Sharing Lessons on Early Introduction of RSV Prevention Programs

The Partnership for International Vaccine Initiatives

Santiago, Chile

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Background and Introduction

Respiratory syncytial virus (RSV) disease is the leading cause of lower respiratory tract illness (LRTI) and hospitalization in children globally and contributes substantially to LRTI related mortality. Impact is greatest in low- and lower-middle-income countries (LLMICs) where most deaths occur. Maternal vaccine and/or monoclonal antibody (mAb) administration for infants are important opportunities to protect pregnant women and infants from vaccine-preventable diseases such as RSV.

To gather information from early adopting countries, The Task Force for Global Health's (TFGH) Partnership for International Vaccine Initiatives (PIVI) in partnership with U.S. Centers for Disease Control and Prevention and the Pan American Health Organization (PAHO) convened a global meeting in Santiago, Chile on August 26-28, 2025 to understand the lessons from introduction experience and ongoing evaluations in countries that have or soon will adopt maternal RSV vaccination programs and/or initiating programs to deliver monoclonal antibody products to infants. The purpose of the meeting was to gather and share lessons learned from early adopting countries to support global implementation. To this end, the meeting covered process and evidence needs to inform NITAG recommendations and policies, implementation decisions and experience with introduction, tools and resources developed, as well as data on safety, effectiveness, coverage and impact. The meeting also created a forum to present tools and strategies for decision making, data collection and monitoring and evaluation.

PAHO began supporting member states to conduct and share RSV surveillance data in 2015. The surveillance has since been integrated into the Global Influenza Surveillance and Response System (GISRS) with 26 countries in PAHO participating in the surveillance.[1] The PAHO Technical Advisory Group recommended in November 2023 maternal RSV vaccination at 32-36 weeks of gestation for pregnant women to prevent RSV disease in infants.[2] In February of 2025 PAHO updated the recommendation to include the use of either the maternal vaccine or mAb given to infants to prevent RSV disease.

In December 2023, a WHO SAGE working group for RSV was formed to review evidence on RSV vaccination to prevent RSV in infants. In September 2024, the working group recommended maternal RSV vaccination in the third trimester of pregnancy (in most settings from 28 weeks of gestation) or a single dose of long-acting mAb for infants at birth or as soon after as possible. In May 2025, WHO published a position paper recommending all countries introduce immunization products to prevent severe RSV disease in infants.[3]

[1] https://dashboards.pahoflu.com/respiratory_viruses/
[2] https://iris.paho.org/handle/10665.2/59314
[3] WHO position paper on RSV, 30 May 2025: https://www.who.int/publications/i/item/who-wer-10022-193-218

Decisions to use maternal vaccination and/or long-acting mAb, such as nirsevimab, should consider factors such as cost, cost-effectiveness, financing, supply, anticipated coverage and feasibility of implementation in the existing immunization programs and health systems. SAGE recommendations are required for WHO pre-qualification (PQ) of medical products and for procurement by Gavi and UN agencies. WHO pre-qualified RSV vaccine has been available in single-dose vials since March 2025.

The Gavi Board approved inclusion of RSV maternal vaccine to prevent RSV in infants into its portfolio at its July 2025 meeting.[4] Program planning and design have begun at Gavi to prepare for implementation in Gavi eligible countries. The Gavi implementation model and financing assumptions are dependent on WHO pre-qualification of the RSV vaccine in multi-dose vials which is anticipated in 2026. Looking ahead, two additional key milestones include the Market Shaping Roadmap, which will outline the envisioned market landscape and provide insights to inform the UNICEF Procurement Strategy, anticipated in 2026. The first country applications for support are anticipated in early to mid-2027 with first introductions a year later in 2028.

In the interim, the work of global partners will be needed to support building needed infrastructure and understanding of best practices for maternal RSV vaccination. The Maternal Immunization Readiness Network in Africa and Asia (MIRNA) supports countries by building the evidence base for key decision-makers in countries to invest in maternal vaccines, assess health system readiness to implement maternal vaccination programs and assess the demand in communities to accept maternal vaccines. Other partners, such as NGOs, intergovernmental organizations, and academic institutions are working on pre-implementation research, Knowledge, Attitude and Practice (KAP) studies, compilation of burden evidence, training materials and tools for assessment. All of this work cumulatively will support development of guidance on best practices for program design and implementation.

Likewise, lessons learned, challenges and barriers identified from early introducing countries are critical to supporting elements of program design and for guiding other countries who are in the process of introducing these products. At the time of this meeting, 71 countries globally had licensed the products for use through their National Regulatory Authorities. The early introducing countries, who have approved use of these products and adopted recommendations for use are mostly high-income countries (21) and three upper middle-income countries from the PAHO region. Currently, there are very few data on the facilitators and barriers to vaccinating pregnant women that could inform strengthening maternal immunization platforms, especially in low- and middle-income countries.

[4] https://www.gavi.org/news/media-room/gavi-board-focuses-health-impact-priority-guiding-principle-resource-constrained

To inform future planning and support, there is a need to understand the landscape of technical and programmatic work as well as the challenges and best practices in early adopting countries. This information will be important to share among global stakeholders and countries to support optimal investments and country implementation plans.

This report summarizes information from participants from early adopting countries and countries that have conducted studies that will support national RSV prevention programs and delivery systems. It is also important to consider that many countries continue to use palivizumab within their current prevention strategies until other mAbs are available. Use of palivizumab is not covered in this report. This report provides an opportunity to understand the landscape of work that is underway or planned by key stakeholders and countries. Lastly, this report serves to share learnings and outline key considerations for countries and stakeholders going forward.

To provide context for the discussions and experiences of participants attending the meeting we are including a table of information on the status of RSV prevention products and timelines for countries presenting and participating in the meeting. In addition to the countries in the following table, global stakeholders also participated from: the US Centers for Disease Control and Prevention (CDC), Gates Foundation (GF), Gavi, the Vaccine Alliance, Maternal Immunization Readiness Network in Africa and Asia (MIRNA), PATH, Pan American Health Organization (PAHO), The Task Force for Global Health (TFGH), and World Health Organization (WHO). Table 1 summarizes the current use of RSV immunization products by country, as of August 2025.

This report briefly outlines key takeaways from each session of the meeting, with a summary of key considerations for countries and stakeholders planning future implementation. A list of resources and tools in development or available for use can be found at the end of the report.

Table 1: Eligible populations, RSV prevention products, uses and timelines from countries participating

Country	RSVpreF vaccine Eligible population	Nirsevimab Eligible population	Timing of Administration	Coverage	Notes/Start date
Argentina	32-36 weeks	Not used	Varies by region	Coverage ~68% (2024)	March 2024 Nirsevimab expected 2026
Chile	Not recommended	All newborn and infants <5 months; at risk: 2 years	Eligibility applied for the season between Oct 2023 and March 2024, Same 2025	Coverage 97% (2024) Coverage 98% (2025)	March 2024
Colombia	32-36 weeks	Not used	N/A	N/A	Currently piloting End 2025 planned
Costa Rica	32-36.6 weeks	Not used	Year-round	TBD	June 2025
Cuba	32-36 weeks	Not used	N/A	N/A	Oct 2025 planned
El Salvador	32-36 weeks	Not used	Year-round	TBD	June 2025
Guatemala	Not recommended	Not recommended	N/A	N/A	Conducting KAP HW, PW
Mexico	Not used	Not used	N/A	N/A	RSVpreF expected 2026
Panama	32-36 weeks	Not used	Year-round	TBD	June 2025 Nirsevimab expected 2026
Paraguay	Not recommended	All newborns and infants <3 months; at risk: 2 years	Seasonal	TBD	March 2025

Peru	Not recommended	Premature infants only	N/A	N/A	Conducting KAP HW
Scotland**	>28 weeks	High risk infants	Seasonal August to March	504%	2024
United States**	32-36 weeks	All newborn and infants <8 months; at risk: 8-19 months	Seasonal approach*: Maternal RSV vaccine: Sept-Jan Infant antibody: Oct -March	2024: Coverage with either product ~51% (18% vx; 43% mAb) Jan 2025: 38.5% vx March 2025: 21-48% by state mAb Estimates from Jan 2024 and March 2025 are not additive	2023
Uruguay	32-36.6 weeks	Not used	Seasonal approach: 2024: August to September 2025: Jan to Aug	2024: Coverage ~62% 2025: Coverage~67%	August 2024 Nirsevimab expected 2026
Zambia	Not recommended	Not recommended	N/A	N/A	Conducting KAP HW, PW

Table note: In some cases, NITAGs recommended the use of mAb, but due to budget and access constraints the countries have not introduced them in 2024 or 2025, but may introduce use in 2026.

*Recommended calendar periods for most of the United States; public health authorities may elect to provide revised guidance regarding the timing of RSV antibody administration based on local epidemiology and feasibility of implementation

** In countries with dual strategies, either maternal vaccination or mAb for infants can be used, but not both

Abbreviations: RSVpreF (RSV pre-fusion), KAP (Knowledge Attitudes and Practices); HW (health workers); PW (pregnant women)

Session 1.
Country Experiences from 2024:
Introductions – Successes, Challenges and Lessons Learned

Four countries, including Argentina, Chile, the United States and Uruguay that introduced RSV prevention products in 2024 or earlier shared their experiences. Prior to introduction, all four countries had well-documented RSV burden in children with an emphasis on burden among children <12 months of age. In each country, NITAGs served as the primary advisory body, playing a central role in guiding the introduction of RSV vaccines into the immunization program. Intentionally we requested countries using different products to present their experiences in order to understand various successes and challenges. Recommendations and products differed with Uruguay and Argentina using RSVpreF maternal vaccine only; the US using both RSVpreF and nirsevimab and Chile using only nirsevimab. It should be noted however, that Argentina has been using palivizumab since 2007 and will change to nirsevimab in 2026. For countries with seasonal administration eligibility was determined by age of the child and or/gestational age of the women relative to the RSV season. RSV seasonality was determined based on (pre- and post-COVID) RSV surveillance data due to anomalies during the pandemic. More than one country mentioned that product availability was also a consideration as quantities planned to purchase did not always match availability. The Chile program was inclusive of newborns and those <6 months old entering in the RSV season (born between 1 October 2023 and 1 March 2024). The US included mAb all infants <8 months or born during their first RSV season and for high-risk infants entering in their second RSV season. Implementation strategies for RSVpreF maternal vaccine focused on pre-natal care clinics through Ob-Gyn and midwives and primary care settings; in the US, RSVpreF was also given in pharmacy settings. Implementation strategies for monoclonal antibody administration focused on hospitals and pediatricians. Giving the birth dose during the birth hospitalization was deemed the best strategy for infants born during RSV season.

A few key takeaways from these four countries:

- Countries reported challenges during the first season of availability with vaccine introduction resulting from a narrow window between when NITAGs recommended introduction of the product and when introduction needed to start to ensure protection for the season, e.g., just before the season (US), or late in the first season (Uruguay); this left limited time to complete planning and train health workers before implementation (US, Argentina).
- All described a need for comprehensive planning across all implementation components, with emphasis on communication and education to health workers and the population, especially pregnant women, on the importance of RSV prevention. Chile described a nationwide approach to education for HWs and pregnant women in preparation for their launch, which resulted in very high coverage and no RSV deaths in the first year.

- Countries described the need and challenge to track data overall and ideally in real time. Good data systems are needed for identifying eligible infants, estimating coverage and for evaluating impact. Chile highlighted their vaccine administration system which allowed for real time tracking. Others described tracking mainly by the administrative method (total or estimated births and total doses administered). The US described a major challenge with maternal and infant records not being linked, which posed difficulties in identifying infants eligible for nirsevimab receipt.
- Meeting participants showed great interest in how countries tracked coverage, particularly the methods for real time tracking to allow follow-up reminders and to ensure data quality.
- There were differences in recommendations of use of RSVpreF vaccine in subsequent pregnancies - recommended in Uruguay and Argentina and not recommended in the US.
- Having a dual strategy with both vaccine and mAb considerably increased the complexity of program implementation which was also reiterated in later sessions by additional countries.
- Countries with maternal RSVpreF vaccine only (Argentina and Uruguay) expressed their interest in introducing nirsevimab next season for children at risk whose mothers were not vaccinated. Uruguay has used palivizumab prior to introduction of the RSVpreF vaccine with long-term plans to change to longer acting mAB (nirsevimab or clesrovimab) to complement maternal vaccination. These countries, as well as others during discussion, expressed difficulties with access to nirsevimab due to the high cost and the manufacturer purchase conditions.

Session 2. Considerations and Lessons Learned:
Introductions of RSV Prevention Programs in 2025

Three countries, El Salvador, Costa Rica (both RSVpreF vaccine) and Paraguay (nirsevimab), shared their experience with the recently introduced RSV vaccine or nirsevimab during 2025. Each country described how decisions for vaccine introduction were driven by the data available and public health priorities. Strategies depended on the epidemiology of RSV to determine year-round or seasonal administration. Like the first session, the importance of having national data on burden of disease (hospitalizations and deaths) to determine the magnitude of the public health problem and to estimate the burden averted by the intervention (impact) was highlighted. The importance of NITAG recommendations for the introduction of new vaccines was also highlighted. Usually, countries introduced these products a few months after the recommendation from their NITAG.

Several key points were discussed during this session:

- Training of HWs and communication to the target population is critical for acceptance.
- Involvement of scientific societies (gynecologists, pediatricians) to ensure endorsement with the strategies and recommendations in order to offer the products to the target populations is important.
- Two of the countries described early review of their immunization programs (about two weeks after the start) to determine if changes needed to be made as very useful for early course correction. Gathering and/or consolidating tools to share for early program review was considered.
- Countries experienced challenges on combating misinformation and "infodemia."
- SMS and phone calls for catch up of children for nirsevimab proved successful.
- Challenges for measuring coverage include estimating denominators for seasonal administration and integrating doses administered from the private sector.
- Discrepancies between the NITAG recommendations and the immunization programs (e.g. NITAG in Argentina and Uruguay recommended hybrid strategy but the immunization program implemented only the vaccine because of cost and access to the mAb) driving home that cost is a limiting factor for nirsevimab. In addition, these countries expressed interest in introducing nirsevimab as a complementary strategy to immunize children at risk including premature infants whose mothers were not vaccinated. Cost and manufacturer conditions (requirement of purchase of high number of doses) were also limiting factors.
- Challenge with a short vaccination window for maternal vaccination: most of the countries are using 32-36 weeks of gestation which may lead to missed opportunities for vaccination during antenatal care (ANC) visits during the third trimester and leave some premature infants unprotected.
- Simultaneous vaccination with other pregnancy vaccines (e.g., influenza) was not recommended in one country due to concern of possible AEFI and vaccine acceptance.

Session 3. Policy Recommendation Process:
Evidence for Decision Making

The session featured presentations from PAHO on RSV NITAG recommendations and the use of surveillance data to inform the immunization strategy and timing. Chile presented data from their RSV and mAb Budget Impact Studies. PAHO is leading efforts to strengthen NITAGs and support the development of evidence-based recommendations.

PAHO is using the NITAG Maturity Assessment Tool (NMAT) to enable NITAGs to systematically assess their strengths and identify areas for improvement.

Building on these assessments, PAHO conducts trainings and workshops to strengthen technical capacity, decision-making, and evidence-informed policy development, complemented by tools designed to support policy formulation, including HORIZON, UNIVAC (cost and cost-benefit), and VISTA.

The importance of strong RSV surveillance and laboratory testing for SARI and ILI cases in countries to support year-round vs seasonal strategies and timing of RSV product use was highlighted. Ongoing efforts to strengthen data quality and integration could be further reinforced to enhance the utility of surveillance for guiding programmatic decisions. The Global Influenza Surveillance and Response System supports and integrated surveillance platform where over 90 countries are routinely conducting RSV surveillance and sharing data with WHO. The use of the regional SARInet system for measuring seasonality and burden of RSV was also highlighted as important for supporting strategies and timing recommendations. The methods used to estimate disease burden based on RSV surveillance through SARInet was described.[5]

Chile presented data from their RSV and mAb budget impact studies, and made a compelling presentation showing very high effectiveness and impact of nirsevimab in 2024 and 2025 to date. These effectiveness/impact data are published in Lancet 2024.[6] They also presented a comprehensive study showing the cost saving of the nirsevimab program when considering hospital and ICU bed days saved, ER visits averted, and parent medical leave averted (net US $20M savings above nirsevimab cost US $47 M). These studies highlight the value of cost assessments beyond vaccine purchase.

The PAHO Revolving Fund for Vaccines (RFV) is important for countries introducing the maternal RSVpreF vaccine. RSVpreF single dose vaccine is WHO prequalified and can be purchased at a cost $49/dose through the PAHO RFV. The cost of mAb is a key issue. Prices are being negotiated, but there is limited flexibility of the manufacturer to negotiate price and quantity as they currently require full cohort purchase. A second long-acting mAb product (Clesrovimab, Merck) has been recently licensed in the US and may be available soon at a decreased cost and may support consideration of countries refining or changing strategies. Nirsevimab will likely be used only in high-income countries due to much higher costs.

Key discussion points of the session revolved around evidence needs for RSV vaccine and mAb introduction and focused on drivers of decision-making including:

- Capacity for achieving coverage with intended program.
- Necessity of integrated work and discussions among partners/stakeholders in developing programs (government, universities, scientific societies, practitioners).

[5] https://sarinet.org/burden-of-disease-resources/
[6] (https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(25)00233-6/abstract

- A need to focus on the countries' economic / financial situation and immunization budget. Conducting budget impact studies beyond just vaccine purchase can help highlight averted burden and hospitalization and support a compelling case for vaccination.
- Considerations of how to measure impact of program, and how to improve capacity to measure coverage and impact.
- Identification of barriers, drivers on how to achieve high coverage; openness to discuss with government. Ability to convince the government the program is worth the funds invested
- Guatemala highlighted that it was helpful to know maternal vaccine coverage for other vaccines (e.g., 40% TdaP) in order to understand expected coverage and identify potential barriers to uptake in pregnant women. Plans to increase coverage and promote advocacy for acceptance will be dependent on facilitators and partners.
- Other topics for consideration were checking availability of vaccine or mAb from manufacturers, cost consideration, cost effectiveness studies, proper cold chain for storage.

Session 4. Policy Recommendation Process:
Measuring, monitoring and building acceptability

This session covered the importance of measuring, monitoring and building acceptability for vaccines. Tools exist for conducting knowledge, attitudes and practice studies (KAP) and Behavioral and Social Drivers (BeSD) tools were highlighted as resources for understanding community perceptions prior to implementation for baseline assessments, program design and as tools for program review to address acceptance and demand. The tools are posted on the WHO Website[7] and there are practical and adaptable tools for health care and front line workers to support communications, advocacy and resource mobilization on Technet21.[8]

Peru presented preliminary results of a KAP study in HWs. CDC and TFGH are conducting a KAP study Strengthening Maternal Platforms for RSV (STaMP-RSV) in partnership with Bangladesh, Guatemala, Jordan and Zambia for HWs and pregnant women. A discussion with panel members from Guatemala, Peru, Scotland and Zambia discussed early findings, observations and lessons learned. All countries participating in the meeting were also invited to share their experiences.

[7] https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/demand
[8] https://www.technet-21.org/en/topics/programme-management/uptake

Key takeaways:

- In several countries there were knowledge gaps in information about RSV disease with as high as 81% of HWs not having knowledge about RSV in Zambia and 50% in Peru.
- An important discussion around the terminology of "RSV" disease versus bronchiolitis, including the use of a short video showing a child experiencing RSV breathing, highlighted that while health workers and pregnant women may not know the term RSV, they are likely familiar with the symptoms, recognize the signs in a video, and understand more common terminology.
- Even without knowledge about RSV, if there was a vaccine that could prevent severe disease in infants, HWs said they would recommend the vaccine to pregnant women or infants and support adding it to the vaccination schedule.
- A key challenge is how to best communicate results to the population, HWs and politicians. Some countries noted that it was important to work with scientific and medical groups to support education and recommendations for the vaccine.
- Differences in perceptions and roles among healthcare professional groups (pediatricians, obstetricians, midwives) highlight the need to understand these perspectives when planning RSV prevention strategies to optimize uptake and acceptance. The role of nurses and midwives is often undervalued in vaccination and they need to be provided with training and education. It was mentioned that in some countries the gynecologists and midwives are not recommending the RSVpreF vaccine.
- In some settings, reaching pregnant women was difficult because of the stigma of conducting research on pregnant women.
- Lower uptake in some settings appeared to be more about lack of knowledge than hesitancy underscoring the need for community education. One country found that mothers would accept vaccines if they understood it would protect their babies. Another noted that women will do what their doctors do or do not recommend. HW recommendations were highlighted as a critical factor for uptake. Ownership of outcomes and vaccination goals by HWs was critical to program success.
- Working with social services, local health committees and country technical experts proved important to conducting KAP studies and evaluations.
- There was a misperception that the maternal vaccine may be some form of birth control in one country.
- Guidance on whether to include mAb in KAP studies in countries where use of mAb is not feasible or available is important.
- Ideally KAP studies should target all groups responsible for implementing the prevention program. Standard protocols and evaluations are critical to compare and evaluate programs.
- The difference in risk perception between pediatricians and gynecologists was highlighted as the pediatrician is the one who sees the sick infants and understands the benefits of maternal vaccination. Gynecologists and obstetricians usually are less in favor of vaccinating pregnant women to avoid any risk during pregnancy. Pediatricians routinely perform vaccination and do see the benefit of vaccinating pregnant women. Regardless of the prevention product used, education among HWs and pregnant women and caregivers is crucial.

- Several participants highlighted the need for an education campaign well in advance of the vaccination program. A rush to train and implement too fast was highlighted as having negative impacts.
- Argentina conducted a BeSD survey for influenza, COVID-19 and RSV vaccines in pregnant women. The main barrier for having the RSV vaccine was the lack of recommendation from the midwives and gynecologists.

Session 5. Vaccine Introduction Process:
Program Implementation Considerations

The focus of this session was to explore differences in country approaches around key decisions such as seasonality, assessing gestational age, use of antenatal care (ANC) vs childhood vaccination (EPI) platforms and data management to program implementation. Cuba kicked off the session by describing their national immunization system and plans for maternal RSV vaccine. All meeting participants were invited to share experiences with implementation in their countries. Some of the key points of discussion:

- Communications with the population and the healthcare professionals are critical.
- Understanding how to integrate private and public hospitals and health care sectors for support and data integration is complex, but important. One country mentioned a system to vaccinate in private hospitals with public vaccines and track administration. A couple of countries noted that while the country buys 100% of the vaccine, some is distributed to the private sector. In some countries private institutions have to register in the public registry system.
- Systems to link the mother and infant to track vaccine status is important, but has proven to be challenging in some countries.
- There was a discussion about the difficulty in how to track mAb given it is not a vaccine, and how to capture that data in registries. Where and how to capture the mAb data can be challenging. In one country, the mAb was treated as a vaccine, but linking mother and child data was difficult.

Session 6. Post Implementation Studies:
Coverage Assessment, Impact Evaluation, AEFI surveillance, Vaccine Effectiveness, Acceptance, Post Introduction Evaluations

A detailed summary of methods and tools for evaluation of RSV vaccination programs including vaccine effectiveness and impact; vaccine coverage; post-introduction evaluation (PIE) tools and safety evaluation was presented. The current status of tools is listed in the Resources section. Various aspects of post implementation studies were presented by several countries.

Brief summaries follow:

- Chile summarized their pharmacovigilance system, and results to date following introduction of nirsevimab during 2024-2025 seasons by passive surveillance at the National level. Broad results with ~280,000 doses given – 28 AEFI (rate 0.99/10,000 doses); 5 serious AEFI (rate 0.18/10,000) with detailed case investigations, only one case was evaluated as consistent to mAb, which referred to a local-type reaction. Understanding AEFI should be considered when implementing strategies, whether for vaccines with RSV or monoclonal antibodies: type of strategy, AEFI that may occur, surveillance system structure and communication plan.
- Scotland summarized vaccine effectiveness in the first season RSVpreF vaccine given at 28 weeks or later in pregnancy (to be published in Lancet ID). Overall, VE for vaccine given >14 days before birth was 82% effective to prevent hospitalization, and 89% if given before 37 weeks gestation during 90 days after birth. Effectiveness of suboptimal doses (<14 days before birth) was not significant (30%, 95% CI: -17% – 59%). The study wasn't powered to evaluate waning immunity after 90 days. Analysis of safety data for RSV dose at >28weeks is underway and will be reported later this year.
- The United States summarized mAb and maternal RSV vaccine effectiveness in the second year of the program (2024-2025) using a test negative design (2 studies) or matched case control (1 study), against several levels of severity. Effectiveness of mAb for emergency department (ED) cases was 63 and 76% (2 studies) and for hospitalized cases was 79 and 82% (2 studies). Effectiveness of maternal RSV vaccine was 54% for ED cases, and 70 and 79% for hospitalized cases. mAb appeared to protect through at least 5 months after receipt. The estimated impact on reduction in RSV-associated hospitalizations in 2024-2025 compared to previous years (2017 to 2020) was 31 and 38% among children 0-7 months in 2 population-based surveillance systems (coverage was 39% vaccine, 21-48% mAb (by state, not additive)). There was no evidence of mAb protection from administration during an infant's first RSV season lasting into their second RSV season.
- Argentina presented the effectiveness of the maternal RSVpreF vaccine in the first year of introduction using a test-negative case control study from their RSV surveillance network. Effectiveness was 62% against hospitalization and 70% against ICU admission during the first six months after birth. The VE was 67% from 0 to 3 months after birth and 51% for 3 to 6 months after birth. VE was higher if the vaccine was given 28-41 days before birth. If the vaccine was given <14 d before birth, vaccine was still effective at 51% with a lower 95% CI~1%.

Key questions from discussion:

- Is using RSV sentinel networks and the test negative design (TND) the best approach to measure vaccine effectiveness or is a cohort approach and measuring other outcomes better (all hospitalization, pneumonia)? The answer depends on resources, systems and data available. TND is an efficient approach since it uses the existing surveillance platforms and provides valid estimates.

- Will vaccines/mAbs displace/delay RSV infection to later in childhood? Possibly, but likely disease would be less severe. In US, second program year, higher RSV hospitalization rates were seen in both 8-19mo and 20-59mo children compared to rates in seasons before introduction of RSV prevention products, but the latter could not be related to the vaccine, likely indicating a more severe RSV overall .
- Could RSV evolve away from protection by mAb, vaccine induced Ab? Programs will need to follow genomics over time. RSV genomics lab surveillance is underway in many countries through GISRS.
- Effectiveness of vaccine at widened pregnancy intervals (eg. <28 weeks). Scotland has inadequate data from first year, but expect second year data to be more robust. Understanding the benefit of wider pregnancy intervals would be important for PAHO countries and those who are mostly using maternal vaccine at 32-36 weeks.

Session 7. Global Support and Next Steps

The partners participating in the meeting gave brief overviews of their current support to generate data and evidence and to support RSV prevention and control program implementation. Following is background and/or links to the background and current RSV work of global partners participating in the meeting.

United States Centers for Disease Control and Prevention: Respiratory Illnesses Data Channel | Respiratory Illnesses | CDC ; Respiratory Virus Activity Levels | Respiratory Illnesses | CDC ; Preliminary Estimates of RSV Burden for 2024-2025 | RSV | CDC https://www.cdc.gov/rsvvaxview/dashboard/index.html

Gates Foundation: The Gates Foundation is focused on enabling rapid, equitable introduction of maternal RSV vaccination in LMICs to protect newborns in the first six months of life. Gates engages closely with support from WHO and Gavi on global policy and financing to support maternal RSV vaccination prioritization and accessibility in Gavi-supported countries. They are supporting acceleration of vaccine introduction in Gavi-eligible countries through grants to potential early adopter countries, building on the Maternal Immunization Readiness Network (MIRNA). They are also funding the multi-country RSV maternal vaccine impact trial, designed to provide efficacy (against severe RSV lower respiratory tract infection) and safety (pre-term birth) data in African countries (South Africa, Ghana, Kenya, and The Gambia). In parallel, they are advancing a pipeline of next-generation maternal RSV vaccines and long-acting monoclonal antibodies to ensure affordable, sustainable protection for newborns in low-resource settings.

Gavi: The Vaccine Alliance: The Gavi Board approved inclusion of RSV maternal vaccine to prevent RSV in infants into its portfolio at its July 2025 meeting. https://www.gavi.org/news/media-room/gavi-board-focuses-health-impact-priority-guiding-principle-resource-constrained Program planning and design have begun at Gavi to prepare for implementation in Gavi eligible countries.

MIRNA: The Maternal Immunization Readiness Network in Africa and Asia focuses on platform preparedness for the introduction of new maternal vaccines including RSV. In the next phase of their work they will support accelerating maternal RSV vaccine introduction in five Gavi-eligible countries. Their work includes providing technical support to national immunization advisory groups (NITAGs) for evidence-based policy decisions, raising awareness among healthcare providers and communities about RSV disease and maternal vaccination, and supporting ministries of health to integrate maternal RSV vaccines into routine immunization programs. MIRNA products that can be used by other LMIC Gavi eligible countries includes maternal immunization readiness toolkits, evidence-packets for NITAGs including burden of disease and health economic analyses to support country decision-making and national vaccine demand strategy plans focused on maternal immunization. https://mirna.tghn.org/

PAHO: supports immunization programs through policy development and NITAG strengthening; implementation of vaccines and monoclonal antibodies; strengthening epidemiological and virological surveillance; conducting acceptance studies; and supporting monitoring and evaluation of immunization, including coverage, effectiveness, impact, and cost analysis.

PATH: PATH's recent work in maternal immunization, and RSV prevention in particular, includes operational research, health economics, and advocacy and communication. PATH is working with partners to conduct maternal immunization feasibility and acceptability studies and readiness assessments in Ghana, Senegal, Tanzania, and Zambia. With many countries choosing to administer maternal RSV vaccine through the antenatal care (ANC) platform, PATH worked with WHO to develop a generic protocol to characterize the timing of these visits relative to vaccine administration recommendations, which differ by country. Results from studies in Mozambique, the PAHO region, and Vietnam will be available soon. PATH also leads and works with partners to fill RSV health economics evidence gaps, including leading numerous studies in LMICs to evaluate RSV cost of illness and RSV intervention cost of delivery, impact, and cost-effectiveness. Advocacy and communication efforts include partnering with WHO to create a suite of LMIC-focused communication materials as part of the WHO RSV Roadshow initiative to raise awareness about RSV and new immunization products that protect infants in early life. The RSV Roadshow includes a series of ten PowerPoint presentations, speakers' notes, and a fact-sheet, which are available on PATH's website and free to use. PATH also led subject matter experts to develop a WHO RSV value profile for maternal vaccines and monoclonal antibodies for the prevention of RSV disease in young infants.

The Task Force for Global Health: Through the Partnership for International Vaccine Initiatives (PIVI), The Task Force supports program evaluation and KAP/BeSD studies in countries that have or are considering introduction and sharing these data with global stakeholders. PIVI is currently funded by US CDC for this work, and intends to expand this work in the next year.

WHO: WHO is supporting countries globally on many fronts. They provide support for burden, impact and safety studies. They develop and update SAGE recommendations as needed.They support the development of guidance and training materials and tools such as a maternal RSV vaccine implementation guide, vaccine management and safety monitoring. Coverage monitoring is supported through the eJRF. They prequalify immunization products and they participate in global surveillance of RSV.

Key Considerations for countries and stakeholders:

- Making sure there is enough time for planning all facets of implementation, understanding seasonality and timing of vaccine, availability of planned products and prior communications to communities and health workers is critical.
- Training and education of HWs and communications and education for target populations is critical for acceptance. One country noted that low coverage was more about lack of education than hesitancy. One country (Chile) focused on a large public education and communication campaign and achieved high coverage. HWs play a critical role for offering and recommending the vaccine or mAb. Challenges with not starting training early enough prior to vaccine rollout were described by several countries as having negative impact. Global sharing of and easy access to training materials was highlighted as important.
- Early KAPs show that many health workers and patients are not familiar with "RSV". Alternative ways to describe the disease in training and communications led to better understanding of the importance of prevention. Using more common terms for providers like bronchiolitis, using videos of an infant with RSV symptoms, using sounds in addition to language were useful in some settings. Studies to support best communication methods and terminology may support greater understanding of RSV disease and the importance of prevention.
- Countries described the need and challenges around data collection and tracking data for coverage and impact assessment. Understanding how to estimate denominators for seasonal administration to estimate coverage and issues with connecting data and records from mothers to infants to evaluate impact were described as challenges in several countries. Participants had great interest in methods to track coverage in real time and with an ability to support follow up. Global or regional guidance on best practices for tracking coverage to support countries as plans are developed would support better country monitoring and better global eJRF reporting and data for sharing.
- Early monitoring shortly after program implementation, as early as two weeks, proved useful for troubleshooting early issues with program implementation and may be essential to making early corrections that boosts uptake and coverage. Global or regional guidance for early monitoring may be beneficial to support optimal RSV program implementation. RSV-PIE are important after implementation (at least six months after introduction) to evaluate the impact of the introduction in the health system. It can also provide valuable information to other countries considering the introduction of any of these products.

- Some countries described challenges with how to track mAb administration as it is not considered a vaccine. Developing best practices for and where to report mAb administration would be useful regionally and globally. Electronic immunization records are recommended to interoperate with other registries.
- Sharing best practices, tools and resources on how to integrate the public and private sector into vaccine and mAb administration and data reported will support more complete prevention and control, consistent communication and messaging and better data capture.
- NITAG recommendations were critical to moving prevention and control efforts for RSV forward. There were challenges with discrepancies between NITAG recommendations and feasibility, availability and cost of products ultimately recommended. Sharing of compendiums of knowledge online or via a platform to support global implementation and NITAGs would be beneficial.
- Some countries did not introduce nirsevimab despite the NITAG recommendation due to high cost and manufacturer conditions for purchase. Countries required a strong collaboration through the PAHO Revolving Fund for Vaccines to ensure affordable access to these products and sustainability of this strategy.
- Protocols and considerations for how to measure the impact of programs need to be shared. Regional data can support country decision making. Compilations of global and regional data on vaccine effectiveness and mAb effectiveness in reducing hospitalizations, ICU visits and deaths can support country decisions. Economic evaluations and protocols that can be adapted to countries would support generation of local data that may be compelling to policy makers and support financing decisions.
- Aligning RSV prevention strategies with broader maternal and child health programs may enhance both efficiency and effectiveness at the population level, leveraging existing platforms and resources. Understanding maternal vaccination coverage for other maternal vaccines supported identification of potential barriers and drivers to inform ways to achieve high coverage. Countries that are conducting KAP studies are understanding barriers that need to be addressed such as terminology, communications, misinformation and stigmas. Understanding HWs and pregnant women's perceptions has implications for program design, feasibility and affordability. KAPs may need to be modified or tailored to only address those options feasible within a country.
- Partnerships, both within a country and internationally, with a wide variety of stakeholders was noted as important for everything from conducting studies, to best packaging communications and conducting training and implementing vaccine programs. The importance of partnerships was a recurring theme throughout the meeting and noted as a prospective means of sharing resources developed, awareness of on-going studies, lessons learned and new findings. Ideally sharing would occur in real time to support decision making.

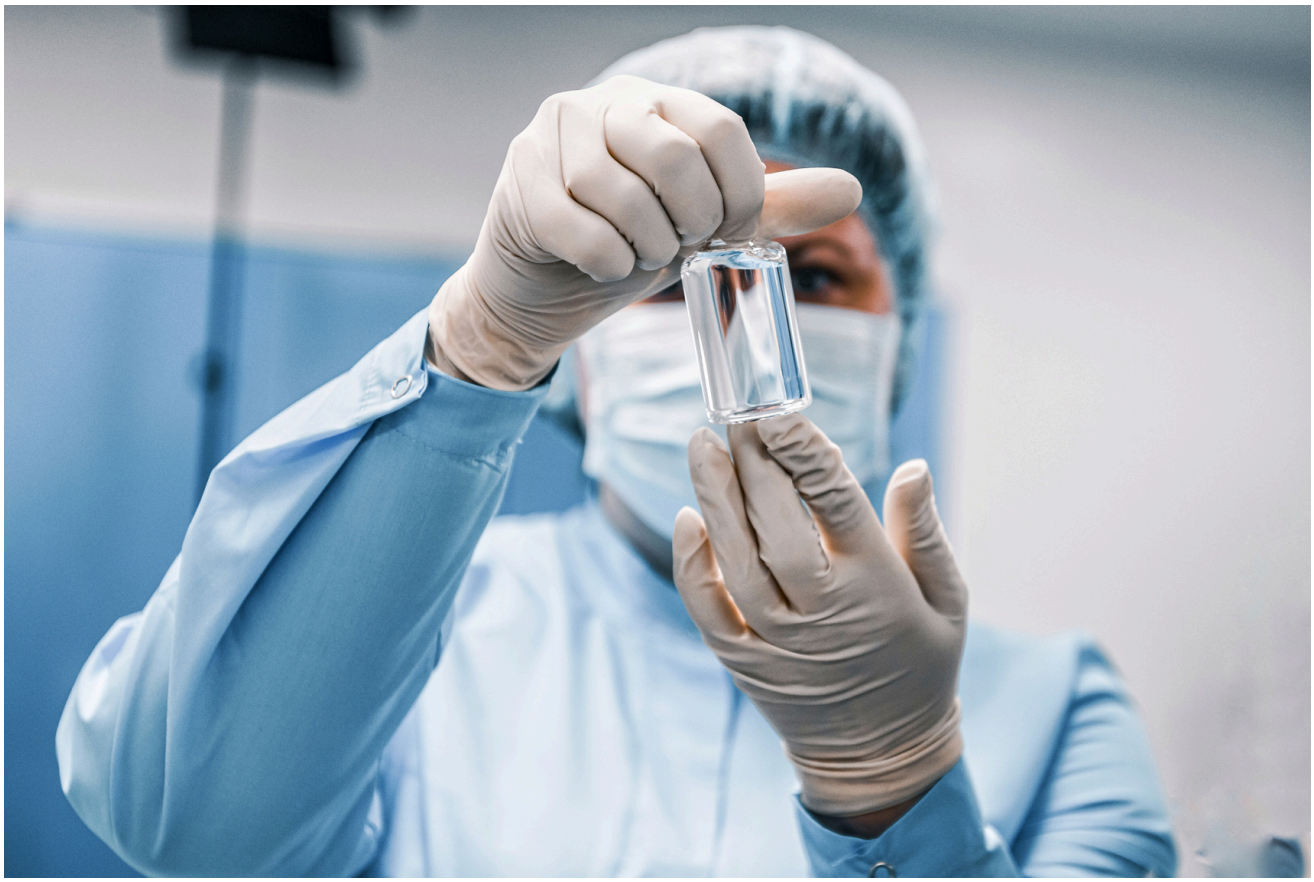
- Gavi and many partners are targeting support to low-income countries. Middle-income countries (MIC) can also benefit from guidance, best practices and tools. Support to meet their needs should be considered as planning moves forward to optimize global prevention and control for RSV. MICs may be a good source of lessons learned to inform implementation in other countries and may have information sooner than Gavi roll out.

Where more data are needed:

- Data on real-world effectiveness and population-level impact in special populations, including preterm infants, multiple pregnancies, and infants with comorbidities, are limited. Generating such data could inform targeted implementation strategies, optimize program impact, and support equity-focused decision-making.
- There were differences in recommendations of maternal RSVpreF vaccine in subsequent pregnancies. Information on duration of protection, lasting effects of a single maternal vaccine in subsequent births and effects on repeat vaccinations are needed. Understanding duration of protection for mAbs is also needed. In addition, understanding the protection conferred by breastfeeding is important.
- There are challenges with a short vaccination window for maternal vaccine as most of the countries participating in the meeting are using 32-36 weeks of gestation which may lead to missed opportunities for vaccination during ANC visits during third trimester. More information about the benefits and safety of expanding vaccination window during the third trimester (to start at 28 weeks) would support countries in decisions about expanding the window.
- More information about co-administration with other pregnancy vaccines (e.g. influenza, Tdap) is needed. Several countries do not co-administer vaccines due to concerns of possible AEFI and/or vaccine acceptance.
- Understand changes in epidemiology after introduction (e.g., whether any displacement or delay in RSV infection to later in childhood are observed following introduction of prevention in infants).
- Monitor susceptibility/resistance of RSV to these products. The importance of genomic sequencing was highlighted to monitor changes in circulating RSV.
- More extensive published data on the safety of RSVpreF in pregnancy from countries that have implemented national programs

Conclusion

The meeting served to share experiences, successes and challenges which led to some early lessons which will help future countries navigate best ways for implementation. The countries shared further data on the effectiveness and impact of products. At least two countries reported no RSV deaths in infants following robust vaccine campaigns. Some countries, such as Chile, achieved high coverage likely due to a well-planned, nationwide education campaign. The value of sharing information cannot be understated. Global stakeholders and countries need to strive to share best practices, protocols, publications and tools. We hope through this report some of the learnings can be applied to support optimizing program implementation in future countries.



Resources and Tools

RSV Post-Immunization Evaluation (rPIE) A tool has been developed by PAHO and TFGH and will be piloted in two countries in the coming months. Countries wishing to pilot the tool prior to publication can reach out to The Task Force for Global Health.

Behavioral and Social Drivers (**BeSD**) Addressing low vaccination requires an adequate understanding of the determinants of the problem, tailored evidence-based strategies to improve uptake, and monitoring and evaluation to determine the impact and sustainability of the interventions. More information can be found at this link: https://www.who.int/teams/immunization-vaccines-and-biologicals/essential-programme-on-immunization/demand

NITAG Maturity Assessment Tool (NMAT) The NMAT is a practical planning, monitoring and evaluation tool to guide NITAG development and strengthening. More information can be found at this link: https://www.nitag-resource.org/resources/nitag-maturity-assessment-tool-nmat

HORIZON: is an Excel tool designed to help NITAGs—including their Secretariats and Working Groups— to rapidly assess and prioritize vaccine policy options. By supporting fair, efficient appraisal alongside the Evidence-to-Recommendation (EtR) process, HORIZON ensures high-value vaccine policies are not overlooked. More information can be found at this link: https://sites.google.com/view/horizon-vaccines

UNIVAC: is an Excel-based decision-support model for national teams, led by Ministries of Health in LMICs, to evaluate the impact of vaccine policy options. It facilitates training, stakeholder engagement, evidence synthesis, and communication with NITAGs, estimating program costs, health outcomes, DALYs, cost-utility, and benefit-risk for different options. More information can be found at this link: https://sites.google.com/view/univac

VISTA: is an Excel tool designed for NITAGs—including their Secretariats and Working Groups—to systematically define and evaluate vaccine policy options using criteria tailored to the country context. By complementing the Evidence-to-Recommendation (EtR) process, it supports a structured appraisal of up to four options, helping ensure that key policy decisions are informed by clear, organized evidence. More information can be found at this link: https://sites.google.com/view/vista-tables

KAP Studies: KAP studies are underway by many countries/partners. Once piloting of the four country KAP study being conducted with Bangladesh, Guatemala, Jordan and Zambia concludes, the protocol will be fine-tuned and shared. Countries wishing to pilot prior to finalization, can contact The Task Force for Global Health.

PAHO TAG recommendations

- https://www.paho.org/sites/default/files/2025-01/1999-2024-tag-recommendations-rsv.pdf
- https://iris.paho.org/bitstream/handle/10665.2/59314/PAHOCIM240005_eng.pdf?sequence=5&isAllowed=y

SAGE recommendations - WHO Position Paper

- https://www.who.int/publications/i/item/who-wer-10022-193-218

PAHO Maternal and neonatal immunization field guide for Latin America and the Caribbean: Annex on maternal respiratory syncytial virus vaccine:

- https://iris.paho.org/handle/10665.2/62361

PAHO Webinar on RSV maternal vaccine:

- https://www.paho.org/en/events/maternal-vaccination-preventing-respiratory-syncytial-virus-associated-disease-infants

Surveillance dashboard for RSV in the Americas:

- https://www.paho.org/en/respiratory-syncytial-virus-rsv-situation-region-americas

PAHO Severe Acute Respiratory Infections Network—SARInet:

- A regional network in PAHO that support development of burden of disease estimates for RSV using sentinel surveillance sites. https://sarinet.org/burden-of-disease-resources/

PAHO Revolving Fund for Vaccines

- https://www.paho.org/en/news/1-11-2024-paho-facilitate-access-maternal-vaccines-protect-babies-americas-respiratory

RSV Roadshow: WHO and PATH have developed a toolkit of communication materials that public health stakeholders and advocates can use to share information about RSV disease, new prevention tools, and delivery considerations. More information can be found at this link: https://www.path.org/our-impact/resources/on-the-verge-of-rsv-disease-prevention-an-information-toolkit/

Influenza Toolbox Many of the tools and communications materials in the influenza vaccine tool box can be adapted to RSV.

Technet21 Guides and tools and practical resources to assist programmes and partners in efforts to boost vaccine uptake More information can be found at this link: https://www.technet-21.org/en/topics/programme-management/uptake

Guidance on an adapted evidence to recommendation process for NITAGs: Guide to present the EtR process More information can be found at this link: https://www.who.int/europe/publications/i/item/WHO-EURO-2022-5497-45262-64756

Selected Background Reading:

Li Y et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. Lancet. 2022; 399(10340):2047–64.

Feikin DR et al. The full value of immunisation against respiratory syncytial virus for infants younger than 1 year: effects beyond prevention of acute respiratory illness. Lancet Infect Dis. 2024;24:e318–27.

RSV vaccine and mAb snapshot. https://www.path.org/our-impact/resources/rsvvaccine-and-mab-snapshot/

Simões EAF et al. Prefusion F protein-based respiratory syncytial virus immunization in pregnancy. N Engl J Med. 2022;386(17):1615–26. doi:10.1056/NEJMoa2106062.

Simões EAF et al., MATISSE (Maternal Immunization Study for Safety and Efficacy) clinical trial group. Efficacy, safety and immunogenicity of the MATISSE maternal respiratory syncytial virus prefusion F protein vaccine trial. Obstet Gynecol. 2025;145(2):157–67. doi:10.1097/AOG.0000000000005816.

Kampmann B et al. Bivalent prefusion F vaccine in pregnancy to prevent RSV illness in infants. N Engl J Med. 2023;388:1451–64.

Gonzalo Perez M et al. Lancet infectious diseases. Published online on 5 May 2025 (https://doi.org/10.1016/ S1473-3099(25)00156-2).

Williams TC et al. Bivalent prefusion F vaccination in pregnancy and respiratory syncytial virus hospitalisation in infants: results of a prospective, multi-centre, test-negative study. Social Science Research Network (https://ssrn.com/abstract=5184994).

Cost-effectiveness analysis of both products. Presented to the Strategic Advisory Group of Experts on Immunization (SAGE). Geneva, 23–26 September. PowerPoint slides 2024 (https://terrance.who.int/mediacentre/data/sage/SAGE_Slidedeck_September-2024.pdf).

Safety of maternal vaccination against RSV. Global Advisory Committee on Vaccine Safety

(GACVS). https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/rsv

Simões EAF et al. Efficacy of nirsevimab against respiratory syncytial virus lower respiratory tract infections in preterm and term infants, and pharmacokinetic extrapolation to infants with congenital heart disease and chronic lung disease: a pooled analysis of randomised controlled trials. Lancet Child Adolesc Health. 2023;7(3):180–9. doi:10.1016/S2352-4642(22)00321-2.

Ares-Gómez S et al. Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalisation for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study. Lancet Infect Dis. 2024;8:817–28.

López-Lacort M et al. Early estimates of nirsevimab immunoprophylaxis effectiveness against hospital admission for respiratory syncytial virus lower respiratory tract infections in infants, Spain, October 2023 to January 2024. Euro Surveill. 2024;29(6):2400046. doi:10.2807/1560-7917.ES.2024.29.6.2400046.

Effectiveness and impact of nirsevimab in Chile during the first season of a national immunisation strategy against RSV (NIRSE-CL): a retrospective observational study. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(25)00233-6/abstract

How Gavi support for RSV immunisation will advance health equity https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(25)01117-1/fulltext

How can we accelerate maternal vaccination globally? https://journals.lww.com/pidj/fulltext/2025/02001/how_can_we_accelerate_maternal_vaccination.4.aspx

Nirsevimab effectiveness

Moline HL, Toepfer AP, Tannis A, et al. Respiratory Syncytial Virus Disease Burden and Nirsevimab Effectiveness in Young Children From 2023-2024. JAMA Pediatr. Feb 1 2025;179(2):179-187. doi:10.1001/jamapediatrics.2024.5572

Payne AB, Battan-Wraith S, Rowley EAK, et al. Effectiveness of nirsevimab among infants in their first RSV season in the United States, October 2023–March 2024: a test-negative design analysis. The Lancet Regional Health - Americas. 2025/09/01/ 2025;49:101196.

Lefferts B, Bressler S, Keck JW, et al. Nirsevimab Effectiveness Against Medically Attended Respiratory Syncytial Virus Illness and Hospitalization Among Alaska Native Children — Yukon-Kuskokwim Delta Region, Alaska, October 2023–June 2024. MMWR Morb Mortal Wkly Rep 2024;73:1015–1021.

RSV Prevention Product Impact

Patton ME, Moline HL, Whitaker M, et al. Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products-United States, October 2024-February 2025. MMWR Morb Mortal Wkly Rep 2025;74;273-281. DOI: http://dx.doi.org/10.15585/mmwr.mm7416a1