Protecting infants from RSV through effective immunisation strategies

Policy report

OCTOBER 2024

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The Health Policy Partnership

Contents

About this report

This report is part of a project on health system readiness for respiratory syncytial virus (RSV) prevention. The report aims to help policy- and decision-makers effectively implement immunisation strategies to protect infants from serious RSV-related illness. It complements an implementation framework for long-acting monoclonal bodies (mAbs) for RSV prevention, and includes insights from the application of the framework in France, Spain and the US.

The implementation framework includes five domains:

1. Governance and leadership
2. Reimbursement and funding
3. Demand
4. Service provision
5. Monitoring and assessment

The content of these domains has been organised into four policy priority areas in this report on RSV immunisation more broadly, in order to best present the content and available data. This report is informed by desk research and expert interviews conducted to assess the implementation of the long-acting mAb in France, Spain and the US, as well as additional reviews of published and grey literature on maternal immunisation, other RSV immunisation strategies and the broader immunisation policy landscape. For more information about this project, and to download the implementation framework and additional resources, please visit www.healthpolicypartnership.com/project/preventing-rsv-in-infants/.

Throughout this report, we make reference to immunisation delivered during pregnancy, known as maternal immunisation. We recognise that not all people who experience pregnancy and childbirth identify as women or mothers, so we have tried to use gender-neutral terms where possible, except when citing data from a source that specifically uses a gendered term.

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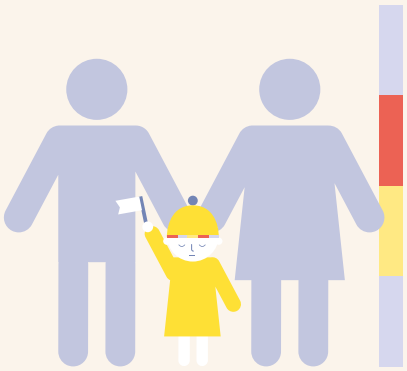
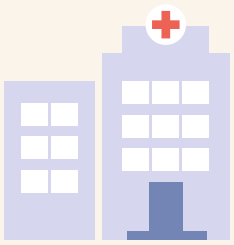
Executive summary

What is RSV and why is it significant?

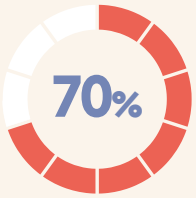


Respiratory syncytial virus (RSV) is a common seasonal virus that infects most children by the age of two, causing flu-like symptoms that range from mild upper respiratory tract infection to serious lower respiratory tract infection (LRTI) requiring hospitalisation.[1] When infants are hospitalised with RSV it also affects their families; parents can experience stress, anxiety and depression.[2-4] They also often miss work and/or are less productive at work.[2 4 5] When RSV peaks during the winter, it causes severe disruption to healthcare services.[6]

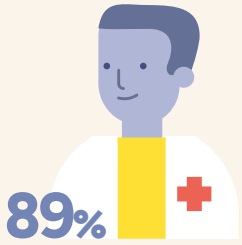


RSV is the leading cause of bronchiolitis and pneumonia in infants, and a leading cause of infant hospitalisation[1 7 8]

More than



of children who become seriously ill with RSV are otherwise healthy and born at term, pointing to the importance of protecting all infants from the virus[7 9]



of healthcare professionals from 20 European countries reported moderate to extreme disruption to healthcare services during the peak of RSV season[6]

How can RSV be prevented?

RSV prevention for otherwise healthy infants has historically been limited to infection prevention and control measures such as handwashing,[10] although one immunisation has been in use for more than 20 years for the small proportion of infants considered to be at increased risk of severe infection.[11] Recently, there have been significant advances in the development of RSV immunisation for both adults and infants, and some new options have become available in many countries, with more in development.[11-15] Immunisations designed to protect the broad infant population are now available. They include both a long-acting monoclonal antibody (mAb), which is administered directly to the infant just before the start of RSV season (or at birth for infants born during the season); and a maternal immunisation administered during pregnancy that can provide protection for the infant through transfer of maternal antibodies.[11] Both approaches have been

shown to prevent RSV-associated LRTI and RSV-related hospitalisation among infants,[16-20] but prevention must be timed to the seasonal circulation of the virus to offer the best protection. RSV vaccines for older infants and children are in development, but are not yet available.[15 21]

Policy priorities for implementing effective RSV immunisation programmes

Because these RSV immunisation strategies for infants only became available recently, many countries have not yet fully implemented an RSV immunisation programme for all infants. This leaves some infants at risk of becoming seriously ill, leading to avoidable hospitalisations, deaths and pressure on health systems. Policy- and decision-makers can learn from countries where RSV immunisation has been implemented, and ensure their health systems are ready to implement these new strategies by focusing on four priority areas.

Recommendations for policymakers and health system planners

To plan and deliver successful immunisation programmes, policymakers and health system planners may consider the following areas:

1.

Governance structures that support timely access to innovative immunisation strategies

2.

Plans and protocols for the organisation and delivery of RSV immunisation strategies

3.

Awareness of RSV and immunisation strategies among healthcare professionals and the public

4.

Systems for collecting and sharing data on RSV infection and uptake of immunisation strategies

Protecting infants from RSV

What is RSV and why is it important?

Respiratory syncytial virus (RSV) is a common virus that can cause severe illness in young children.

- RSV frequently causes difficulty breathing, especially in younger infants, and globally it results in thousands of infant deaths each year.[1 22]
- Most children are infected with RSV by the time they reach their second birthday.[1]
- Children may experience cold- or flu-like symptoms ranging from mild upper respiratory illness to serious lower respiratory tract infection (LRTI).[1]
- Infants born prematurely or with certain health conditions are at increased risk of severe illness from RSV, but more than 70% of children who become seriously ill are otherwise healthy and born at term – although this figure varies by country.[6 7 9]
- Among infants hospitalised for RSV, around 50% were born before RSV season.[23 24]

RSV places significant pressure on health systems, particularly during the winter months.

- It is a leading cause of hospitalisation for children in their first year of life and the most common cause of bronchiolitis and pneumonia in infants.[1 7]
- Globally in 2019, there were 33 million cases of acute LRTI associated with RSV in children up to five years of age, and 3.6 million required hospital admission.[22]
- RSV activity peaks during the winter months in regions with temperate climates, including most of Europe and North America, and parts of Asia.[1 25 26]

More than 70% of children who become seriously ill are otherwise healthy and born at term

Among infants hospitalised for RSV, around 50% were born before RSV season

RSV is a leading cause of hospitalisation for infants in their first year of life

Globally in **2019**, there were

33 million

cases of acute LRTI associated with RSV in children up to five years of age.

Of these,

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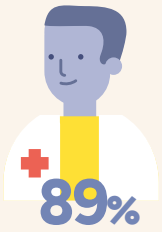
- RSV imposes a substantial burden on healthcare services each winter.[6 27]
- In a large survey of healthcare professionals from 20 European countries, 89% reported that RSV-related disruption to healthcare services ranged from moderate to extreme.[6]



of healthcare professionals reported moderate to extreme disruption to healthcare services

RSV-related hospitalisation is stressful and costly for families.

- Parents and carers of children who are hospitalised with RSV often experience stress, anxiety, depression and worsening quality of life.[2-4]
- Missing work and/or being less productive at work are common among parents and carers whose infants are hospitalised with RSV.[2 4 5]

Parents often experience stress, anxiety and depression, and worsening quality of life

How can infants be protected from RSV?

Prevention is key to protecting all infants from potentially serious illness, as there is no targeted treatment for RSV. Treatments developed for RSV and RSV-associated bronchiolitis have mostly failed to significantly reduce hospitalisations.[28] RSV prevention for the majority of infants has traditionally been limited to infection prevention and control measures, such as handwashing.[10] However, several options have become available in many countries, with more in development (*Box 1*).

Recent years have seen significant advances in the development of RSV immunisation for both adults and infants

BOX 1

Current and emerging immunisations for RSV prevention in infants and young children

Maternal immunisation

There are three RSV vaccines available for adults, and one is approved in many countries for use during pregnancy (RSVpreF).[12-14] An RSV vaccine given during pregnancy produces antibodies that are passed to the infant through the placenta, giving protection from RSV-related LRTIs for up to the first six months of life, with waning efficacy from three months.[16 29]

In Europe, maternal RSV immunisation is approved for use between 24 and 36 weeks of pregnancy,[30] although many countries in other parts of the world recommend administration between 32 and 36 weeks.[12 31 32] It is typically recommended for people who are expected to give birth during RSV season.[12 31]

Monoclonal antibodies

Monoclonal antibodies (mAbs) are passive immunisations, as opposed to traditional vaccines. They provide protective antibodies directly, without depending on the infant's immune system.[29] A short-acting mAb (palivizumab) has been available for over 20 years; it must be given monthly during RSV season and is reserved for infants at increased risk of severe illness from RSV.[11 33] A long-acting mAb (nirsevimab), offering protection for at least five months, became available in 2023, and has been approved and recommended for universal use in many countries.[34-50]

The long-acting mAb should be given as soon as possible after birth to infants born during RSV season, ideally before discharge from hospital.[51-53] For other infants, the long-acting mAb should be given close to the start of the RSV season.[51-53] Infants whose mothers received the maternal immunisation as recommended (and at least two weeks before giving birth) are usually not recommended to receive the long-acting mAb.[31 52] The long-acting mAb is also recommended for infants at increased risk of severe illness who are entering their second RSV season.[51 54]

Vaccines

Many RSV vaccine options for young children are undergoing clinical development and trials.[28] Some early trial data suggest that live attenuated vaccines may be effective in reducing RSV-associated lower and upper respiratory tract infections that require medical attention in children aged 6–24 months.[15] Vaccine development for infants under six months is challenging because of their immature immune system; a vaccine for this age group is not expected to become available in the near future.[11]

What are the potential benefits of RSV prevention?

Clinical trial data and some real-world evidence show that the available RSV immunisations can significantly reduce severe illness and hospitalisations. The RSV immunisations that are currently available work in different ways, but all provide passive immunisation and have been shown in clinical trials to protect infants from RSV-associated LRTI (*Box 2*). By reducing severe infection and hospitalisations, RSV immunisation programmes can protect infants, parents and health systems from the direct and indirect effects of the virus.

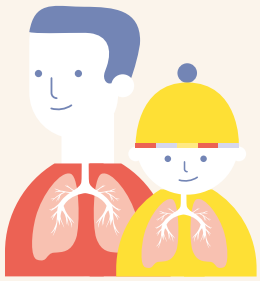
BOX 2.

Efficacy and effectiveness of currently available RSV immunisations

CLINICAL TRIAL	REAL-WORLD EVIDENCE
Maternal immunisation (RSVpreF, currently marketed as Abrysvo®)	
Results showed **82% efficacy** in preventing medically attended, severe RSV-associated LRTI **within 90 days of birth**, reducing to **69% by 180 days after birth**.[16]	Not yet available.
Short-acting mAb (palivizumab, currently marketed as Synagis®)	
Results showed a **55% reduction in RSV hospitalisations** among **infants at increased risk of severe illness**, and **78% among premature infants** without other risk factors.[55]	Evidence has shown a **58% reduction in RSV hospitalisations** among **high-risk infants**, and **74% among premature infants** without other risk factors.[56]
Long-acting mAb (nirsevimab, currently marketed as Beyfortus®)	
Two clinical trials showed a **reduction of 70–79%** in medically attended LRTI **150 days after the injection**.[17 57-59] A pragmatic, randomised clinical trial, conducted in close-to-real-world settings, found an **83% reduction in hospitalisations** for RSV-associated LRTI.[20]	Evidence has demonstrated a **reduction in hospitalisation** from RSV-related illness ranging from **82% to 98%**.[18 19 60-65]

Severe RSV infections in early life are associated with an increased frequency of other, potentially avoidable respiratory conditions.

There is a significant association between severe RSV infection in infancy and other respiratory conditions, such as asthma and wheeze in later childhood or adulthood.[66 67] It is therefore possible that reducing the burden of RSV would also reduce the burden of other respiratory conditions, but it is not yet known whether RSV causes these conditions or whether some people are more susceptible to both chronic respiratory conditions and severe illness from RSV.[68 69] By reducing the burden of RSV through immunisation, longer-term follow-up studies could help investigate the association.



Many studies have demonstrated a significant association between severe RSV infection in infancy and other respiratory conditions, such as asthma and wheeze in later childhood or even adulthood

RSV prevention could reduce the use of antibiotics and aid in the fight against antimicrobial resistance. Viruses, including RSV, cannot be treated with antibiotics.[70] However, inappropriate use of antibiotics to treat RSV is common in some countries; this represents poor use of healthcare resources and contributes to antimicrobial resistance.[71-73] RSV sometimes contributes to ear infections and secondary bacterial respiratory infections, and is therefore also a cause for appropriate but potentially avoidable antibiotic use.[5 74] Clinical trial data have shown that preventing RSV in infants through maternal immunisation reduced antibiotic prescribing for infants by almost 13% over the first three months of life,[75] and the long-acting mAb reduced antibiotic prescriptions by 24% in the first 150 days after injection.[59] These findings highlight the role RSV prevention could play in fighting antimicrobial resistance.

RSV immunisations reduce antibiotic prescribing for infants

Through maternal immunisation, by almost

13% over the first three months of life

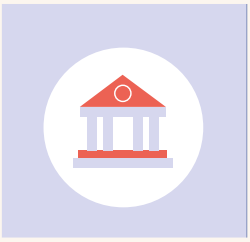
With the long-acting mAb, by

24% in the first 150 days after injection

Policy priorities for implementing RSV immunisation strategies

The implementation of new and emerging RSV immunisation strategies requires careful coordination and planning across the health system. Many countries have not yet fully implemented RSV immunisation aimed at protecting all infants. This leaves some infants at risk of becoming seriously ill, leading to avoidable hospitalisations and deaths.

Policy- and decision-makers can prepare their health systems to implement these new strategies by addressing four priority areas:



1.

Governance structures that support timely access to innovative immunisation strategies

2.

Plans and protocols for the organisation and delivery of RSV immunisation strategies

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Awareness of RSV and immunisation strategies among healthcare professionals and the public

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Systems for collecting and sharing data on RSV infection and uptake of immunisation strategies

1. Governance structures that support timely access to innovative immunisation strategies

Policymakers could consider actions to help make innovative RSV immunisations available to infants without delay. This would involve ensuring that regulatory processes and assessments – including review and approval timelines, access pathways and funding decisions – are efficient and support rapid, equitable access for the recommended population.

Expedited pathways for regulatory review and health technology assessment

Existing frameworks and pathways for health technology assessment can impede timely access to innovative immunisations and therapies. Regulatory and access pathways are review processes conducted by national and regional government bodies. These bodies evaluate the evidence to ensure the safety and efficacy of new medicines, and make decisions about pricing and reimbursement or payment.[76 77] These indispensable processes can be protracted, although time frames vary significantly between countries. For example, the average time to reimbursement for innovative treatments in Europe ranges from 133 days in Germany to more than 899 days in Romania,[78] resulting in considerable variations in access and exacerbating health disparities. Reasons for these delays include:[78]

- slow regulatory processes
- delays in reimbursement decisions
- variations in evidence requirements between countries
- slow decision-making at national and regional levels.

The average time to reimbursement for innovative treatments in Europe ranges from

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While reviews and approvals are typically faster in the US than in Europe,[79] there is still a noted discrepancy in the US between the rapid pace of

innovation and the slow evolution of corresponding regulatory frameworks. Typically, these processes only change in response to a problem, rather than being regularly reviewed and updated.[80]

Priority review pathways and expedited funding decisions for products that address a significant gap in care have been key to the implementation of RSV prevention solutions. Some regulatory bodies, including the Food and Drug Administration (FDA) in the US and the European Medicines Agency (EMA), have priority pathways for medicines that address a gap in care or represent a significant improvement on the currently available options.[79 81-83] Examples include:

In Europe, the EMA granted approval for the long-acting mAb and maternal immunisation through schemes which allowed for faster review.[30 84]

In the US, expedited reviews were granted for the long-acting mAb and the maternal immunisation for RSV,[37 85] facilitating their rapid implementation in 2023.

The relevant authorities in Spain provided rapid approvals and recommended the implementation and funding of the long-acting mAb.[38] Although there were limited cost-effectiveness data to inform reimbursement decisions at the start, policymakers agreed to fund the long-acting mAb before analyses had been completed so that it could be implemented in time for the start of the 2023/24 RSV season.[38 51]

In France, a centralised governmental procurement scheme was implemented to provide accelerated access to the long-acting mAb for infants in time for the 2023/2024 RSV season.[86]

In 2024, Ireland also recommended implementing the long-acting mAb, based on the available real-world evidence, while formal assessments were still underway.[46]

The long-acting mAb has been approved via expedited regulatory review in many other countries, including China.[87]

In countries where RSV immunisations have not yet been fully assessed, policymakers could address barriers that limit timely access. Thorough assessment of the available evidence is necessary. Given the positive experiences associated with expedited reviews and funding approvals in some countries in 2023, policy- and decision-makers could use rapid review mechanisms, or take exceptional funding decisions, to implement universal immunisation programmes for RSV before the next season begins. Further reviews could be conducted for future years, when more complete real-world data become available.

Review and funding of RSV immunisations using the same processes as used for vaccines

By reviewing and managing RSV immunisations in the same way as vaccines, and including them in national immunisation programmes, decision-makers can leverage existing systems that are designed to maximise access and public health impact. In some countries, recommended vaccines are provided at no charge to families or healthcare providers. In other countries, there are government assistance or insurance schemes in place to cover most or all of the costs associated with immunisation.[88-91] When new RSV immunisations are assessed by national immunisation technology assessment groups (NITAGs) and included in national immunisation programmes, the programmes benefit from these established structures and functions.

Countries which have assessed the long-acting mAb in the same way as a vaccine have been able to secure universal funding and inclusion in national immunisation programmes. Regulatory, legislative and/or policy frameworks had to evolve in some countries to embrace the long-acting mAb for RSV, as it was a new technology that had not yet been implemented widely for prevention.[92] For example:

The scope of the US NITAG was updated in 2022 to include preventive antibody products.[93 94] This meant they could review and recommend the long-acting mAb, and include it in the national immunisation programme.[34] Consequently, insurance companies were legally required to cover it, and it was available free of charge for uninsured, underinsured and other disadvantaged infants through the Vaccines for Children programme.[88]

In Spain, the long-acting mAb was assessed as an immunisation, and its recommendation by the Spanish Paediatrics Association led to the national vaccination calendar becoming the national immunisation calendar.[95] Accordingly, the long-acting mAb is managed and monitored in the same way as a vaccine by regional governments.[51]

Policy change may be needed to allow RSV immunisation technologies, such as preventive mAbs, to be assessed and implemented in the same way as vaccines. Policymakers should consider taking steps to ensure that RSV immunisation strategies are assessed, recommended and funded like other childhood vaccinations. This may involve policy action and legal amendments, such as expanding the stated scope of the NITAG and immunisation calendars.

2. Plans and protocols for the organisation and delivery of RSV immunisations

The successful delivery of RSV immunisation programmes requires careful planning and organisation. Programmes must be designed in line with the seasonality of the virus and the need to protect infants either before the start of the season (for those born outside of the season) or as soon as possible after birth – ideally before discharge from hospital – for those born during the season. This may mean that immunisation needs to be offered and administered in different settings, requiring coordination and interoperability of immunisation information systems across hospitals and primary care, workforce planning and demand forecasting.

Logistical plans for the delivery of RSV prevention programmes

The seasonality of RSV is a key consideration when planning prevention programmes. RSV immunisations are recommended to be administered at different times and in different settings, according to the RSV season, with recommendation and guidance depending on when the child is born and whether their mother received a vaccination during pregnancy.[31 52 96] Programmes must be planned carefully to ensure immunisation is offered at the most appropriate time and place for infants born before and during the RSV season, and the plans must be communicated effectively to healthcare professionals.

In countries where RSV immunisation has been implemented, it has generally been delivered in both hospitals and primary care; but the programmes varied and were adapted to local contexts. The long-acting mAb was fully implemented in France, Spain and the US during the 2023/24 RSV season, but each country delivered the immunisation programme differently. For example:

In France, the long-acting mAb was typically given to infants born during RSV season in hospital maternity departments before discharge, although it was occasionally administered in community centres that were providing antenatal and postnatal care. Most catch-up campaigns for infants born before the RSV season were delivered in primary care, leveraging existing vaccination infrastructures.[86]

In Spain, the long-acting mAb was usually administered to infants born during the RSV season before they were discharged from hospital, with catch-up campaigns in primary care. Some regions, however, delivered all doses in hospital settings.[97 98] Reportedly, Spanish settings also implemented strategies to facilitate higher levels of uptake, such as direct phone calls and text messages from healthcare professionals, and offering convenient, flexible appointments, leveraging systems that were developed to support immunisation against COVID-19.[97 99-101]

In the US, recommendations about when and where to administer the long-acting mAb were flexible, and organisation varied by state.[34] Experts reported that, while some states had high levels of hospital participation, many hospitals across the country did not participate in the programme during the first year, and it was primarily delivered by paediatricians during routine infant health checks.[102-104] Maternal immunisation was also rolled out in medical offices and retail pharmacies, but it is not clear from the available data where most pregnant people were immunised.[105]

In both France and Spain, acceptance of the long-acting mAb in hospital before discharge was at least 80%.[51 106] In the US, an estimated 43% of infants received the long-acting mAb and 18% of eligible pregnant people received the maternal immunisation.[105] It is possible that uptake of the long-acting mAb in the US could have been higher but there were supply constraints which limited availability.

RSV immunisations may be delivered in different settings by a range of healthcare professionals, and implementation plans should clearly set out the local approach. Given the different target populations and the need to time immunisation campaigns according to RSV seasonality, immunisation strategies will likely need to be offered in primary care, hospitals and specialist settings such as paediatrics and antenatal care. To ensure that the immunisations are given as intended, clear guidelines and protocols should be developed and made available to specify exactly how programmes are organised, including strategies to support easy and convenient access.

Evidence-based estimates of demand to support planning

Planning the implementation of new immunisation programmes for RSV will involve estimating demand for all available options and procuring enough doses before RSV season begins. As with immunisations for diseases such as influenza, RSV immunisations need to be ordered each year in advance of the season, allowing for manufacturing and delivery lead time, in preparation for the rapid administration of catch-up doses at the start of the season and routine administration throughout. For influenza, estimates of demand are based on long-term, reliable global data on vaccine uptake.[107] Data on the uptake of RSV immunisation, however, are less extensive. Planning may need to be informed by various sources, including survey data and evidence from countries where RSV immunisation has already been implemented.

Demand for RSV immunisation in 2023 was high in countries where it was introduced, outpacing supply in some cases.

Public health leaders in Spain ordered enough doses of the long-acting mAb to cover 100% of eligible infants to avoid shortages, according to an expert in the country.[100]

In France, demand was expected to be around 30% based on the uptake of previous new childhood immunisations, so a smaller number of doses was procured.[108] In reality, demand exceeded supply, and infants born during the season and those at high risk of severe illness were prioritised.[109]

While there was no shortage of the maternal immunisation in the US, supplies of the long-acting mAb ran short due to high demand at the start of the programme.[105] Infants who were born during the season and those at high risk were therefore prioritised until supply had increased.[105 110]

Based on this experience, France and the US are planning to cover a much larger proportion of the population in the 2024/25 season.[105 111]

Health system planners and decision-makers may need to identify or collect data to inform demand forecasting, while acknowledging the potential for uptake to be higher than anticipated. As RSV immunisations are new, existing data on uptake of childhood immunisations and immunisations during pregnancy should be considered, but may be inadequate in some countries. When multiple options are available (i.e. long-acting mAbs and maternal immunisation), parents' attitudes towards maternal immunisation vs. a novel long-acting mAb for their infant may affect which option is accepted.[112] It may be helpful to conduct surveys on these attitudes and on parents' intentions to accept either option. In the US, data on intention to accept the long-acting mAb are regularly collected through an existing survey system, and could be used to inform demand forecasting and planning (*Case study 1*).[113]

Case study 1.
Estimating demand for the long-acting mAb in the US

Collecting data on parental intent to immunise is essential for estimating demand for immunisation strategies. The Centers for Disease Control and Prevention (CDC) collects monthly data on vaccine uptake and intent through the National Immunization Survey-Adult COVID Module (NIS-ACM).[113] The survey includes questions of intent to accept the long-acting mAb, which were aimed at:

- mothers with an infant under eight months old
- pregnant women
- women who were trying to get pregnant

In the latest results of this survey, from February to March 2024, 94% of pregnant women reported that they would probably or definitely accept the long-acting mAb.[114] Similarly, 47% of women with an infant under eight months said they would probably or definitely accept it, and 41% reported that their infant had already received it.[114] These insights will be useful in predicting demand for the next RSV season, especially considering shortages that were driven by high demand in 2023/24.

3. Awareness of RSV and available immunisations among healthcare professionals and the public

Education strategies for healthcare professionals and the public must be designed to support delivery and uptake of RSV immunisations. Given the novelty of RSV immunisation and the number of options available, healthcare professionals must be adequately trained to discuss these options with parents, and to understand when to administer an immunisation and to whom. Parents should also be made aware of RSV, and of the immunisation options available to them, so they can make informed decisions and seek out immunisation if it is not offered.

Accessible information and training for healthcare professionals

Experiences from the US, Spain and France demonstrate the importance of adequate training for healthcare professionals in delivering RSV immunisations.

During the 2023/24 RSV season in the US, training for healthcare professionals was reportedly limited in some states, which may have been due to the short time frame between the publication of recommendations and the implementation of the immunisation programmes.[104 105] There was reportedly a lack of simple, accessible resources that would have been useful as a quick reference, especially for those in more technical roles, such as medical assistants.[104] This may have contributed to the vaccine administration errors that occurred across the US and reports of some pregnant people receiving an RSV vaccine that was not approved for use in that population.[115]

In Spain, experts stated that a range of strategies – such as leaflets, websites, and online and in-person training – were developed and implemented by each regional health department,[100 116-118] and delivery and uptake of the long-acting mAb were generally high.[51]

In France, national and regional governments, alongside professional and scientific societies, produced various guidelines and resources for healthcare professionals, which helped build consensus and secure buy-in.[119-124]

National organisations in some countries have now produced more accessible information and tools to help healthcare professionals better understand the recommendations and communicate these to parents.
To support delivery of maternal immunisation and the long-acting mAb in the 2024/2025 season, some countries have developed clear information for healthcare professionals, outlining key details about the available immunisation options, so they can counsel parents effectively. For example:

In France, the Haute Autorité de Santé published a press release to complement the formal recommendation to introduce maternal immunisation alongside the long-acting mAb. The press release summarised the evidence and practical considerations for implementation, and included a table listing the benefits and disadvantages of each option.[125]

In the US, the CDC and the American College of Obstetricians and Gynecologists produced an infographic for obstetrician-gynaecologists to share with parents, explaining when they (or their child) should receive the maternal immunisation or long-acting mAb, and summarising the benefits of each.[126] The CDC also published a slide deck on RSV immunisation recommendations for healthcare professionals who care for pregnant people.[127]

Information and educational materials for healthcare professionals must be accessible and delivered proactively.
Delivery of RSV immunisation strategies could involve doctors, nurses, midwives, pharmacists and other healthcare professionals working across hospitals, primary care and the community. While publishing official information online or sending leaflets can be helpful, it is not always enough to make healthcare professionals feel confident that they understand the recommendations and can answer questions from parents.[104 128] Formal training is reportedly much more effective at preparing healthcare professionals to offer and administer RSV immunisations.[100 104]

Public awareness campaigns that leverage existing knowledge and attitudes

Public understanding of RSV as a potentially serious illness can support acceptance of immunisation. A recent survey of people who were pregnant or planning to become pregnant in the US found that those who thought RSV was serious were most likely to accept the immunisation.[129] Indeed, confidence in the importance of immunisation is the greatest predicter of uptake around the world.[130] In France and Spain, bronchiolitis was much more widely recognised than RSV as a serious condition, so public awareness campaigns often focused on the opportunity to prevent bronchiolitis.[100 131-133]

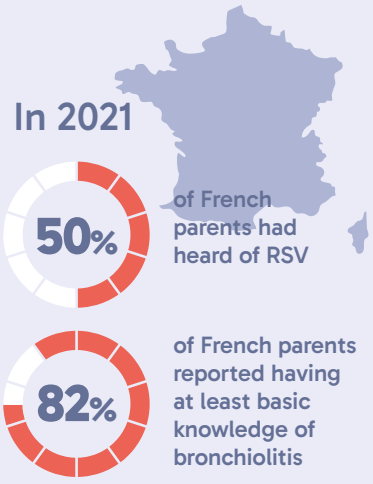
Public attitudes about immunisation differ from country to country, leading to variations in communication about RSV immunisations. Attitudes and beliefs about the safety, efficacy and importance of vaccines vary widely and change over time, affecting vaccine uptake.[130 134] In countries, states or regions where low vaccine confidence is a barrier to uptake, communication strategies can be developed to address the public's concerns.[135] For example:

	In France, vaccine confidence is relatively low,[136] so the long-acting mAb was framed as a preventive treatment (*Case study 2*).[137 138]
	In Spain, on the other hand, vaccine confidence is high, and the long-acting mAb was often framed as a vaccine or immunisation.[100 139-141]
	In the US, vaccination in pregnancy is often lowest among Black people,[142 143] and uptake of the RSV maternal immunisation was lowest among this population in the 2023/24 season.[144] To encourage Black people to accept recommended immunisations (including for RSV), a targeted communication campaign, 'From Me, To You', was developed with input from Black parents to raise awareness and highlight the urgency of immunisation to protect their infants.[105 144]

Parents' perceptions about vaccines also are likely to inform which RSV immunisation they prefer; decisions will be influenced by their feelings about vaccination during pregnancy and the use of mAbs, which are novel and may not be presented as a traditional vaccine.[112]

Case study 2.
Public awareness strategy for the long-acting mAb in France

Health authorities, professional organisations and media outlets in France developed awareness campaigns for the long-acting mAb that leveraged public knowledge and attitudes. In 2021, only 50% of French parents had heard of RSV, while 82% reported having at least basic knowledge of bronchiolitis.[133] Additionally, vaccine confidence is relatively low, with only around 30% of children receiving recommended childhood vaccinations.[108 136]



To address public perceptions, the long-acting mAb was often framed as a preventive treatment for bronchiolitis. For example:

- Regional health authorities campaigned for bronchiolitis prevention by hosting webinars and sharing information online.[121 122 145]
- A website aimed at parents explained that the long-acting mAb could help prevent bronchiolitis.[137 146]

Many of these resources referred to the long-acting mAb as a preventive treatment or medicine rather than a vaccine.[137 138]

These strategies appear to have been effective; early estimates suggest that eight in ten parents wanted their infant to receive the long-acting mAb during their maternity stay, with the main reason being a desire to prevent bronchiolitis.[106]

Public awareness strategies should highlight the impact of RSV and be adapted to attitudes and preferences towards maternal and infant immunisation. Health system leaders, including health authorities and public health bodies, should work alongside healthcare professionals and other advocates to ensure that the population is aware of the potential consequences of RSV. Communication strategies can also be tailored to address differing views about immunisation, and parents must be adequately educated about their immunisation options during pregnancy so they have enough time to make an informed decision.

4. Systems for collecting and sharing data on RSV infection and immunisation

Robust data collection and sharing systems can support the monitoring and ongoing delivery of effective immunisation programmes for RSV. Epidemiological surveillance and monitoring systems are necessary to collect data on RSV infection and on the uptake, impact and safety of immunisations. These data can be published rapidly to inform prevention efforts in real time. Additionally, it can be helpful if immunisation records are shared easily across hospital and primary care systems so all families are offered appropriate options.

Real-time RSV surveillance

Consideration should be given to the national collection of data on RSV infections to monitor the virus's spread and impact, and to help decision-makers plan effective and timely immunisation campaigns. Collected data can be used to understand when the RSV season begins and ends; measure the burden of RSV in different population groups; estimate the uptake and impact of RSV immunisation programmes; and adapt future prevention and response strategies.[147] Experts from across Europe recommend that systems either use active sentinel surveillance (where a small number of sites perform testing and collect detailed data on the number and proportion of people who have RSV)[148] across both hospitals and community settings; or use routine electronic health records linked with virological testing data.[147] These systems can be built as standalone RSV surveillance systems or added to surveillance systems for other respiratory illness such as influenza and COVID-19.[38 147]

Many countries have established RSV surveillance systems, but gaps remain. RSV surveillance, including at least basic virological testing, is commonly available in Europe and in countries including Canada, Australia and the US.[149-153] However, these systems are organised differently and do not always collect comprehensive data on RSV infection. For example, some

systems are based primarily or exclusively on sentinel surveillance in hospitals, excluding data on people attending primary care with RSV symptoms.[154] RSV is a notifiable disease in some countries, including Australia,[152] which supports comprehensive and rapid data collection. However, formal reporting of all RSV may not be feasible in all countries.[154] Finally, there is a noted lack of standardisation in case definitions, approaches to testing, and the data collected in Europe and around the world, making it difficult to share and compare data between countries.[149 155] However, some initiatives, including the World Health Organization Global Influenza Programme and the Innovative Medicines Initiative PROMISE platform, are developing standardised multinational surveillance networks for RSV.[156 157]

Decision-makers may consider reviewing their RSV surveillance systems to ensure that they collect and report adequate data to inform the planning and ongoing delivery of RSV immunisation programmes. While national and regional systems vary – based on a country's needs, available resources and existing data collection efforts for other diseases – they should align with international expert recommendations. If testing and reporting become more standardised, national surveillance systems could aim to adopt uniform procedures so that information about circulating RSV strains and the impact of prevention programmes can be shared and compared.

Digital systems for collecting and sharing immunisation data

Healthcare providers must have access to information about uptake of RSV immunisation to support best practice. Given the various settings, and the different age and risk groups, targeted by RSV immunisation strategies, accurate and easily accessible information about who is eligible for an immunisation – and who has already received one – should be available to all relevant healthcare professionals, to avoid challenges. For example:

In the US, healthcare professionals reportedly found it difficult to confirm whether infants were eligible for the long-acting mAb because they could not access mothers' immunisation records to determine if or when they had received the maternal immunisation during pregnancy.[103 104] This could be addressed by updating data-sharing policies and by linking mothers' RSV immunisation status to their infants' health records.

Data on immunisation coverage, safety and impact can help decision-makers plan for future RSV seasons and encourage uptake among healthcare professionals and the public. Immunisation registries are used to collect data on the uptake of immunisations to monitor coverage, safety and impact, including the generation of real-world evidence of effectiveness.[158] This is important for:[158]

- planning and monitoring RSV immunisation programmes, including demand forecasting
- monitoring uptake across different population groups and geographical areas to identify gaps
- assessing the impact of the programmes.

Many countries have national immunisation registries, although they often draw data from smaller local registries, which can be inconsistent and incomplete.[159 160] In France, Spain and the US, detailed safety and effectiveness data were collected and reported as part of the implementation of RSV immunisation programmes.[20 51 161-165] The resulting real-world evidence showed that the programmes prevented a significant number of RSV-related hospitalisations, and that the products were safe.[18 20 60 163 164] This evidence informed planning and decision-making for the next RSV season (*Case study 3*) and was used to reassure healthcare professionals and the public.[51 105]

Case study 3.

NIRSE-GAL study to evaluate the effectiveness of the long-acting mAb in Galicia, Spain

In 2023, the regional government of Galicia, Spain, became one of the first in the world to incorporate the long-acting mAb for RSV into its immunisation calendar.[18] As real-world data were limited, implementation and reimbursement were agreed based on preliminary data, with a commitment to revisit the decision after one year, when more data on the impact of the long-acting mAb would be available.[18] To facilitate the comprehensive collection and reporting of such evidence, public health authorities and academic institutions in the region collaborated to run the NIRSE-GAL study.[18]

NIRSE-GAL is a three-year study that began in 2023 to evaluate the effectiveness of the long-acting mAb in preventing hospital admissions for RSV-associated LRTIs. It also evaluates immunisation coverage, the impact on other relevant health outcomes and the impact of immunisation on healthcare usage.[18]

Data for the study is drawn from seven regional registries:

1. The Galician registry healthcare card
2. The vaccine registry
3. Hospital admissions
4. Test results from microbiology laboratories
5. The registry for screening tests of metabolic disorders in newborns
6. The regional Healthy Child programme
7. The Minimum Basic Data Set hospital registry

The study publishes weekly reports on the uptake and impact of the long-acting mAb during RSV season, allowing policymakers and the public to understand the results in real time.[165]

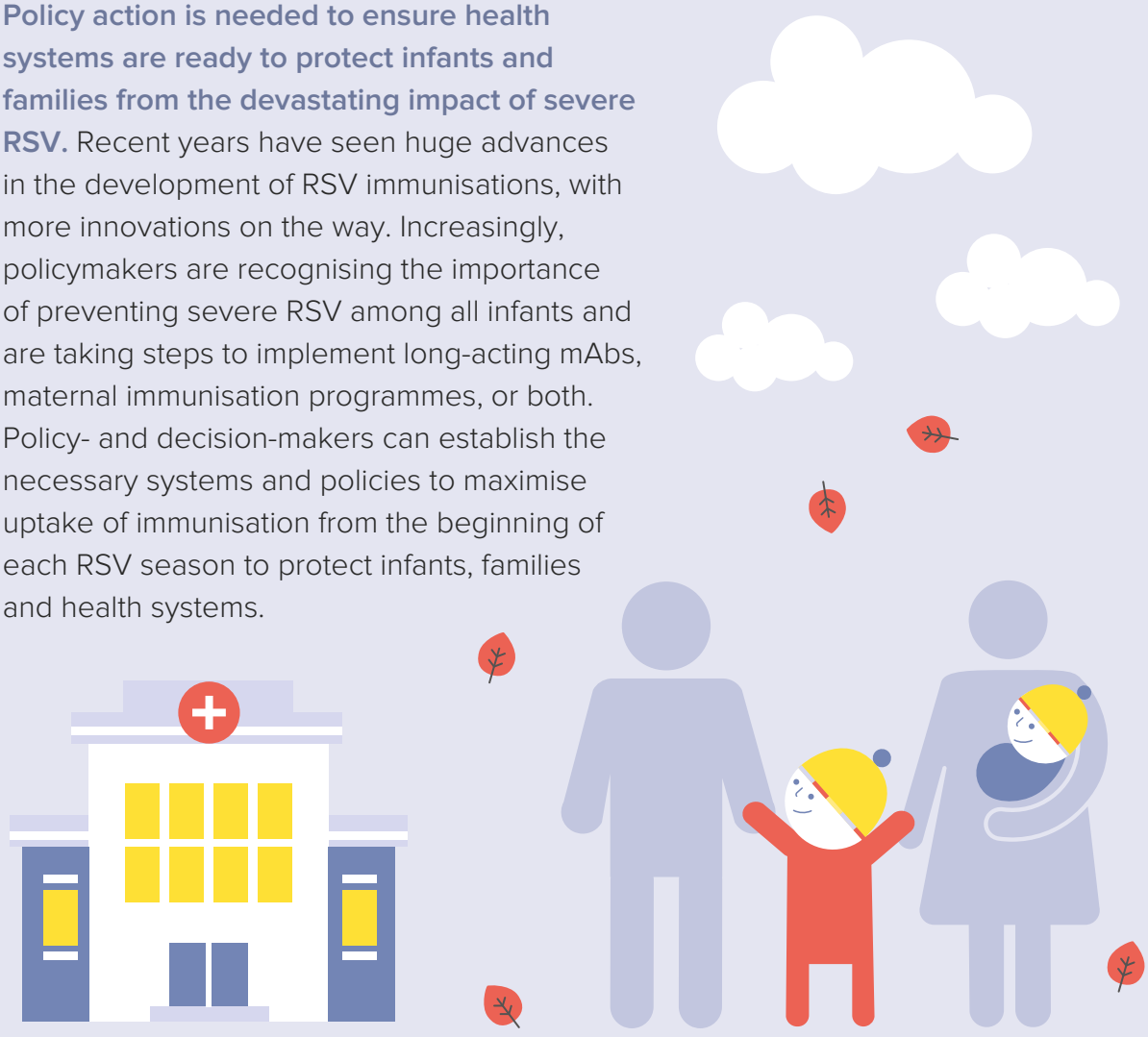
By March 2024, the weekly report showed that 92% of infants born during the season, and 84% of those born before the season, were immunised during the campaign.[166] The study also found that immunisation with the long-acting mAb reduced RSV-related LRTI hospitalisation by 82%.[18]

Policymakers and health system leaders should consider reviewing their immunisation registries and reporting systems to identify improvements that could be made to support more complete reporting. Efforts should be made to standardise data collection and system interoperability to enable data collection to be robust and consistent.[159] Minimum data sets should be implemented to ensure that data are collected on all immunisations for all age groups.

Conclusion

Each winter, RSV causes severe illness among many infants and places immense pressure on hospitals and health systems. While many infants experience relatively mild symptoms, some become very unwell with bronchiolitis or pneumonia and require hospitalisation.[1] Most of these infants are otherwise healthy,[7] highlighting the importance of universal prevention programmes rather than efforts to protect only those at highest risk of severe illness. In addition to the affected infants and their families, health systems struggle under the burden of respiratory illnesses, of which RSV constitutes a significant part.[6 27]

Policy action is needed to ensure health systems are ready to protect infants and families from the devastating impact of severe RSV. Recent years have seen huge advances in the development of RSV immunisations, with more innovations on the way. Increasingly, policymakers are recognising the importance of preventing severe RSV among all infants and are taking steps to implement long-acting mAbs, maternal immunisation programmes, or both. Policy- and decision-makers can establish the necessary systems and policies to maximise uptake of immunisation from the beginning of each RSV season to protect infants, families and health systems.



To support this, policy- and decision-makers should consider the following recommendations:

1.
Governance structures that support timely access to innovative immunisation strategies

- Employ rapid review and access mechanisms to implement RSV immunisation programmes in time for the next season.
- To ensure equitable access, treat RSV immunisation products like vaccines, by assessing them for inclusion in national immunisation programmes and ensuring access in line with other childhood immunisations.

2.
Plans and protocols for the organisation and delivery of RSV immunisation strategies

- Develop clear and detailed implementation plans to reach all infants at the right time. Programmatic plans must be tailored to the local context and may benefit from leveraging existing immunisation infrastructure.
- Estimate the likely demand for RSV immunisation strategies based on available evidence, including from parent and provider surveys and the experience of similar countries.

3.
Awareness of RSV and immunisation strategies among healthcare professionals and the public

- Ensure that all relevant healthcare professionals are fully trained and educated to discuss RSV immunisation options with parents, and to prescribe and administer them.
- Develop public awareness campaigns tailored to the population's knowledge about RSV and attitudes towards immunisation.

4.
Systems for collecting and sharing data on RSV infection and uptake of immunisation strategies

- Implement and support robust data collection systems that provide a clear picture of the spread and impact of RSV, and of the uptake and impact of immunisation.
- Update data systems and policies to allow data sharing between healthcare professionals, so they have the information they need to offer RSV prevention to all infants.

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