Protecting the next generation: how maternal Respiratory Syncytial Virus (RSV) vaccination during pregnancy safeguards child health

Ricardo Ney Cobucci [1]
https://orcid.org/0000-0002-0184-2061

[1] Postgraduate Program in Applied Sciences for Women's Health. Federal University of Rio Grande do Norte. Av. Nilo Peçanha, 259. Petrópolis. Natal, RN, Brazil. Postal Code: 59.012-310. Email: ricardo.cobucci.737@ufrn.edu.br

Introduction

Respiratory Syncytial Virus (RSV) is a principal etiological agent of acute lower respiratory tract infections (LRTIs) in infants and young children, contributing substantially to morbidity and mortality on a global scale. RSV accounts for approximately 33 million LRTIs annually, resulting in over 3 million hospitalizations and 120,000 deaths among children under five years of age, particularly in low- and middle-income countries (LMICs). The burden of RSV-associated LRTIs is most pronounced during the first six months of life, underscoring the necessity for effective preventive strategies during this critical developmental period.[1]

Maternal vaccination during pregnancy has emerged as a promising strategy to safeguard infants against RSV-associated LRTIs. By facilitating the transfer of protective antibodies from the mother to fetus via the placenta, maternal vaccination can confer passive immunity to infant during the initial months of life, a period marked by heightened susceptibility to severe RSV infection.[2] This viewpointpaper presents the latest evidence regarding the efficacy, safety, and public health implications of maternal RSV vaccination, with a specific focus on the bivalent prefusion F protein-based vaccine.

Efficacy of Maternal RSV Vaccination

Recent clinical trials have established the efficacy of maternal RSV vaccination in mitigating the incidence of severe RSV-associated LRTIs in infants.[2,3] The MATISSE study, a phase 3 randomized controlled trial, assessed the efficacy of the bivalent prefusion F protein-based vaccine in pregnant women and reported a 70% reduction in the incidence of medically attended severe RSV-associated LRTIs within the first 90 days of life.[2] Additionally, a systematic review and meta-analysis conducted by Ma *et al*.[1] indicated that maternal RSV vaccination significantly diminished the risk of RSV-associated LRTIs in infants by 65% relative to placebo.

The efficacy of maternal RSV vaccination is particularly relevant in LMICs, where the burden of RSV-associated LRTIs is most considerable. A study by Madhi *et al*.,[3] conducted in South Africa, demonstrated that maternal RSV vaccination resulted in a 63% reduction in the incidence of severe RSV-associated LRTIs among infants born to vaccinated mothers, accentuating the potential of maternal vaccination to alleviate the global burden of RSV-associated infant mortality.

Safety of Maternal RSV Vaccination

The safety of maternal RSV vaccination has been a pivotal consideration throughout its development and implementation. Clinical trials have consistently indicated that maternal RSV vaccination is safe for both pregnant women and their infants.[2,3] The Matisse study found no significant differences in adverse pregnancy outcomes, including preterm birth, low birth weight, or congenital anomalies, between vaccinated and unvaccinated cohorts.[2] Similarly, a Cochrane review found no evidence of an increased risk of adverse maternal or neonatal outcomes associated with maternal RSV vaccination.[4]

Nonetheless, continuous surveillance is imperative to monitor the long-term safety of maternal RSV vaccination, particularly across diverse populations and settings. The

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safety profile of maternal RSV vaccination is a critical determinant of its acceptance and uptake, and further research is warranted to address any potential concerns and to ensure the safety of this intervention.[5]

Public Health Impact of Maternal RSV Vaccination

The public health impact of maternal respiratory syncytial virus vaccination extends beyond the individual benefits conferred upon vaccinated mothers and their infants. By diminishing the incidence of severe RSV-associated lower respiratory tract infections (LRTIs) in neonates, maternal vaccination can alleviate the burden on healthcare systems, particularly in low- and middle-income countries (LMICs) where resources are often constrained. A study by Pecenka *et al*.,[6] conducted in the United States in 2024, estimated that maternal RSV vaccination could prevent up to 1.5 million cases of severe RSV-associated LRTIs annually, resulting in significant reductions in hospitalizations and healthcare costs.

Moreover, maternal RSV vaccination possesses the potential to mitigate health disparities by safeguarding infants in resource-limited settings, where access to healthcare and other preventive measures may be restricted. By integrating maternal RSV vaccination into existing antenatal care programs, it is possible to ensure that all infants, irrespective of their socioeconomic status, have access to this life-saving intervention.[1,4]

On August 21, 2023, the United States Food and Drug Administration (FDA) approved the RSV vaccine Abrysvo® for use in pregnant women to prevent RSV-associated lower respiratory tract diseases and its severe form in babies from birth to 6 months of age. The vaccine was approved for administration between 32 and 36 weeks of gestational age as a single-dose intramuscular injection.[7] In line with this approval, BrazilianFederation of Gynecology and Obstetrics Associations (FEBRASGO) recommends that Brazilian healthcare professionals consider implementing this vaccination strategy during pregnancy, particularly targeting the same gestational window of 32-36 weeks.[8]

Challenges and Opportunities for Implementation

Despite the encouraging outcomes from clinical trials, several challenges persist regarding the implementation of maternal RSV vaccination programs.[5,6] One primary challenge is ensuring equitable access to the vaccine, particularly in LMICs, where the incidence of RSV-associated LRTIs is most pronounced. The high cost of the vaccine and the necessity for cold chain storage may hinder its availability in resource-limited contexts. Additionally, robust health systems are required to deliver the vaccine and monitor its safety and efficacy.[9,10]

Global collaboration and partnerships are vital to surmount these challenges and facilitate the successful implementation of maternal RSV vaccination programs. The World Health Organization (WHO) and other international organizations play a critical role in supporting the development and implementation of these programs, particularly in LMICs. Through collaborative efforts, it is possible to maximize the public health benefits of maternal RSV vaccination and diminish the global burden of RSV-associated infant mortality and morbidity.

Conclusion

Maternal RSV vaccination during pregnancy has the potential to significantly alleviate the burden of RSV-associated lower respiratory tract infections in infants, particularly in low- and middle-income countries where the incidence is highest. Nevertheless, challenges remain in ensuring equitable access to the vaccine and in establishing robust health systems to deliver and monitor it. By addressing these challenges and fostering collaboration, we can ensure that all infants have access to this life-saving intervention, thereby reducing the global burden of RSV-associated infant mortality and morbidity.

Authors' contribution

The author conceived the article and declare no conflict of interest.

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