A cost-benefit analysis of RSV prophylaxis in high-risk infants
Schrand L M, Elliott J M, Ross M B, Bell E F, Mutnick A H

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 respiratory syncytial virus immune globulin (RSV-IG) and palivizumab as prophylactic drugs to prevent hospitalisation from RSV-related infections in high-risk infants. The comparator used was no prophylaxis.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study comprised infants aged less than two years who were born at high-risk of RSV between 1994 to 1995 and 1998 to 1999. The high-risk groups included infants who were born prematurely, those who developed chronic respiratory disease in the perinatal period, and those who suffered from bronchopulmonary dysplasia, interstitial pulmonary fibrosis of prematurity or Wilson-Mikity syndrome. The groups also included infants who had an unspecified respiratory condition or who had chronic lung disease and congenital heart disease. High-risk infants also included those born into a low socioeconomic family, boys, those who attended a day care centre, those who were born in the 6 months before the RSV season, those who were exposed to smoke and those who were part of a multiple birth.

Setting
The setting was primary care. The economic study was carried out in Iowa City, USA.

Dates to which data relate
The effectiveness data were drawn from observed outcomes for the two groups. For the control group this was during 1994 to 1995. For the intervention group this was during 1998 to 1999. The cost data for both groups were obtained from the UIHC health information database and adjusted to 1999 dollars.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was retrospective and was undertaken on the same population as that used in the effectiveness study.

Study sample
The sample size was not determined in the planning stage. There were 40 patients in the control group and 61 in the intervention group. These were identified as follows.
Five hundred and seven patients who could have potentially been used in the control group (1994 to 1995) were identified as being at high risk of RSV by their ICD-9 code. Of these patients, 357 were excluded due to the lack of follow-up data. Patients who would have failed the UICH Pharmacy and Therapeutic Subcommittee-approved criteria for the use of RSV-IG or palivizumab agents were also excluded.

Six hundred and ten patients who could have potentially been used in the intervention group (1998 to 1999) were identified from computer records as having received a RSV-IG or palivizumab agent. These patients all had the same ICD-9 codes as the patients in the control group. For 536 of these patients there were no follow-up data. A further 9 patients were lost to follow-up, another 3 patients did not meet the inclusion criteria and one patient received RSV-IG as treatment rather than as prophylaxis.

**Study design**
This was a comparative study with a historical control, which was carried out in a single centre. No information about data collection or the length of follow-up for record keeping, was given.

**Analysis of effectiveness**
The analysis was conducted on the 61 patients identified between the two groups. The measure of effectiveness used was the reduction in the chance of hospitalisation. The intervention and control groups were not found to be statistically significantly different in terms of gestational age, birth weight, gender or multiple births.

**Effectiveness results**
The benefit of the prophylactic was a 23.4% lower chance of each infant being hospitalised. No p-values or confidence intervals were given.

**Clinical conclusions**
RSV prophylaxis resulted in a 23.4% lower chance of hospitalisation due to RSV-related infections.

**Modelling**
A decision analysis model was used to assess the costs and the outcomes of the prophylaxis and no prophylaxis regimes.

**Measure of benefits used in the economic analysis**
The measure of health benefit used in the analysis was the average savings made by reducing the chance of hospitalisation.

**Direct costs**
The direct costs to the hospital were included. The costs in the control group were those incurred by a hospitalised infant. The costs in the intervention group were for the prophylactic agents, pharmacy time, nursing time, the clinic and hospitalisation. The hospital costs for the intervention group were estimated from the costs of hospitalisation for the control group. Discounting was not performed as only the immediate costs were reported. All the costs were adjusted for inflation and were reported in 1999 dollars.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included in the study.
Currency
US dollars ($).

Sensitivity analysis
A one-way sensitivity analysis was carried out on the success rate of prophylaxis. The success rate was changed to that found in other studies.

Estimated benefits used in the economic analysis
At baseline, the hospitalisation rate was 25% for those who did not receive prophylaxis and 1.6% for those who did. Therefore, there was a 23.4% lower chance per child of hospitalisation when receiving prophylaxis. This resulted in an average saving in the hospitalisation costs of $3,985 per infant in the prophylaxis group.

Cost results
One patient in the intervention group was hospitalised with a RSV-related infection. The total cost for this patient, which included the mean cost of the intervention and the average cost of hospitalisation, was $20,492. The only costs incurred for the other 60 patients were those of the prophylaxis programme, which amounted to $3,461 per patient.

Ten patients in the control group were hospitalised with RSV-related infections, at a cost per patient of $17,031. The remaining 30 patients incurred no costs.

The weighted average of the costs was $3,733 for the intervention group and $4,258 for the control group.

Synthesis of costs and benefits
The savings from reduced hospitalisation, arising from the use of RSV-prophylaxis, were compared to the prophylaxis costs using a benefit-to-cost ratio. At baseline, this ratio was 1.15:1 in favour of using prophylaxis.

The one-way sensitivity analysis showed that, with a hospitalisation chance per infant of 4.8% using prophylaxis, the benefit-to-cost ratio was reduced to $3,440:$3,461. With a hospitalisation chance per infant of 8% using prophylaxis, the benefit-to-cost ratio was $2,895:$3,461. In the worst case reported, in which the hospitalisation rates for infants who did or did not receive the prophylaxis were used, the benefit-to-cost ratio was $4,939:$3,461.

Authors' conclusions
The benefits of respiratory syncytial virus (RSV) prophylaxis, in the form of reduced hospitalisation costs, were greater than the costs of the prophylaxis itself when used in high-risk groups.

CRD COMMENTARY - Selection of comparators
The comparator was justified on the grounds that no prophylaxis was the only real alternative. Data were collected on a cohort of patients treated before the introduction of the prophylaxis drug and a cohort of patients treated after its introduction. You should decide if this is appropriate in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a comparative study with a historical control, which was appropriate for the study question. This type of study design is prone to confounding. However, the patient groups were shown to be comparable at analysis for a few factors. It is hard to tell if the study sample was representative of the study population. In addition, there may have been selection bias between the groups given the different time periods. No information was provided about the data collection.
Validity of estimate of measure of benefit
The measure of benefit used was the savings made by reducing the chance of hospitalisation. The instrument used to derive the measure, a decision analysis model, was appropriate.

Validity of estimate of costs
Most of the categories of cost relevant to the perspective adopted were included in the analysis. However, the outpatient cost of RSV-related infections was not. Further, as the authors acknowledged, all of the costs were taken from cost data recorded in 1994 to 1995. Therefore, the costs for the prophylaxis (intervention) group will be overestimated since resource consumption should have been reduced. The costs were reported in detail. Only the costs to the programme, and not the patient or parents, were considered. A broader perspective would include the patients’ transportation costs and the loss of payment to relatives.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The costs were only considered from the perspective of the UHIC pharmacy and therapeutic subcommittee. You should decide whether the costs would be substantially different in your own setting. The authors stated that the benefit-cost results found elsewhere differed from their results in terms of which high-risk groups the prophylaxis is used for.

The study enrolled infants aged less than two who were at high risk of being hospitalised with an RSV-related infection, and this was reflected in the authors’ conclusion. The authors reported a number of limitations to their study. For example, two different RSV seasons were compared, and most hospitalisations occurred at local hospitals and not at the UIHC. The costs were therefore not incurred by the UHIC, although they were still included in the analysis.

Implications of the study
Palivizumab and RSV-IG will be continued to be provided to high-risk infants throughout the RSV season. This will result in savings from reduced hospitalisations, which will outweigh the costs of prophylaxis to the UIHC pharmacy and therapeutics subcommittees.

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