Research Square

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Estimated additional infant RSV deaths when maternal RSV vaccination in Gavi-eligible countries starts late or scales up slowly

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Abstract

Gavi's RSV vaccination program is starting amid donor funding shortfalls. In a model of 56 Gavi-eligible countries, a schedule built from Gavi's investment case would prevent 73,000 deaths among infants born 2028–2037. A one-year delay would reduce deaths prevented by 14,300 (20%), and slower coverage scale-up by 12,400 (17%).

Background

Respiratory syncytial virus (RSV) is the most common cause of acute lower respiratory tract infection in young children globally, with more than 97% of RSV-attributable deaths occurring in low- and middle-income countries [1]. WHO recommends that all countries introduce maternal vaccination or infant long-acting monoclonal immunoprophylaxis, both of which reduce severe RSV illness in the first months of life [2]. In July 2025, Gavi approved a funding window for maternal RSV vaccination, contingent on available resources and a prequalified multidose vial [3, 4]. WHO prequalified the multidose vial on August 24, 2026 [5], and eligible countries can now apply for Gavi support [4].

Gavi's investment case projected that seven countries would introduce the vaccine during its 2026–2030 strategic period and that 37 countries would introduce it by 2040, with Ethiopia starting in 2032, Pakistan in 2034, and the Democratic Republic of the Congo (DRC) in 2037 [3]. As of October 2026, no Gavi-supported introduction has occurred.

In 2024, the United States pledged at least US$1.58 billion to Gavi for 2026–2030 [6], but in 2025 made further support conditional on reforms [7]. In July 2026, it announced the release of US$600 million appropriated for fiscal years 2025 and 2026 after Gavi agreed to changes, but did not address the remainder of the five-year pledge [7]. By Gavi's June 2025 pledging summit, donors had committed more than US$9 billion toward a US$11.9 billion target for 2026–2030 [8]. Failure by the United States and other donors to fulfill their commitments could delay maternal RSV vaccine introduction or slow coverage scale-up.

We estimated infant hospitalizations and deaths prevented under a schedule built from Gavi's investment case and the additional deaths from delayed introduction or slower coverage scale-up.

Methods

We estimated vaccine demand and infant outcomes for the 56 countries eligible for Gavi support in 2026 using an independent reconstruction of a published maternal RSV vaccine impact model [9]. The Supplement provides data sources, country start years, model validation, and sensitivity analyses. We followed Gavi's investment case for introduction timing, uptake, annual coverage increases, wastage, and buffer stock, used published antenatal contact data and national coverage estimates, and obtained RSV rates and efficacy from the published impact model.

The baseline schedule followed Gavi's investment case, using its number of new introductions in each year and its start years for Ethiopia, Pakistan, and the DRC [3]. The investment case describes the eight Gavi-eligible members of the Maternal Immunisation Readiness Network in Africa and Asia, a consortium preparing for maternal vaccine introduction, as potential early implementing countries [3]. Two of them, Ethiopia and Pakistan, have start years from the investment case. We assigned the six remaining network members (Bangladesh, Burkina Faso, Ghana, Kenya, Nigeria, and Uganda) to the earliest available introduction years, followed by the other countries. Within each group, we ordered countries by their mean interval before introducing pneumococcal conjugate, rotavirus, and human papillomavirus (HPV) vaccines, measured from each vaccine's first introduction among the 56 countries. Nineteen countries had no introduction scheduled by 2040 in this scenario.

In delay scenarios, we moved each country's start year 1 to 5 years later and kept the rise to the initial coverage target unchanged. In slower coverage scale-up scenarios, we kept start years unchanged and increased coverage in equal steps to the initial coverage target over 5 years in Ethiopia, Pakistan, and the DRC and over 3 years in all other countries. We also combined slower coverage scale-up with one- and two-year delays. In three historical introduction scenarios, RSV vaccine followed the introduction pattern of pneumococcal conjugate, rotavirus, or HPV vaccine. Each country's RSV introduction year was 2028 plus its introduction interval for that vaccine, rounded to whole years. These scenarios do not predict when countries will introduce RSV vaccine. To assess sensitivity to country order, we tested two approaches while retaining the investment-case introduction years for Ethiopia, Pakistan, and the DRC. First, we ordered the remaining countries by mean introduction interval, without priority for the readiness network. Second, we generated 1,000 constrained random country orders by shuffling countries within the readiness network and within the group of remaining countries. We evaluated each order with RSV rates and efficacy at their point estimates, and we report the median and the 2.5th–97.5th percentiles (95% range) across orders.

Pregnancies were country-level estimates of births plus stillbirths. We applied coverage to pregnancies to estimate women vaccinated and to live births to estimate infant outcomes. We counted women as vaccinated if they received vaccine at an antenatal contact at 28–36 weeks, and we obtained the probability of a contact in that window from a longitudinal study of 123,867 women in six countries [10]. We used country-specific probabilities for the six study countries and pooled probabilities for all others. The pooled probability was 53% for women with one to three antenatal visits and 84% for women with four or more antenatal visits, and we applied these probabilities to each country's share of women with each number of visits. We used 2024 first-dose diphtheria-tetanus-pertussis (DTP1) vaccine coverage as the probability of vaccination at a contact, a proxy for routine vaccine delivery. The initial coverage target, the share of pregnant women expected to be vaccinated based on antenatal care and DTP1 coverage, had a median of 55% across countries. Following the investment case, coverage in a country's first year was 80% of its initial coverage target and reached that target in the second year, except in Ethiopia, Pakistan, and the DRC, where it rose in equal steps over three years [3]. From the year after a country reached the initial coverage target, coverage rose by 3 percentage points a year in countries whose initial coverage target was below 70% and by 1 percentage point a year in countries whose initial coverage

target was 70–90%, up to 90% [3]. The investment case does not specify whether these are absolute or relative increases or when they begin. Vaccination was year-round, as in the investment case [3]. We calculated annual dose requirements as women vaccinated × 1.13 for wastage, plus buffer stock equal to 25% of the increase in demand from the previous year and summed them over 2028–2037. Buffer stock was 25% of demand in a country's first year and zero in years when demand fell.

We independently reconstructed the published UNIVAC maternal RSV analysis from its reported methods and inputs, without accessing or using the UNIVAC software [9]. Inputs included disease rates by income group, age distributions, and vaccine efficacy against severe disease of 69.4% through age 6 months (97.58% confidence interval, 44.3–84.1%) [11]. As in the published analysis, we assumed vaccine efficacy against RSV death equaled efficacy against severe RSV disease. We counted outcomes among infants born during 2028–2037. When we applied our reconstruction to the published inputs, the deaths prevented differed from the published estimate by 1.1%.

We used 10,000 draws to account for parameter uncertainty. We sampled rates of severe disease, hospitalization, and death by income group from lognormal distributions that we fitted to the published bounds [9]. All countries in an income group shared one draw. We sampled efficacy against severe disease from a two-piece logit-normal distribution fitted to the point estimate and confidence limits. We applied the same draws to every schedule and calculated differences from baseline within each draw.

This analysis used only publicly available, aggregate data with no individual-level information. It did not meet the definition of human subjects research, and institutional review board review was not required.

Results

Under the baseline schedule, seven countries introduced maternal RSV vaccine by 2030 and 36 by 2037. An estimated 157 million women were vaccinated (Table S1), and 186.6 million doses were required. Among infants born in 2028–2037, vaccination prevented an estimated 1.56 million RSV hospitalizations (95% uncertainty interval [UI] 0.97–2.35 million) and 73,000 RSV deaths (95% UI 48,600–95,000) (Table 1, Fig. 1). The deaths prevented represented 17% (95% UI 11–20%) of RSV deaths before age 6 months across the 56 countries.

Table 1

Modeled infant RSV deaths prevented in 56 Gavi-eligible countries when maternal RSV vaccine introduction is delayed or coverage scales up more slowly, infants born 2028–2037

Schedule	Countries introduced by 2030 / 2037	Deaths prevented (95% UI)	Change from baseline, deaths (95% UI)	Change from baseline, %[a]
Baseline	7 / 36	73,000 (48,600–95,000)	Reference	Reference
1-year delay	4 / 34	58,700 (39,100–76,400)	−14,300 (− 18,600 to − 9,500)	−20
2-year delay	1 / 30	45,800 (30,500–59,600)	−27,200 (− 35,300 to − 18,100)	−37
3-year delay	0 / 25	34,400 (22,900–44,800)	−38,600 (− 50,200 to − 25,700)	−53
4-year delay	0 / 19	24,700 (16,400–32,100)	−48,300 (− 62,800 to − 32,200)	−66
5-year delay	0 / 17	17,100 (11,400–22,300)	−55,900 (− 72,600 to − 37,200)	−77
Slower coverage scale-up, baseline dates	7 / 36	60,600 (40,400–78,800)	−12,400 (− 16,100 to − 8,300)	−17
Slower coverage scale-up, 1-year delay	4 / 34	47,800 (31,800–62,200)	−25,200 (− 32,800 to − 16,800)	−35
Slower coverage scale-up, 2-year delay	1 / 30	36,500 (24,300–47,600)	−36,500 (− 47,400 to − 24,300)	−50

Uncertainty intervals are the 2.5th and 97.5th percentiles of 10,000 draws of RSV mortality rates and vaccine efficacy, with the same draws applied to every schedule. Values are rounded to the nearest 100 after differences were calculated. The baseline schedule is built from Gavi's investment case. Delayed schedules move every introduction later by the number of years shown, with the same rise to the initial coverage target. Hospitalizations and sensitivity analyses are in the Supplement. On the baseline schedule, coverage in a country's first year is 80% of its initial coverage target and reaches the initial coverage target in the second year. With slower coverage scale-up, coverage rises in equal steps over 3 years. In Ethiopia, Pakistan, and the Democratic Republic of the Congo, coverage rises in equal steps over 3 years at baseline and over 5 years with slower coverage scale-up. After a country reaches the initial coverage target, coverage rises by 3 percentage points a year in countries whose initial coverage target is below 70% and by 1 percentage point a year in countries whose initial coverage target is 70–90%, up to 90%.

a. The percentage reduction in deaths prevented compared with the baseline schedule. For example, a one-year delay prevents 58,700 deaths, 20% fewer than the 73,000 prevented on the baseline schedule. Across 1,000 constrained random country orders, 95% of values were within 3 percentage points of those shown.

Abbreviations: RSV, respiratory syncytial virus; UI, uncertainty interval.

Delaying all introductions by one year resulted in 303,000 additional hospitalizations (95% UI 187,000–455,000) and 14,300 additional deaths (95% UI 9,500–18,600), a 20% reduction in deaths prevented compared with baseline. A two-year delay resulted in 582,000 additional hospitalizations (95% UI 360,000–874,000) and 27,200 additional deaths (95% UI 18,100–35,300), a 37% reduction in deaths prevented. With delays of three, four, and five years, 53%, 66%, and 77% fewer deaths were prevented, respectively (Table 1, Fig. 1). Slower coverage scale-up without delayed introduction resulted in 266,000 additional hospitalizations (95% UI 164,000–399,000) and 12,400 additional deaths (95% UI 8,300–16,100). Combining slower coverage scale-up with a one-year delay resulted in 536,000 additional hospitalizations (95% UI 332,000–805,000) and 25,200 additional deaths (95% UI 16,800–32,800).

Across 1,000 constrained random country orders, the median number of deaths prevented under the baseline schedule was 67,100 (95% range 61,500–74,300). The primary analysis was near the upper end of this range because countries with historically faster vaccine introduction also achieved higher coverage. The percentage reductions from delay and slower coverage scale-up varied little across country orders. A one-year delay reduced deaths prevented by a median of 20% (95% range 19–21%). A two-year delay reduced them by 38% (95% range 36–39%) (Table S2). Without priority for readiness network countries, ordering countries by introduction history reduced deaths prevented under the baseline schedule by 13,900 (95% UI 8,100–20,500), or 19%, to 59,100 (Table S1).

If RSV vaccine followed the introduction pattern of pneumococcal conjugate, rotavirus, or HPV vaccine, 47, 43, and 14 countries introduced by 2037, respectively. These scenarios prevented 96,800 (95% UI 64,500–125,300), 71,600 (47,700–92,700), and 11,900 (7,900–15,700) infant RSV deaths, compared with 73,000 under the baseline schedule (Table S1).

Discussion

In this analysis, maternal RSV vaccination on a schedule built from Gavi's investment case prevented an estimated 73,000 deaths among infants born in 2028–2037. This was 17% of the estimated RSV deaths before age 6 months in the 56 Gavi-eligible countries. A one-year delay in all introductions reduced deaths prevented by 14,300 (95% UI 9,500–18,600). Across 1,000 constrained random country orders, the 95% range for the reduction from a one-year delay was 19–21%. Slower coverage scale-up from the same start dates reduced deaths prevented by 12,400 (95% UI 8,300–16,100), a loss similar to that from a one-year delay.

Financing for this schedule is uncertain. Maternal RSV vaccine is a discretionary program in Gavi's country vaccine budgets [12]. When country needs exceed available funding, Gavi's budget policy gives lowest priority to new introductions in discretionary budgets, apart from a minimum reserved for initial self-financing countries. If resources fall, funding is removed in the reverse order [13]. Gavi's July 2026 Vaccine Budget Policy identified a US$111 million funding gap for higher-priority needs in 2029–2030 [13], when six of the first seven introductions were projected [3]. Funding shortfalls could therefore delay maternal RSV vaccine introduction.

Gavi's investment case provides start years for only three countries. We assigned years to the others, but the percentage loss from delay changed little across 1,000 constrained random country orders. Our uncertainty intervals included RSV rates and efficacy but not coverage or start years. Coverage estimates rely on antenatal contact data from six countries and use DTP1 coverage as a proxy for vaccine delivery. We did not estimate how specific funding shortfalls would change introduction dates or coverage.

Countries can now apply for Gavi support for RSV vaccine introduction. Ethiopia, Pakistan, and the DRC have three of the four largest birth cohorts among the 56 countries, yet their introductions are projected for 2032–2037 in the investment case, with coverage increasing over three years. If RSV vaccine followed the introduction pattern of pneumococcal conjugate vaccine, an additional 23,800 deaths among infants born 2028–2037 would be prevented (95% UI 15,700–31,600). Delayed introduction or slower coverage scale-up of maternal RSV vaccine, whether from funding shortfalls or other causes, will cost infant lives.

Declarations

Conflicts of interest.

A.M.L., A.J.D., K.S.B., J.P.C., and J.M. report no competing interests. M.C.F. reports personal fees for participation on the Global Payers Panel for Sanofi Pasteur and grant funding from Gavi, the Vaccine Alliance, to her institution for RSV impact modeling research, outside the submitted work. J.R.O. reports consulting fees from ENA Respiratory Pty Ltd.; service on the Moderna New Vaccines Advisory Board; authorship as an expert content contributor for UpToDate; service as co-chair of the American Thoracic Society Vaccine and Immunization Advisory Group; institutional research funding from ENA Respiratory Pty Ltd., BlueWillow, Ltd., Vaccine Company, Inc., and Pfizer; and grant funding from Gavi, the Vaccine Alliance, to his institution for RSV-related research, all outside the submitted work.

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Author contributions.

Conceptualization: A.M.L., M.C.F., J.R.O. Methodology: A.M.L., A.J.D., M.C.F., J.R.O. Supervision: M.C.F., J.R.O. Project administration: J.R.O. Funding acquisition: J.R.O. Investigation: A.M.L., A.J.D., K.S.B., J.M., M.C.F., J.R.O. Data curation: A.M.L., K.S.B., J.M., M.C.F., J.R.O. Formal analysis: A.M.L., J.R.O. Software:

A.M.L., J.M., J.R.O. Validation: M.C.F., J.R.O. Writing – original draft: A.M.L., M.C.F., J.R.O. Writing – review & editing: A.M.L., A.J.D., K.S.B., J.P.C., J.M., M.C.F., J.R.O. Visualization: J.R.O.

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Data availability.

Country inputs with their sources and country introduction schedules for every scenario are in Data Files 1 and 2 of the Supplement. The analysis code is available at https://github.com/justin-ortiz/rsv-maternal-delay-gavi.

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Figures

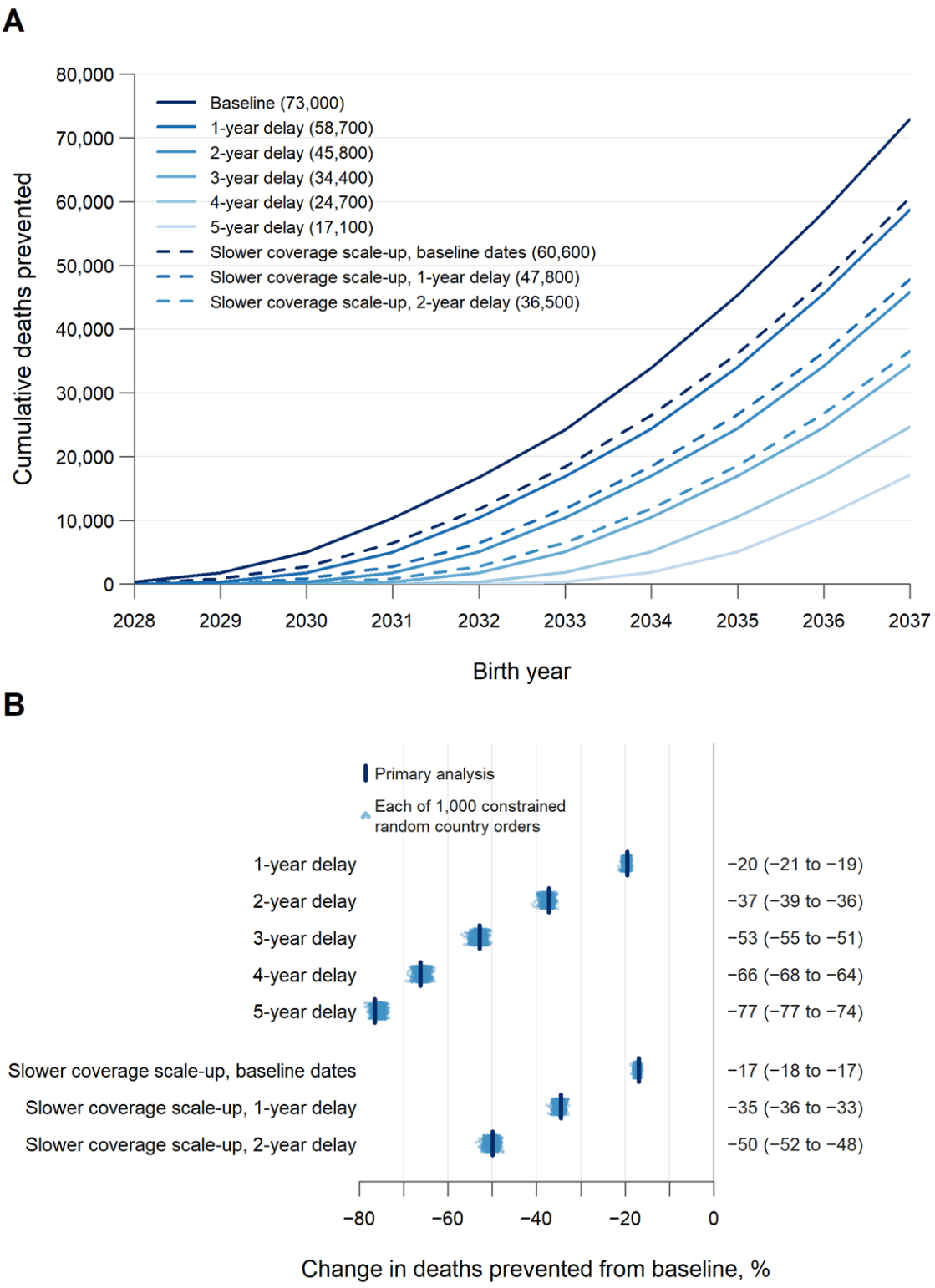


Figure 1

Infant RSV deaths prevented when maternal RSV vaccine introduction is delayed or coverage scales up more slowly (A), and the percentage reduction in deaths prevented in the primary analysis and in 1,000 constrained random country orders (B)

(A) Cumulative RSV deaths prevented among infants born 2028–2037 on each introduction schedule. Dashed lines show slower coverage scale-up. Totals are in parentheses. (B) Change in deaths prevented from the baseline schedule, as a percentage. Vertical marks show the primary analysis. Points show each of 1,000 constrained random country orders within two groups. The first group comprises the six Gavi-eligible members of the Maternal Immunisation Readiness Network in Africa and Asia without investment-case start years (Bangladesh, Burkina Faso, Ghana, Kenya, Nigeria, and Uganda). The second comprises the remaining countries without fixed start years. Gavi's investment case identifies the network's members as potential early implementing countries. The network's other two Gavi-eligible members, Ethiopia and Pakistan, and the Democratic Republic of the Congo keep their investment-case start years in every order. Numbers on the right show the primary analysis, with the 2.5th–97.5th percentiles across constrained random country orders in parentheses.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- DataFile1countryinputs.xlsx
- DataFile2introductionschedules.xlsx
- Gavi56introductionintervalsJRO20261024.xlsx
- RSVmaternaldemandGavi56JRO20261024.xlsx