

Cost-Effectiveness of RSVpreF in Pregnant Individuals for the Prevention of RSV Among Infants in Canada

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INTRODUCTION

- Respiratory syncytial virus (RSV) is common among children in Canada, with severe outcomes most frequent among young infants in their first year of life
- Over 50% of RSV hospitalizations in children are among infants aged <6 months, over 80% are among infants born full term, and over 90% are among infants with no underlying comorbidities^{1,2}
- Although RSV often causes mild upper respiratory tract disease, progression to lower respiratory tract disease (LRTD) is associated with significant morbidity, mortality, and high costs, especially among young infants, those born prematurely, and those with certain risk conditions:^{3,4}
 - In December 2023, RSVpreF, Pfizer's novel RSV vaccine, was approved by Health Canada for the prevention of LTRD and severe LTRD caused by RSV in infants from birth through 6 months of age by active immunization of pregnant individuals from 32 through 36 weeks of gestational age⁵

OBJECTIVE

- To evaluate the cost-effectiveness of maternal RSVpreF for prevention of RSV among infants in Canada aged <1 year

METHODS

Model Overview

- Cohort model characterized cost-effectiveness in terms of incremental cost per quality-adjusted life-year (QALY):
 - Clinical outcomes: cases of medically-attended RSV-RTD by care setting (hospital [H], emergency department [ED], physician office [PO]), attributable deaths, and QALYs
 - Economic costs: direct costs, indirect costs related to caregiver work loss and future lost earnings associated with premature RSV-LRTD-related death
- Model population was characterized by age, calendar month of birth, and term status defined by gestational age in weeks (wGA) at birth (full-term, ≥37; late preterm, 32-36; early preterm, 28-31; extreme preterm, ≤27)
- Costs and QALYs were discounted at an annual rate of 1.5%

Estimation of Model Inputs

- Population (N=370,858 infants) was estimated based on Statistics Canada data⁶ and distributed by term status⁷
- Incidence rates (assumed to vary by term status⁸, calendar month⁹, and age¹⁰) were stratified by care setting (Table 1):
 - RSV-H: based on a recent Canadian modelling study^{11,12}
 - RSV-ED and RSV-PO: derived from a US-based study¹³
- Case fatality was assumed to occur among hospitalized cases only (range: 0.1-1.0 per 100 cases, age/term dependent), and was estimated based on global meta-analysis⁴ and US data¹⁴
- Age-specific rates of general population mortality¹⁵ were allocated by term status based on US data¹⁶
- Monthly vaccine effectiveness (VE) for full term/late preterm infants derived from MATISSE efficacy data (severe RSV + medically-attended (MA) LRTI for RSV-H; RSV + MA-LRTI for RSV-ED/PO)¹⁷ for 0 - <6 months; VE was then assumed to wane linearly to 0% by age 9-<10 months (Figure 1)¹⁸
- VE for early/extreme preterm infants and infants born <2 weeks after RSVpreF administration assumed to be 0%

METHODS

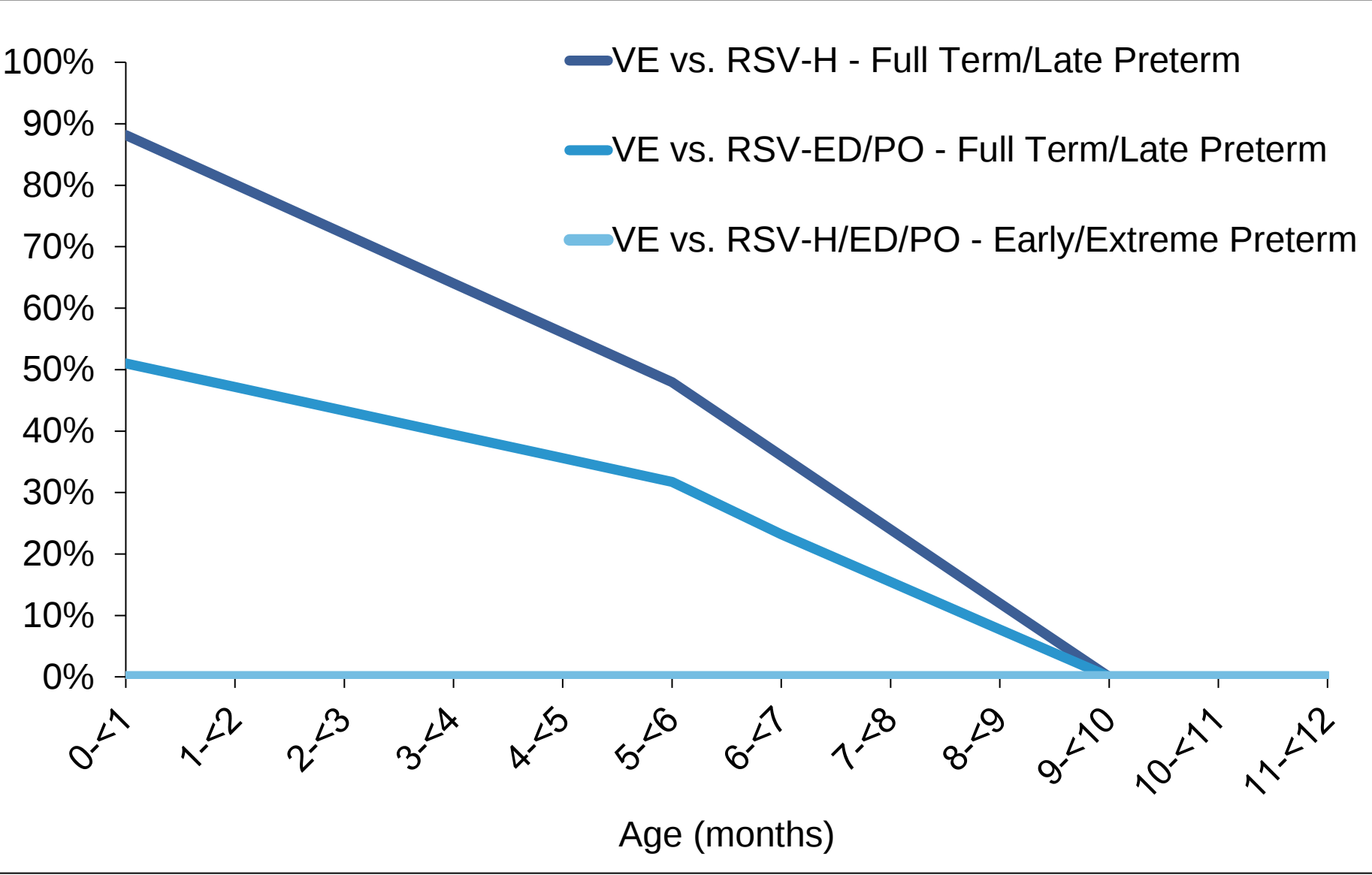
Estimation of Model Inputs (continued)

- Direct costs per episode based on Canadian data¹⁹⁻²² (RSV-H: full term, \$9,528, late preterm, \$11,984, early preterm, \$17,635, extreme preterm, \$11,600; RSV-ED: \$341; RSV-PO: \$130)
- Indirect costs were estimated based on Canadian labor force, morbidity, and mortality data²³⁻²⁶ as well as caregiver work loss days (RSV-H: 6.7; RSV-ED: 3.4; RSV-PO: 2.6)²⁶
- RSVpreF cost was \$230 (list price); administration fee \$4.50²⁷
- Utility for infants without RSV assumed to be 1; annual QALY loss associated with RSV-RTD was 0.0157 for hospitalized infants and 0.0061 for ambulatory patients²⁸
- Age-specific utilities for adults were based on EQ-5D-5L index scores of residents from Alberta, Canada²⁹
- Caregiver QALY loss was estimated based on US data³⁰ (RSV-H: 0.0066; RSV-ED: 0.0068; RSV-OC: 0.0041)
- Year-round RSVpreF uptake was 64.8% based on maternal Tdap uptake³¹; administration was assumed to occur between 32-36 wGA (70% administered between 32-33 wGA)

Table 1. Rates of RSV-RTD (per 100K)

	Month of Age											
	0<1	1<2	2<3	3<4	4<5	5<6	6<7	7<8	8<9	9-<10	10-<11	11-<12
Hospital												
Full term	22	38	27	18	16	13	11	9	9	10	7	7
Late preterm	38	67	48	45	39	31	19	16	15	17	12	12
Early/Extreme PT	10	18	13	43	38	30	77	64	58	67	48	48
ED												
Full term	19	62	70	96	106	65	75	51	51	51	37	51
Late preterm	33	108	121	237	261	160	128	88	87	87	63	87
Early/Extreme PT	9	29	33	228	251	154	511	351	347	347	252	347
PO												
Full term	82	181	225	212	241	263	242	190	254	208	221	236
Late preterm	143	315	393	523	596	651	414	324	434	355	378	403
Early/Extreme PT	39	85	107	503	574	626	1,654	1,295	1,736	1,420	1,510	1,613

Figure 1. Vaccine effectiveness



Analyses

- Base case analyses evaluated the cost-effectiveness of RSVpreF vs. no intervention among infants in Canada aged <1 year, applying inputs described herein
- Deterministic sensitivity analyses (DSA) were conducted to evaluate impact of changes to vaccine uptake, RSV-H rates, medical cost of RSV-H, and initial VE
- Scenario analyses were conducted to evaluate alternative assumptions for vaccine price, discount rate, initial VE, and vaccine duration of protection (DoP)
- Probabilistic sensitivity analyses (PSA; 1,000 replications) were conducted to account for uncertainty surrounding estimates of key model parameters

RESULTS

Base Case Analyses

- Use of RSVpreF prevented 33% of hospitalizations, 16% of ED visits, 13% of physician office visits, and 26% of deaths versus no intervention (Table 2)
- With medical costs reduced by 28% (Figure 2) and indirect costs reduced by 18%, total costs with RSVpreF increased by 9% resulting in cost-effectiveness ratio of \$43,935/QALY from the societal perspective
- While RSV-H comprises only 11% of overall reduction in cases, 87% of the total reduction in medical care costs is attributable to RSV-H averted (Figure 3)

Table 2. Base case results

	No Intervention	RSVpreF	Difference
Clinical outcomes			
RSV-H cases	5,994	4,026	-1,968
RSV-ED cases	24,233	20,413	-3,820
RSV-PO cases	84,618	73,222	-11,396
No. of deaths	14	10	-4
QALYs	15,291,851	15,292,119	268
Economic costs (millions)			
Medical care	77.72	56.03	-22
Vaccination	0.00	54.37	54
Non-medical	95.30	78.14	-17
Total	173.02	185.54	16
Cost-effectiveness (per QALY)			
Healthcare system	--	--	\$92,513
Societal	--	--	\$43,935

Figure 2. Medical costs associated with RSV-RTD

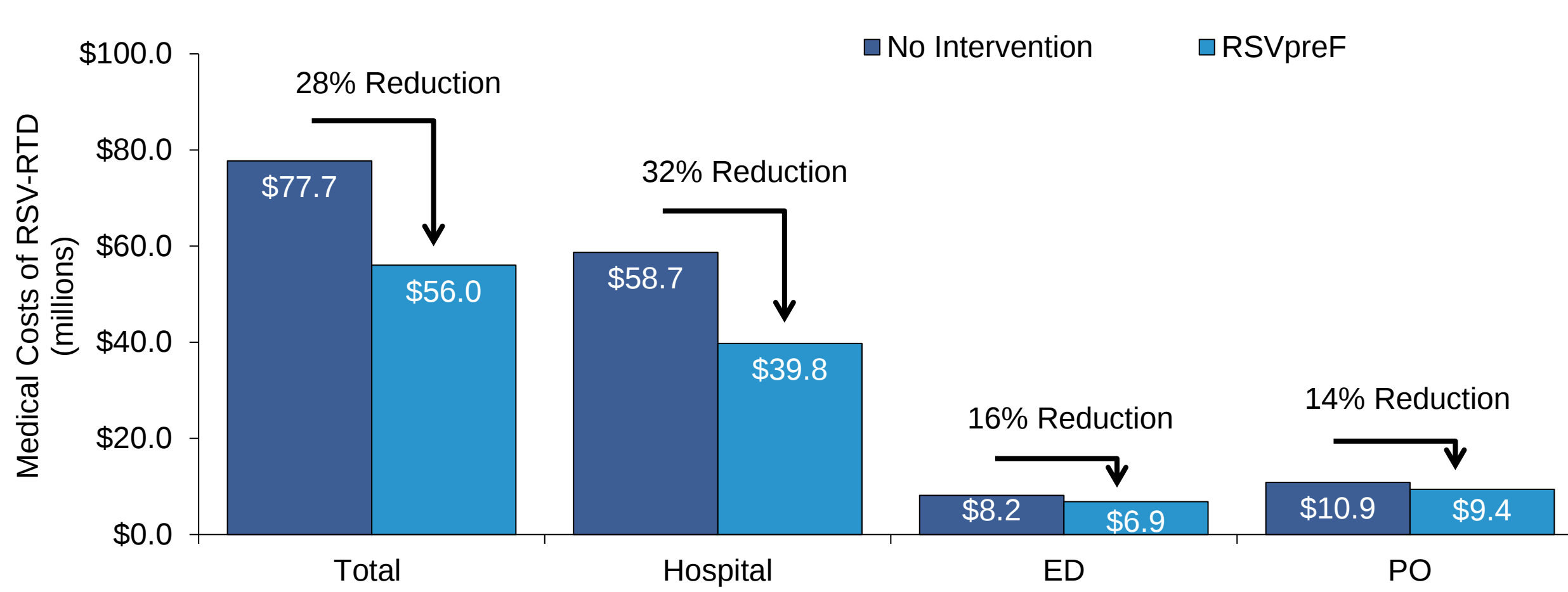
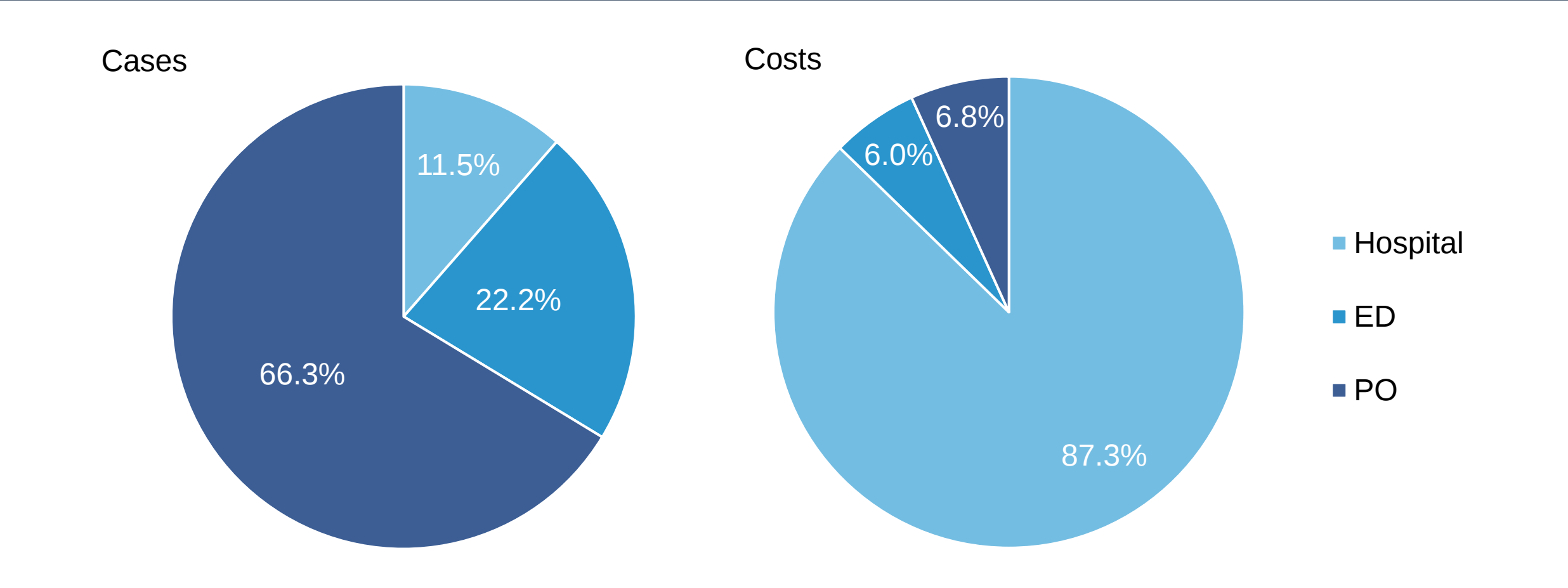


Figure 3. Distribution of prevented outcomes



LIMITATIONS

- Initial VE and waning through age 6 months were based on MATISSE, however, waning during months thereafter (i.e., 6-<10 months) were informed by evidence on kinetics and decay of maternal transfer of antibodies
- Conservatively assumed 0% VE for early and extreme preterm infants
- US-specific or global data was applied in instances where Canada-specific data was not available (e.g., ambulatory RSV rates, case-fatality, work-loss days)
- Several benefits of maternal vaccination not accounted for (e.g., reduction in societal costs of RSV, reduction in long term consequences of RSV, protection for vaccinated women, herd immunity)

REFERENCES

- Bourdeau M, et al. *JAMA Network Open*. 2023;6(10):e2336863.
- Buchan SA, et al. *Pediatr Infect Dis J*. 2023;12(7): 421-430.
- National Advisory Committee on Immunizations. Recommended use of palivizumab to reduce complications of RSV infections in infants. 2022.
- Li Y, et al. *Lancet*. 2022;399(10340): 2047-2064.
- National Advisory Committee on Immunizations. Respiratory syncytial virus (RSV): Canadian Immunization Guide. 2023.
- Statistics Canada. Table: 13-10-0428-01. 2022.
- Liu S, et al. *J Obstet Gynaecol Can*. 2021;43(12): 1406-1415.
- Rha B, et al. *Pediatrics*. 2020;146(3): e20193611.
- Public Health Agency of Canada. Respiratory Virus Report. 2019.
- Curns AT, et al. *Pediatrics*. 2024;153(3):e2023062574.
- Schanzer DL, et al. *Pediatr Infect Dis J*. 2006;25(9): 795-800.
- Schanzer DL, et al. *Influenza Other Respir Viruses*. 2018;12(1): 113-121.
- Lively JY, et al. *J Pediatric Infect Dis Soc*. 2019;8(3): 284-286.
- Hansen CL, et al. *JAMA Network Open*. 2022;5(2): e220527-e220527.
- Statistics Canada. Table 13-10-0713-01. 2022.
- National Vital Statistics System. CDC WONDER Online Database. 2021.
- Munjal I, et al. Presented at: RSVVW'24; Mumbai, India.
- Kampann B, et al. *N Engl J Med*. 2023;388(16): 1451-1464.
- Interactive Health Data Application. 2019.
- Ontario Ministry of Health. Schedule of Benefits: Physician Services Under the Health Insurance Act. 2022.
- Tarride J-E, et al. *ClinicoEcon Outcomes Res*. 2012;4: 287-298.
- Thampi N, et al. *CMAJ Open*. 2021;9(4): e948-e956.
- Statistics Canada. Table 13-10-0837-01. 2022.
- Statistics Canada. Table 14-10-0320-01. 2023.
- Statistics Canada. Table 14-10-0287-01. 2023.
- Pfizer Inc., data on file.
- Abu-Raya B, et al. *Front Immunol* 2020;11:1282.
- Roy LMC. Deriving health utility weights for infants with Respiratory Syncytial Virus (RSV) 2013.
- University of Alberta: School of Public Health. September 25, 2018.
- Hutton D. Presented at: Meeting of the ACIP; February 23, 2023; Atlanta, GA.
- Public Health Agency of Canada. Results of the Survey on Vaccination during Pregnancy 2021. 2022.

Sensitivity and Scenario Analyses

- In DSA, initial VE had the greatest impact on results (\$23K-\$82K/QALY) (Figure 4); among all other DSA, cost per QALY ranged from \$25K-\$58K
- In scenario analyses, vaccine price had greatest impact on results (\$6K/QALY) (Figure 5); among other scenario analyses, cost per QALY ranged from \$30K-\$64K
- Increasing vaccine uptake to 80% prevented >4,000 additional cases of RSV-RTD
- In PSA, 97.8% of replications were below \$100K/QALY and the mean cost-effectiveness ratio was \$39K/QALY (Figure 6)

Figure 4. DSA results

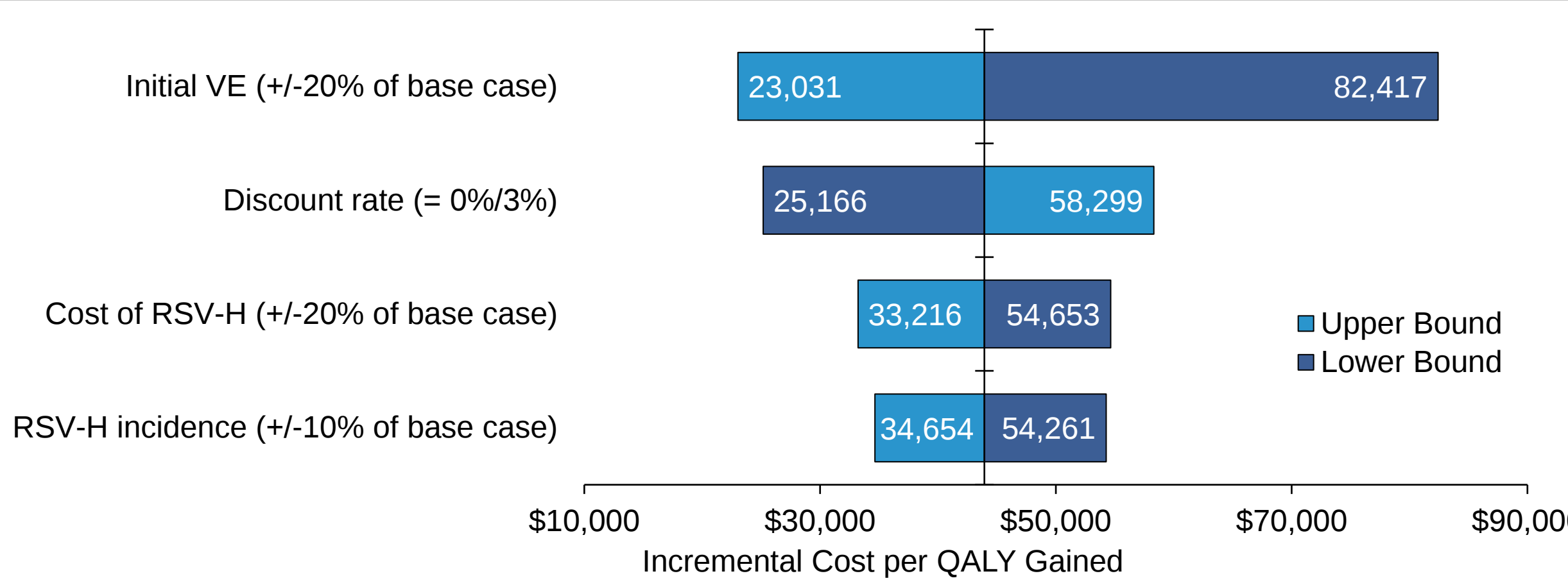


Figure 5. Scenario analysis results

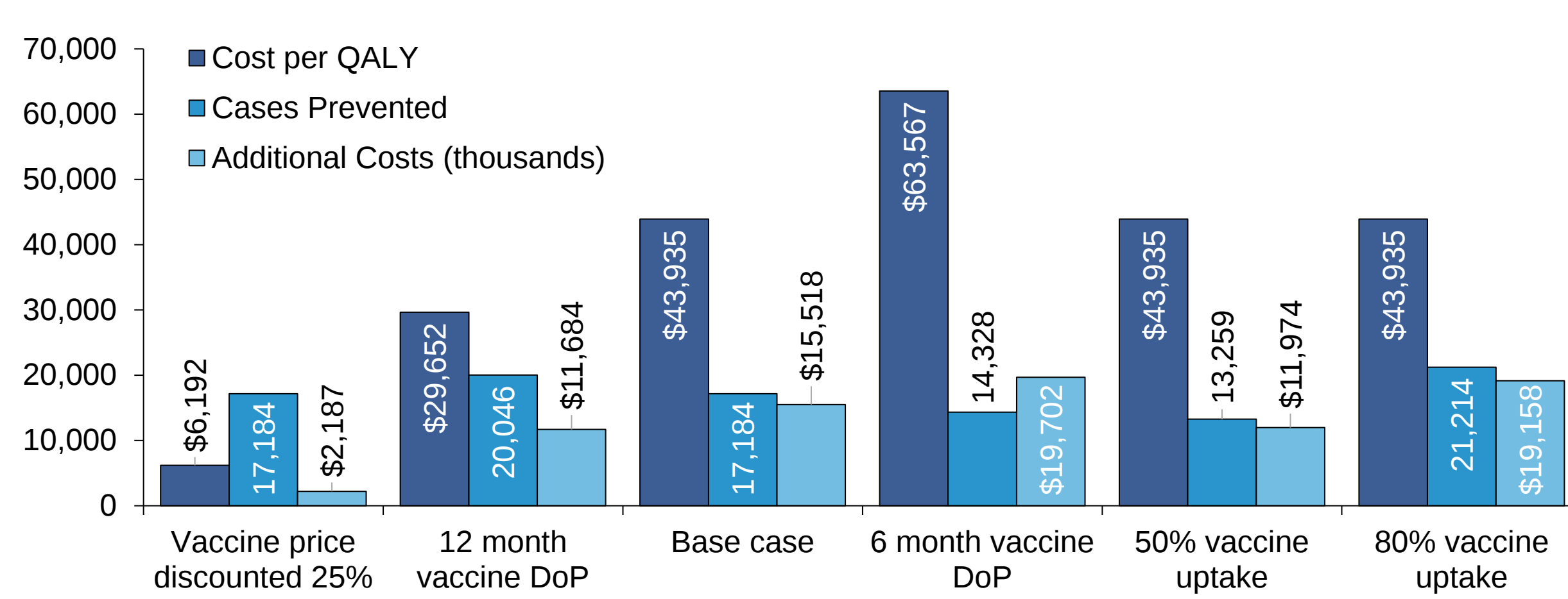
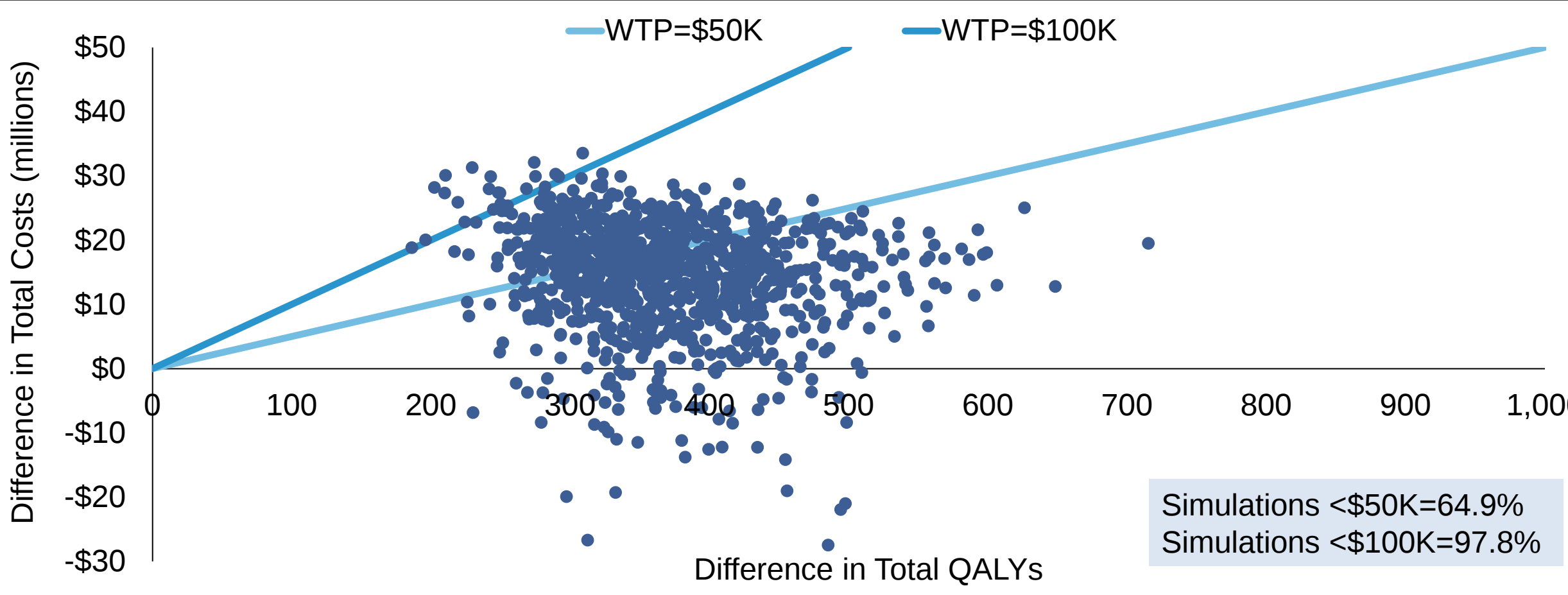


Figure 6. PSA results



CONCLUSION

An RSV immunization program including RSVpreF for pregnant individuals would substantially reduce the clinical and economic burden of RSV among young infants in Canada from the time of birth and would be considered cost-effective at list price