The economic burden of hepatitis B viral infection in Bulgaria

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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
The universal vaccination of all newborns against hepatitis B viral (HBV) infection was studied. The comparator was a strategy without vaccination.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The target population comprised the birth cohort of 88,000 in 1992 in Bulgaria.

Setting
The setting appears to have been the community. The economic study was carried out in Bulgaria.

Dates to which data relate
The effectiveness evidence was derived from papers published between 1987 and 2000. The health costs were obtained from financial reports and hospital files for 1993 to 1998. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a synthesis of completed studies, official statistics reports, and personal study.

Modelling
The author stated that a decision tree model was used. The purpose of the model appears to have been to show disease progression and the probabilities of moving from one stage to another following HBV infection. The time horizon was 100 years.

Outcomes assessed in the review
The following parameters were obtained from an ad hoc review:

the demographic and epidemiological parameters,
the probabilities for different outcomes of HVB infection, and
the efficacy of vaccination.
Study designs and other criteria for inclusion in the review
The review was ad hoc and there were no inclusion criteria.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Approximately 12 studies were included in the review.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
In 1992, in Bulgaria, the birth cohort size was 88,000.

The age-specific mortality rate was 1.46 to 12.33%.

HBV prevalence by age was 1.0 to 40%.

For patients with acute symptomatic HBV infection, the probability of being hospitalised was 100%.

Five per cent of patients with acute HBV infection would become chronic carriers, of whom 45% were at the active viral replication stage and 55% were .healthy/ carriers.

After 20 years, 0.5% of .healthy/ carriers would have primary hepatocellular carcinoma (PHC).

Every year, 1.0 to 2.0% of .healthy/ carriers move to the active viral replication stage.

The vaccination schedule comprised a first dose given during the first 24 hours after birth, a second dose at 1 month and a third dose at 6 month. Vaccination coverage was 95%.

The vaccine efficacy was 40% for the first dose, 80% for the second dose and 99% for the third dose.

Measure of benefits used in the economic analysis
The measures of benefit used were the expected number of HBV infections and the expected number of deaths due to HBV infections.
Direct costs
The direct costs comprised the costs of treating acute and chronic HBV infection. The direct costs for clinical acute cases included ambulatory visits, hospital treatment, laboratory tests, and post hospital follow-up visits. The direct hospital costs for chronic HBV infections were based on the daily hospital costs and the average duration of hospital stay. The direct costs per PHC case treated according to disease stage included hospital costs, surgical treatment, post-surgical follow-up and follow-up with symptomatic therapy. The minimal costs for funeral after death due to HBV infection were also included. The cost data were obtained from financial reports and hospital files in the Hospital of Infectious Disease and the Fifth City Hospital in Sofia and Sofia City Oncology Dispensary. Regulation 22, 1997 and its Amendment in 1998 of the Ministry of Health were used for the assessment of medical services, home visits, laboratory tests and hospital stay. Estimates of liver transplants costs were based on the costs for this treatment in Europe (around $95,000 or BGN 180,000). The quantities and the costs were reported separately. Despite the fact that the time horizon for the evaluation was 100 years, no discounting was carried out. The price year was not stated.

Statistical analysis of costs
No statistical analysis of the costs was reported.

Indirect Costs
The indirect costs were not included.

Currency
Bulgarian new leva (BGN).

Sensitivity analysis
No sensitivity analysis was reported.

Estimated benefits used in the economic analysis
When comparing the strategy .universal vaccination of all newborns/ against the strategy .without vaccination/, the expected number of acute and chronic HBV infection for 100 years would fall an average of 92.9% (from 9,797 to 693 for acute HBV infection and from 18,762 to 1,332 for chronic HBV infection).

The total number of deaths caused by acute HBV infection would be reduced from 150 to zero.

The expected number of death caused by chronic HBV infection would fall by 87.68%, from 211 to 26.

Cost results
Over 100 years, the total direct medical costs related to HBV infection would be reduced on average by 95.39% (22 times), from BGN 6,265,770 without vaccination to BGN 288,841 with .universal vaccination of all newborns/.

The costs for acute and chronic HBV infection would fall by 93.2% (15 times) and 97.33% (37 times), respectively.

Synthesis of costs and benefits
The estimated benefits and costs were not combined.

Authors’ conclusions
The strategy of universal vaccination of all newborns against hepatitis B viral (HBV) infection, introduced in Bulgaria since 1991, would significantly reduce not only the direct medical losses but also the economic burden of the disease.
CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. It was current practice before the universal vaccination strategy was introduced in 1991. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were based on a synthesis of published papers and official statistical reports. The author did not state whether a systematic review of the literature had been undertaken to derive the effectiveness and epidemiological parameters, or report the methods used to derive estimates of effectiveness. The author did not consider the impact of differences between the studies identified when estimating effectiveness.

Validity of estimate of measure of benefit
The measure of benefit used was the expected number HBV infections and the expected number of deaths due to the disease.

Validity of estimate of costs
The perspective adopted in the study was not reported, but it appears to have been that of the health care system and of society as the study considered the direct medical losses and the economic burden of HBV infections. Only direct medical costs related to HBV infection were included. The indirect costs, related to production losses due to morbidity and mortality, were not considered. The author stated that all direct costs of treating HBV infection were underestimated since the yearly amortisation of the building and equipment, as well as the direct non-medical costs, was not included. The costs and the quantities were reported separately, but no statistical or sensitivity analyses of the costs or quantities were performed. The price year was not reported. Discounting was not carried out, although it was methodologically necessary given that the costs were estimated over 100 years.

Other issues
The author did not compare the findings with those from other studies, so it is not known how far the results agree with other published results. The author did not address the issue of the generalisability of the results to other settings. The results do not appear to have been presented selectively. The author's conclusions reflected the scope of the analysis.

Implications of the study
The strategy of universal vaccination of all newborns against HBV infection should be used.

Source of funding
None stated.

Bibliographic details

Indexing Status
Subject indexing assigned by CRD

MeSH
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