



# Efficacy of maternal vaccination during pregnancy against infant respiratory viruses

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**Maternal vaccinations were effective in preventing RSV-associated lower respiratory tract infection and influenza in infants. The protection for infants against influenza was highest at 2 months and gradually declined up to 6 months of age.** <https://bit.ly/3ry3DAH>

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## Commentary on:

- Madhi SA, *et al.* Respiratory syncytial virus vaccination during pregnancy and effects in infants. *N Engl J Med* 2020; 383: 426–439.
- Omer SB, *et al.* Efficacy, duration of protection, birth outcomes, and infant growth associated with influenza vaccination in pregnancy: a pooled analysis of three randomised controlled trials. *Lancet Respir Med* 2020; 8: 597–608.

## Context

Pregnant women and infants have high mortality and a high risk of hospitalisation, and are more vulnerable to respiratory infectious diseases than the general population [1–3]. During pregnancy, women experience physiological and immunological changes that increase the risk of infections and associated complications. Furthermore, there is suggested evidence that transplacental (vertical) transmission of viral infections may occur from mother to fetus [4]. Even without transplacental transmission, being seriously ill while pregnant may still have an adverse impact on the fetus [5]. It is essential to protect pregnant women and infants against respiratory infectious diseases. Infants are significantly more vulnerable to severe illness post-infection, due to their undeveloped immunity [6]. Globally, the most common respiratory infectious diseases affecting infants are influenza and respiratory syncytial virus (RSV) [6, 7].

It is estimated that influenza causes approximately 270 000 hospitalisations [6] and an average of 113 influenza-associated deaths per year in young infants under 6 months [8]. Comparably, RSV infections in 2015 were estimated at 33.1 million cases, 3.2 million hospitalisations and 59 600 in-hospital deaths in children aged <5 years [7]. Complications associated with influenza result in early-life respiratory diseases, including childhood asthma, respiratory symptoms, and lung inflammation, leading to systematic inflammation [9]. Similarly, RSV infection can cause severe illnesses, including pneumonia and bronchiolitis, and in some cases it can cause repeated RSV infections [10].

Primary prevention of influenza and RSV infections is crucial for infants and could save millions of lives around the world. Unfortunately, there is no available influenza or RSV vaccine for infants aged <6 months [11, 12]. However, maternal vaccination could provide passive immunity to the fetus by transferring antibodies across the transplacental barrier [2]. There is evidence that maternal influenza vaccination protects infants after delivery, but the extent of this protection and that of maternal vaccination for other respiratory diseases is not fully understood [1, 3]. Infants are vulnerable to repeated RSV



infections and complications after influenza infection, emphasising the urgent need to evaluate the impacts of maternal RSV and influenza vaccines [9, 10]. This article will discuss the vaccine efficacy of maternal vaccination on infant influenza and RSV infection, as reported by MADHI *et al.* [13] and OMER *et al.* [14].

## Methods

### *MADHI et al. [13]*

A randomised, observer-blinded, placebo-controlled trial was conducted, including healthy women aged 18–40 years with low-risk singleton pregnancies recruited across 87 sites from 11 countries. Study participants were randomised 1:1 in the first global RSV season, and 2:1 thereafter, to receive either 120 µg of RSV fusion (F) protein vaccine adsorbed to 0.4 mg of aluminium, or placebo (without aluminium). Vaccines were administered at 28–36 weeks of gestation. Participants with pregnancy complications in the current pregnancy or a history of stillbirth, neonatal death or preterm delivery  $\leq 34$  weeks were excluded. Women who received any other vaccine within the 14 days prior to receiving the study vaccination or who had previously received an RSV vaccination were also excluded.

The main objective of the trial was to understand the efficacy of maternal vaccination with RSV F protein vaccines for the protection against infant RSV-associated, lower respiratory tract infection up to 90 days of life. Vaccine efficacy at 120, 150 and 180 days of life would also be examined if the trial vaccine was seen to be efficacious up to 90 days. Infection was defined as at least one manifestation of lower respiratory tract infection (including cough, nasal flaring or movement of the lower chest wall), plus hypoxaemia or the presence of tachypnoea, and a laboratory-confirmed nasal swab indicating the presence of RSV.

Weekly follow-up was conducted on parents and caregivers until 180 days after delivery for the detection of RSV-associated symptoms. Trained staff performed complete physical examinations to assess symptoms, and molecular RSV diagnostic assays were tested from symptomatic participants. In addition to weekly follow-up and physical examinations, parents or caregivers also reported suspicious symptoms to initiate evaluations.

Vaccine efficacy was estimated using per-protocol and intention-to-treat analysis. The per-protocol population was defined as infants who were born at  $\geq 37$  weeks of gestation, had mothers who received the randomly assigned vaccine or placebo at least 2 weeks prior to delivery, did not receive prophylactic treatment with palivizumab between birth and 180 days post-delivery and did not have any major protocol deviations that could affect the primary end-point. The intention-to-treat population comprised all living infants, regardless of gestational age, proximity of maternal vaccination to delivery, or presence of treatment errors or protocol deviations.

### *OMER et al. [14]*

OMER *et al.* [14] conducted a pooled analysis on three randomised controlled clinical trials of maternal influenza vaccination. In the three trials, pregnant women were recruited from Nepal, Mali and South Africa. All study participants were randomised 1:1 to receive either the study vaccine, trivalent inactivated influenza vaccine (IIV), or placebo (which was normal saline in the Nepal and South Africa trials, and quadrivalent meningococcal conjugate vaccine in the Mali trial). Enrolment occurred all year round in the Nepal and Mali trials, with vaccinations administered at 17–34 weeks of gestation in Nepal and  $\geq 28$  weeks of gestation in Mali. In contrast, the South Africa trial coincided enrolment and vaccination with the influenza season, administering vaccinations at 20–36 weeks of gestation. Women with history of miscarriages and abortions were excluded from all analyses.

Several objectives were investigated in this publication; however, we primarily focused on the overall vaccine efficacy of maternal influenza vaccination against infant PCR-confirmed influenza. Influenza strains, including influenza A (H1N1, H3N2) and influenza B, were also identified and analysed. To ensure influenza cases were identified, infants and mothers were assessed weekly for influenza-like symptoms through active surveillance until infants were either 6 months of age (in Nepal and Mali) or 24 weeks (in South Africa).

## Results

### *Summary findings from MADHI et al. [13]*

Of the 4626 women enrolled (4636 underwent randomisation) in the study by MADHI *et al.* [13] between 3 December 2015 and 2 May 2018, 52.3% (n=2419) were enrolled from South Africa and 23.3% (n=1080) were enrolled from the USA. There were 4579 live births, of which 4195 infants (91.5%) were included in the per-protocol analysis and 4527 infants (98.9%) were included in the intention-to-treat analysis (table 1). A total of 2051 women (65.8%) were allocated to receive the RSV F vaccine and showed a decrease in the

TABLE 1 Summary characteristics of the included studies

Study design	Sample size	Vaccine received	Age at inclusion	Follow-up	Key findings	Analysis method
<b>MADHI <i>et al.</i> [13]</b>						
Multi-country RCT in 87 sites and 11 countries <sup>#</sup>	4636 women underwent randomisation Vaccine: n=3045, trial completed in 2907 Placebo: n=1581, trial completed in 1510 Infant group: vaccine n=3008, male n=1556; placebo n=1561, male n=799	RSV F protein nanoparticle vaccine in intervention, or placebo	Healthy women aged 18–40 years were enrolled at 28–36 weeks of gestational age	180 days and 364 days	Vaccine efficacy in infants against RSV-associated LRTI: per-protocol analysis 39.4%; intention-to-treat analysis 32.2% Vaccine efficacy in infants against RSV-associated LRTI with severe hypoxaemia: per-protocol analysis 48.3%; intention-to-treat analysis 44.4% Vaccine efficacy in infants against RSV-associated LRTI and hospitalisation: per-protocol analysis 44.4%; intention-to-treat analysis 48.1%	Per-protocol and intention-to-treat analysis
<b>OMER <i>et al.</i> [14]</b>						
Pooled analysis from three RCTs conducted in Nepal (2011–2014), Mali (2011–2014) and South Africa (2011–2013)	Maternal group: n=10 002 (vaccine n=5017, control n=4985) <sup>†</sup> Nepal: n=3693 (vaccine n=1847, control n=1846) Mali: n=4193 (vaccine n=2108, control n=2085) South Africa: n=2116 (vaccine n=1062, control n=1054) Infant group: n=9800 (vaccinated mothers n=4910, control mothers n=4890)	Trivalent IIV <sup>+</sup> in intervention, or placebo (placebo was normal saline in Nepal and South Africa, meningococcal conjugate vaccine in Mali)	Pregnant women with gestational age 17–34 weeks in Nepal, ≥28 weeks in Mali and 20–36 weeks in South Africa	6 months in Nepal and Mali, 24 weeks in South Africa	Vaccine efficacy in women: 50% against PCR-confirmed influenza 42% during pregnancy; 60% postpartum Vaccination <29 weeks, efficacy 30%; >29 weeks, efficacy 71% <sup>§</sup> H1N1, efficacy 65%; H3N2, efficacy 40%; influenza B, efficacy 63%	Data were pooled and analysed using a onestage meta-analysis; Poisson regression models were used
		NA	NA	NA	Pooled efficacy of maternal vaccination: First 2 months 56%; 2–4 months 39%; 4–6 months 19% Vaccination <29 weeks, efficacy 34%; >29 weeks, efficacy 35% H1N1, efficacy 46%; H3N2, efficacy 45%; influenza B, efficacy 13%	
RCT: randomised controlled trial; RSV: respiratory syncytial virus; F: fusion; LRTI: lower respiratory tract infection; IIV: inactivated influenza vaccine; NA: not applicable. <sup>#</sup> : study conducted in Argentina, Australia, Bangladesh, Chile, Mexico, New Zealand, the Philippines, South Africa, Spain, the UK and the USA. <sup>†</sup> : numbers do not sum because every assigned mother had a liveborn infant, and some had twins. <sup>+</sup> : VAXIGRIP (SanofiPasteur), sourced from Mumbai (India) in Nepal, and from Lyon (France) in Mali and South Africa. <sup>§</sup> : no overall association reported between maternal vaccination and low birthweight, stillbirth, preterm birth, and gestational age; at 6 months of infant age, the intervention and placebo were similar in terms of being underweight (weight-for-age), stunted (length-for-age) and wasted (weight-for-length).						

percentage of infants diagnosed with RSV-associated lower respiratory tract infection in the first 90 days of life. The estimated vaccine efficacy for the per-protocol population was 39.4% (95% CI 5.3–61.2%), whereas the estimates were not significant for the intention-to-treat population (table 2). When the authors expanded the data source on the intention-to-treat population to include information used for primary and secondary end-points supplemented with hospital records, the estimated vaccination efficacy increased to 41.4% (95% CI 18.0–58.1%). There was no difference in baseline characteristics of all participants at the time of vaccine administration, even after stratifying by country income level. Estimated vaccine efficacies declined from 90 days through to 120, 150 and 180 days of life. Despite this, the vaccine efficacy for preventing hospitalisation for RSV-associated lower respiratory tract infection was 44.4% (95% CI 19.6–61.5%) for the per-protocol population, 48.1% (95% CI 26.1–63.5%) in the intention-to-treat population, and 46.4% (95% CI 24.7–61.9%) in the expanded-data intention-to-treat analysis. These estimates for preventing hospitalisation were similar across 90, 120, 150 and 180 days.

Adverse birth outcomes of the trial demonstrated similar results between the placebo and the intention-to-treat population. The numbers of low-birthweight infants for the two groups were 98 (6.3%) and 149 (5.0%), respectively. Similar results of low numbers of adverse events were observed for stillbirths (placebo n=9 (0.6%), intention-to-treat n=15 (0.5%)), preterm births (placebo n=90 (5.7%), intention-to-treat n=175 (5.7%)) and infants small for gestational age (placebo n=72 (4.6%), intention-to-treat n=151 (5.0%)).

**Summary findings from OMER et al. [14]**

OMER et al. [14] performed a meta-analysis on 9800 liveborn eligible infants from the 10 002 women across the three trials (table 1). A total of 5017 women (1847 from Nepal, 2108 from Mali and 1062 from South Africa) were randomised to receive the trivalent IIV vaccine and, of the 4910 live infants born within this group (1820 from Nepal, 2064 from Mali and 1026 from South Africa), 143 were diagnosed with PCR-confirmed influenza at ≤6 months, compared to 219 in the placebo group (table 2). Pooled vaccine efficacy was calculated for infants at ≤2 months, ≤4 months and ≤6 months of age. The efficacy was found to be highest at 56% (95% CI 28–73%) at ≤2 months; it decreased to 46% (95% CI 28–60%) at ≤4 months and 35% (95% CI 19–47%) at ≤6 months. The pooled vaccine efficacy was nonsignificant (19% (95% CI –9–40%)) between 4 and 6 months of age when age was used as noncumulative. Maternal vaccinations were effective in preventing infant influenza across all three sites, and a decline in vaccine efficacy with increasing age was observed, even when results were further stratified by study sites.

TABLE 2 Cross-study comparison of maternal vaccination against infant disease			
Population	Vaccine group	Placebo group	Vaccine efficacy % (95% CI)
<b>MADHI et al. [13]<sup>#</sup></b>			
Per-protocol analysis	1.5 (41/2765)	2.4 (35/1430)	39.4 (5.3–61.2)
Intention-to-treat analysis	1.6 (47/2980)	2.3 (36/1547)	32.2 (–4.2–55.9)
Expanded-data intention-to-treat analysis	2.3 (70/2980)	4.0 (62/1547)	41.4 (10.0–58.1)
<b>OMER et al. [14]<sup>¶</sup></b>			
Age ≤2 months			
Nepal	1.1 (20/1820)	1.7 (31/1826)	35 (–14–63)
Mali	0.1 (2/2064)	0.5 (10/2041)	80 (19–96)
South Africa	0.2 (2/1026)	1.3 (13/1023)	85 (32–97)
Pooled	0.5 (24/4910)	1.1 (54/4890)	56 (28–73)
Age ≤4 months			
Nepal	2.4 (43/1820)	3.3 (61/1826)	29 (–4–52)
Mali	0.5 (11/2064)	1.7 (35/2041)	69 (38–84)
South Africa	1.4 (14/1026)	2.9 (30/1023)	54 (13–75)
Pooled	1.4 (68/4910)	2.6 (126/4890)	46 (28–60)
Age ≤6 months			
Nepal	4.1 (74/1820)	5.8 (105/1826)	29 (5–48)
Mali	2.4 (50/2064)	3.8 (77/2041)	35 (8–55)
South Africa	1.9 (19/1026)	3.6 (37/1023)	49 (12–70)
Pooled	2.9 (143/4910)	4.5 (219/4890)	35 (19–47)
Data are presented as percentage of infants (number/total number), unless otherwise stated. <sup>#</sup> : vaccine efficacy as reported at 90 days of age across all three population groups. <sup>¶</sup> : cumulative data for each age group; pooled data equals the total across Nepal, Mali and South Africa.			

However, results were not significant in the Nepal trial (table 2). Pooled vaccine efficacy also varied by influenza type and subtype. Maternal vaccination appeared to be efficacious against influenza A but not against influenza B (vaccine efficacy 13%, 95% CI -21–37%). Within influenza A, maternal vaccination was 65% (95% CI 41–80%) effective in protecting infants from H1N1 influenza and 45% (95% CI 21–61%) effective against H3N2. Gestational age at the time of vaccine administration appeared to have no impact on vaccine efficacy in this analysis. Vaccine efficacy for vaccinations before and after 29 weeks' gestation was similar. At enrolment, maternal and gestational age were similar between the two study groups.

Vaccine safety for mothers and infants, including adverse birth outcomes, was also reported. Maternal vaccination demonstrated the highest protection for low birthweight in Nepal (risk ratio (RR) 0.85, 95% CI 0.74–0.96); however, there was no strong evidence of protective factors against low birthweight in Mali (RR 1.14, 95% CI 0.94–1.40) and South Africa (RR 1.09, 95% CI 0.86–1.37). Additionally, the pooled analyses showed no association between maternal vaccination and stillbirth (RR 1.02, 95% CI 0.74–1.42), preterm birth (RR 0.97, 95% CI 0.87–1.08) or infants small for gestational age (RR 0.99, 95% CI 0.93–1.06). Early stillbirths were not entirely captured, due to vaccine administration at 17–34 weeks gestational age.

### Commentary

Protecting infants from respiratory infectious diseases is pivotal in reducing early childhood respiratory diseases and further reducing infant mortality rates. The studies by MADHI *et al.* [13] and OMER *et al.* [14] have demonstrated that providing infants with passive immunity through maternal vaccinations during pregnancy may be an effective approach in protecting infants from infections.

There has been extensive research throughout the decades that has focused on the development of a safe and effective RSV vaccine. The multi-country large clinical trial by MADHI *et al.* [13] was the first to investigate maternal RSV vaccines in pregnant women; therefore, previous research evaluating RSV vaccines was not directly comparable. A trial on mice published by EICHINGER *et al.* [15] found that offspring born to mothers vaccinated with RSV pre-F protein vaccine formulated with Advax-SM had higher levels of neutralising antibody titres compared to offspring born to mothers who received the control vaccine. When challenged with RSV exposure, those offspring also had undetectable virus in their lungs, showing evidence of the protective immunity that maternal vaccinations can offer to the offspring. The results from MADHI *et al.* [13] resonated with this finding, as maternal vaccination was approximately 40% efficacious in preventing infant infection in both the per-protocol and the expanded-data intention-to-treat analysis.

MADHI *et al.* [13] also identified that maternal vaccination was effective in decreasing RSV-associated hospital admissions. Infant hospitalisation from RSV was lower in the vaccination group as vaccine efficacy was found to be approximately 44–48%, depending on the type of analysis. A mathematical model by SCHELTEMA *et al.* [16] predicted that maternal vaccination at 30 weeks' gestation could prevent 29–48% of the global RSV-related in-hospital deaths of healthy full-term infants, and significantly prevent RSV-related paediatric intensive care unit admissions. Similarly, a cohort model by BARAL *et al.* [17] estimated that 2.8–4.0 million infant hospitalisations could be prevented over 12 years. These all suggest that maternal RSV vaccinations could result in fewer severe and life-threatening infections in infants. MADHI *et al.* [13] also found that vaccine efficacy for preventing hospitalisation, and thus severe infection, remained similar across 90, 120, 150 and 180 days post-delivery, despite the vaccine efficacy for preventing infection decreasing with infant age. This indicates that, although maternal vaccination may only provide short-term protection against respiratory viral infection, it may provide longer-term protection against severe and possibly fatal infection.

The safety profile of the RSV vaccine is a critical factor to evaluate in the trial of MADHI *et al.* [13]. Adverse birth outcomes were reported to be low and were similar in both the placebo and vaccinated groups, suggesting vaccine safety. Despite this, this trial was the first to evaluate adverse birth outcomes, which warrants further investigation into the vaccine safety profile of the RSV F protein vaccine in pregnant women.

One of the limitations of the trial was that it was terminated early due to the slower than expected enrolment. The trial had planned to recruit 8618 pregnant women but only recruited 4626 women over 2 years before the decision was made to discontinue the trial and conduct an informational analysis. Combined with the low number of infants who had reached the primary end-point, the trial was statistically underpowered, and the reported results could be underestimates of the true vaccine efficacies. Despite this limitation, maternal vaccinations do appear to have a protective influence on infant infections, and studies with a larger sample size would be required to provide higher statistical power and confidence in the

results. Since 2020, two larger clinical studies, the investigational RSV maternal vaccine study (GRACE) and a clinical trial sponsored by Pfizer, have been set up to evaluate maternal RSV vaccinations' ability to prevent infant RSV infections [18]. Both studies have shown promising results and are currently in phase III of their trial.

### Implications for clinical practice

Respiratory viruses, such as RSV and influenza, have resulted in high infant hospitalisations and mortality each year. Both studies included in this article have shown that maternal vaccinations could effectively prevent early-life respiratory infections in infants when vaccines are not safe or available for the infants themselves. This could decrease the high rates of infant morbidity and mortality around the world. However, the issue of waning immunity as infants age poses a threat to the effectiveness of maternal vaccination in preventing infant infections, and more research is required to investigate factors that could slow down the waning rate. RSV-associated hospitalisation rates were also found to be consistent across infant age groups of those born to vaccinated mothers, indicating that vaccinations could provide long-term protection against severe disease. More research should be dedicated to identifying the duration of this protection and its influential factors.

Conflict of interest: The authors declare no potential conflicts of interest in connection with this article.

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