TAG RECOMMENDATION FOR RESPIRATORY SYNCYTIAL VIRUS (RSV)

Pan-American Health Organization (PAHO), 2024

PAHO
Pan American Health Organization
World Health Organization
Americas Region

Contents

2023 Recommendations

- PAHO welcomes the approval of Pfizer's (Abrysvo®) Bivalent Prefusion F (RSVpreF) vaccine in pregnant women to prevent RSV disease in infants by the U.S. Food and Drug Administration and the European Medicines Agency (EMA), since it addresses the considerable burden of disease in infants across the Americas and specifically targets pregnant women, who are often excluded from vaccine clinical trials and therefore are delayed in reaping their benefits.

- PAHO is encouraged by the results of the Phase 3 Maternal Immunization Study for Safety and Efficacy (MATISSE) study, which suggest high vaccine efficacy against severe RSV-associated disease in infants from birth through 6 months. In the trial, over 7000 pregnant women from 18 countries were included in the study. However, data were collected only from upper-middle-income countries (UMIC) and high-income countries (HIC). The impact study recommended by the SAGE in its October 2022 meeting in lower-middle-income countries is urgently needed to confirm the findings on vaccine safety and efficacy the MATISSE study outside of UMIC and HIC settings.

- PAHO notes the high cost of the RSVpreF vaccine in the United States and urges the PAHO Procurement and Supply Management Department and the PAHO Revolving Fund to negotiate a lower price for countries in the Americas to avoid inequitable implementation of this vaccine into the national immunization programs of the Region.

- PAHO assesses that maternal RSVpreF vaccine is best given in pregnant women at 32–36 weeks of gestation to prevent RSV disease in infants while minimizing the risk of preterm birth. Any introduction of maternal RSVpreF vaccine should be accompanied by:
    - Identification of the optimal timing of vaccine administration according to country-specific RSV seasonality patterns
    - Robust vaccine effectiveness and impact studies
    - Well-designed safety, cost-effectiveness, economic burden, and affordability studies
    - Studies of behavioral and social factors to facilitate vaccine uptake
    - Integration with other prenatal immunization programs (e.g., influenza), services, and outreach operations
    - Careful balance between the resources needed for the introduction of this vaccine and the requirements and goals of existing vaccination programs (e.g., maintaining measles elimination)

- Documentation of the programmatic challenges of new vaccine introduction, especially in the context of a recovering national immunization program and limited financial resources.