Experts call for monitoring of respiratory vaccine after trials suggest possible increase in preterm births

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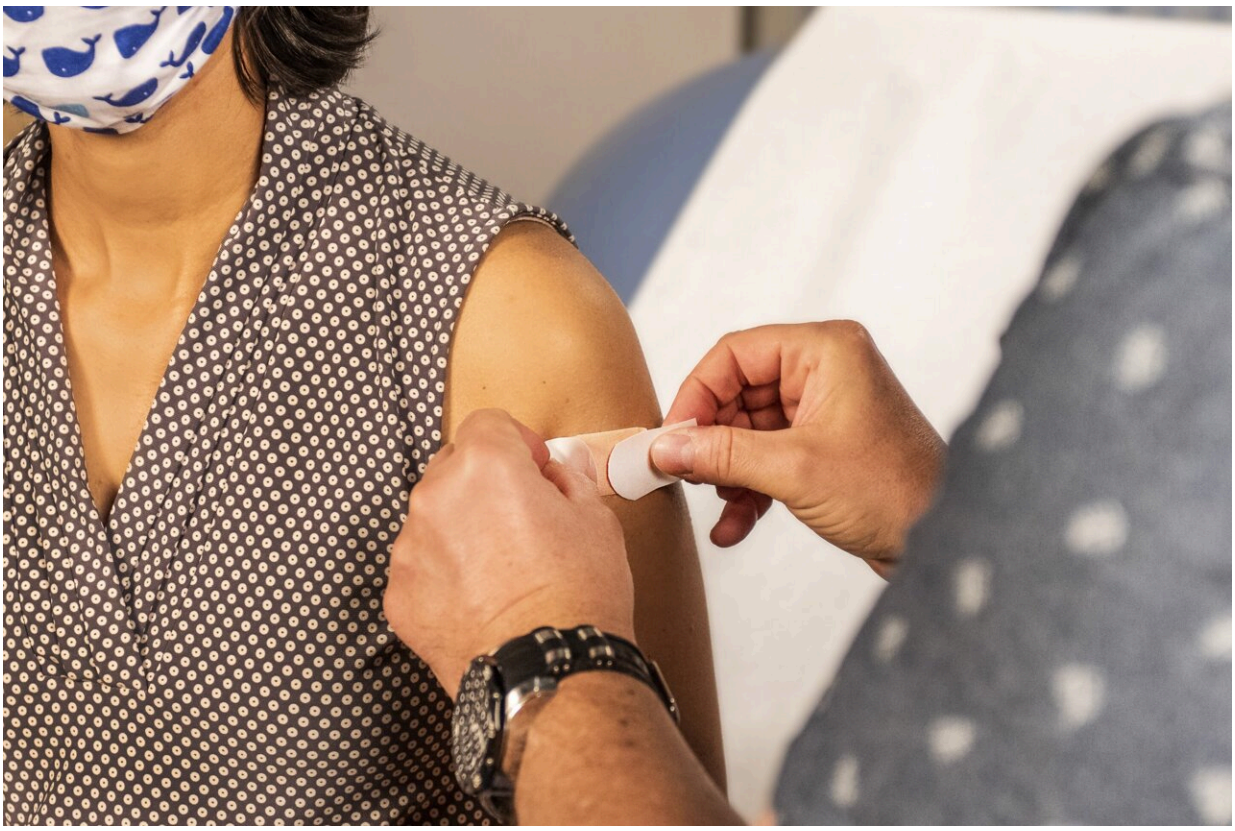

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Experts have called for further scrutiny of a new Pfizer vaccine given during pregnancy to prevent respiratory infection in infants, after trials

of a similar GSK vaccine were stopped after a rise in preterm birth and infant deaths.

Pfizer says its vaccine is safe and effective, but experts contacted as part of an investigation published by *The BMJ* today, say Pfizer's trial data should be reviewed in light of the signal for preterm births seen in GSK's trial.

Pfizer's maternal RSV vaccine aims to protect infants from severe illness caused by the respiratory syncytial virus (RSV). RSV is very common but can be fatal, especially in young children. In 2019, an estimated 3.6% of all deaths worldwide in children aged 1–6 months were due to RSV, with 97% of these deaths occurring in low and middle income countries.

The vaccine has not yet been approved for use, but a decision by the U.S. Food and Drug Administration is expected by August. The European Medicines Agency is also set to make a decision about the vaccine later this year.

In February 2022, GSK halted vaccination in its phase 3 trials of its maternal RSV vaccine after finding an increased risk of preterm birth in vaccinated mothers, mainly in low and middle income countries.

Pfizer published the results of an interim analysis of its phase 3 trial last month, saying that the vaccine was effective against medically attended severe RSV in children and that no safety concerns were identified.

And while the difference in preterm births in the Pfizer trials was not statistically significant, the results have raised concerns about a possible increase in preterm births, and now experts are calling for further analyses of the data and post-approval monitoring of the vaccine should the FDA approve it.

"My interpretation of all these data is that there may be a safety signal for preterm births that should be followed up on," said Klaus Überla, director of the Virological Institute of the University Hospital Erlangen and member of the RSV working group of the Standing Committee on Vaccination (STIKO), which develops national recommendations for the use of licensed vaccines in Germany.

And a scientist at the National Institutes of Health (NIH) said the Pfizer data should be analyzed using more sensitive measures such as average birth weight and subgroup analyses to detect possible signals.

Meanwhile, Cody Meissner, professor of pediatrics and medicine at the Dartmouth Geisel School of Medicine and consultant in the US Centers for Disease Control and Prevention (CDC)'s maternal RSV working group, predicts that possible adverse effects such as premature births will be "closely monitored" in assessment programs by FDA and CDC. "We need a safe vaccine," he added.

Pfizer did not respond when asked about a possible increase in preterm births associated with its vaccine, but told *The BMJ* that "no imbalance of neonatal deaths was observed" in its phase 3 trial.

In a linked editorial, researchers point to challenges for RSV vaccine development and the main approaches to protection currently being pursued.

They argue that, while the burden of illness caused by RSV is substantial worldwide, it is particularly important that new vaccines and other prevention strategies are available to infants in low and middle income countries, where the greatest illness and deaths occur.

And they say further research is urgently needed "to identify the best prevention strategies for low and middle income countries, where

affordability is paramount and timing of administration is complicated by the lack of predictable seasonal RSV epidemics."

More information: Maternal RSV vaccine: Further analysis is urged on preterm births, *The BMJ* (2023). DOI: 10.1136/bmj.p1021

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