Cost-efficacy analysis of palivizumab in the prevention of respiratory syncytial virus infections in young children with hemodynamically significant congenital heart disease

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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 assessed the cost-effectiveness of prophylaxis with palivizumab, compared with no prophylaxis, for children with congenital heart disease. The authors concluded that their model suggested that palivizumab was cost-effective at the generally accepted Italian threshold of 60,000 Euros per additional life-year gained. The methods were satisfactory and the results were well reported, but the analysis might have omitted some important costs. Despite this, the authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to assess the cost-effectiveness of prophylaxis with palivizumab, compared with no prophylaxis, in children with congenital heart disease.

Interventions
Palivizumab was used to prevent respiratory syncytial virus (RSV), a serious pathogen affecting children with congenital heart disease. Palivizumab was compared with no preventive treatment.

Location/setting
Italy/out-patient secondary care.

Methods
Analytical approach:
A decision-analytic model was used to combine the data from published studies. The time horizon was the lifetime of the patient. The authors reported that the perspective adopted was that of the third-party payer, which was the Italian National Health Service.

Effectiveness data:
The effectiveness data were from a multinational, randomised, double-blind, placebo-controlled trial of 1,287 children, with 639 randomised to palivizumab and 648 to placebo. The results of this trial were extrapolated using data reported by the British Heart Foundation and in published literature. The main effectiveness estimate was the relative reduction in RSV hospitalisations. This evidence was from the multinational trial.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
The measure of benefit was life-years gained.

Cost data:
The direct costs analysed were those of palivizumab and hospitalisation. Hospitalisation resource use was from the multinational trial used for the effectiveness data. The costs of palivizumab were those applicable to hospitals purchasing it. The hospitalisation costs were from national tariffs for diagnosis-related groups. All costs were reported
in Euros (EUR).

Analysis of uncertainty:
A one-way sensitivity analysis was performed by varying three parameters: the discount rate for life-years gained (zero in the base case); the costs of hospitalisation based on length of stay rather than diagnosis-related groups; and the mortality from RSV infection. The results were presented in a bar graph. A scenario was considered, in which palivizumab was assumed to have no impact on mortality.

Results
The average cost was EUR 3,990 for palivizumab prophylaxis compared with EUR 596 for no prophylaxis. The average life-years gained were 51.3 years with palivizumab compared with 50.8 years with no prophylaxis.

Compared with no prophylaxis, palivizumab was associated with an incremental cost per life-year gained of EUR 7,186.

In the sensitivity analysis, the results were most sensitive to the discount rate for survival. With a 5% discount rate the incremental cost-effectiveness ratio increased to EUR 22,562. When the length of stay was used for hospitalisation costs, the incremental cost per life-year gained fell to EUR 6,662. In the scenario where palivizumab did not affect mortality, the cost per life-year gained increased to EUR 38,038.

Authors’ conclusions
The authors concluded that their model suggested that palivizumab prophylaxis was cost-effective at the generally accepted Italian threshold of EUR 60,000 per additional life-year gained.

CRD commentary
Interventions:
The interventions were reported clearly and in detail. They were appropriate comparators and the population was described. It appears that palivizumab was the usual care, but this was not explicitly stated.

Effectiveness/benefits:
The main measure of effectiveness was from a large randomised multinational trial and an appropriate summary of this trial was provided, including its main results. It is likely that the effectiveness estimates were internally valid. The extrapolation of these results was appropriately reported, with details of the sources and methods used. It was unclear if a systematic review was undertaken and therefore unclear if all the best available evidence was used. The measure of benefit was appropriate. Discounting was not undertaken in the base case, but was assessed in the sensitivity analysis.

Costs:
The perspective was reported, but only the costs of prophylaxis and hospitalisations were analysed; other costs, such as out-patient consultations, general practitioner visits, and other treatments, were not included and might have been relevant. The authors assumed that patients only incurred costs in the first year of the study; it is likely that patients with congenital heart disease will incur costs throughout their lives and, with different effectiveness between the two interventions, these future costs would differ. As the costs were assumed to occur over one year, discounting was not relevant. The price year was not reported, which will hamper future inflationary exercises.

Analysis and results:
The cost and outcome information was appropriately synthesised, using a decision analytic model. The details of the model, including a diagram, were provided. The authors performed a limited one-way sensitivity analysis, which goes some way towards identifying the impact of uncertainty on the results, but a probabilistic sensitivity analysis would have more thoroughly tested the overall model uncertainty. The authors reported as their main limitation that they did not assess the impact of the interventions on quality of life, and so did not use quality-adjusted life-years as their measure of benefit.

Concluding remarks:
The methods were satisfactory and the results were well reported, but the analysis might have omitted some important
costs. Despite this, the authors’ conclusions appear to be appropriate.

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