with chronic disease or cirrhosis. The authors concluded that tenofovir was the most cost-effective treatment from the perspective of the Italian national health system. The cost-effectiveness methods were conventional, but limited reporting might affect the validity of the authors’ conclusions.

Type of economic evaluation
Cost-utility analysis

Study objective
This study examined the cost-effectiveness of various first-line treatments for hepatitis B virus (HBV) infection in adult patients with chronic disease or cirrhosis.

Interventions
The initial monotherapies were tenofovir, lamivudine, adefovir, entecavir, telbivudine, or pegylated interferon. Rescue therapy was given to those who did not respond to the first-line therapy. These options were compared with no treatment.

Location/setting
Italy/secondary care.

Methods
Analytical approach:
The analysis was based on a Markov model, with both a one-year and a 10-year horizon. The authors stated that the analysis was carried out from the perspective of the Italian National Health System.

Effectiveness data:
The clinical data were from published literature. The efficacy of the treatments was the key input for the model. Data on the natural history of disease were from an economic evaluation of patients with chronic hepatitis B, in Spain. Some of the data were from clinical trials and the epidemiological data referred to the Italian setting. Some assumptions were needed, where there were no published data available.

Monetary benefit and utility valuations:
The utility values were from published sources that used the Health Utilities Index (HUI) to measure them.

Measure of benefit:
Quality-adjusted life-years (QALYs) were the summary benefit measure and the discount rate was zero to 3% for the long-term benefits.

Cost data:
The economic analysis included the costs of diagnosis, laboratory testing, drugs, follow-up, disease complications, and monitoring of renal function for patients on tenofovir. The costs were presented as annual expenditures for drugs and
disease states, and were derived from official Italian sources, as well as published Italian studies. All costs were in Euros (EUR) and the price year was 2009. A zero to 3% discount rate was applied.

Analysis of uncertainty:
Deterministic one-way sensitivity analyses were carried out on selected inputs to the model, including the proportion of patients who were hepatitis B e antigen (HBeAg) positive or negative; the proportion with cirrhosis; the costs of tenofovir, entecavir, and overall patient management; the inclusion of bone mineral densitometry for those on tenofovir; and the discount rate.

Results
The projected annual costs per patient were EUR 2,572.84 with no treatment, EUR 5,116 with tenofovir, EUR 5,276 with pegylated interferon switched to tenofovir after a year, EUR 6,206 with pegylated interferon switched to entecavir after a year, EUR 4,737 with lamivudine and the early addition of tenofovir, EUR 6,302 with entecavir, EUR 6,970 with telbivudine, and EUR 7,679 with adefovir.

The annual QALYs were 0.815 with no treatment, 0.896 with tenofovir, 0.897 with pegylated interferon then tenofovir, 0.897 with pegylated interferon then entecavir, 0.862 with lamivudine plus tenofovir, 0.895 with entecavir, 0.885 with telbivudine, and 0.876 with adefovir.

Compared with no treatment, the incremental cost per QALY gained was EUR 31,291 with tenofovir, EUR 32,863 with pegylated interferon then tenofovir, EUR 44,243 with pegylated interferon then entecavir, EUR 45,513 with lamivudine plus tenofovir, EUR 46,498 with entecavir, EUR 62,642 with telbivudine, and EUR 83,475 with adefovir.

Tenoforv alone and pegylated interferon then tenofovir were the most cost-effective treatments. More favourable ratios were found for HBeAg-positive patients and less favourable ratios were found for patients with cirrhosis. These base-case findings were confirmed in the sensitivity analyses.

Authors' conclusions
The authors concluded that tenofovir was the most cost-effective treatment from the perspective of the Italian national health system.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear as the interventions were the available and recommended treatments for HBV infection. All treatments were licensed in Italy. They were not compared with each other; each was compared against no treatment.

Effectiveness/benefits:
The approach used to identify the data sources was not described and relevant data might have been missed. Little information was provided on the data sources and it is not possible to judge the validity of the clinical inputs. The authors acknowledged that the treatment efficacy data were from studies, with relatively short follow-up periods, which might not have been sufficient for long-term modelling. QALYs were an appropriate benefit measure as the disease affects both survival and quality of life. The utility values were from published studies that used a validated instrument (HUI) to elicit them, but no further information was provided.

Costs:
The categories of costs were relevant to the perspective adopted and the sources were representative of the Italian context. The annual costs for each disease stage were reported, but the unit costs and resource quantities were generally not reported separately reducing the reproducibility of the analysis. Some costs were varied in the sensitivity analysis. The price year was appropriately reported, but it was unclear which discount rate was used in the base case. The mean cost per patient per year and the total cost over 10 years were reported in graphs.

Analysis and results:
The results were clearly presented and an appropriate incremental approach was used to synthesise the costs and benefits of the strategies. An incremental analysis between the treatment options was not performed and this would have established their relative cost-effectiveness. The uncertainty was only partly investigated in a deterministic analysis that considered variations in selected inputs. The results of these sensitivity analyses were presented selectively. The discount rate ranged from zero to 3%, but the results of the different rates were not reported and the base-case rate was not stated. The transferability of the results was not discussed and it was unclear whether these findings might be relevant in other settings.

Concluding remarks:
The cost-effectiveness methods were conventional, but the limited reporting might affect the validity of the authors’ conclusions.

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