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RESEARCH ARTICLE



Budget impact analysis of bivalent respiratory syncytial virus prefusion F (RSVpreF) maternal vaccination for preventing respiratory syncytial virus in Egyptian infants

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ABSTRACT

Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract infections (LRTIs) in infants in low- and middle-income countries, and Egypt faces a clinical and economic burden associated with it. This study aimed to estimate the 5 y budget impact of maternal RSV Prefusion F (RSVpreF) vaccination, compared with no vaccination, from the public healthcare payer perspective in Egypt. A deterministic cohort model simulated weekly birth cohorts for five years, assuming a 10% maternal uptake of RSVpreF administered year-round at 24–36 weeks' gestation. Outcomes included RSV-LRTI cases, healthcare use (hospitalizations, emergency department, and outpatient), and RSV-related deaths among infants, with costs reported both in aggregate and as per-member-per-year (PMPY). Deterministic sensitivity analysis (DSA) varied clinical and economic inputs by $\pm 30\%$. Without vaccination, 425,421 RSV-LRTI events, 1,173 RSV-related deaths, and EGP 1,652.3 million in medical costs were projected over five years among 9,877,775 live births. With 10% maternal vaccination, 16,784 RSV-LRTI events and 69 deaths were averted, yielding medical cost offsets of EGP 95.0 million. Vaccination costs of EGP 8,578.1 million produced an incremental PMPY of EGP 15.92 (USD 0.3) under list-price assumptions. In DSA ($\pm 30\%$), results were most sensitive to vaccine acquisition price, with other parameters exerting smaller effects, and the conclusions remained unchanged. Conclusively, maternal RSVpreF vaccination can reduce RSV burden in Egypt's public sector, and at list price, the program results in a net incremental budget of EGP 15.92 (USD 0.3) PMPY; lower public procurement prices would proportionally reduce the net impact while preserving clinical gains.

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Introduction

Respiratory syncytial virus (RSV) is a major cause of lower respiratory tract infections (LRTIs) in infants and young children globally. RSV infection can lead to serious illness in some infants, causing severe pneumonia and bronchiolitis, especially in those under one year of age. The global burden of RSV is significant, accounting for more than 100,000 deaths and over three million hospitalizations each year, predominantly in low- and middle-income countries, where approximately 97% of RSV-related deaths take place. A key framing for policy and burden-of-disease work is that about 2% of all under-five deaths globally, roughly “1 in 50,” are attributable to RSV, rising to approximately 3.6% (“1 in 28”) among infants aged 28 d to 6 months.¹

A systematic review of studies conducted in the Middle East and North Africa (MENA) region estimated RSV infection rates ranging from 19% to 70% among hospitalized children, depending on their presenting symptoms. Among these cases, complications such as ICU admission and mechanical ventilation were

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common.² In Egypt, RSV represents a significant public health concern. Findings from local studies show that the virus is widely prevalent, with rates among children with acute respiratory illness ranging from more than 60% to over 80%.^{3,4} Notably, Egypt's 2022 multicenter severe acute respiratory illness (SARI) survey across 21 referral hospitals found that infants aged ≤ 1 y accounted for 58.3% of admissions; among positive tests, viral etiologies predominated (92.1%), led by RSV (63.8%), underscoring the concentration of burden in early infancy.⁴

Due to the absence of specific treatments for RSV, prevention remains essential for reducing severe disease and associated hospitalizations in infants. Currently, immunization strategies include the use of maternal vaccination during late pregnancy.^{5,6} The approval of Pfizer's bivalent prefusion F (RSVpreF) vaccine in multiple countries, including Egypt, marks a major advancement in RSV prevention. Administered during pregnancy, RSVpreF offers passive immunity to newborns through maternal antibody transfer. Findings from the Phase III MATISSE trial demonstrated high efficacy of RSVpreF in preventing severe RSV-related LRTI in infants during the first six months of life, with a favorable safety profile for both mothers and infants.⁶ Beyond trial efficacy, early real-world data show substantial population impact of maternal RSVpreF. In Argentina's 2024 national program (BERNI study), vaccine effectiveness (VE) against RSV-associated lower respiratory tract disease leading to infant hospitalization was 78.6% from birth to 3 months and 71.3% through 6 months, with 76.9% VE against severe lower respiratory tract disease; all in-hospital RSV deaths occurred in infants of unvaccinated mothers. In the United Kingdom, a multicenter test-negative study reported 72% VE against RSV-associated acute lower respiratory infection hospitalization for infants whose mothers were vaccinated at least 14 d before delivery (and 58% when vaccinated at any time before delivery), aligning with current program guidance.^{7,8}

While the clinical effectiveness of RSVpreF has been established, evidence on its potential economic impact in low- and middle-income countries remains limited. In March 2025, the World Health Organization granted prequalification to RSVpreF vaccine, enabling its procurement in low- and middle-income countries.^{9–13}

As healthcare systems in resource-constrained settings must weigh clinical benefit against cost, understanding the budgetary implications of implementing maternal RSV vaccination is critical for informed policy-making. Hence, this study aimed to model and quantify the 5 y budgetary impact of implementing maternal RSVpreF vaccination, compared to no vaccination, for the prevention of RSV-LRTI in Egyptian infants aged below 1 y from the public sector perspective.

Methods

Model overview

To assess the clinical and economic implications of RSV-LRTIs in infants under one year of age, we developed a deterministic cohort model. The model estimates the projected impact of administering Pfizer's RSVpreF vaccine to pregnant women on reducing infant disease burden and related healthcare costs in Egypt, assuming full population coverage under the public healthcare sector.

The model simulates a population of infants born over a five-year period, represented by weekly birth cohorts. Each infant is tracked from birth until completion of their first year of life, death, or the end of the five-year modeling window, whichever occurs first. At birth, infants are stratified by gestational age (in weeks) and maternal vaccination status. Two strategies were modeled: maternal RSVpreF vaccination of pregnant women and the current standard of no vaccination. Infants born to vaccinated mothers were assumed to receive passive protection through transplacental antibody transfer if vaccination occurred ≥ 2 weeks before delivery.

Clinical and economic outcomes were projected weekly for each strategy, accounting for infant age, gestational maturity at birth, RSV disease risk, RSV-specific mortality, and maternal immunization status. Clinical outcomes included medically attended RSV-LRTI episodes, stratified by care setting, hospitalizations, emergency department (ED) visits, and outpatient encounters, as well as RSV-related deaths following hospitalization. The model also accounted for background (non-RSV) mortality, which was modeled as a function of infant age and gestational age at birth (Figure 1).

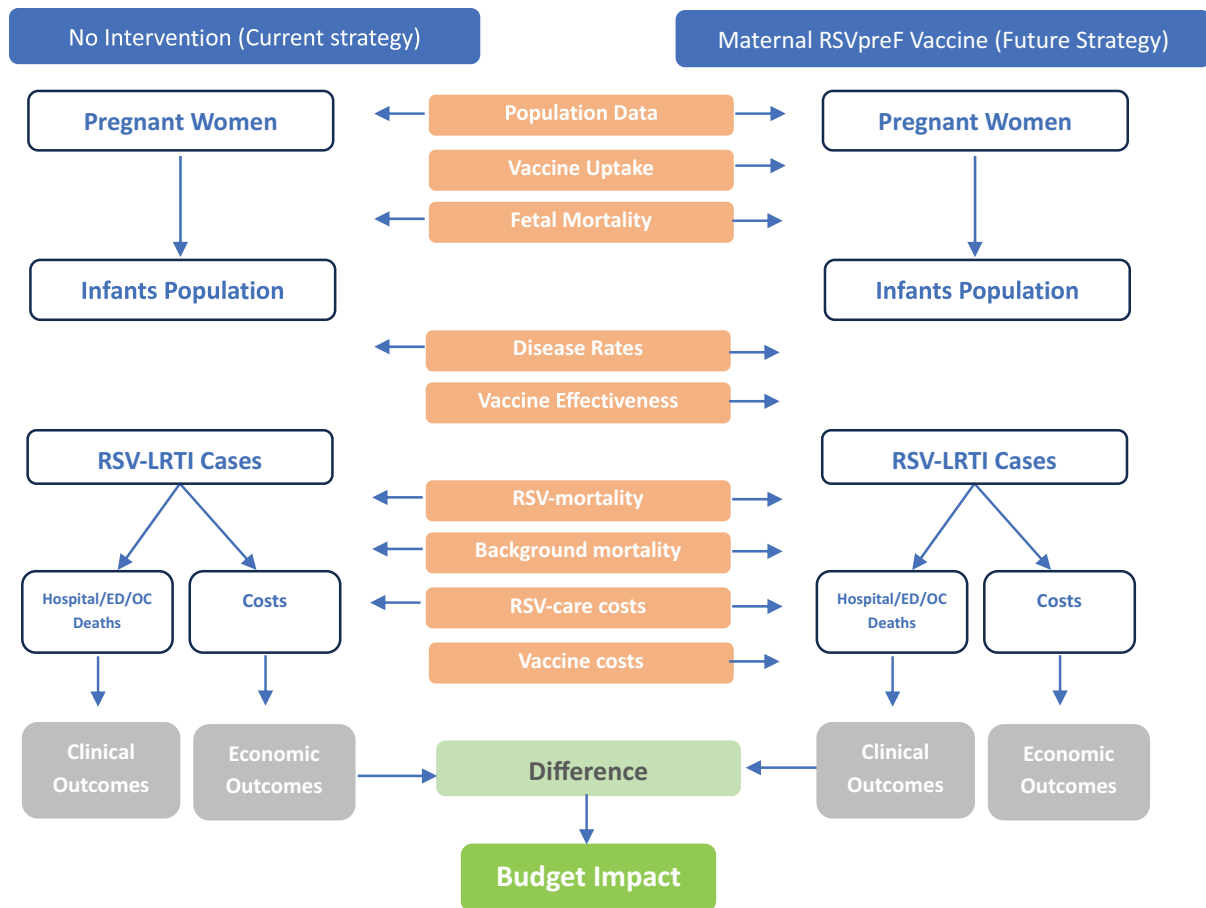


Figure 1. Model schematic. ED, Emergency department; LRTI, lower respiratory tract infection; OC, Outpatient clinic; RSV, Respiratory Syncytial Virus.

The effectiveness of maternal immunization was modeled to vary by care setting (hospital, ED, or outpatient), gestational age at birth, and infant age at exposure. Infants were assumed to experience the highest protection early in life, with vaccine effectiveness waning monthly from birth through the first nine months.

Economic evaluation included both direct medical costs for RSV-related episodes and intervention costs (vaccine costs). Medical costs were calculated by multiplying RSV-LRTI incidence by the average cost per episode. Budget impact was calculated by comparing total costs under each strategy and was reported both in aggregate and on a per-member-per-year (PMPY) basis, considering the entire population as the total number of members.

Target population

For each year of the model, it was estimated that 1,925,070 women delivered a total of 1,989,471 infants, including both live births and stillbirths, according to data from the Central Agency for Public Mobilization and Statistics (CAPMAS).¹⁴ Of these, 1,975,555 were liveborn infants. The infant population was further stratified by term status using weeks of gestational age (wGA) at birth as follows: full term (≥ 37 wGA), late preterm (32–36 wGA), early preterm (28–31 wGA), and extreme preterm (≤ 27 wGA).

In the absence of local data, inputs from other countries, including Saudi Arabia, England, and the UAE, were used to estimate the distribution of all infants by term status, as well as the distribution of liveborn infants by individual gestational week (Suppl. 1).^{11,15,16}

Table 1. RSV-LRTI rates (per 1,000).

Model Parameter	Age in Months											
	<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	16	28	20	16	14	11	10	8	7	9	6	6
Late preterm	27	48	35	39	34	27	17	14	13	15	10	10
Early/extreme preterm	7	13	9	37	33	26	67	56	51	59	42	42
ED												
Full term	7	24	27	17	19	12	11	8	8	8	5	8
Late preterm	13	41	47	43	47	29	19	13	13	13	9	13
Early/extreme preterm	3	11	13	41	45	28	76	52	52	52	37	52
OC												
Full term	1	2	2	38	43	47	18	14	19	15	16	18
Late preterm	1	3	4	94	107	117	31	24	32	26	28	30
Early/extreme preterm	0	1	1	90	103	112	123	96	129	106	112	120

ED, Emergency Department; OC, Outpatient Clinic; RSV-LRTI, Respiratory Syncytial Virus – associated Lower Respiratory Tract Infection; wGA, weeks of gestational age; Full term: ≥ 37 wGA; Late preterm: 32–36 wGA; Early preterm: 28–31 wGA; Extreme preterm: ≤ 27 wGA.

Disease incidence

RSV-hospitalizations (RSV-H) rates were based on data from a global meta-analysis,¹ of which data from a sub-analysis for developing countries was applied in the model by distributing events across each month of infant age (Table 1).

RSV-emergency department (RSV-ED) visits rates were estimated based on the ratio of RSV-H rates, RSV-outpatient clinic (RSV-OC) visits rates, and RSV-ED rates, respectively, observed in developing countries.¹ To capture only RSV cases presenting as LRTI, ambulatory rates were adjusted to exclude upper respiratory tract infections.¹⁷ Rates were then adjusted for gestational age by applying the relative risk of RSV by term status.¹⁸ Finally, seasonal variation was incorporated by distributing monthly rates according to the observed pattern of RSV episodes from the UAE (Suppl. 1).¹⁹ Cross-validation of the modeled RSV-H rates was performed against the only available Egyptian pediatric RSV-H estimate,²⁰ which reported a rate of 17.45 per 1,000 infant-years for children under 12 months of age in Egypt. Our model produced a weighted average RSV-H rate of approximately 13.5 per 1,000 infant-years in the no-vaccination scenario, approximately 22% lower than the estimate reported by Rowlinson et al.,²⁰ confirming that the model is conservative in its assessment of RSV burden.

Mortality

General infant mortality rates from causes unrelated to RSV across different infant ages were obtained from the National Egyptian Health Statistical Yearbook 2024 and were modeled to vary according to term status based on data from the United States.^{14,21} Deaths attributable to RSV were assumed to occur only in hospitalized RSV-LRTI cases. The case-fatality rate for RSV hospitalizations was assumed to differ by age group and was sourced from the developing countries subset of the global systematic review due to a lack of local data (Suppl. 1).¹

Vaccine effectiveness

Vaccine effectiveness from birth to one year of age was modeled to vary according to care setting, RSV-H, RSV-ED, and RSV-OC, as well as by infant age and gestational maturity at birth. Infants were categorized as full-term, late preterm, or early/extreme preterm, with VE for late preterm infants assumed to be equivalent to that of full-term infants. The VE assumptions are consistent with those from previously published cost-effectiveness and budget impact analyses in Mexico, Spain, UAE, and the United States^{22–25} (Table 2). This conservative assumption is supported by the MATISSE trial protocol⁶ (Table 2).

Monthly VE estimates for full-term and late preterm infants from birth to 6 months of age were obtained from the MATISSE trial.⁶ VE was assumed to wane linearly from 6 months to 0% by 10 months (Suppl. 1). Data on severe RSV-positive medically attended LRTIs in MATISSE were used to estimate VE against RSV-H, while VE on RSV-positive medically attended LRTIs informed VE estimates for RSV-ED and RSV-OC

Table 2. Estimates of vaccine effectiveness (by age) for full term and preterm infants.

Age group	Hospital	ED/OC
0–<1 months	84%	70%
1–<2 months	79%	63%
2–<3 months	73%	56%
3–<4 months	67%	48%
4–<5 months	61%	41%
5–<6 months	55%	34%
6–<7 months	41%	25%
7–<8 months	28%	17%
8–<9 months	14%	8%
9–<12 months	0%	0%

ED, Emergency Department; OC, Outpatient Clinic; wGA, weeks gestational age.

Full term: ≥ 37 wGA; Late preterm: 32–36 wGA; Early preterm: 28–31 wGA; Extreme preterm: ≤ 27 wGA.

*Vaccine effectiveness assumed to be 0% for early and extreme preterm infants and for infants born < 2 weeks after vaccine was administered.⁶

settings.^{5,6} Even though the study enrolled pregnant women as early as 24 weeks of gestation age (wGA), it did not report VE estimate for infants born < 28 wGA subgroup, meaning no direct VE data exist before 28 wGA from the per-protocol VE analysis and required a minimum 14 d interval from maternal vaccination to delivery. Physiologically, transplacental IgG transfer is substantially impaired in extreme preterm infants born before 28–30 wGA, limiting the protective benefit of maternal immunization. Given limited clinical evidence for early/extreme preterm infants and for births less than 2 weeks post-vaccination, we conservatively assumed VE = 0% for these subgroups.²⁶

Costs

The model included direct medical costs only, encompassing both the cost of the RSVpreF vaccine and the expenses associated with managing RSV-LRTI episodes. The vaccine price was set at EGP 9,000 (\$188) per dose, reflecting the publicly available list price, with no additional costs for vaccine administration. Per-episode RSV-LRTI costs were stratified by age group (0 to < 6 months; 6 to < 12 months) and care setting as a proxy for disease severity, consistent with published maternal RSVpreF budget impact analyses in comparable settings.²² Healthcare resources utilized and cost estimates for each RSV-LRTI episode were stratified by patient age and care setting using a micro-costing approach based on structured one-on-one interviews with 4 co-author clinicians (2 pediatricians [E.M.F., M.B.H.] and 2 obstetricians [E.E.A., Y.A.T.]) to estimate resource use per RSV episode by care setting (hospitalization, ED, outpatient clinic) and age group (< 6 months; 6 to < 12 months), comprising daily room, physician consultation, and monitoring investigations. Unit costs were sourced from Egyptian governmental payer. Final composite per-episode costs were agreed by experts. Each expert independently estimated resource quantities and episode costs. Results were aggregated and reconciled. Final composite costs were validated against available published Egyptian RSV hospitalization cost data where available (Table 3). In the absence of published Egyptian RSV hospitalization cost data stratified by length of stay, a structured expert opinion approach was used to derive per-episode composite estimates. Remaining uncertainty in hospitalization costs is addressed in the deterministic sensitivity analysis, in which costs were varied by $\pm 30\%$ (Figure 4).

Table 3. Disease-related costs in EGP (USD).

Care Setting	0 to < 6 months	6 to < 12 months
RSV hospitalization	13,004 (\$271.9)	7,821 (\$163.5)
RSV ED encounter	1,700 (\$35.5)	1,700 (\$35.5)
RSV OC encounter	150 (\$3.1)	150 (\$3.1)

ED, Emergency Department; OC, Outpatient Clinic; EGP, Egyptian Pound; RSV, Respiratory Syncytial Virus.

Analysis

The analysis was conducted from the public healthcare payer perspective in Egypt, without consideration of caregiver impact or indirect costs. The modeled analysis assumed all pregnant women and their infants receive care within the public healthcare system, reflecting public tariffs and utilization patterns. A 10% vaccine uptake was applied consistently year-round among pregnant women during the five-year time horizon, administered between 24 and 36 weeks of gestation, consistent with the approved indication.

Clinical outcomes were expressed as reductions in RSV-LRTI cases, stratified by care setting, hospitalizations, ED visits, and outpatient encounters, and RSV-related mortality. Economic outcomes were reported as total and incremental costs, both in aggregate and on a PMPY basis. PMPY estimates were calculated using the total population in Egypt of 106,556,174 as the denominator. All costs were reported in EGP and converted to USD using an exchange rate of 47.83 as of September 2025.

Outcomes were presented to reflect differences in unit costs, healthcare utilization, mortality, and budget impact between the current and vaccine uptake scenarios, with all costs undiscounted (0% annual discount rate) over the 5 y horizon.

We conducted one-way deterministic sensitivity analysis (DSA) varying clinical parameters (setting-specific incidence, case-fatality rates, VE by age/setting, waning profile) and economic parameters (unit costs by setting, vaccine uptake) by $\pm 30\%$ around base-case values. All costs were evaluated over the 5 y horizon and results were summarized as changes in total budget impact and PMPY relative to the base case.

Three additional scenario analyses were conducted to examine alternative VE assumptions: (1) a conservative waning scenario in which VE declines to 0% by infant month 6, rather than month 9 (Table 4); (2) an extended waning scenario in which VE wanes linearly to 0% by infant month 12 (Table 5); and (3) a preterm VE scenario in which early and extreme preterm infants (≤ 31 wGA) receive 50% of full-term VE, rather than 0% (Table 6).

Results

Base-case results

Over a 5 y horizon, without RSVpreF, the model projected 425,421 RSV-LRTI episodes among 9,877,775 live births, including 121,614 hospitalizations (RSV-H), 124,018 ED visits (RSV-ED), and 179,788 outpatient cases (RSV-OC). The number of RSV-related deaths was 1,173 (Table 7).

Without maternal vaccination, total RSV-related medical expenditures were estimated at EGP 1,652.3 million (US\$34.5 million) (Table 8).

Table 4. Estimates of vaccine effectiveness (by age) for full term and preterm infants waning over 6 months.

Age group	Hospital	ED/OC
0–<1 months	84.4%	70.5%
1–<2 months	78.5%	63.1%
2–<3 months	72.7%	55.7%
3–<4 months	66.8%	48.4%
4–<5 months	60.9%	41.0%
5–<6 months	55.1%	33.6%
6–<7 months	0.0%	0.0%
7–<8 months	0.0%	0.0%
8–<9 months	0.0%	0.0%
9–<12 months	0.0%	0.0%

ED, Emergency Department; OC, Outpatient Clinic; wGA, weeks gestational age Full term: ≥ 37 wGA; Late preterm: 32–36 wGA; Early preterm: 28–31 wGA; Extreme preterm: ≤ 27 wGA.

*Vaccine effectiveness assumed to be 0% for early and extreme preterm infants and for infants born <2 weeks after vaccine was administered.²³

Table 5. Estimates of vaccine effectiveness (by age) for full term and preterm infants waning over 6 months; linear waning to 0% by 12 months.

Age group	Hospital	ED/OC
0-<1 months	84.4%	70.5%
1-<2 months	78.5%	63.1%
2-<3 months	72.7%	55.7%
3-<4 months	66.8%	48.4%
4-<5 months	60.9%	41.0%
5-<6 months	55.1%	33.6%
6-<7 months	47.2%	28.8%
7-<8 months	39.3%	24.0%
8-<9 months	31.5%	19.2%
9-<12 months	23.6%	14.4%

ED, Emergency Department; OC, Outpatient Clinic; wGA, weeks gestational age Full term: ≥ 37 wGA; Late preterm: 32–36 wGA; Early preterm: 28–31 wGA; Extreme preterm: ≤ 27 wGA.

*Vaccine effectiveness assumed to be 0% for early and extreme preterm infants and for infants born <2 weeks after vaccine was administered.²³

Table 6. Estimates of vaccine effectiveness (by age) for early and extreme preterm infants waning over 6 months; linear waning to 0% by 9 months.

Age group	Hospital	ED/OC
0-<1 months	42.2%	35.2%
1-<2 months	39.3%	31.5%
2-<3 months	36.3%	27.9%
3-<4 months	33.4%	24.2%
4-<5 months	30.5%	20.5%
5-<6 months	27.5%	16.8%
6-<7 months	20.7%	12.6%
7-<8 months	13.8%	8.4%
8-<9 months	6.9%	4.2%
9-<12 months	0.0%	0.0%

ED, Emergency Department; OC, Outpatient Clinic; wGA, weeks gestational age Full term: ≥ 37 wGA; Late preterm: 32–36 wGA; Early preterm: 28–31 wGA; Extreme preterm: ≤ 27 wGA.

*Vaccine effectiveness for full term and preterm are the same as base case.

Table 7. Base case results: population data and clinical outcomes projected over 5 y for the simulated cohort of infants <1 y.

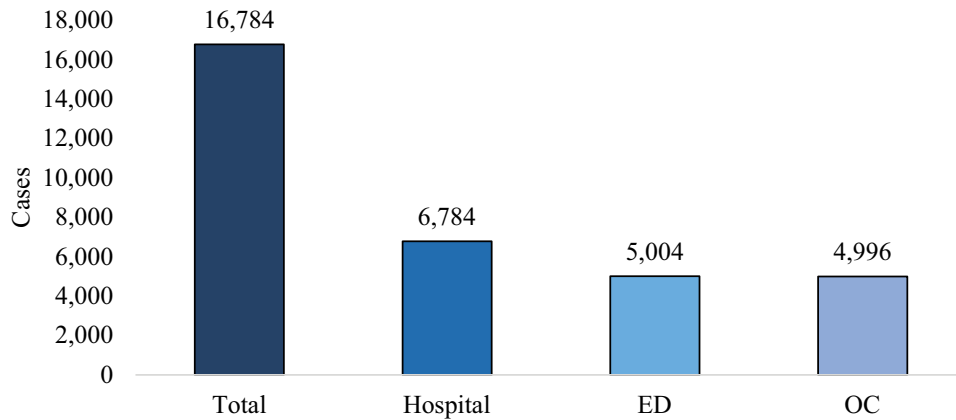
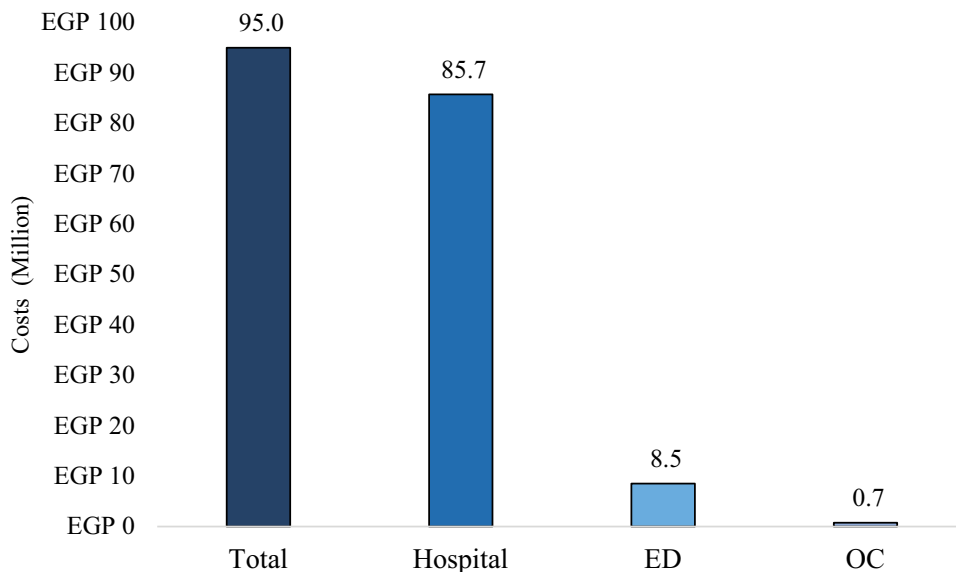
Population	No Intervention	Maternal Vaccine	Difference
No. of pregnant women	9,625,351	9,625,351	—
No. of infants born	9,947,355	9,947,355	—
No. of live births	9,877,775	9,877,775	—
Use of interventions			
No. receiving maternal vaccine	—	953,123	953,123
% infants adequately protected	—	99.1%	99.1%
Clinical outcomes			
No. of cases			
RSV hospitalization	121,614	114,830	−6,784
RSV ED encounter	124,018	119,014	−5,004
RSV OC encounter	179,788	174,792	−4,996
No. of RSV-related deaths	1,173	1,104	−69

'Difference' represents the 5 y cumulative difference between the Maternal Vaccine and No Intervention scenarios for the full modeled cohort; negative values indicate events averted under vaccination. The model is deterministic; no inferential statistics are applicable. Parameter uncertainty is addressed through the deterministic sensitivity analysis (Figures 4 and 5). ED, Emergency Department; OC, Outpatient Clinic; RSV, Respiratory Syncytial Virus.

Table 8. Base case results: economic outcomes projected over 5 y for the simulated cohort of infants <1 y.

Costs in EGP (USD)	No Intervention	Maternal Vaccine	Difference
Population costs (Millions)			
RSV Medical costs	1,652.3 (\$34.5)	1,557.3 (\$32.6)	−95.0 (\$−2.0)
Intervention costs	—	8,578.1 (\$179.3)	8,578.1 (\$179.3)
Total costs	1,652.3 (\$34.5)	10,135.4 (\$211.9)	8,483.1 (\$177.4)
Budget impact			
PMPY Cost	3.1 (\$0.1)	19.02 (\$0.4)	15.92 (\$0.3)

'Difference' represents the 5 y cumulative incremental cost of the Maternal Vaccine strategy vs. No Intervention; positive values indicate additional expenditure under vaccination. PMPY was calculated using the total enrolled population as the denominator. EGP, Egyptian Pound; PMPY, per-member-per-year; RSV, Respiratory Syncytial Virus.

**Figure 2.** Number of prevented cases, total and by care setting. ED, Emergency department; OC, Outpatient clinic.**Figure 3.** Medical costs avoided, total and by care setting. ED, Emergency department; OC, Outpatient clinic.

Introduction of RSVpreF was estimated to avert 16,784 RSV-LRTI episodes in infants under one year of age and reduce RSV-related deaths by 69 infants (Figure 2). This reduction translated into medical cost offsets of EGP 95.0 million (US\$2.0 million) due to fewer RSV-related healthcare events (Figure 3). The incremental PMPY was estimated at EGP 15.92 (US\$0.3) (Table 8).

In the scenario analyses, under the conservative waning scenario (VE declining to 0% by infant month 6 rather than month 9), RSVpreF was estimated to avert 15,444 RSV-LRTI events and 65 deaths over

5 y (Table 9), with an incremental PMPY of EGP 15.93 (USD 0.33) (Table 10). Under the extended waning scenario (VE waning linearly to 0% by month 12), 18,006 LRTI events and 73 deaths were averted (Table 11), with an incremental PMPY of EGP 15.92 (USD 0.33) (Table 12). When early and extreme preterm infants were assumed to have 50% of full-term VE, the model estimated 16,831 RSV-LRTI events averted and 69 deaths prevented (Table 13), with an incremental PMPY of EGP 15.92 (USD 0.33) (Table 14). Across all three scenarios, the incremental PMPY remained within 0.01 EGP of the base case, indicating that the overall budget impact is robust to alternative VE assumptions.

Deterministic sensitivity analysis

One-way DSA ($\pm 30\%$ around base-case values) was conducted, excluding vaccine cost (Figure 4). In this analysis, variations in maternal VE, RSV hospitalization incidence, and hospitalization unit cost produced the greatest shifts in budget impact, while all remaining clinical and economic inputs exerted relatively small effects. A separate DSA including vaccine cost as a parameter is presented in Figure 5.

Discussion

Over a five-year period in a birth cohort exceeding 9 million infants, RSVpreF maternal vaccination is projected to prevent more than 16,700 RSV-LRTI cases, including over 6,700 hospitalizations, and reduce more than 69 RSV-related deaths, assuming a 10% uptake among pregnant women. These results indicate that introducing maternal RSVpreF vaccination could substantially reduce the clinical and economic burden of RSV-LRTI. To our knowledge, this is the first published budget impact analysis assessing maternal RSVpreF vaccine to protect infants in Egypt.

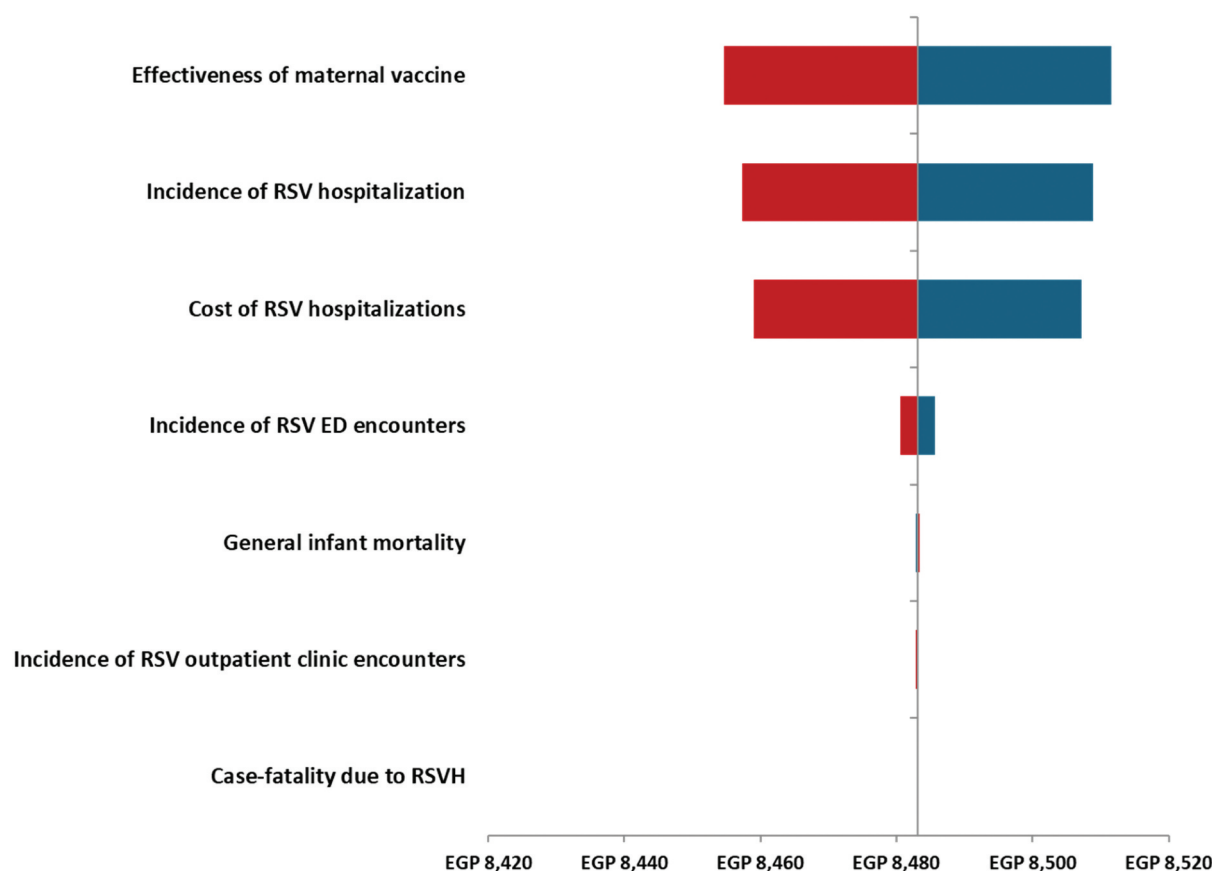


Figure 4. Tornado diagram of one-way deterministic sensitivity analysis ($\pm 30\%$). (in millions). ED, Emergency department; RSV, Respiratory Syncytial Virus. RSV-H, RSV hospitalizations.

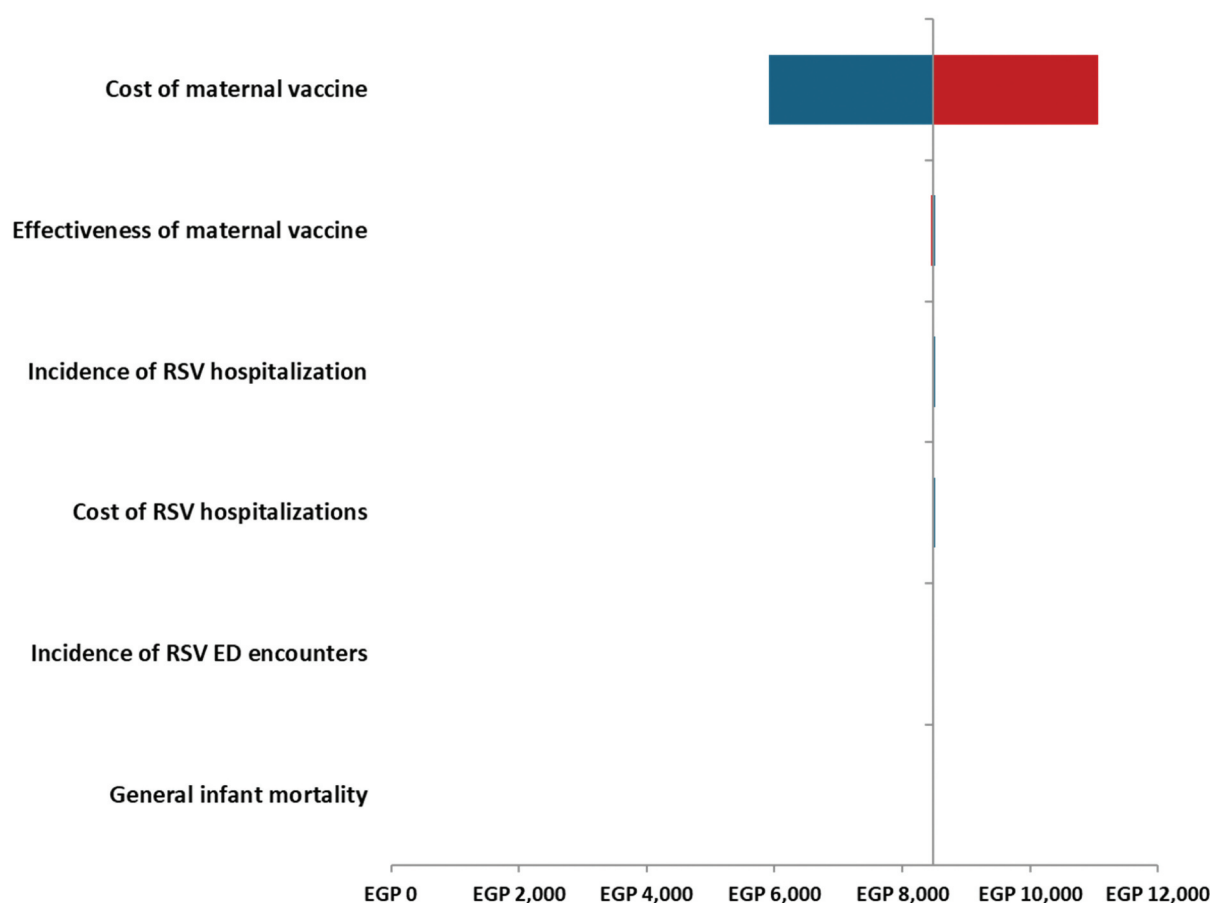


Figure 5. Tornado diagram of one-way deterministic sensitivity analysis (DSA) ($\pm 30\%$) (in millions), including vaccine cost as a parameter. ED, Emergency Department; RSV, Respiratory Syncytial Virus.

Table 9. Population data and clinical outcomes projected over 5 y: scenario 1: conservative waning (vaccine effectiveness declining to 0% by infant month 6).

Population	No Intervention	Maternal Vaccine	Difference
No. of pregnant women	9,625,351	9,625,351	—
No. of infants born	9,947,355	9,947,355	—
No. of live births	9,877,775	9,877,775	—
Use of interventions			
No. receiving maternal vaccine	—	953,123	953,123
% infants adequately protected	—	99.1%	99.1%
Clinical outcomes			
No. of cases			
RSV hospitalization	121,614	115,308	−6,306
RSV ED encounter	124,018	119,322	−4,697
RSV OC encounter	179,788	175,347	−4,441
No. of RSV-related deaths	1,173	1,108	−65

Population values are the same as base case (Table 7). 'Difference' represents the 5 y cumulative difference between the maternal vaccine and no-intervention strategies. ED, Emergency Department; OC, Outpatient Clinic; RSV, Respiratory Syncytial Virus.

While maternal RSV preF vaccination was projected to lower RSV-related medical costs by approximately EGP 95.0 million (US\$2.0 million), the inclusion of vaccine costs shifts the net budget to an incremental total of EGP 8,483.1 million over five years, equivalent to a PMPY impact of EGP 15.92 (USD 0.3). These two metrics serve distinct decision-making functions: the PMPY figure informs benefit package design and premium setting, while the aggregate 5 y figure reflects the fiscal commitment relevant to national budget planning.

The model demonstrated robustness in the DSA, with variations in all clinical and cost parameters within plausible ranges having minimal effect on the results, except for vaccine costs. It is important to note that

Table 10. Economic outcomes projected over 5 y: scenario 1: conservative waning (vaccine effectiveness declining to 0% by infant month 6).

Costs in EGP (USD)	No Intervention	Maternal Vaccine	Difference
Population costs (Millions)			
RSV Medical costs	1,652.3 (\$34.5)	1,561.7 (\$32.6)	−90.7 (\$-1.9)
Intervention costs	—	8,578.1 (\$179.3)	8,578.1 (\$179.3)
Total costs	1,652.3 (\$34.5)	10,139.8 (\$212.0)	8,487.4 (\$177.4)
Budget impact			
PMPY Cost	3.1 (\$0.1)	19.03 (\$0.4)	15.93 (\$0.3)

Costs in EGP (USD). Population values are the same as base case (Table 8). 'Difference' represents the 5 y cumulative difference between strategies. EGP, Egyptian Pound; PMPY, per-member-per-year; RSV, Respiratory Syncytial Virus.

Table 11. Population data and clinical outcomes projected over 5 y: scenario 2: extended waning (vaccine effectiveness declining to 0% by infant month 12).

Population	No Intervention	Maternal Vaccine	Difference
No. of pregnant women	9,625,351	9,625,351	—
No. of infants born	9,947,355	9,947,355	—
No. of live births	9,877,775	9,877,775	—
Use of interventions			
No. receiving maternal vaccine	—	953,123	953,123
% infants adequately protected	—	99.1%	99.1%
Clinical outcomes			
No. of cases			
RSV hospitalization	121,614	114,410	−7,204
RSV ED encounter	124,018	118,767	−5,252
RSV OC encounter	179,788	174,238	−5,550
No. of RSV-related deaths	1,173	1,101	−73

Population values are the same as base case (Table 7). 'Difference' represents the 5 y cumulative difference between the maternal vaccine and no-intervention strategies. ED, Emergency Department; OC, Outpatient Clinic; RSV, Respiratory Syncytial Virus.

Table 12. Economic outcomes projected over 5 y: scenario 2: extended waning (vaccine effectiveness declining to 0% by infant month 12).

Costs in EGP (USD)	No Intervention	Maternal Vaccine	Difference
Population costs (Millions)			
RSV Medical costs	1,652.3 (\$34.5)	1,553.5 (\$32.5)	−98.8 (\$-2.1)
Intervention costs	—	8,578.1 (\$179.3)	8,578.1 (\$179.3)
Total costs	1,652.3 (\$34.5)	10,131.6 (\$211.8)	8,479.3 (\$177.3)
Budget impact			
PMPY Cost	3.1 (\$0.1)	19.02 (\$0.4)	15.92 (\$0.3)

Costs in EGP (USD). Population values are the same as base case (Table 8). 'Difference' represents the 5 y cumulative difference between strategies. EGP, Egyptian Pound; PMPY, per-member-per-year; RSV, Respiratory Syncytial Virus.

Table 13. Population data and clinical outcomes projected over 5 y: scenario 3: 50% vaccine effectiveness for early/extreme preterm infants.

Population	No Intervention	Maternal Vaccine	Difference
No. of pregnant women	9,625,351	9,625,351	—
No. of infants born	9,947,355	9,947,355	—
No. of live births	9,877,775	9,877,775	—
Use of interventions			
No. receiving maternal vaccine	—	953,123	953,123
% infants adequately protected	—	99.1%	99.1%
Clinical outcomes			
No. of cases			
RSV hospitalization	121,614	114,815	−6,799
RSV ED encounter	124,018	119,003	−5,015
RSV OC encounter	179,788	174,771	−5,017
No. of RSV-related deaths	1,173	1,104	−69

Population values are the same as base case (Table 7). 'Difference' represents the 5 y cumulative difference between the maternal vaccine and no-intervention strategies. ED, Emergency Department; OC, Outpatient Clinic; RSV, Respiratory Syncytial Virus.

Table 14. Economic outcomes projected over 5 y: scenario 3: 50% vaccine effectiveness for early/extreme preterm infants.

Costs in EGP (USD)	No Intervention	Maternal Vaccine	Difference
Population costs (Millions)			
RSV Medical costs	1,652.3 (\$34.5)	1,557.1 (\$32.6)	−95.2 (\$−2.0)
Intervention costs	—	8,578.1 (\$179.3)	8,578.1 (\$179.3)
Total costs	1,652.3 (\$34.5)	10,135.2 (\$211.9)	8,482.9 (\$177.4)
Budget impact			
PMPY Cost	3.1 (\$0.1)	19.02 (\$0.4)	15.92 (\$0.3)

Costs in EGP (USD). Population values are the same as base case (Table 8). 'Difference' represents the 5 y cumulative difference between strategies. EGP, Egyptian Pound; PMPY, per-member-per-year; RSV, Respiratory Syncytial Virus.

the vaccine price applied in this analysis represents the list price, which does not account for potential procurement discounts, tiered pricing, or negotiated reductions typically achieved through national immunization initiatives or public health programs. In practice, the cost of RSVpreF is expected to be lower when procured under large-scale public initiatives, which would further improve the budgetary profile and economic attractiveness of maternal vaccination in Egypt. The DSA including vaccine cost as a parameter demonstrates that vaccine price is the single most dominant driver of total budget impact. This underscores that achieving favorable procurement pricing is the most impactful lever for improving the affordability of the maternal RSVpreF program in Egypt.

A budget impact analysis in Dubai, UAE, reported a PMPY of \$0.188, similar to the current findings of this study.²² Several cost-effectiveness analyses align with our findings, demonstrating that maternal RSVpreF vaccination yields significant clinical benefits and, under favorable pricing assumptions, offers strong economic value. For instance, a Spanish NHS analysis found maternal RSVpreF to be cost-saving (dominant) over no intervention.²³ Another model conducted for the United States from a societal perspective estimated an incremental cost-effectiveness ratio (ICER) of US \$89,733 per quality-adjusted life year (QALY) when administered year-round, but found seasonal vaccination to be cost-saving.²⁵ Collectively, published economic evaluations of maternal RSVpreF vaccination confirm that it consistently delivers health gains, but its economic attractiveness is highly sensitive to vaccine cost, seasonality, and regional epidemiology.

This study has some limitations, mainly related to data gaps, requiring the use of non-local inputs, evidence-based assumptions, and applying extrapolations where direct estimates were unavailable. Vaccine effectiveness beyond six months was informed by the decay of maternally transferred antibodies following natural infection and vaccination.^{27–29} Additional limitations included the estimation of RSV incidence in ED and outpatient clinic settings as a proportion of RSV-H incidence, based on ratios from developed countries, in the absence of Egypt-specific ambulatory RSV data; and (ii) use of MATISSE trial endpoints as proxies for care-setting VE in the model (i.e., VE against severe medically attended RSV-LRTI in MATISSE was applied as VE against RSV-H, and VE against all medically attended RSV-LRTI was applied as VE against RSV-ED/OC visits), recognizing that not all severe medically attended LRTIs result in hospitalization.^{5,6} Moreover, most input parameters, apart from population size, infant birth by month, and general infants' mortality rates, were derived from sources not specific to the Egyptian context. To mitigate this limitation, we prioritized data from populations with demographic and epidemiological profiles similar to Egypt and validated all parameters with local clinical experts to ensure their relevance to the national setting.

The model's conservative assumption of zero VE for early and extreme preterm infants (≤ 31 wGA) warrants explicit acknowledgment of the implications for this high-risk subgroup. Published evidence indicates that infants born at ≤ 32 wGA experience RSV-H rates approximately 3–4 times higher than full-term infants; during RSV-H, ICU admission is required in approximately 50% of extreme preterm cases (23–32 wGA) compared with approximately 14% of full-term infants.²⁶ While extreme preterm births represent a small proportion of the total birth cohort, this population carries a disproportionate RSV disease burden that is unmitigated by maternal vaccination under the present model. To assess the sensitivity of this assumption, a scenario analysis was conducted in which the results remain essentially unchanged from the base case – indicating that the conservative VE assumption for this subgroup has minimal impact on total budget impact given their small proportion of the overall birth cohort.

The model may have underestimated potential clinical and economic benefits of maternal RSVpreF vaccination. For example, non-medical costs such as transportation to hospitals, ED, and outpatient clinic were excluded, as were indirect costs related to lost productivity from caregivers' missed workdays. The analysis also did not capture the broader spectrum of RSV-related clinical outcomes and long-term sequelae, such as upper respiratory tract infections, otitis media, secondary bacterial infections, and prolonged or recurrent wheezing and reactive airway disease. The omission of these indirect and long-term costs means that the present analysis underestimates the full economic benefit of preventing RSV-LRTI through maternal vaccination. Additionally, cost estimates were based on per-episode composite values stratified by age group, rather than costs stratified by length of stay; future analyses incorporating Egyptian RSV length-of-stay distributional data, when available, could further refine these estimates.

In our analysis, maternal RSVpreF vaccination was modeled as a year-round program, independent of RSV seasonality. While RSV was reported to have a seasonal pattern across the MENA region, year-round maternal RSVpreF vaccination was selected for four reasons: (1) RSV seasonality in Egypt is variable and cannot reliably define a program administration window^{30,31}; (2) multiple national vaccination programs in and out of the region, including those in the UAE, UK, and Qatar have adopted year-round maternal RSVpreF recommendations, reflecting the operational and equity challenges of a seasonal approach^{32–34}; (3) vaccine-derived protection persists for at least 6 months post-vaccination, ensuring that infants born throughout the year retain meaningful protection during peak RSV season regardless of maternal immunization month; and (4) restricting vaccination to a seasonal window would leave infants born outside that window unprotected, creating an equity risk within the same birth cohort.

Future research should prioritize on generating evidence to support the model assumptions: (1) Egypt-specific real-world evidence on RSV epidemiology, VE, healthcare utilization, and costs; (2) VE in high-risk subgroups (e.g., early/extreme preterm and immunocompromised infants); (3) impact of maternal RSVpreF vaccine on long-term respiratory sequelae and broader RSV-related outcomes not captured in this analysis; and (4) head-to-head comparison of seasonal vs. year-round delivery strategies to identify the most efficient program design for Egypt.

Conclusion

Maternal RSVpreF vaccination could considerably reduce the burden of RSV-LRTI in Egyptian infants aged less than one year. Although implementation is associated with an estimated annual budget impact of EGP 15.92 (US\$0.3) PMPY, the projected health gains support its consideration as a valuable component of national infant health programs.

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Disclosure statement

Ahmed El Hag, Nardine Nabil, Rowan El Masry, Diana Mendes, and Amy Law are employees of Pfizer. Mohamed Aladdin is employee of Accsight, which received funding from Pfizer in connection with this study and the development of this manuscript. Elsayed Elbadawy Awad, Eman Mahmoud Fouda, Moataza Bashir Hamed, and Yasser Abou Talib declare no other competing interests regarding the content of this article.

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Abbreviations

DSA	Deterministic Sensitivity Analysis
ED	Emergency Department
LRTIs	Lower Respiratory Tract Infections
PMPY	Per-Member-Per-Year
RSV	Respiratory Syncytial Virus
RSV-H	RSV Hospitalizations
RSV-OC	RSV Outpatient Clinic Visits
RSVpreF	Respiratory Syncytial Virus Prefusion F
VE	Vaccine Effectiveness
wGA	Weeks of Gestational Age

Data availability statement

The data that support the findings of this study are available upon reasonable request from the corresponding author, MA.

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