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Cost-effectiveness of palivizumab in New Zealand

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Objective: To establish the preterm infant hospitalization risks from respiratory syncytial virus (RSV) in New Zealand and the net cost per hospitalization averted by palivizumab.

Methods: The 437 infants born < 32 weeks' gestation in 1997 and treated at five major neonatal units were identified. Subsequent admissions during the next 2 years for bronchiolitis, pneumonia and croup were tracked, and information collected on RSV tests performed. Data on the length of stay and hospital costs were used to calculate the potential net cost per hospitalization averted associated with the use of palivizumab and the number needed to treat (NNT) to prevent one hospitalization.

Results: Estimated RSV readmission risk before 1 year corrected age in infants <32 weeks' gestation discharged home on oxygen, and those ≤28 weeks' gestation, or between 29 and 31 weeks' gestation with or without chronic lung disease was 42%, 23%, 19%, 10% and 8%, respectively. The NNT with palivizumab to prevent one hospitalization ranged from six to 26 across subgroups. Mean (range) net cost per hospitalization averted was $NZ60 000 ($28 600–$166 700). In no subgroup would prophylaxis result in net cost saving. Prophylaxis for all NZ infants ≤28 weeks' gestation would cost approximately $1 090 000 net and prevent 29 hospitalizations annually, being equivalent to $37 000 net per hospitalization averted, with eight infants treated to prevent one hospitalization. Alternative assumptions about cost and efficacy failed to alter these findings.

Conclusion: If value is placed on preventing morbidity, the priority groups for palivizumab prophylaxis are preterm infants discharged home on oxygen, followed by preterm infants of 28 weeks' gestation or less.

Key words: chronic lung disease; cost effectiveness analysis; epidemiology; palivizumab; prophylaxis; respiratory syncytial virus.

Preterm infants are commonly rehospitalized following discharge from neonatal intensive care. The most frequent cause of readmission is respiratory illness, and respiratory syncytial virus (RSV) is the most common pathogen identified. Recently palivizumab, an intramuscular humanized monoclonal antibody preparation, has become available for prophylaxis of RSV infection in preterm infants. A large multicentre randomized controlled trial, the IMPACT study, has demonstrated that palivizumab prophylaxis in infants <36 weeks' gestation led to a significant reduction in hospitalization rates for RSV illness.[1] However palivizumab is expensive, and controversy exists over its role in clinical practice with more selective targeting being advised.[2,3]

Several recommendations have been made for palivizumab use. The American Academy of Pediatrics (AAP) recommends that palivizumab should be considered for infants and children younger than 2 years of age with chronic lung disease (CLD) who have required medical therapy for their CLD within the 6 months before the anticipated RSV season.[4] At the start of the RSV season infants born ≤28 weeks' gestation but without CLD and those born at 29–31 weeks may also be considered for therapy up to 12 and 6 months of age, respectively. The AAP recommends that therapy for infants born at 32–35 weeks' gestation should be reserved for those with additional risk factors, given the large number of infants in this group.

Others have recommended that local disease patterns should be taken into account when deciding upon appropriate candidates for palivizumab prophylaxis.[5] Community studies show varying rates of RSV-related readmission, with some finding lower rates than were observed in the IMPACT trial[6,7] and others higher readmission rates.[8,9] RSV readmission rates also vary with degree of prematurity and whether CLD is present.[10] Compared with other developed nations, New Zealand infants have high admission rates for many infectious diseases including pneumonia[11] and bronchiolitis.[12]

Palivizumab was licensed in New Zealand in 1999 and is being used at present on an *ad-hoc* basis. Decisions need to be made about identifying priority groups for funding. This study was undertaken to determine cost-effectiveness by subgroups to aid decision-making about palivizumab prophylaxis for local paediatric practice.

METHODS

A list of all preterm infants of <32 weeks' gestation who had been cared for at National Women's Hospital (NWH),

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Middlemore, Waikato, Wellington and Christchurch neonatal units in 1997 was obtained from the individual units. The data provided included National Health Index number (NHI), gestation, birthweight, date of birth, area of domicile and oxygen requirements at 28 days' of life, 36 weeks postmenstrual age and at discharge home. Case mix offices for Starship, Middlemore, Waikato, Hutt, Wellington and Christchurch hospitals provided lists by NHI of admissions for bronchiolitis, pneumonia and croup for 1997–1999. Information included length of stay. Data for January to June 1997 were missing for Waikato hospital. The virology laboratory in each centre provided a list by NHI of RSV tests undertaken and the results. For Christchurch, only the positive results were available.

The lists of preterm infants were matched by NHI number with the case mix admission lists to identify those who were readmitted. Charts were reviewed for the infants identified as being readmitted. Comprehensive information was extracted for RSV positive admissions, and more limited information for RSV negative admissions. The lists of preterm infants were cross-checked with the laboratory lists to check for RSV positive cases that might have been missed. Admission lists to the paediatric intensive care unit at Starship for bronchiolitis, apnoea, asthma, and pneumonia were similarly checked. Regional paediatricians were asked to search for rehospitalization of infants discharged to their region. Data on reason for admission, RSV status and length of stay were collected. Responses were obtained for all but nine infants. The ethics committees of each of the regions involved approved the study.

Denominator data were derived from a composite list of preterm infants treated in each of the five centres. These infants were estimated to represent approximately 80% of NZ preterm infants <32 weeks' gestation (pers. comm., D Donoghue, Director of the Australia and New Zealand Neonatal Network). The analysis focused on < 32 weeks' gestation infants because these infants were likely to be in the highest risk group and the data were believed to be complete.

Estimated risk of hospitalization with RSV was calculated using all documented RSV-positive admissions. Untested admissions were assumed to have the same proportion of RSV infections as the tested admissions, while RSV-attributable days' stay was calculated as the total days' stay associated with documented RSV infection plus the days' stay of untested admissions multiplied by the proportion of positive results in the tested admissions.

Chronic lung disease (CLD) was defined as requirement for supplemental oxygen at 36-weeks postmenstrual age. Subgroup analysis was undertaken for infants born before or after 29 weeks' gestation because the risk of CLD decreases markedly after this gestation;[13] χ^2 and the Wilcoxon tests determined significant differences ($P < 0.05$) in proportions and lengths of stay, respectively.

Cost effectiveness

The net cost per hospitalization averted was estimated for each subgroup. This reflected the net cost of a palivizumab prophylaxis programme (incorporating savings from reduced hospitalizations) divided by the expected number of hospitalizations averted that would have otherwise occurred without prophylaxis. A secondary outcome was the number needed to treat (NNT) to prevent one hospitalization.

Without prophylaxis, an infant's probability of hospitalization was assumed to equal the subgroup specific probabilities derived from the 1997 New Zealand cohort of preterm infants. These relate to an infant's gestational age and whether or not they have CLD. The IMPACT trial estimated that palivizumab prophylaxis reduced hospitalization among infants with and without CLD by 39% and 78%, respectively.[1] Hence, the probability of hospitalization for infants in each subgroup was determined by reducing each subgroup's hospitalization rate by the appropriate percentage (39% or 78%). The number of hospitalization days was estimated by multiplying the number of hospitalized infants by the average length of stay in that subgroup. Table 1 illustrates how this was done for infants ≤28 weeks with CLD.

Estimation of costs

A societal perspective was adopted which included both the medical costs accruing to the government and time loss costs accruing to parents. Medical costs consisted of three elements: the cost of RSV-related hospitalizations, the cost of palivizumab and the cost of administering palivizumab. Time loss costs accruing to parents included time with the infants in hospital and time spent obtaining prophylaxis. All costs are reported in New Zealand dollars (as of the year 2000).

Hospitalization due to RSV

Two hospitals provided costs for each RSV admission from the cohort. Combining the costs from the two hospitals and dividing by the total number of days in hospital gave an estimated cost of $1195 per day in hospital. Costs included overheads.

Cost of palivizumab

Over the 5 months of the RSV season, infants treated with palivizumab would receive five doses of 15 mg/kg (Abbott). A 100-mg vial of palivizumab costs $1750 (Abbott). Our base case assumed no drug wastage and an average infant weight of 5 kg.[1,14] Hence, the cost of palivizumab prophylaxis for one infant was estimated to be $6563 (15 mg/kg × $1750/100 mg × 5 kg × 5 doses).

Palivizumab administration

Following Joffe *et al*., we assumed that these infants would already have regular scheduled physician appointments and that administration of the drug would require two extra visits.[14] In the absence of the cost of drug administration in an outpatient clinic, we used the cost of a nurse's home visit excluding the travel costs ($60) as a proxy. This gave $120 as the estimate of the cost of administering palivizumab.

Time lost due to RSV hospitalization

If an infant is hospitalized, at least one parent is likely to spend time with their hospitalized infant. This time varies according to the length of stay. We assumed an 8-h work day, a 5-day work week, an average wage of $17.72/h[15] and that one parent was always there. Hence, we estimated the time loss cost of hospitalization due to RSV to be $101 × length of stay ($17.72 × 8 × 5/7 × length of stay).

Table 1 Sample method of analysis to illustrate the calculation of cost per case averted for 40 infants with a gestational age ≤28 weeks' gestation with chronic lung disease

	No prophylaxis	Palivizumab	Comment
Number of infants in cohort	40	40	
Government costs			
Palivizumab costs			
acquisition	0	$NZ262 520	$NZ6563 × number in cohort
administration	0	$NZ4800	$NZ120 × number in cohort
RSV hospitalizaton			
numbers	9	5.49	39% efficacy for infants with CLD
days	81	49.41	Hospitalized infants × average length of stay
direct cost	$NZ96 795	$NZ59 045	Number of days × $NZ1195 per day
Total cost to government	$NZ96 795	$NZ326 365	
Incremental cost to government		$NZ229 574	
Cases averted		3.51	
Cost to government per case averted		$NZ65 406	
Cost to family			
Work loss from			
palivizumab administration	0	$NZ2840	$NZ71 × number of babies
hospitalization	$NZ8181	$NZ4990	$NZ101 × number of hospital days
Overall cost			
Total cost	$NZ104 976	$NZ334 195	
Incremental cost of palivizumab		$NZ229 219	
Cases averted		3.51	
Cost per case averted		$NZ65,305	

RSV, respiratory syncytial virus; CLD, chronic lung disease.

Time lost due to drug administration

Administration of palivizumab requires the parents to transport their infants to the health care provider and be present during treatment. Visits were assumed to take an hour plus one hour's total travelling time. Assuming two extra visits, and an average wage of $17.72/h, the time loss cost of drug administration was estimated to be $71 per infant (2 h × 2 visits × $17.72).

Sensitivity analyses

We tested the sensitivity of the model for variations in prophylaxis dosage (from five to four doses), prophylaxis wastage (one dose = one vial), infant weight (from 5 kg to 3 kg), efficacy of the prophylaxis (using average efficacy as opposed to subgroup specific efficacy), and hospital costs (± 50%).

RESULTS

RSV rehospitalizations

The denominator population comprised 437 infants, of whom 197 (45%) were ≤28 weeks' gestation, and 50 (11%) were on oxygen at 36-weeks postmenstrual age. There were 19 (4%) infants discharged home on oxygen. Of these all but two were born at ≤28 weeks' gestation.

Before one-year corrected age there were 228 rehospitalizations for lower respiratory infections, of which 183 were from bronchiolitis, 36 admissions from pneumonia, and nine were with croup. Of the tested admissions 51/133 (38.4%) were positive for RSV: there was no difference in the proportion RSV positive by diagnosis (chi-squared = 0.18, d.f. = 2, $P = 0.9$). From June–October, 41.5% were positive. Among the tested group there was no difference in length of stay according to RSV result (Wilcoxon 2 sample test $Z = 1.29$, $P = 0.2$).

Table 2 shows that the risk of rehospitalization was highest for those discharged home on oxygen (42.1%). Risk was moderate for infants of ≤28 weeks' gestation with CLD (22.9%), and only slightly lower for those very preterm infants without CLD (18.5%). In contrast, the risk of readmission was substantially lower for infants of 29–31 weeks' gestation, both with (10.2%) and without CLD (12.4%) (Table 2). Almost 80% (404/509) of total RSV-associated days' stay by 1 year corrected age was contributed by infants born at <29 weeks' gestation, who comprised 45% of the infants at risk.

National mortality register data showed there were no deaths from bronchiolitis, pneumonia or croup amongst the cohort in 1997. There were no deaths amongst those hospitalized. There were 23 intensive care admissions for these illnesses, of which 12 were RSV positive, nine were RSV negative and two were untested. Excluding the RSV-negative admissions, two were of babies ≤28 weeks with CLD, seven of babies ≤28 weeks without CLD, and five of infants 29–31 weeks without CLD. All occurred during the months when prophylaxis would be offered. Only one infant was over 12 months of age.

Cost effectiveness by subgroup

Table 2 shows that the cost of prophylaxis per hospitalization averted varied from $29 000 for infants discharged home on oxygen, to $167 000 for infants 29–31 weeks with CLD. The NNT varied from six to 26 in the same two subgroups.

Palivizumab is most cost-effective for children discharged home on oxygen, for infants ≤28 weeks, and for infants without CLD (because the prophylaxis is more efficacious among infants without CLD).[1]

Sensitivity analyses

As illustrated in Table 3, reducing the number of doses from five to four significantly increased cost effectiveness. Increasing drug wastage to the worst case scenario of using a new vial for each infant substantially increased the costs in every subgroup. Reducing the average infant weight from 5 kg to 3 kg more than doubled the cost effectiveness of prophylaxis for infants ≤28 weeks without CLD and also markedly improved cost effectiveness in all the other subgroups.

Replacing subgroup specific efficacy with average efficacy from the IMPACT trial (55%) increased the cost effectiveness of the subgroups on home oxygen and with CLD but reduced the cost effectiveness of those without CLD.[1] However, the model was robust in that the use of palivizumab remained most cost effective for infants on home oxygen followed by those of ≤28 weeks with or without CLD. The results were not sensitive to changes in hospital costs.

Total net cost of providing prophylaxis in New Zealand

There were 197 infants in this study with a gestational age ≤28 weeks. Extrapolating our results to the 222 infants ≤28 weeks' gestation nationwide who survived the neonatal period in 1998 gave an estimated total net cost for prophylaxis of $1 090 000. Approximately 29 infants would avoid hospitalization and the net cost per hospitalization averted would be $37 000.

DISCUSSION

This study establishes a rational basis for palivizumab use in the New Zealand setting. We found that the risk of readmission with RSV for preterm babies ranged from 8 to 42%, with greatest risk for those discharged home on oxygen and for the more preterm infants. Risk was not associated with CLD, unless the child was discharged home on oxygen. There was no mortality from RSV in this cohort. The number needed to treat (NNT) varied from 6 to 26 by subgroup, with an overall mean of 14. The calculated NNT to prevent one hospitalization from the IMPACT trial is 17 (95% CI 11–36).[16] Cost-effectiveness similarly varies by subgroup. All groups incurred a net cost with treatment. However, the cost-effectiveness analysis was most favourable for those discharged home on oxygen and for the youngest infants.

Groups to consider for prophylaxis in order of priority would be first children discharged home on oxygen (21 nationally), then infants ≤28 weeks without (n = 177) and finally with (n = 45) CLD, respectively. Infants 29–32 weeks' gestation with (n = 17) and without CLD (n = 402) would incur higher net costs.

Table 2 Estimated risk of hospitalization with RSV under 1-year corrected age

Subgroup	No. patients in cohort	Babies readmitted n (%)	Total stay (days)	NNT	Cost ($NZ) per case averted
Discharged home on oxygen	19	8 (42.1)	77	6	28 700
≤28 weeks					
CLD	40	9 (22.9)	81	11	65 000
no CLD	157	29 (18.5)	323	7	32 000
29–31 weeks					
CLD	10	1 (10.0)	5	26	166 700
no CLD	230	19 (8.2)	100	16	98 000
Total	437	58 (13.3)	509	14‡	60 000

CLD, chronic lung disease; NNT, numbers needed to treat; RSV, respiratory syncytial virus; ‡Overall mean NNT.

Table 3 Net (incremental) cost of prophylaxis by subgroup

Sensitivity analyses	Cost per hospitalization averted ($NZ)				
	Discharged home on oxygen	≤28 weeks CLD	≤28 weeks No CLD	29–31 weeks CLD	29–31 weeks No CLD
Base case	29 000	65 000	32 000	167 000	98 000
4 doses of palivizumab	21 000	50 000	23 000	133 000	78 000
Significant drug wastage	42 000	90 000	48 000	223 000	132 000
Average infant weight of 3 kg	13 000	35 000	14 000	99 000	57 000
Average efficacy across subgroups	17 000	43 000	52 000	142 000	142 000
50% increase in hospital costs	23 000	60 000	26 000	164 000	95 000
50% decrease in hospital costs	34 000	71 000	39 000	170 000	101 000

CLD, Chronic lung disease.

Readmissions

The rates of readmission in our study were similar to those found in two recent studies in the USA and Spain[10,17] but significantly higher than those reported in some other recent studies in the USA and UK.[7,18] The findings in the present study confirm those of others that the risk of readmission increases with decreasing gestational age.[10]

Base case assumptions

Our base case assumption that no wastage of palivizumab would occur is very optimistic. Palivizumab is sold in 100 mg vials. Once a vial is opened, it has a shelf life of a few hours. The worst-case scenario as far as wastage is concerned is one vial providing one dose of prophylaxis for just one infant with the remaining contents of the vial being wasted. If this happened in every case, the cost per case averted in each subgroup would increase by approximately 50% (Table 3). In practice, babies in neonatal intensive care units (NICU) can sometimes be cohorted when administering prophylaxis to reduce waste.[19]

The number of doses is usually determined by the length of the RSV season. While in Northern California the RSV season lasts just 4 months,[14] in New Zealand it lasts 5 months from June through October.[20] Infants discharged during the season may receive fewer doses, and thus incur lower costs. Further investigations are desirable to assess whether there is potential for increasing the spacing between injections to 6 weeks in the later part of the RSV season.

We used an estimated average infant weight of 5 kg as did Joffe *et al*. In contrast Stevens *et al*. considered an average weight of 3.5 kg.[10,14] We did not assume that any mortality would be averted nor that there would be any long-term benefits of prophylaxis. Hence, our estimate is conservative in terms of overall cost-effectiveness.

Comparison with previous studies

The present study indicates that prophylaxis incurs a net cost in all groups. Similar results have been found in other analyses. A cost-effectiveness analysis based on readmission data from a health maintenance organization in California showed that the use of palivizumab was associated with a net cost.[14] The analysis was most favourable for the subgroup of infants ≤32 weeks' gestation, who required oxygen at 28 days and who were discharged from September through November, immediately prior to the RSV season. However, this study is open to criticism. By limiting the analysis to two groups between 23–32 and 33–36 weeks' gestation, respectively, using four rather than five doses per infant, and assuming a reduction in mortality proportionate to the reduction in hospitalization, the analysis is biased towards favouring prophylaxis.[14] Another study in Rochester, New York also concluded that there would be a net cost associated with prophylaxis for all subgroups considered, but that the most favourable groups to consider were the most preterm infants and those requiring respiratory support at 36 weeks postmenstrual age.[10] It assumed an average infant weight of 3.5 kg (c.f. 5 kg in the present study) thus reducing the estimated drug acquisition costs.

Strengths and limitations of the study

The present study included approximately 80% of the infants born at <32 weeks' gestation nationwide and is unlikely to be biased by centre effects, including readmission policies. It followed a substantial number of infants, whereas some previous studies have recruited much smaller numbers, especially of infants ≤28 weeks' gestation.[18]

The present study was retrospective and it is possible that RSV readmissions may have been overlooked. Considerable effort was made to cross-check for infants admitted to other centres. However, some infants may have been admitted to regional hospitals, other than the one at which they were discharged from the neonatal unit. Some infants may also have been admitted with other diagnoses, although the laboratory data sets were cross-checked for RSV positive admissions. For the 95 (42%) infants not tested for RSV, we estimated the attributable proportion by extrapolating from the babies who were tested.

It was not possible to assess risk for infants discharged home off oxygen but who subsequently became oxygen dependent. Nor was it possible to make an assessment about whether RSV hospitalization prolonged the need for home oxygen therapy. The estimate of cost-effectiveness for this subgroup is therefore likely to be an underestimate.

There are important intangible costs borne by parents that could not be quantified. The distress and anxiety associated with having an infant readmitted with respiratory illness shortly after discharge from neonatal intensive care may be considerable.

Other issues

Efficacy data in clinical practice needs to be assessed, as real life experience is frequently different from the clinical trial situation. Compliance may vary, patient education will be maximized in the trial situation, and underlying hospitalization rates might be different. Atkins *et al*. reported on experience pre- and post-use of palivizumab.[8] Among 100 infants who received prophylaxis only one was readmitted with RSV. The pre-prophylaxis admission rate was 22%, and it remained high among those eligible for but not receiving palivizumab (mostly discharged from NICU before the RSV season).

Palivizumab has not been proven to reduce mortality. To assess mortality as an outcome would require enormous numbers, as mortality is currently low, even in high risk infants.

At present there is no information about the long-term outcome of infants treated with palivizumab and whether treatment influences the rate of subsequent respiratory illness including asthma. Follow-up studies of infants from the IMPACT trial can be expected to provide additional data, and future estimates of cost-effectiveness will need to be modified to take account of this information.[21]

Our analysis does not indicate a cost saving associated with the use of palivizumab for any subgroup. The data do provide guidance in determining priority groups for access. In terms of relative cost-effectiveness, the priority groups for prophylaxis are preterm infants discharged home on oxygen, followed by preterm infants of ≤28 weeks' gestation. The Paediatric Society of New Zealand is currently developing consensus recommendations for the use of palivizumab.

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