Background

Respiratory Syncytial Virus (RSV) is considered to be the most significant viral pathogen for young children. RSV was responsible for an estimated 3.4 million hospitalizations and 200, 000 deaths globally in 2005 in children < 5 years of age (1). Infants in Arctic Canada have extremely high rates of lower respiratory tract infections (LRTIs) (2-6) where RSV has been identified as the major pathogen (6, 7). In the Qikiqtani Region (QIR) of Nunavut, RSV hospitalization rates in the rural communities (without a hospital) in 2002 were 166 per 1000 infants in their first year of life and 328 per 1000 infants who were < 6 months of age.

The majority of Inuit infants in the Canadian Arctic reside in 3 regions; Northwest Territories (NT), Nunavut, which is divided into three sub-regions [Kitikmeot Region (KTR), Kivalliq Region (KQR) and QIR] and Nunavik in northern Quebec. Most of these infants only have access to local health centres, and infants requiring hospitalization are evacuated by air over large distances to regional or tertiary hospitals in more southern parts of Canada. Very high rates of RSV combined with expensive medical evacuations makes RSV hospitalizations the greatest health expenditures for infants in Nunavut (7-9).

Palivizumab, a monoclonal antibody against RSV, was licensed in Canada in 2002. By 2005, government-funded programs were implemented across the Canadian Arctic. Initially palivizumab guidelines included premature birth, significant congenital heart disease (CHD) or chronic lung disease (CLD) (10-13). In 2002 a budget impact analysis (BIA) in QIR examined universal palivizumab prophylaxis in a real cohort of infants of all gestational ages (10). A potential cost savings was found in Inuit infants under 6 months of age during RSV season in the

rural communities (7) with a number-needed-to-treat (NNT) of 3.9 per RSV hospital admission prevented (HAP) (7). Subsequently the Canadian Paediatric Society (CPS) recommended considering palivizumab for *term* Inuit infants < 6 months of age at the start of the RSV season and residing in remote communities with a persistent high rate of RSV hospitalization (14, 15). However, this has not been implemented. It remains unclear which regions in the Canadian Arctic have the highest costs associated with RSV admissions and could benefit from universal prophylaxis with palivizumab.

This study is an economic evaluation of different palivizumab prophylaxis scenarios using data from a cohort of healthy term infants who were < 6 months of age at the beginning of the 2009 RSV season across 8 regions of the Canadian Arctic. The actual costs of RSV admission were compared to the hypothetical costs with universal palivizumab prophylaxis of term infants to calculate the NNT and cost per HAP. This analysis identifies populations who may benefit most from palivizumab prophylaxis.

Methods

The parent study obtained ethics and internal review from all sites. The study was licensed though the Aurora Research Institute and the Nunavut Research Institute and had extensive consultation with Inuit advocacy groups.

Surveillance of LRTI admissions

Data were extracted from a 2009 prospective surveillance of all LRTI admissions for infants residing in the Canadian Arctic in NT, Nunavut, and Nunavik and admitted with LRTIs to

regional and tertiary hospitals serving these populations (9). Through this surveillance, all admissions were captured for infants < 6 months of age. The RSV season in the Canadian Arctic can be delayed and prolonged. We can confirm that 96% of the total annual number of RSV admissions for infants < 1 year of age occurred January 1st 2009 to June 30th, 2009 [14] which is our defined study period. Infants born < 36 weeks gestational age or with significant underlying CHD or CLD leaving healthy *term infants* (Figure 1). All data were collected prospectively except for the QIR, where data were collected retrospectively.

Microbiology testing

Nasopharyngeal aspirates were collected for all prospectively enrolled infants and processed at the Regional Virology Laboratory, McMaster University, Hamilton, Ontario (ON) using a viral multiplex PCR (Luminex Molecular Diagnostics, Toronto, ON) (16) Additionally, the results of clinical NPA were documented for specimens processed at the Provincial Public Health Laboratory in Edmonton, Alberta, Cadham Provincial Laboratories, Winnipeg, Manitoba or at the Microbiology Lab, Montreal Children's Hospital, Montréal, Québec. Additionally some regional labs performed rapid RSV testing using enzyme-linked immunoassay. An infant was considered to have an RSV infection if any of the RSV laboratory tests were positive.

Costs

Costs for each RSV hospitalization, including transportation, hospitalization, parental accommodation and physician fees, were estimated as previously described (9). Transportation costs included: 1) cost of medical air evacuation from residential community to regional and/or

tertiary hospitals, and 2) return travel back to residential community. Hospital per diem rates were obtained hospital finance departments or from regional governments.

The cost of palivizumab was calculated at $225.75 per kg based on a quoted price from Abbvie Canada ($15.05/mg at a dose of 15 mg/kg) based on weight estimated from CDC growth charts, with 5% added for wastage [21] and $50 administration fee per dose. Palivizumab routinely gets transported with other vaccines on regularly scheduled flights therefore no additional cost for transportation of palivizumab.

This economic evaluation was conducted from the public payer's perspective and included direct costs associated with RSV prophylaxis and medical care. All costs were based in 2011 Canadian dollars (1 Canadian $ = 1 US $) and were not inflated. The time line is the 6-month RSV season.

Data Analysis

Palivizumab doses were scheduled monthly starting from the last week of December 2008 and were assumed to provide one month of protection. This analysis assumes that births were equally distributed across the year (1/12 of term births each month) and that compliance was 100%.

The actual costs associated with the 2009 RSV hospital admissions for all healthy term infants (9) were compared to the estimated cost of palivizumab prophylaxis if provided to all healthy term infants combined with the estimated decreased cost of RSV admissions with prophylaxis comparing two models (Figure 1). In both models, infants were eligible to receive palivizumab if

they were 6 months of age on Jan 1st 2009 or born between Jan 1st 2009 and May 31st 2009. Model A offered all infants prophylaxis until May 31st, 2009 even if they were over 5 months of age. Model B offered infants prophylaxis only until they reached 5 months of age or until May 31st 2009, whichever came earlier. The maximum number of doses was six in both models.

The efficacy of palivizumab in healthy term Inuit infants is not known. A randomized controlled trial demonstrated efficacy of 78% in otherwise healthy preterm infants who were primarily non-Indigenous (10). A recent study of palivizumab effectiveness in primarily preterm Inuit infants in Nunavut estimated efficacy to be as high as 96% (17). Therefore, we performed analyses using both 78% and 96% efficacy. The rates of RSV admission, cost per HAP and NNT were compared between NT, Nunavik, Nunavut and its three sub-regions. As the 2002 BIA (7) demonstrated large differences in the NNT and cost HAP in Iqaluit (with a regional hospital) compared to the smaller rural communities (18) we also performed analyses in Nunavut and QIK excluding Iqaluit. This resulted in a total of eight regions studied for comparison.

Data on annual births was obtained from Statistics Canada or from the territorial governments for each region (18). In Nunavut, for the 2011/2012, 2012/2013 and 2013/2014 RSV seasons, 61, 94 and 80 infants were offered prophylaxis with palivizumab respectively (Dr. M. Bakie, Government of Nunavut). This is an average of 9.3% of the birth cohort, with approximately 8% being < 6 months of age at the beginning of the RSV season. Therefore, we estimated that 8% of the birth cohort were palivizumab candidates, leaving 92% as healthy term infants. The formula used to calculate NNT was NNT = 1 / Absolute risk reduction. Absolute risk reduction was defined as the untreated admission RSV rate – ((1-efficacy) x untreated RSV admission rate).

Untreated admission rate = #admissions with RSV in those not treated / population at risk [22]. The approximate population at risk for Model A was 6/12 of the annual births at the start of the season with the monthly addition of 1/12 of annual birth 51/72 x annual births (Table 1). In Model B, the population at risk was 6/12 of the annual births and remained constant as an equivalent number of infants outgrew the 6 month age criteria as were born (Table 2).

Results

In Model A there were 204 admissions for LRTI in infants born after July 1st 2008 and admitted between January 1st and June 30th 2009, where 184 (90%) were tested for RSV with 101 positive results. Eleven of these were excluded (9 preterm, 2 preterm with CHD) resulting in 90 admissions for RSV (Figure 1). In this model a reduction of 78% to 96% efficacy of these admissions would result in 19.8 to 3.6 revised admissions. In Model B, there were 155 admissions for LRTI who were 6 months of age during the RSV season. 149 were tested (96%) for RSV with 80 positive results. Six were excluded (5 preterm, 1 preterm with CHD) resulting in 74 admissions for RSV with 16.3 to 3 a revised admissions. Tables 3 and 4 summarize the RSV admission rate, cost per HAP, incremental cost per RSV admission avoided, NNT and number of doses for both models. There was a large range for the incremental cost per HAP from $698,135 in NT in Model A, to a cost savings of up to $48,489 in KTR in Model B. The NNT also ranged from 77.2 in NT to 3.2 in KTI. Model B had much lower cost per HAP, and lower NNTs in all categories. Model A had 1.6 times the expense and resulted in 1.4 times the doses of palivizumab being administered as Model B.

Interpretation

In this study, we used two different models to assess the impact of universal prophylaxis in Arctic Canada. Model A was 60% more expensive and resulted in 40% more doses being administered than Model B, where prophylaxis was discontinued when the infant reached 5 months of age. Model B had much lower costs per admission avoided and lower NNTs in all categories and appeared to be more cost effective. This is explained by reduced RSV hospitalizations with increasing age. In implementing palivizumab in the Canadian Arctic to Inuit infants, Model B is more cost effective and is the preferred model.

The CPS guidelines recommend that term Inuit infants < 6 months of age at the start of RSV season and residing in remote communities with a persistent high rate of RSV hospitalizations should be considered for palivizumab prophylaxis (14, 15). The current study informs and supports the CPS recommendation. When comparing the rates of RSV admissions across the Canadian Arctic, there is a great heterogeneity. NT, despite a similar birth rate, had one quarter the rates of RSV admission compared to Nunavut, and one tenth the rate of KTR. In addition in NT, a NNT of 44.3 to 54.5 to prevent one RSV admission translates into a cost of $327,000 per HAP. This analysis suggests that KTR had a NNT of only 3.2 to 4 with a cost savings of up to almost $50,000 per HAP. To our knowledge, this degree of cost savings from palivizumab has not been described in the literature. Even in KQR, the NNT is 8.4 to 10.3 with a possible cost savings of almost $3,000 per HAP (9). This data provides very strong evidence that RSV prophylaxis is cost effective in these regions. The rates of RSV admission are also extremely high in Nunavik, with a low NNT of 5 to 6.1. However the costs associated with medical

evacuations are lower with shorter distances so the cost per HAP is $16,000 to $25,000 per HAP. This cost is comparable to the estimated cost of palivizumab for standard indications. For example, the incremental cost of palivizumab to prevent one day of hospitalization was $15,514 per child per RSV season in a study of Canadian children with CHD (19). Universal prophylaxis in QIR did not appear to be cost effective, however this should be interpreted with caution as RSV testing was incomplete for this region. As only one admission came from Iqaluit, there may be a protective factor of living in this larger community (6); exclusion of Iqaluit would allow for cost savings to be transferred to areas in higher need.

The rates of RSV admission in KTR and Nunavik are high for these otherwise healthy term infants with no typical risk factors for severe RSV. Some of this risk may be explained by factors such as multiple siblings, overcrowding, smoking, poverty, food insecurity and decreased access to health care (6, 20) (21). The rates of RSV admission and severity of disease in Inuit infants communities in Nunavut and Nunavik are higher than in preterm infants or those with CLD or CHD (15) infants who are currently eligible for RSV prophylaxis in Canada (15).

A systematic literature review of pharmacoeconomic analyses of international palivizumab strategies for RSV in different regions of the world found variability in results, with a favourable outcome in some populations but not all and variability in the tolerance for costs among countries and healthcare settings (22). In general, an incremental cost-effectiveness ratio (ICER) threshold of $50,000 CDN per quality adjusted life-years (QALY) is commonly accepted in North America (22). An analysis of cost effectiveness of palivizumab prophylaxis in term Inuit infants under 6 months of age in QIR in 2002, estimated the ICER at $24,750/QALY and seen as

a dominant (cost saving) strategy in rural infants (23). Australian Indigenous infants also have elevated rates of RSV, however the transportation costs were not substantial resulting in a cost per HAP of $70,000 to $90,000 (Australian) (24).

Limitations:

This study likely underestimates the costs and the number of admissions related to RSV. There may be long-term morbidities from RSV hospitalizations, resulting in further costs. Not all the LRTI admissions had viral testing, with lower proportions in QIR, possibly underestimating the cases of RSV. It is possible that some infants may have been hospitalized outside the typical referral patterns. There were no additional costs added for evening or weekend assessment fees, emergency visits or resuscitations, surgical procedures, readmissions, medications and societal costs. Ideally more than one year of data would be analyzed to ensure the robustness of the findings, but previous studies in the areas with the highest RSV admission rates have yielded similar results (2, 4, 7, 9).

Conclusion

This study demonstrates great variability in the rates of RSV admission and cost per HAP in the Canadian Arctic. A model universal palivizumab prophylaxis of term infants stopping at 5 months of age was more cost effective than continuing to the end of the season. Universal prophylaxis of term infants KTR was projected to result in a significant cost savings. In KQR and Nunavik, the NNT and cost HAP were low. This information provides further justification for consideration of RSV prophylaxis in these high risk communities.

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Figure 1 Comparing Model A and B for Palivizumb Prophylaxis for Term Infant across the Canadian Arctic

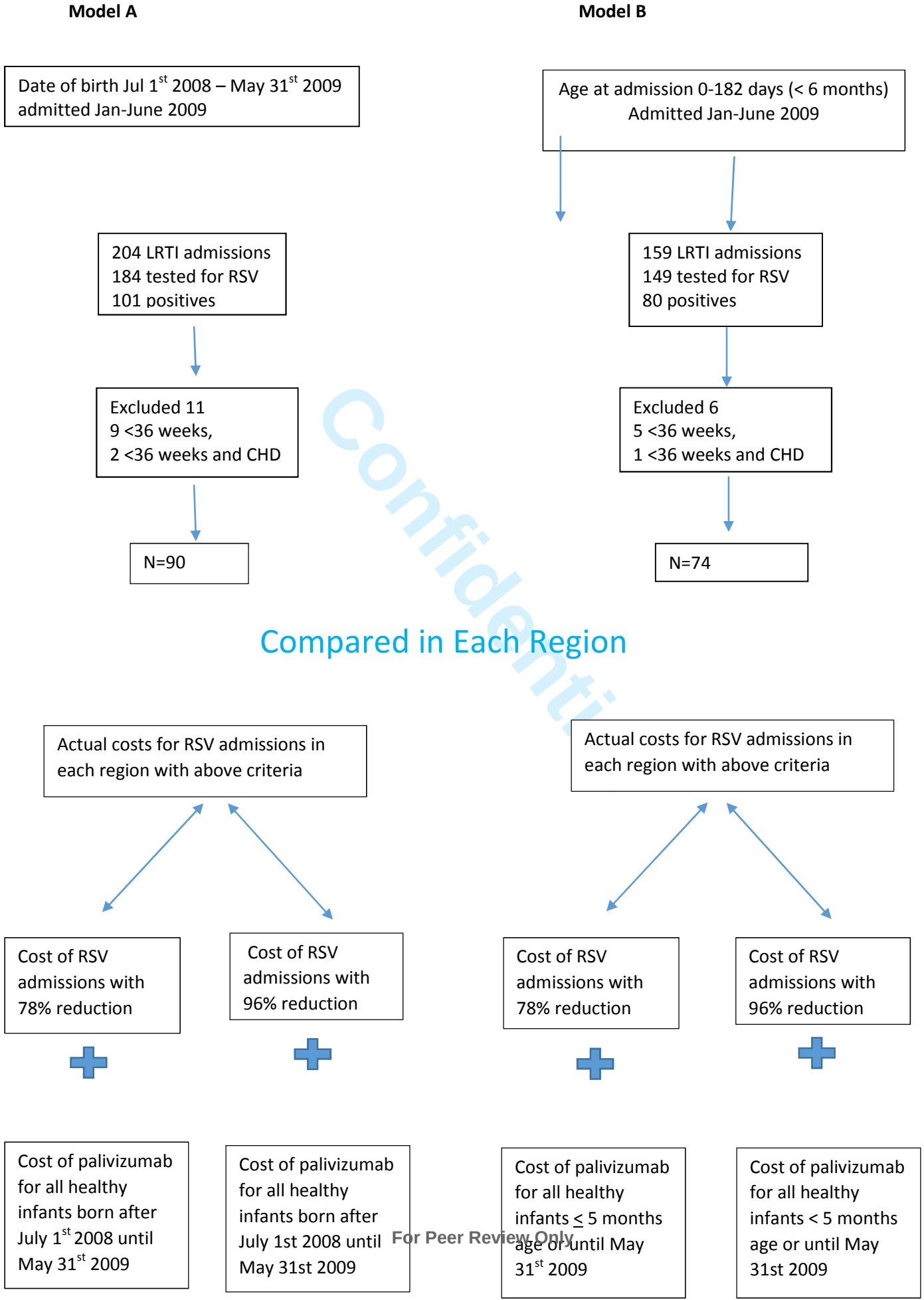

Table 1 Model A: Cost, Doses and Population at Risk for Universal Palivizumab Prophylaxis for Healthy Term Infants for Maximum 6 months where Palivizumab Discontinued by May 31st 2009

Costs per dose per eligible healthy term infant each month*

Age category, weight (kg)	December 2008	January 2009	February 2009	March 2009	April 2009	May 2009	
Birth (3.5)	$880	$880	$880	$880	$880	$880	
1 month (4.3)	$1,069	$1,069	$1,069	$1,069	$1,069	$1,069	
2 month (5.05)	$1,247	$1,247	$1,247	$1,247	$1,247	$1,247	
3 month (5.75)	$1,413	$1,413	$1,413	$1,413	$1,413	$1,413	
4 month (6.45)	$1,579	$1,579	$1,579	$1,579	$1,579	$1,579	
5 month (7.0)	$1,709	$1,709	$1,709	$1,709	$1,709	$1,709	
6 month (7.55)	x	$1,840	$1,840	$1,840	$1,840	$1,840	
7 month (8.05)	x	x	$1,958	$1,958	$1,958	$1,958	
8 month (8.45)	x	x	x	$2,053	$2,053	$2,053	
9 month (8.85)	x	x	x	x	$2,148	$2,148	
10 month (9.25)	x	x	x	x	x	$2,243	
							SUM
Sum	$7,897	$9,737	$11,695	$13,748	$15,896	$18,139	$77,112
Dose categories per month	6	7	8	9	10	11	51

Eligible infants for palivizumab include health term infants who would be less than 6 months of age by Jan 1st 2009 (born July 1st 2008 to end of May 31st 2009) and discontinued by May 31st 2009.

*based on 15 mg/kg at $15.05 per mg +5% wastage + $50 administration fee/dose

The annual healthy births (AHB) are term infants without congenital heart disease or chronic lung disease born in 2009.

Annual cost per region =sum of monthly costs x 1/12 AHB =$6,423.82 x AHB
monthly doses= doses categories per months x 1/12 AHB
Annual doses = 51 x 1/12 annual healthy births = 4.25 AHB
Population at risk = 51/72 of AHB
*actual calculation $6,423.82 based on costs on table 1 (above table rounded off)

Table 2: Cost, Doses and Population at Risk for Universal Palivizumab Prophylaxis for Infants for Maximum 6 months Protection (last does 5 months of age or May 2009)

	Costs per dose per eligible healthy term child each month*						
Age	Dec-08	Jan-09	Feb-09	Mar-09	Apr-09	May-09	
birth	$880	$880	$880	$880	$880	$880	
1 month	$1,069	$1,069	$1,069	$1,069	$1,069	$1,069	
2 month	$1,247	$1,247	$1,247	$1,247	$1,247	$1,247	
3 month	$1,413	$1,413	$1,413	$1,413	$1,413	$1,413	
4 month	$1,579	$1,579	$1,579	$1,579	$1,579	$1,579	
5 month	$1,709	$1,709	$1,709	$1,709	$1,709	$1,709	
6 month	x	x	x	x	x	x	
7 month	x	x	x	x	x	x	
8 month	x	x	x	x	x	x	
9 month	x	x	x	x	x	x	
10 month	x	x	x	x	x	x	
11 months	x	x	x	x	x	x	
							Sum
Sum	$7,897	$7,897	$7,897	$7,897	$7,897	$7,897	$47,382
Dose categories per month	6	6	6	6	6	6	36

Eligible infants for palivizumab include health term infants who would be less than 6 months of age by January 1st 2009 or born before May 31st 2014. Model assumes that an equivalent number of infants are born as outgrow the age criteria.

*based on 15 mg/kg at $15.05 per mg +5% wastage + $50 administration fee/dose

The annual healthy births (AHB) are term infants without congenital heart disease or chronic lung disease born in 2009.

Annual cost per region = $7,897 x 6/12 AHB =*$3,947.29AHB
Monthly doses = dose categories per month x 1/12AHB = 6/12 AHB
Annual doses = 6 x 6/12 AHB
Population at risk = 36/72 (.5) of AHB
*Above table rounded off

Table 3: Model A - Palivizumab prophylaxis for all healthy term infants who were less than 6 months of age at the beginning of RSV season or born during RSV season with palivizumab continued to the end of RSV season across the Canadian Arctic, comparing 78% and 96% palivizumab effectiveness

	Location	NT	NU	NU Without Iqaluit	KTR	KQR	QIR	QIR without Iqaluit	NK
A	**Total annual births in 2009**	739	816	701	114	245	457	342	250
B	**Healthy term births***	679.9	750.7	644.9	104.9	225.4	420.4	314.6	230
C	**Total number of RSV admissions documented in 2009 in healthy term infants**	8	52	51	22	18	12	11	30
E	**Estimated rate of RSV admissions per 1000 live births****	16.6	97.8	111.6	296.1	112.7	40.3	49.4	184.1
F	**Number of doses of palivizumab**	2890	3190	2741	446	958	1787	1337	978
Estimated Costs for RSV admissions in healthy term infants									
G	Average cost per admission	$1,794	$55,214	$56,011	$68,017	$60,811	$23,347	$24,145	$21,071
H	Total cost of admissions	$14,353	$2,871,137	$2,856,561	$1,496,365	$1,094,603	$280,169	$265,593	$632,139
I	Estimated cost of Palivizumab in Model A	$4,367,555	$4,822,362	$4,142,722	$673,859	$1,447,929	$2,700,574	$2,020,934	$1,477,479
Model with 78% effectiveness for healthy term infants									
J	Revised total number of RSV admissions	1.8	11.4	11.2	4.8	4.0	2.6	2.4	6.6
K	Revised total costs of admissions	$3,158	$631,650	$628,443	$329,200	$240,813	$61,637	$58,430	$139,071
L	Incremental cost for universal prophylaxis	$4,356,360	$2,582,875	$1,914,604	($493,306)	$594,139	$2,482,042	$1,813,771	$984,410
M	Incremental cost per HAP	$698,135	$63,680	$48,130	($28,747)	$42,318	$265,175	$211,395	$42,069
N	NNT to prevent one RSV admission	77.2	13.1	11.5	4.3	11.4	31.8	26.0	7.0
Model with 96% effectiveness for healthy term infants									
O	Revised total number of RSV admissions	0.3	2.1	2.0	0.9	0.7	0.5	0.4	1.2
P	Revised total costs of admissions	$574	$114,845	$114,262	$59,855	$43,784	$11,207	$10,624	$25,286
Q	Incremental cost for universal prophylaxis	$4,353,776	$2,066,070	$1,400,423	($762,652)	$397,111	$2,431,611	$1,765,965	$870,625
R	Incremental cost per HAP	$566,898	$41,388	$28,603	($36,110)	$22,981	$211,077	$167,231	$30,230
S	NNT to prevent one RSV admission	62.7	10.7	9.3	3.5	9.2	25.8	21.1	5.7

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*Healthy term births estimated to be 92% of all births – Data on total births obtained from Statistics Canada
**RSV admissions Jan 1st –June 30th 2009, with population at risk of healthy term infants born after July 1st 2008 to May 31st 2009
NT= Northwest Territories,
NU= Nunavut,
KTR= Kitikmeot Region, Nunavut,
KQR=Kivalliq Region, Nunavut,
QIR= Qikiqitani Region, Nunavut,
NNT=Number needed to treat
HAP= hospital admissions prevented =C-J and C-O
K=78% x H, P=96% X H
L=K+I-H, Q=P+I-H,
M=L/J, R=Q/O

Table 4: Model B palivizumab prophylaxis for health term infants who were less than 6 months of age during the 2009 RSV season comparing 78% and 96% palivizumab effectiveness across the Canadian Arctic

	Location	NT	NU	NU without-Iqaluit	KTR	KQR	QIR	QIR without Iqaluit	NK
A	**Total annual births in 2009**	739	816	701	114	245	457	342	250
B	**Healthy term births***	679.9	750.7	644.9	104.9	225.4	420.4	314.6	230
C	**Total number of RSV admissions documented in 2009 in healthy term infants**	8	42	34	17	14	11	10	24
E	**Rate of RSV in healthy infants <6 months age Jan to June 2009 per 1000 live births**	23.5	111.9	105.4	324.1	124.2	52.3	63.6	208.7
F	**Number of doses of palivizumab**	2040	2252	1935	315	676	1261	944	690
	Estimated Costs for RSV admissions in healthy term infants								
G	**Average cost per admission**	$22,157	$58,955	$60,037	$73,861	$68,922	$23,232	$24,097	$23,830
H	**Total cost of admissions Total**	$177,256	$2,476,100	$2,461,523	$1,255,638	$964,915	$255,547	$240,971	$571,929
I	**Estimated cost of palivizumab**	$2,683,762	$2,963,231	$2,545,607	$414,071	$889,719	$1,659,441	$1,241,817	$907,877
Model with 78% effectiveness for healthy term infants									
J	Revised total number of RSV admissions	1.8	9.2	7.5	3.7	3.1	2.4	2.2	5.3
K	Revised total costs of admissions	$38,996	$544,742	$541,535	$276,240	$212,281	$56,220	$53,014	$125,824
L	Incremental cost for universal prophylaxis	$2,545,503	$1,031,873	$625,619	($565,327)	$137,086	$1,460,114	$1,053,860	$461,772
M	Incremental cost per HAP	$407,933	$31,498	$23,590	($42,634)	$12,554	$170,176	$135,110	$24,667
N	NNT to prevent one RSV admission	54.5	11.5	12.2	4.0	10.3	24.5	20.2	6.1
Model with 96% effectiveness in healthy term infants									
O	Revised total number of RSV admissions	0.3	1.7	1.4	0.7	0.6	0.4	0.4	1.0
P	Revised total costs of admissions	$7,090	$99,044	$98,461	$50,226	$38,597	$10,222	$9,639	$22,877
Q	Incremental cost for universal prophylaxis	$2,513,597	$586,175	$182,545	($791,342)	($36,599)	$1,414,116	$1,010,486	$358,825
R	Incremental cost per HAP	$327,291	$14,538	$5,593	($48,489)	($2,723)	$133,912	$105,259	$15,574
S	NNT to prevent one RSV admission	44.3	9.3	9.9	3.2	8.4	19.9	16.4	5.0

Model B, all healthy term infants per prophylaxed if they were less than 6 months of age during the RSV season January 1st to June 30th 2009
*Healthy births =92% of all births

NT= Northwest Territories,
NU= Nunavut,
KTR= Kitikmeot Region,
KQR=Kivalliq Region,
QIR= Qikiqitani Region,
NNT=Number needed to treat
HAP= hospital admissions prevented =c-J
K=78% x H, P=96% X H
L=K+I-H, Q=P+I-H,
M=L/J, R=Q/O