Respiratory syncytial virus prophylaxis: cost-effective analysis in Argentina

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 use of palivizumab for the treatment of respiratory syncytial virus (RSV) in preterm infants and children with bronchopulmonary dysplasia (BPD).

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children meeting the following criteria:

- 35 weeks' gestation or less and 6 months of age or younger;
- 28 weeks' gestation or less and 1 year of age or younger;
- age 24 months or younger and a clinical diagnosis of BPD requiring medical treatment in the last 6 months.

Setting
The setting was secondary care. The economic study was carried out in Buenos Aires, Argentina.

Dates to which data relate
The effectiveness and resource use data were gathered in 1998 and 1999. The price year was 2000.

Source of effectiveness data
The effectiveness evidence was derived from a single study and a published study.

Link between effectiveness and cost data
The costing was carried out retrospectively on the same sample of patients as that included in the effectiveness study.

Study sample
Power calculations to determine the sample size were not reported. Of the 80 eligible patients identified at the study hospital in 1998 and 1999, 38 were excluded because they lived too far from the hospital (24), were already enrolled in a different study (10), or were lost to follow-up (4). Therefore, the final sample comprised 42 patients. Of these, 24 had BDP and 18 were preterm.
Study design
This was a historical case series that was carried out in a single centre, the Hospital de Pediatria 'Prof. Dr. J. P. Garrahan', a Level III public reference centre for high complexity patients. The length of follow-up was not reported. Four patients were lost to follow-up.

Analysis of effectiveness
The analysis of effectiveness was limited to the sample of 42 patients after excluding the 4 patients lost to follow-up. The outcome used in the analysis was the hospitalisation rate in 1998 and 1999.

Effectiveness results
During the two seasons, 16 of the 42 patients were hospitalised. Ten had RSV infection, 2 had adenovirus, 1 had measles pneumonia and 3 had negative virologic diagnosis tests. Therefore, the average hospitalisation rate due to RSV infection was 23.8% (95% confidence interval: 12 - 39). The hospitalisation rate was 33% in 1998 and 16% in 1999.

Clinical conclusions
The effectiveness study showed that a very high hospitalisation rate was associated with RSV infection in high-risk patients.

Outcomes assessed in the review
The outcome assessed was the reduction in the hospitalisation rate due to palivizumab. This was estimated from the literature.

Study designs and other criteria for inclusion in the review
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
Only one study was used.

Methods of combining primary studies
Not relevant (single study used).

Investigation of differences between primary studies
Not relevant (single study used).
Results of the review
The reduction in the hospitalisation rate due to palivizumab was 55%.

Measure of benefits used in the economic analysis
The summary benefit measure used was the reduction in the hospitalisation rate. This was derived from the published study.

Direct costs
Discounting was not applied since the costs were incurred during less than two years. The unit costs were reported but the quantities of resources used were not. The health services included in the economic evaluation were palivizumab and administration costs, and hospitalisation in a paediatric room or neonatal intensive care unit. It was assumed that there would be no drug wastage. The cost/resource boundary of the study was unclear. Resource use was estimated using data retrospectively gathered in 1998 and 1999 from the sample of patients who were involved in the effectiveness study. The costs were estimated from manufacturers’ prices and from the Department of Costs at the study hospital. The price year was 2000.

Statistical analysis of costs
No statistical tests of the costs were performed.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
US dollars ($).

Sensitivity analysis
One-way sensitivity analyses were carried out to address the issue of uncertainty in the hospitalisation rate. The ranges of variations explored were the confidence interval and the 1998 and 1999 rates observed in the single study.

Estimated benefits used in the economic analysis
The hospitalisation rate was 23.8% without palivizumab, as observed in the single study. This was reduced by 55%, as reported in the published study. The actual figure for the hospitalisation rate with palivizumab was not reported.

Cost results
In the whole group, the cost of hospitalisation was $184,777. The cost of hypothetical palivizumab use would be $185,064.

Synthesis of costs and benefits
The authors stated that, applying the 55% reduction in hospitalisation, the cost per avoided hospitalisation was $15,358 and the number-needed-to-treat was 7.9. The process used to calculate these figures was unclear. The sensitivity analysis showed that the cost to avoid one hospitalisation decreased when the rate of hospitalisation increased.

Authors’ conclusions
Palivizumab represented a very costly strategy for the treatment of respiratory syncytial virus (RSV) in high-risk patients with bronchopulmonary dysplasia (BPD). However, as the treatment was also very effective, the results of the
present cost-effectiveness study represented an important instrument to assist decision-making in developing countries.

**CRD COMMENTARY - Selection of comparators**
The choice of the comparator (no intervention) appears to have been appropriate because it permitted the additional value of palivizumab to be assessed. You should decide whether no intervention represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The analysis of effectiveness was based on a historical case series for patients in the no intervention group, and on data from a published study for the outcome associated with the study intervention. With the use of a historical case series, the design of the study was weak since a single group of patients was considered and a retrospective analysis was carried out. A prospective trial would have provided more reliable results. The data that were derived from the literature came from a study whose details were not provided. Only the reduction in the hospitalisation rate was reported. Thus, it was difficult to estimate the validity of the source used and it was unclear whether the two populations were comparable. Sensitivity analyses were carried out on one estimate only and uncertainty around the remaining values was not investigated.

**Validity of estimate of measure of benefit**
The summary benefit measure was derived from the effectiveness study and was specific to the disease under evaluation. Therefore, comparisons with the benefits of other health care interventions are likely to be difficult. Further, the use of reduction in hospitalisation rate was inappropriate for assessing the impact of the intervention on the patients' health, as this represented an intermediate rather than a final measure.

**Validity of estimate of costs**
The true perspective adopted in the study was unclear. It appears that only the direct costs relevant to the service provided have been included, despite the fact that the authors stated that a societal perspective was adopted. The indirect costs and non-medical costs were not considered, although the authors provided a justification for such exclusions. The source of the cost data, price year and unit costs were reported, which means that replication of the study in other settings should be possible. The details of resource use were less clear. Discounting was irrelevant and was not carried out.

**Other issues**
The authors made several comparisons of their findings with those from other studies. They stated that the differences, in terms of hospitalisation rate between developed and developing countries, were mainly due to the low-income contexts from which most patients enrolled in the present study were selected. For consistency, developing countries should not extrapolate data published by developed countries due to the wide variations in treatment and epidemiological patterns, as well as in cost data. The issue of the generalisability of the study results to other settings was not addressed and few sensitivity analyses were conducted. This reduced the external validity of the analysis. The authors noted some limitations to their study. Specifically, the selection of outborn patients, the small number of patients and the exclusion of drug wastage. In addition, a group of children who were already receiving palivizumab could not be included in the study.

**Implications of the study**
The authors suggested that a reduction in drug wastage, the identification of high-risk populations, and prescription of four rather than five doses would enhance the cost-effectiveness of palivizumab in developing countries.

**Source of funding**
None stated.
Bibliographic details

PubMedID
12075758

Other publications of related interest

Indexing Status
Subject indexing assigned by NLM

MeSH
Antibodies, Monoclonal; Antibodies, Monoclonal, Humanized; Antiviral Agents; Argentina; Cohort Studies; Cost-Benefit Analysis; Female; Health Care Costs /statistics & numerical data; Hospitalization /economics; Humans; Infant; Infant, Newborn; Infant, Premature; Intensive Care Units, Neonatal; Male; Palivizumab; Respiratory Syncytial Virus Infections /complications /drug therapy /economics; Respiratory Syncytial Viruses /pathogenicity; Retrospective Studies; Risk Factors

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