Cost-effectiveness of a potential future Helicobacter pylori vaccine in the Netherlands: the impact of varying the discount rate for health

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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 a potential vaccine against *Helicobacter pylori*, in infants aged under one year, for the prevention of peptic ulcer disease and gastric cancer, compared with no vaccination, with a focus on the impact of discounting and disease prevalence. The authors concluded that vaccination could be cost-effective in the Dutch setting at a *Helicobacter pylori* prevalence of 20% or more. The methods were valid and the authors’ conclusions highlighted the impact of assumptions on the results.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
This study examined the cost-effectiveness of a potential vaccine against *Helicobacter pylori*, in infants aged under one year, for the prevention of peptic ulcer disease and gastric cancer, compared with the current situation of no vaccination, with a focus on the impact of discounting and disease prevalence on the expected benefits of vaccination.

Interventions
The intervention was a *Helicobacter pylori* vaccine, which had not been marketed at the time and was, therefore, a potential health technology. It was assumed that three doses of the vaccine were given before the age of one year. This was compared with no vaccination, which was the usual pattern of care at the time.

Location/setting
Netherlands/primary care.

Methods
Analytical approach:
The analysis was based on a Markov model of disease progression, with a lifetime horizon (85 years). The authors did not explicitly state the perspective adopted.

Effectiveness data:
The clinical data sources appear to have been selected from those known to the authors. Some Dutch databases and studies were used for the disease prevalence and most of the transition probabilities. The key clinical input was the vaccine efficacy and its estimation was based on data reported by the manufacturers. Assumptions were needed because the vaccine was not marketed and few data were available.

Monetary benefit and utility valuations:
Not considered.

Measure of benefit:
Life-years (LYs) were the summary benefit measure and two annual discount rates were used: 1.5% and 4%.

Cost data:
The economic analysis included the costs of vaccination and the direct medical costs associated with gastric cancer and peptic ulcer disease. The cost of vaccination was set by the authors using an assumed three-dose administration pattern.
The costs of disease treatment were from a Dutch source, the details of which were not given. All costs were in Euros (EUR) and the price year was 2003. A 4% annual discount rate was applied.

Analysis of uncertainty:
The issue of uncertainty was investigated by means of a probabilistic sensitivity analysis, in which the vaccine efficacy and rates of population-attributable risks were varied. A Monte Carlo simulation was undertaken and the results were presented in cost-effectiveness acceptability curves, with a cost-effectiveness threshold of EUR 20,000 per LY gained. A univariate sensitivity analysis was carried out on the efficacy of vaccination (50% or 100%), as this parameter was uncertain.

Results
Depending on the disease prevalence, which ranged from 10% to 50%, in a birth cohort of 200,297 children, the expected LYs gained with vaccination over no vaccination ranged from 145 to 467 with a 4% annual discount rate and from 810 to 2,598 with a 1.5% discount rate. Vaccination costs amounted to EUR 30.04 million and the total costs prevented ranged from EUR 1.18 million to EUR 3.58 million depending on the disease prevalence.

Depending on disease prevalence, the incremental cost per LY gained with vaccination in comparison with no vaccination ranged from EUR 198,704 to EUR 56,667 with benefits discounted at 4% and from EUR 35,632 to EUR 10,183 with benefits discounted at 1.5%. At the informal cost-effectiveness threshold of EUR 20,000 per LY gained, with a discount rate of 1.5% for benefits and a prevalence of at least 20%, vaccination could be considered to be cost-effective. With a discount rate of 4% for benefits, vaccination was not cost-effective at any prevalence.

The probabilistic simulation corroborated these conclusions. The deterministic analysis showed that the vaccine efficacy affected the results of the analysis. When vaccine efficacy was increased to 100% the incremental cost-effectiveness ratio decreased by approximately 25% and when vaccine efficacy was decreased to 50% the cost-effectiveness ratio increased by 58%.

Authors' conclusions
The authors concluded that vaccination had the potential to be cost-effective in the Dutch setting at a Helicobacter pylori prevalence of 20% or more.

CRD commentary
Interventions:
The rationale for the selection of the comparators was clear since the current pattern of care (no vaccination) was compared with the proposed health technology. As the Helicobacter pylori vaccine was a potential technology, no vaccination was the appropriate comparator in all settings.

Effectiveness/benefits:
Selecting the sources of clinical evidence can be a valid approach as long as they reflect the epidemiological setting of the study. In this study, Dutch databases and country-specific studies were used to derive the clinical inputs, and they should, therefore, be valid for the scope of the analysis. The key input was the vaccine efficacy, which was based on manufacturers’ recommendations and, as this was uncertain, it was tested in a specific sensitivity analysis. The use of only Dutch data limits the impact of potential differences from mixed sources. The benefit measure was appropriate for capturing the effects of the disease on the most relevant dimension of health, which was survival. Two discount rates were applied, as was appropriate for the objective of the analysis.

Costs:
The economic analysis focused on the setting and the health care system, but this was not explicitly reported. The economic analysis was not presented in detail and the key cost category, which was the disease treatment costs, was not separated into individual items. These costs were from a previous study and the methods of this were not reported. Other aspects of the analysis, such as the price year, use of discounting, and statistical analyses, were reported and consistent with Dutch guidelines.

Analysis and results:
The expected costs and benefits were clearly presented and the incremental approach was appropriate for identifying the optimal strategy. The issue of uncertainty was satisfactorily investigated and was well discussed. The authors acknowledged some limitations of their analysis, which mainly related to the need for many assumptions, since the vaccine was not registered and clinical data were not available.

Concluding remarks:
- The methods were valid and the authors' conclusions highlighted the impact of model assumptions on the study results.

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