Assessing cost and cost effectiveness of pneumococcal disease and vaccination

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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 vaccination of infants with a 7-valent pneumococcal conjugate vaccine (PCV7) for the prevention of pneumococcal diseases such as otitis media, pneumonia, meningitis and bacteraemia, was examined.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical birth cohort of 3.8 million infants in the USA.

Setting
The setting of the study was primary care. The economic study was conducted in the USA.

Dates to which data relate
The effectiveness evidence was based on 1997 data from a managed care organisation (MCO) and other literature that was not referenced. The costs were derived from the same MCO database. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a review or synthesis of completed studies and from an MCO database.

Modelling
An economic model, in the form of a decision tree, was developed to assess the cost-effectiveness of the PCV7. Routine vaccination and no vaccination were the two alternatives compared. The number of cases of otitis media, pneumonia, meningitis, bacteraemia and other pneumococcal-related diseases resulting from each of the two options were calculated. The total costs and benefits associated with each option were then estimated and compared. The time horizon of the analysis (the time in which the costs and benefits were incurred) was not specified.

Outcomes assessed in the review
The outcomes assessed were the probabilities of pneumococcal disease, based on the age-specific incidence of invasive disease. Probabilities were assessed separately for otitis media, pneumonia, meningitis, bacteraemia, invasive pneumococcal disease and other, less frequent forms.
Study designs and other criteria for inclusion in the review

Much of the data were derived from a randomised controlled trial assessing the efficacy of the PCV7 (Lieu et al. 2000, see ‘Other Publications of Related Interest’ below for bibliographic details), and an MCO database. Data from the database were obtained for a cohort of children under 5 years of age in 1997 who were continuously enrolled in the organisation and had drug coverage. Additional data were derived from unspecified literature.

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
Apart from the MCO database, no reference to other studies included in the review was made. The number of primary studies included is unknown.

Methods of combining primary studies
Not stated. It is possible that the primary studies were not combined.

Investigation of differences between primary studies
Potential differences between the primary studies were not discussed.

Results of the review

Within one year, among 60,000 children under 2 years of age, 89,000 visits for otitis media (with 64% of them accounting for new cases) and 500 clinical episodes of pneumonia were reported.

Among an unknown number of children under 5 years of age, 86 cases of invasive pneumococcal disease were reported.

The probabilities for other pneumococcal-related diseases were not provided.

Measure of benefits used in the economic analysis

Two measures of benefits were used in the economic analysis. These were the number of cases of pneumococcal disease prevented by the PCV7 and the number of life-years saved (LYS). The LYS were discounted at an annual rate of 5%. The time horizon of the analysis for which the benefits were estimated was not specified.

Direct costs

The direct costs consisted of medical costs only. These comprised the costs of pneumococcal disease (medical visits, diagnostic testing and medication) and vaccination (vaccine costs plus administrative costs). The costs and the quantities were not analysed separately, although in some cases elements of resource use (such as the number of medical visits per case) were reported. The estimation of the quantities and unit costs associated with invasive pneumococcal disease, pneumonia and otitis media was based on automated laboratory, pharmacy and clinical diagnostic data series available in an MCO (Northern California Kaiser Permanente). Resource use related to year 1997. Actual costs, rather than billing costs or moneys received, were used. The costs were based on reimbursement rates in the community at the time.
the cost management system was established. The total costs were estimated using modelling. The costs were discounted at an annual rate of 5%. The price year was not reported.

**Statistical analysis of costs**
The costs were treated deterministically. No statistical analysis of the costs was undertaken.

**Indirect Costs**
The indirect costs included in the analysis were those associated with time lost from work for the parent, the need for additional child-care, and loss of productive life function for the child. The costs and the quantities were not provided separately. Data on the indirect costs were obtained from interviews with parents of 650 children with pneumonia, otitis media or invasive pneumococcal disease, and related to 1997. The total costs were based on modelling. Discounting was carried out at an annual rate of 5%. The price year was not reported.

**Currency**
US dollars ($).

**Sensitivity analysis**
No sensitivity analysis was undertaken to investigate the impact of uncertainty on the results.

**Estimated benefits used in the economic analysis**
In a birth cohort of 3.8 million infants in the USA, the number of episodes of pneumococcal disease prevented by vaccination was 1.1 million. This comprised 560 cases of meningitis, 12,000 cases of bacteraemia, 53,000 cases of pneumonia and around 1 million cases of otitis media. The number of LYS due to pneumococcal vaccination was not reported.

**Cost results**
From a societal perspective (direct and indirect costs), the total cost-savings from pneumococcal vaccination were $763 million per 3.8 million infants, or $181 per infant vaccinated.

From the perspective of a health care payer (direct costs only), the total cost-savings from pneumococcal vaccination were $307 million per 3.8 million infants, or $61 per infant vaccinated.

These savings did not include the intervention costs (cost of vaccine and administration costs); they only referred to savings arising from disease cases averted. The timeframe over which the costs were incurred was not stated. The total costs were discounted at an annual rate of 5%. The costs associated with potential complications of vaccination were not included in the analysis.

**Synthesis of costs and benefits**
The costs and benefits were combined in the form of incremental cost-effectiveness ratios (ICERs), expressing the cost per disease episode prevented and the cost per LYS. However, the results were reported only in terms of the cost per LYS due to vaccination. The ICERs were calculated by dividing the difference between the cost of vaccination and the savings from cases of pneumococcal disease averted, by the LYS saved due to vaccination.

From a societal perspective, the ICER was $21,000 per LYS for a cost of $40 per vaccine dose, and $107,000 per LYS for a cost of $60 per vaccine dose.

From the perspective of a health care payer, the ICER was $107,000 per LYS for a cost of $40 per vaccine dose, and $194,000 per LYS for a cost of $60 per vaccine dose.
Authors’ conclusions
Vaccines such as the 7-valent pneumococcal conjugate vaccine (PCV7) resulted in better economic outcomes for society than for health care payers. Vaccination could be considered cost-effective without being cost-saving.

CRD COMMENTARY - Selection of comparators
Vaccination for pneumococcal disease was compared with no vaccination, which enables the active value of the intervention to be assessed.

Validity of estimate of measure of effectiveness
It was not stated that a systematic review of the literature had been undertaken. The majority of the effectiveness data were derived from a randomised controlled trial and an MCO database. Any other literature used was not referenced. In addition, the authors failed to provide details of the methodology used to extract the effectiveness data. It is likely that primary studies potentially included in the review were not combined. The authors did not undertake any sensitivity analyses. Therefore, it was difficult to assess the validity of the estimates.

Validity of estimate of measure of benefit
The estimation of benefits was modelled. The decision tree used was appropriate for the analysis. However, the choice of measure of benefit used for the estimation of ICERs (i.e. the number of LYS by the PCV7) was not appropriate, as this was not the main benefit provided by vaccination. The major benefit of PCV7 vaccination was the number of pneumococcal disease cases (otitis media, pneumonia, meningitis etc.) averted. A measure of benefit that incorporates quantity and quality of life, such as quality-adjusted life-years, would be a relevant and thus appropriate outcome measure with which to evaluate the cost-effectiveness of the pneumococcal vaccine. In addition, the time over which the benefits were assessed was not stated.

Validity of estimate of costs
The authors performed two analyses, one from a societal perspective and the other from the perspective of a health care payer. Direct non-medical costs, such as travel costs and out-of-pocket expenditure, were omitted from the estimation of societal costs. It is not known whether their inclusion would have had an impact on the results. All the other costs relevant to the perspectives adopted were included in the analysis. The costs and the quantities were not analysed separately, which hinders the reproducibility of the results. Nevertheless, in the case of otitis media, resource use (such as medical visits per case) was reported. A sensitivity analysis of the costs was not undertaken, but separate ICERs for two different vaccine cost values were provided. Discounting was undertaken, but the time horizon of the analysis (the time over which the costs were incurred) was not stated. The price year was not reported and this limits the generalisability of the results.

Other issues
The authors compared their findings with those from other studies, in order to assess the cost-effectiveness of the vaccine for pneumococcal disease in relation to that of other vaccines and medical interventions. The issue of generalisability to other settings was implicitly addressed. The authors reported, as a limitation of their analysis, the fact that resource use and related cost data derived from their MCO might not be representative of other organisations of this kind. In addition, they acknowledged that several factors were not considered in the analysis. For example, changes in antibiotic resistance patterns of pneumococcal disease (which might affect future costs of pneumococcal disease) and the potential reduction in disease incidence in older children and adults. The potential for cross-protection between serotypes, or herd immunity, was also not considered. The authors did not present their results in full and their conclusions reflected the scope of the analysis.

Implications of the study
It can be inferred from the results of this study that the vaccination of infants with the PCV7 should be routinely
performed, as it is a cost-effective intervention.

**Source of funding**
None stated.

**Bibliographic details**

**Other publications of related interest**

**Indexing Status**
Subject indexing assigned by NLM

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