Vaccination against hepatitis B virus in Spain: a cost-effectiveness analysis

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
Recombinant Hepatitis B vaccination.

Type of intervention
Primary prevention and screening.

Economic study type
Cost-effectiveness analysis.

Study population
The hypothetical population cohorts consisted of 13-year-old adolescents and neonates.

Setting
Community and hospital. The study was set in Spain.

Dates to which data relate
Effectiveness data were retrieved from studies previously published between 1981 and 1993. Resource use data were derived from official data for 1990 and 1992. The price year was 1993.

Source of effectiveness data
Effectiveness data were derived from a review of studies and expert opinion.

Modelling
Decision trees supported by Markov models with Monte Carlo simulation were used for the calculation of disease costs, and a mathematical model of differential equations was used for the simulation of the effectiveness of vaccination.

Outcomes assessed in the review
The outcomes assessed included the probabilities of clinical disease categories, efficacy rate, compliance rate, and the transmission coefficient.

Study designs and other criteria for inclusion in the review
Randomised controlled trials were selected. Inclusion/exclusion criteria were not stated.

Sources searched to identify primary studies
Not stated.

**Criteria used to ensure the validity of primary studies**
Not stated.

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

**Number of primary studies included**
Approximately 16 studies were included in the review.

**Methods of combining primary studies**
Not stated.

**Investigation of differences between primary studies**
Not stated.

**Results of the review**
Decision tree probabilities were provided for acute and chronic clinical categories for both adults and children. For example, the probability of liver transplantation for acute hepatitis was 0.001 (adults) and 0.001 (children) and for chronic hepatitis was 0.25 (adults) and 0.25 (children). All other probabilities used in the decision tree are comprehensively listed in the article. The efficacy rate was estimated to be 90%. The non-compliance rate was assumed to be 90% and 68% in infants and adolescents, respectively.

**Methods used to derive estimates of effectiveness**
Effectiveness estimates were also derived from expert opinion.

**Estimates of effectiveness and key assumptions**
Deaths due to chronic infection complications have been estimated at around 3-5% annually from 30 years of age.

**Measure of benefits used in the economic analysis**
The measure of benefit was the number of cases of Hepatitis B infection prevented.

**Direct costs**
Costs were discounted at an annual rate of 5%. Quantities and costs were reported separately. The direct costs included the vaccination costs (costs of vaccine doses, cost of personnel and materials). The quantity/cost boundary adopted was that of society. The estimation of quantities and costs was based on a Markov model with Monte Carlo simulation. The price year was 1993.

**Statistical analysis of costs**
Not reported.

**Indirect Costs**
Transportation costs for the target population were included.

**Currency**
US dollars ($).

**Sensitivity analysis**
A sensitivity analysis, which included one-way and threshold analyses, was conducted to address the uncertainty surrounding variables such as disease costs, vaccine costs, discount rate and seroepidemiological data.

**Estimated benefits used in the economic analysis**
The combined programme of mass vaccination of adolescents and neonates was the most effective (discount rate = 0%). 19,622 cases were avoided for 10 years of follow-up, 79,672 cases for 20 years of follow-up, and 143,041 cases for 30 years of follow-up.

**Cost results**
The total costs for each alternative were not reported.

**Synthesis of costs and benefits**
Mass adolescent vaccination had a net cost per avoided case of $13 in the long run. Adolescent vaccination plus screening had a marginal cost of $240 per avoided case, thus becoming the most cost-effective strategy. In the sensitivity analysis, vaccine price was the most sensitive variable.

**Authors' conclusions**
Mass adolescent vaccination is, under every assumption, the strategy that shows the best cost-effectiveness. This ratio can be further improved when this strategy is combined with a screening programme for HBSAG in pregnant women.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear.

**Validity of estimate of measure of effectiveness**
The effectiveness results depend on the prevalence rates. These rates may differ widely across different regions. Therefore, the generalisability of the results to other settings depends on the extent of similarity of the region or country in question in terms of population structure and Hepatitis B seroepidemiological parameters.

**Validity of estimate of measure of benefit**
Indirect benefits, such as working hours gained as a consequence of vaccination, were not included. The authors could have selected other endpoints, including the number of avoided cases of delta hepatitis, or the death and suffering associated with Hepatitis B infection.

**Validity of estimate of costs**
Not all costs have been considered. For instance, the costs of vaccines that are currently administered to populations at risk that would no longer be necessary, and costs arising from treatment of possible adverse side-effects were excluded.

**Other issues**
Other diseases, such as HIV infection, may affect the cost-effectiveness analysis, causing an over-estimation of mass vaccination benefits.

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