Alarm bells fade: One pregnancy vaccine raised fears, but its earliest real-world test tells a different story

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Study finds no association between RSVpreF vaccination during pregnancy and preterm birth. Credit: www.kaboompics.com: https://www.pexels.com/photo/a-person-injecting-vaccine-5207032/

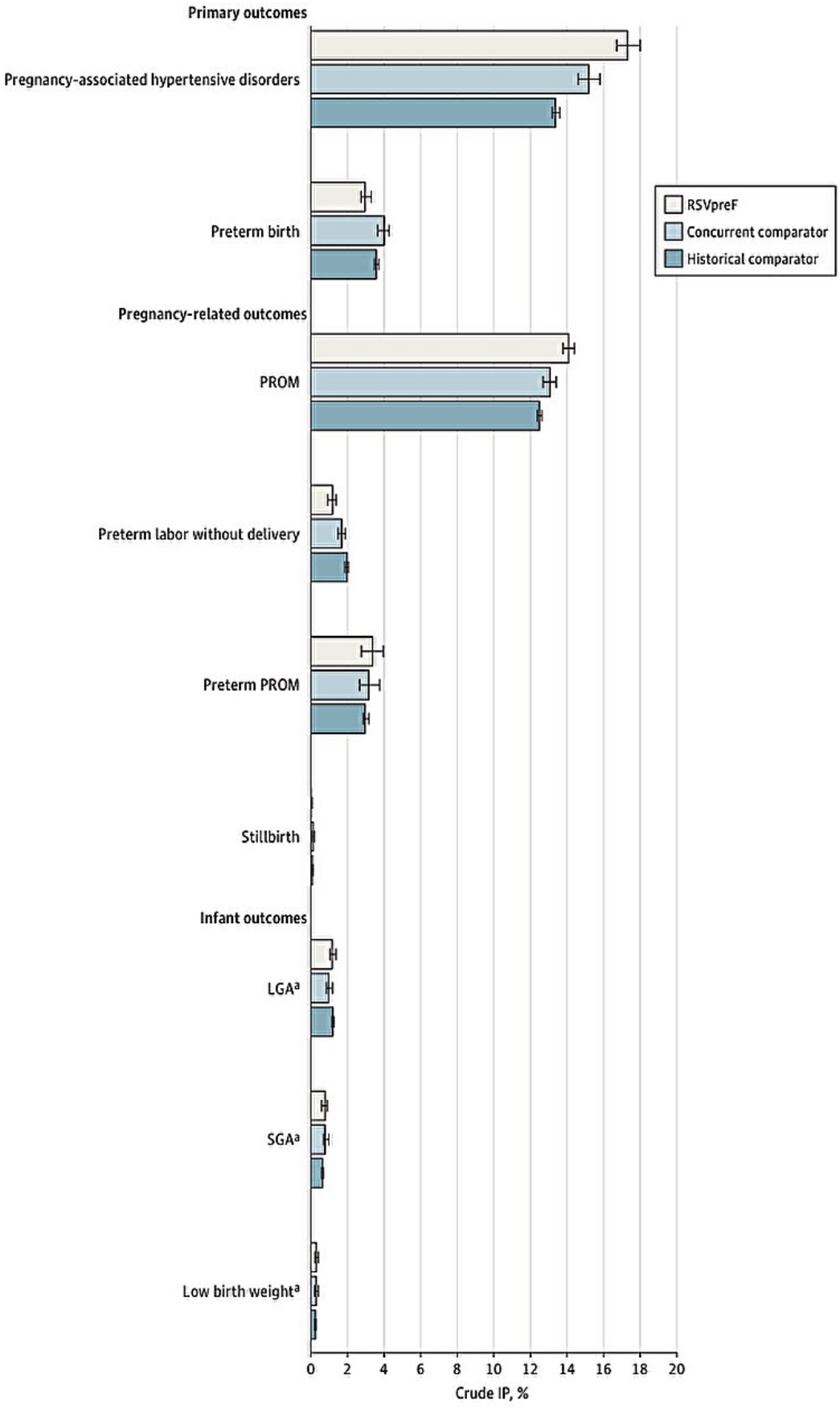
Questions about the safety of the RSVpreF vaccine, designed to protect infants from respiratory syncytial virus (RSV), for both mothers and babies during pregnancy have fueled considerable debate. One of the key concerns is preterm birth. A recent study conducted in the United States involving over 10,000 pregnant women found that receiving the vaccine during pregnancy did not increase this risk.

RSV is a common pathogen that infects the lungs and airways. In most cases, it results in symptoms ranging from mild fever and congestion to sore throat, but the virus can disproportionately harm infants and older adults. It remains one of the leading causes of infant hospitalizations worldwide.

In August 2023, the FDA approved an unadjuvanted RSVPreF vaccine for pregnant people at 32–36 weeks of gestation. Unlike standard formulations, it contains no immune-boosting additives, instead, it works by generating maternal antibodies that cross the placenta, giving newborns passive protection during their most vulnerable early months, especially in the winter.

Prof Simon Drysdale, a pediatric infectious diseases expert, unrelated to this study, said that the early US findings are reassuring as they show no increase in preterm delivery after RSV vaccination during pregnancy. They hope the findings encourage more people to get vaccinated when offered.

The findings are published in *JAMA Network Open*.


Primary outcomes
Pregnancy-associated hypertensive disorders
Preterm birth
Pregnancy-related outcomes
PROM
Preterm labor without delivery
Preterm PROM
Stillbirth
Infant outcomes
LGA[a]
SGA[a]
Low birth weight[a]
RSVpreF
Concurrent comparator
Historical comparator
0
2
4
6
8
10
12
14
16
18
20
Crude IP, %

Horizontal Bar Graph of Crude Incidence Proportions (IPs) for Safety Outcomes. Credit: *JAMA Network Open* (2026). DOI: 10.1001/jamanetworkopen.2026.6190

Early or on-time?

The study focused on pregnant individuals aged 15 to 54 who had reached at least 32 weeks of pregnancy. Researchers tracked three groups: 13,619 people who received the RSVpreF vaccine between weeks 32 and 36 of pregnancy; 14,747 people who were pregnant during the same period and received other routine vaccines, but not the RSV vaccine; and 143,459 people who were pregnant between 2018 and early 2023, before the RSV vaccine became available.

They tracked 10 different health outcomes, among which were preterm birth, high blood pressure, water breaking, unusual birth weight and Guillain-Barré syndrome, which is a rare neurological disorder.

The team monitored the data continuously, not just at the end, but at five separate check-ins across the year. This approach is called sequential surveillance and is often adopted to catch any safety signals early, before they go unnoticed.

Their analysis revealed that the RSVpreF did not increase the risk of babies being born before 37 weeks. There was no rise in cases of stillbirth, low birth weight, or Guillain-Barré syndrome.

However, they observed some potential risks, such as a higher risk of pregnancy-related high blood pressure in those who received the vaccine

compared to those who did not and a very few cases where the water broke early. The researcher cautioned that the findings could not be definitively linked to the vaccine due to limited data and confounding factors.

For instance, the fact that vaccinated individuals were slightly older on average and were more likely to have used fertility treatments, which can have an impact on blood pressure levels.

With many parents and health care providers concerned about vaccine safety during pregnancy, researchers say larger and more diverse studies will be needed to determine whether the potential risks observed are truly linked to the vaccine or the result of other factors.

More information: Ashley I. Michnick et al, Sequential Safety Surveillance of RSVpreF Vaccination During Pregnancy Early in the Postapproval Period, *JAMA Network Open* (2026). DOI: 10.1001/jamanetworkopen.2026.6190