

Real-World Effectiveness of a Bivalent Prefusion F Vaccine (RSVpreF) During Pregnancy to Prevent Hospitalization for Respiratory Syncytial Virus (RSV)-Associated Lower Respiratory Tract Illness in Infants from Birth to Six Months of Age: 2024 RSV Season Results from a Multicenter Test-Negative Case-Control Study Conducted in Argentina

In December 2023, Argentina became one of the first countries in the world to incorporate the RSVpreF vaccine into its National Immunization Program. Starting in March 2024, maternal immunization with RSVpreF was implemented nationwide as the primary strategy to reduce the burden of respiratory syncytial virus (RSV)-related illness in infants. RSV is the leading cause of bronchiolitis, an acute respiratory infection most prevalent during the fall and winter months, primarily affecting children under one year of age.

A collaborative study was designed by *iTriaLs / TSTriaLs* in partnership with the **Health Policy and Equity Innovation Hub at the National University of San Martín** and **Pfizer, Inc.**, with funding provided by the latter. The objective was to estimate the vaccine effectiveness (VE) of RSVpreF in preventing RSV-associated lower respiratory tract illness (LRTI) hospitalizations and severe LRTI hospitalizations in infants under six months during the first RSV season following the program's implementation.

The **BERNI Study** (*Real World Impact and Effectiveness of ABRYSSVO™ Vaccination During Pregnancy Against RSV Illness in Infants*) is a multicenter, retrospective, test-negative case-control study conducted between April and September 2024 across 12 hospitals, including public, private, and social security centers in five provinces of Argentina. Data were collected from medical records, epidemiological surveillance, and hospital statistics. The study included infants under six months of age hospitalized for LRTI and tested for RSV.

2024 RSV Season Results.

The BERNI Study included 505 infants (286 RSV-positive cases and 219 RSV-negative controls). Key findings include:

Vaccine Effectiveness (VE):

- Prevention of hospitalized LRTIs in infants 0–3 months: **72.7%** (95% CI: 60.0–81.4).
- Prevention of hospitalized LRTIs in infants 0–6 months: **68.0%** (95% CI: 56.2–76.6).
- Prevention of severe hospitalized LRTIs in infants 0–6 months: **73.9%** (95% CI: 53.2–85.4).

RSV-Associated Deaths: Three deaths due to RSV-associated LRTIs occurred, all in infants born to mothers who did not receive RSVpreF vaccine during pregnancy.

These results from the 2024 RSV season in Argentina demonstrate the high effectiveness of RSVpreF in preventing RSV-associated LRTI hospitalizations and severe LRTI hospitalizations during the first six months of life. These real-world data from the program's first season confirm and support findings from the phase 3 clinical trial. A manuscript detailing full study results is in preparation.

The generation of local evidence on the effectiveness of public health strategies is essential for informed decision-making. These results are crucial for building confidence among healthcare providers in recommending the vaccine and among pregnant individuals in seeking it, thereby fostering a positive impact on community health. In this context, the participating technical and scientific teams consider it a priority to share these findings in real time to support the effective implementation of health policies. These efforts aim to benefit the population in Argentina during the upcoming RSV season and to provide evidence to other countries considering the adoption of this preventive strategy against RSV-associated LRTI in infants. In this context, the introduction of this vaccine represents a pioneering advancement in reducing hospitalizations and severe respiratory infections during the early months of life.



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***Antonio BERNI** was one of the most prominent Argentine painters. A renowned exponent of New Realism in Latin America, his work is distinguished by a strong social and political commitment, often portraying the struggles and challenges faced by the most vulnerable populations, including children. His most iconic character was Juanito Laguna, the protagonist of this painting (Detail of *Juanito Asleep*, 1974).