

ECDC ASSESSMENT

Rapid scientific advice on protecting infants against respiratory syncytial virus disease for the European 2025/26 winter season

November 2025

Key messages

The 2025/26 season for respiratory diseases is starting in Europe, marked by increased detections of respiratory syncytial virus (RSV) in several countries and rising rates of influenza-like illness infections in primary care settings. In the coming weeks and months, groups who are vulnerable to severe illness from respiratory diseases, particularly infants, are at risk of infection. This document outlines effective ways for European Union and European Economic Area (EU/EEA) countries to mitigate the impact of RSV disease in infants through immunisation interventions. The target audience for this document is policymakers and those working in public health institutes.

RSV among infants in the EU/EEA

- RSV is a common respiratory virus which disproportionately affects newborns and infants, with infants under six months of age being at high risk of experiencing severe infections.
- Severe RSV illness, especially among babies born prematurely or with chronic lung disease, can result in bronchiolitis or pneumonia requiring hospitalisation, and on rare occasions can lead to death.
- During the 2024/2025 winter season, half of the detected RSV infections occurred in children 0–4 years of age. Infants 0–2 months of age accounted for a large proportion of admissions to intensive care units.

Immunisation interventions to protect infants from RSV disease

- Since 2022, the EU has authorised safe and effective RSV immunisation products to prevent RSV disease in infants. These include long-acting monoclonal antibodies (mAbs) for infants and maternal vaccines for pregnant people.
- Twenty-three EU/EEA countries recommend RSV immunisation and 19 have funded long-acting mAbs programmes. Sixteen countries recommend universal long-acting mAbs for all infants and three countries recommend long-acting mAbs for infants at high risk of severe illness.
- Three countries use maternal vaccination exclusively and five countries offer it as an alternative alongside long-acting mAbs.

ECDC advice to strengthen RSV prevention interventions in EU/EEA countries

As the 2025/26 RSV season is starting in Europe, ECDC recommends the following interventions to strengthen the protection of infants against RSV disease:

- Countries should raise awareness in the community and among healthcare providers about the risk of RSV to infants, the risk factors for more severe disease in infants and children, and the availability of immunisation and information on other preventative measures such as maintaining good hygiene and respiratory etiquette.

- Countries making decisions on whether to implement RSV immunisation programmes can learn from the experience of EU countries which have effective infant RSV immunisation programmes (long-acting mAbs, maternal vaccination, or a combination of both) already in place.
- Countries with implemented RSV programmes should prepare, implement or strengthen systems to monitor the effectiveness of immunisation programmes, using surveillance systems and systems that link immunisation data to individual infant health records. Furthermore, continuous monitoring of the safety of RSV immunisation products should be conducted.
- Countries should strengthen surveillance for RSV through integration with established respiratory infection surveillance networks, enabling comprehensive understanding of RSV epidemiology, including RSV disease trends, severity and age distribution.

To support EU/EEA countries, ECDC will continue to provide surveillance guidance, assess emerging evidence, and monitor the effectiveness of RSV immunisation programmes.

Background

Respiratory syncytial virus (RSV) is a common respiratory virus that in most instances causes mild, cold-like symptoms. Infants under six months of age are at risk of being hospitalised with severe illness which in rare cases can lead to death. RSV can also worsen existing medical conditions and cause serious complications that can be life-threatening in children and adults with underlying conditions and in older individuals such as those over 65 years of age. In infants, RSV is a leading cause of bronchiolitis and pneumonia.

As of early November 2025, surveillance data indicate an increase in RSV detections from baseline levels in some EU/EEA countries, particularly among children under five years of age. At this stage, RSV hospitalisations remain low. However, based on previous seasonal trends, RSV-related hospitalisations are expected to rise in the coming weeks. The current increase in RSV case numbers is occurring in parallel with gradually rising seasonal influenza circulation and ongoing SARS-CoV-2 transmission. The simultaneous circulation of respiratory viruses, including RSV, may place additional pressure on primary care providers, emergency services and paediatric hospital capacity [1].

In the last two years, the European Commission has approved immunisation products to prevent RSV in both infants and adults. In 2022, the first RSV long-acting monoclonal antibodies (mAbs) product to protect infants during their first RSV season was authorised, and in 2023, an RSV vaccine was authorised for pregnant people to provide newborns with protection against RSV-associated lower respiratory tract disease (LRTD) through transplacental transfer of RSV-neutralising antibodies.

As RSV starts to be detected at increasing levels in the EU, this document aims to support countries in halting the expected disease impact in infants by:

- Assessing the current epidemiological situation and expected impact in infants based on available historical surveillance and disease burden data to enable healthcare systems preparedness.
- Providing information on the use of long-acting monoclonal antibodies in infants and immunisation of pregnant people based on successful country programmes and data on safety, effectiveness, and impact.
- Proposing ways to strengthen RSV prevention programmes.

Methods

The information provided in this report is based on:

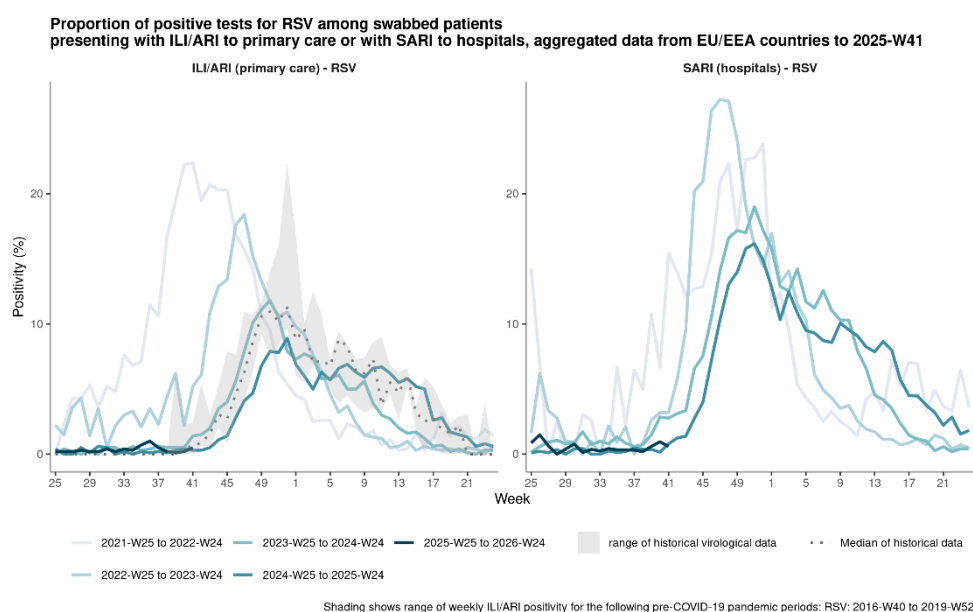
- Data reported to ECDC via [EpiPulse](#) - the European surveillance portal for infectious diseases.
- Evidence from peer-reviewed publications and grey literature.
- Information on RSV immunisation recommendations and implementation collected in October 2025 by ECDC via a survey with the [ECDC NITAG Collaboration](#) Members and from a desk review of relevant EU/EEA country official public health websites on RSV infant immunisation plans.

RSV epidemiology in infants and children in the EU/EEA

RSV seasonality in the EU/EEA

Before the COVID-19 pandemic, RSV activity (based on the proportion of positive tests among influenza-like illness/ acute respiratory infections (ILI/ARI) patients swabbed in primary care surveillance sites) was characterised by regular epidemics between October and April, with peak activity observed between weeks 49-1 (Figure 1, also [2]). In the EU/EEA, this seasonality was disrupted by the pandemic, with a stepwise year on year return to pre-pandemic timing including for season onset and peak. Similar trends have been observed in secondary care surveillance (Figure 1). In 2024/2025, there remained considerable between-country variation in epidemic timing, with a general west – east gradient in onset and peak, and a rather protracted season [3].

Figure 1. Proportion of positive tests for RSV among swabbed patients presenting with ILI/ARI to primary care or with SARI to hospitals, aggregated data from EU/EEA countries to week 41, 2025



Age-specific burden and risk factors for severe disease

Surveillance data indicate that the youngest infants remain at highest risk of hospitalisation and intensive care admission from RSV infection.

In the 2024/2025 winter season (week 40, 2024 to week 20, 2025), over 4 500 RSV detections were reported within ILI/ARI virological surveillance and over 6 000 within severe acute respiratory infections (SARI) surveillance data.

During the past winter season within ILI/ARI virological surveillance, RSV test positivity peaked among infants and children aged 0–4 years at 32% (week 50, 2024 and week 52, 2025) and among adults aged 65 years and over at 13% (week 52, 2024 to week 1, 2025) (see [ERVISS.org](https://www.euro.ecdc.europa.eu/en/eroviss)).

Based on case-based SARI surveillance data submitted to the European Surveillance System from three countries (Belgium, Romania, and Spain) during the 2024/2025 winter season, 3 266 individuals tested positive for RSV. Of these, 51% (n=1 653) were infants and children aged 0–4 years, of whom 12% were admitted to the intensive care units (ICU) and one died. The youngest infants (0–2 months of age) accounted for 10% of all cases but represented 27% of ICU admissions among RSV-positive SARI cases in the 2024/2025 winter season, corresponding to an admission rate of 24% within this group. In comparison, the ICU admission rate among older infants and children (three months to four years of age) was 9%.

Comorbidities were reported for 17% (n=282) of these RSV-positive SARI cases in those aged 0–4 years. Comorbidities tended to be more commonly reported among older infants and children (three months to four years of age) (19% of hospitalised and 24% of ICU-admitted cases) than among the youngest infants (0–2 months of age) (6% of hospitalised and 14% of ICU-admitted cases), which is supported by recent findings for severe RSV cases [4].

This suggests that, among SARI cases, the presence of underlying conditions is a stronger risk factor for severe disease among older infants and children than it is among the youngest infants. Of the 282 cases with comorbidities, 85% had one and 15% had two or more comorbidities reported. Among these cases, the most commonly reported comorbidities were prematurity (41%) and chronic lung disease (36%). Of note, SARI surveillance data are limited by variability in reporting of comorbidities and, as such, the absence of reported comorbidities does not necessarily indicate that a case had no underlying conditions.

Further evidence on the burden of RSV in young children was provided by the Respiratory Syncytial Virus Consortium in Europe (RESCEU) project, which analysed national RSV-associated hospitalisation data collected between 2006 and 2018 across several European countries. Based on regression-derived estimates from Denmark, England, Finland, Norway, the Netherlands, and Scotland, supplemented with additional data from France and Spain, the study estimated an annual average of approximately 250 000 RSV-associated hospitalisations among children aged under five years in 28 EU countries. Around 75% of these hospitalisations occurred in children aged 0–11 months, and 96% in those aged under two years [5]. These results highlight the concentration of severe RSV disease in the first months of life and are consistent with SARI surveillance data for the 2024/2025 season. SARI surveillance also supports countries monitoring severe cases of RSV requiring hospitalisation and analysis of risk factors associated with severe disease.

RSV immunisation

EU authorised immunisation products for the prevention of RSV in infants

There are two RSV immunisation products that have been authorised in the EU over the last three years to provide passive protection to infants from severe RSV disease.

- One long-acting monoclonal antibody product administered directly to neonates and infants (Beyfortus [6]).
- One maternal vaccine to provide protection to infants through transplacental transfer of RSV neutralising antibodies (Abrysvo [7]).

In September 2025, another long-acting monoclonal antibody product administered directly to neonates and infants (Enflonsia [8]) received a positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), who recommended market authorisation to be granted. Authorisation from the European Commission is pending at the time of publication.

Before 2022, the only RSV prevention product authorised for infants was the monoclonal antibody Synagis, which contains the active substance palivizumab. Synagis was authorised in 1999 in the EU and is indicated for the prevention of serious LRTD requiring hospitalisation caused by RSV in children at high risk for RSV disease. It is given once a month when there is a risk of RSV infection in the community with approximately five monthly injections administered over the RSV season [9].

For more detailed information on the authorised use of these RSV immunisation products see Annex 1.

Implementation of infant RSV immunisation programmes in EU/EEA countries

Several EU/EEA countries are making decisions around the introduction of these products into their national immunisation programmes. Factors to consider in national decision-making include:

- the epidemiological context;
- the effectiveness and safety of the different immunisations available;
- the impact and cost-effectiveness of the immunisations;
- ease of implementation, equity considerations and expected acceptance of the different immunisations;
- availability of the monoclonal antibodies and of the vaccines;
- national public health priorities/priorities of the immunisation programme.

As of October 2025, 23 countries have issued recommendations on the use of RSV immunisation aimed at protecting infants.

Specifically, 16 of the 23 EU/EEA countries have implemented funded/reimbursed universal RSV long-acting mAbs programmes for infants, offering them seasonally to every infant entering their first RSV season. Most programmes run from September/October to March/April, with 12 out of 16 countries planning catch-up programmes for infants who were born outside the RSV season and are entering their first RSV season. For three of the 16 countries, a recommendation on the maternal programme has also been issued, however the maternal programme is not funded. Two of the 23 countries are funding mAbs programmes for infants at risk of severe disease exclusively.

Three of the 23 countries have implemented funded maternal RSV vaccination programmes exclusively, with most offering seasonal vaccination from September to early spring. One of the 23 countries has implemented a maternal programme combined with a programme with long-acting mAbs in infants at risk of severe disease. Another of the 23 countries has issued a recommendation for maternal RSV vaccination but the programme is not funded.

Eight of the 16 countries with universal infant long-acting mAbs have also recommended maternal vaccination programmes (for five countries the programme is fully funded), recommending that only one of the two interventions be used (except in instances such as when insufficient time has passed for adequate protection between administration of maternal vaccination and birth). For more detailed information on EU/EEA country recommendations for implementing RSV immunisation programmes for infants please see Annexes 2 and 5.

There are limited data on coverage of the different RSV immunisation products in the EU/EEA. In a systematic review and meta-analysis of studies across different countries reporting uptake of the long-acting mAb nirsevimab, the RSV maternal vaccine and RSV vaccines for older adults, the pooled estimate of nirsevimab uptake for the target population for intervention (infants <6 months old) during the 2023/24 RSV season was 90.1% in Spain [10]. Uptake data from this review for the RSV maternal vaccine and RSV vaccines for older adults came from the US and showed population-level uptake of 30.5% and 18.2%, respectively. In Luxembourg, neonatal figures from maternity wards showed a coverage of 84% for long-acting mAbs during the 2023 season [11]. Ireland reported a nationwide immunisation uptake of 83% among infants in a pilot long-acting mAbs immunisation programme between September 2024 and February 2025 [12]. Maternal vaccination data from a cross sectional survey from France, a country with both strategies operating in parallel for the 2024/25 season, indicated an uptake of 27.2% [13]. Among other European countries, the UK, which implemented a combined strategy, published monthly RSV maternal vaccination coverage during the last season with a gradual increase by month, reaching an overall coverage of 54.7% in March 2025 [14].

Brief evidence overview of infant RSV immunisation products

RSV-specific long-acting mAbs for newborns and infants

Efficacy, safety, effectiveness and impact

Based on clinical trials and post authorisation data, the long-acting mAbs show strong protection against severe disease and RSV-associated hospitalisation in infants, with similar efficacy and effectiveness estimates ranging between 76% and 86%, [15-17].

Studies have also provided real-world data on the significant impact of the nirsevimab immunisation campaign in preventing severe bronchiolitis and hospitalisation for immunised infants. For example, in an end of season analysis from Galicia, Spain, mAbs contributed to reducing RSV-related LRTI hospitalisations by a median of 89.2% (IQR 89.1–91.4) in the overall cohort of infants and by 95.2% (94.8–96.2) in the seasonal cohort of infants [18]. Nirsevimab showed a very good safety profile in clinical trials before and after receiving EMA recommendation for authorisation and there have been no substantial safety concerns in the three months post immunisation [6]. After evaluating the data to date, the duration of protection following administration of mAbs is estimated to be approximately six months [19]. For a more detailed evidence review on the efficacy, safety, effectiveness and impact of RSV long-acting mAbs for protecting infants, see Annex 3.

RSV maternal vaccination

Efficacy, safety and effectiveness

A systematic review and meta-analysis of clinical trials shows that RSV maternal vaccination reduced severe RSV-associated cases in infants with a vaccine efficacy of 74% (95% CI 44–88) within three months of birth. Maternal vaccination also reduced hospitalisation due to RSV disease in infants with a vaccine efficacy of 54% (95% CI 27–71) [20]. Post authorisation studies have so far found similar estimates of effectiveness against severe disease in infants following maternal vaccination, as was found in the clinical trials. In Argentina, vaccine effectiveness against RSV-associated LRTD leading to infant hospitalisation was 78.6% (CI 62.1–87.9) from birth to three months and 76.9% (95% CI 45.0–90.3) from birth to age six months [21]. Real-world estimates of RSV maternal vaccination in preventing infant hospitalisation in the UK was 72% (95% CI 48–85) for infants whose mothers were vaccinated more than 14 days before delivery [22].

The clinical trials found a slight, though not statistically significant, numerical imbalance in premature births between pregnant people who were vaccinated and not vaccinated, however a post-authorisation observational study conducted during the 2023–2024 RSV season showed no increased risk of preterm births or adverse perinatal outcomes associated with Abrysvo [23]. Further monitoring of safety aspects is continuing. At present, due to lack of data, the need for revaccination with subsequent pregnancies has not been established [7]. For a more detailed evidence review on the efficacy, safety and effectiveness of maternal RSV vaccination see Annex 3.

ECDC multi-country RSV vaccine effectiveness monitoring in the EU/EEA

ECDC continuously monitors the effectiveness of passive and active immunisation against RSV infection in infants within the [vaccine effectiveness, burden and impact studies \(VEBIS\) project](#) under the umbrella of the [Vaccine Monitoring Platform](#) (a platform aiming to generate real-world evidence on the safety and effectiveness of vaccines in EU/EEA countries jointly established and coordinated by ECDC and EMA). A pilot case-control study using the test-negative design was implemented in the 2024-25 season. The study was an EU/EEA multi-country hospital-based study in infants/children aged six months or younger and 24 months or younger, that received immunisation through maternal vaccination or the administration of mAb (depending on recommendations at the study site/country level), respectively. It included 791 cases and 1 410 controls from three countries. The overall immunisation effectiveness was 79% (95% CI 58% to 89%). The results showed that effectiveness of RSV mAbs immunisation were in the same range as estimates that have been published globally [24]. The study is planned to continue for the 2025-26 season and to include additional countries, for a total of seven planned countries as of October 2025.

ECDC advice to strengthen RSV prevention interventions for infants in EU/EEA countries

RSV continues to pose a significant disease burden across the EU, particularly among infants. Available evidence from both clinical trials and post-authorisation studies shows that both maternal RSV vaccines and long-acting RSV mAbs are safe and provide strong protection against severe disease in infants. Continued monitoring and assessment of new evidence as well as of context-specific factors are needed to inform decisions. At this stage, there is limited evidence to conclude what is the most effective and cost-effective strategy, especially as these aspects are highly context specific. In the light of available evidence, and in line with the May 2025 World Health Organization Position paper on immunisation to protect infants against RSV disease [25], and following on the experience of several EU/EEA countries, ECDC recommends strengthening the following interventions aimed at protecting infants from RSV, as the 2025/26 RSV season starts.

RSV immunisation strategies

Since the 2023/24 RSV season, a number of EU countries have rolled out immunisation programmes to protect infants against RSV disease. Building on these successful programmes, countries planning similar programmes may consider the following immunisation strategies.

Table 3. RSV infant immunisation programmes for protecting infants against RSV disease

RSV infant immunisation programmes	Strategies for implementation based on the specific country context
One dose of long-acting mAb administered to all newborn and infants during their first RSV season	<ul style="list-style-type: none"> There is limited evidence to advise for a seasonal programme vs. year-round programme. All countries who have implemented this strategy have opted for seasonal programmes, with the mAbs administered soon after birth. Catch-up programme for infants who are born outside of the RSV season but entering their first RSV season is implemented in majority of EU countries (catch-up for the cohort of infants born between approx. April and Sept – depending on the country's RSV seasonality).
One dose of long-acting mAb administered to newborn infants with specific risk-factors for severe disease	<ul style="list-style-type: none"> Administering to only groups at high risk of severe disease, based on underlying conditions (this could be a convenient approach when universal immunisation is not feasible). Underlying risk factors can include for example, prematurity, lung disease of prematurity and serious heart disease. Immunisation of children at risk of severe disease up to 24 months of age through their second RSV season.
One dose of vaccination administered to pregnant people to their protect newborns and infants from RSV disease in their first months of life	<ul style="list-style-type: none"> Maternal vaccination is authorised as a single dose in weeks 24 to 36 of pregnancy, some countries are opting to recommend administering in later weeks. (There is limited evidence to advise for a seasonal programme vs. year-round programme). At this stage the need for revaccination with subsequent pregnancies has not been established.
Implementation of a combined immunisation programme of universal long-acting mAb and maternal vaccination	<ul style="list-style-type: none"> The pregnant individual chooses one strategy, either the option of a one-dose of long-acting monoclonal antibodies for their infant or a one-dose vaccination for themselves. mAbs may also be offered if not enough time has passed from maternal vaccination and birth (less than two weeks), and/or the baby has high-risk factors for severe disease.

Monitor immunisation coverage

Countries should monitor the immunisation coverage of maternal vaccination and/or immunisation of infants with long-acting mAbs. Immunisation uptake indicators will provide information about the performance and efficiency of the immunisation programme and its capability of reaching most of the key population groups. In addition, they will help inform how equitable access to immunisation products is and what the level of acceptance is. Data collected at the most local geographical level and in specific population groups will allow areas with low coverage and which have pockets of individuals susceptible to acquiring the infection to have specific interventions tailored to their needs. If uptake does not meet expected levels, additional strategies or promotional efforts may be needed to reach specific groups.

Monitoring doses of long-acting mAbs immunisation administered may fall into the same recording system as for other infant vaccination (immunisation information system, other administrative immunisation reporting system) or in a separate system. In the latter case, additional efforts to link data or the assessment of other systems might be needed. Countries may also use other tools and methods (e.g. immunisation coverage surveys).

Immunisation coverage indicators require a clear definition of the numerator and the denominator. The denominator is the target group for immunisation (e.g. number of live births, number of pregnant people reaching the target week of pregnancy for vaccination) all year round or during the target season. The numerator is the number of infants and pregnant people immunised during the same period. For countries that have a maternal vaccination programme but would like to report the immunisation status of the infant, systems should allow good data linkage between the immunisation status of mothers and their infant. For countries having different immunisation strategies in place, a coverage indicator summarising both strategies could be produced.

Perform post-marketing studies on the impact, effectiveness and safety of RSV immunisations

Countries should prepare, implement or strengthen systems to monitor the effectiveness of immunisation programmes, using surveillance systems as well as systems that enable linking immunisation data to individual infant health records. Furthermore, continuous monitoring of the safety of RSV immunisation products should be conducted.

Ensure RSV surveillance systems are robust

Specific surveillance objectives for RSV are:

- To monitor potential changes in RSV epidemiology in different age groups and settings.
- To monitor co-circulating respiratory viruses through integrated surveillance, as changes in RSV prevalence due to immunisation may influence the circulation patterns and epidemiology of other respiratory viruses in infants [26].
- To consider performing genetic and phenotypic characterisation of circulating RSV strains to detect mutations that may lead to antibody escape, impacting both vaccine effectiveness and the clinical efficacy of monoclonal antibodies.
- To assess the burden of RSV disease across age groups over time.
- To monitor risk factors for severe illness. This could be particularly important if initiation of a priority-based approach is planned, but it is relevant in all countries as current recommendations may need to be updated in the future.
- To quantify the expected infants at risk of severe RSV to estimate the demand for mAbs.

Increase immunisation acceptance through communication efforts

Risk communication activities should highlight that RSV is a common virus that circulates throughout the year, with peaks during autumn and winter. They should raise awareness about the risk of RSV for infants, the risk factors for more severe disease in infants and children, the availability of immunisation and the importance of respiratory etiquette. A [factsheet](#) for the general public, including information on the disease, symptoms and prevention is available in the European Vaccination Information Portal in all EU/EEA languages.

Due to wider circulation during the winter, communication activities on RSV prevention can be integrated into messaging and campaigns on staying healthy during the winter season, highlighting the importance of immunisation against respiratory viruses for groups at risk of severe disease as per national recommendations.

Understanding the factors that can act as facilitators or barriers for acceptance of RSV immunisation strategies when these are implemented (infant immunisation and vaccination for pregnant people) is key for promoting uptake, including increasing awareness of the effective means for prevention among healthcare professionals as they play a key role in providing recommendations to patients/caregivers. Operational tools provided in an ECDC report on the 'Tools and methods for promoting vaccination acceptance and uptake: a social and behavioural science approach' (including a survey tool) can support countries in the diagnosis of barriers and facilitators, and help in the design of tailored interventions to improve acceptance and uptake of preventive strategies [27]. The report is available in all EU/EEA languages.

Evidence knowledge gaps

As the infant RSV immunisation products have been recently authorised in the EU, there continues to be various areas of research required to increase the evidence and knowledge on various key questions, such as:

- The duration of immunity and protection of mAbs and RSV vaccines (i.e. if early-immunised infants are protected throughout the RSV season and if there is a need for revaccination in subsequent pregnancies).
- Any difference in vaccine effectiveness by RSV type.
- The effectiveness of RSV immunisation products by specific groups of infants and older children at high risk of severe disease.
- Further assessment of the cost-effectiveness of RSV immunisation programs in different healthcare settings and populations.

ECDC will continue to monitor the evolving evidence on immunisation products to prevent severe RSV in infants. See Annex 5 for details on ECDC future activities and plans in this area.

Annex 1. Immunisation products for the prevention of RSV disease in infants in the EU

Table 1. Immunisation products for the prevention of RSV disease in infants in the EU

Immunisation product	Manufacturer	Product type/platform	Summary of indication and posology	Date of authorisation
Long-acting monoclonal antibody for infants and children				
Beyfortus [6]	AstraZeneca/Sanofi	Long-acting monoclonal antibody with active substance nirsevimab	Prevention of RSV lower respiratory tract disease in: <ul style="list-style-type: none"> - Neonates and infants during their first RSV season. The recommended dose is a single dose. Beyfortus should be administered from birth for infants born during the RSV season. - Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. The recommended dose is a single dose. Beyfortus should be administered ideally prior to the start of the second RSV season. 	31 October 2022
Enflonsia [8]	Merck Sharp & Dohme B.V	Long-acting monoclonal antibody with active substance clesrovimab	Prevention of RSV lower respiratory tract disease in: <ul style="list-style-type: none"> - Neonates and infants during their first RSV season 	Not authorised by the EC at the time of publication of this document but has been recommended for authorisation by EMA's CHMP on 18 September 2025.
Monoclonal antibody for infants and children who are at high risk for disease				
Synagis [9]	AstraZeneca AB	Monoclonal antibody with active substance palivizumab	Prevention of serious lower-respiratory-tract disease requiring hospitalisation in children at high risk for RSV disease: <ul style="list-style-type: none"> - Children born at 35 weeks of gestation or less and less than six months of age at the onset of the RSV season. - Children less than two years of age and requiring treatment for bronchopulmonary dysplasia within the last six months. - Children less than two years of age and with haemodynamically significant congenital heart disease. <p>Synagis is given once a month when there is a risk of RSV infection in the community. Children generally receive a total of five monthly injections</p>	13 August 1999
Maternal vaccination				
Abrysvo [7]	Pfizer	RSV pre-fusion F protein-based vaccine (bivalent, recombinant)	Passive protection against lower respiratory tract disease caused by RSV in infants from birth through 6 months of age following maternal immunisation during pregnancy. <ul style="list-style-type: none"> - A single dose should be administered between weeks 24 and 36 of gestation. - The need for revaccination with subsequent pregnancies has not been established. <p>Active immunisation of individuals 18 years of age and older for the prevention of lower respiratory tract disease caused by RSV. A single dose should be administered.</p>	23 August 2023*

* An extension to the indication to extend the use of Abrysvo to adults from 18 years of age authorised by EC on 1 April 2025. On 23 August 2023 Abrysvo was authorised for those 60 years of age and older.

Annex 2. Status of implementation of fully funded infant RSV immunisation programmes in EU/EEA countries - 2025/2026 season

RSV long-acting mAbs fully funded/reimbursed immunisation programme

Based on a desk review and a survey with countries in 2024 and 2025, 16 EU/EEA countries (Austria, Belgium, Cyprus, Czechia, Finland, France, Germany, Greece, Iceland, Ireland, Liechtenstein, Luxembourg, the Netherlands, Portugal, Spain and Sweden) have included and implemented fully funded/reimbursed universal RSV long-acting mAbs infant immunisation programmes in the 2025/26 season, with all offering them seasonally to every infant. Three additional countries (Denmark, Latvia and Lithuania) have implemented funded long-acting mAbs programmes only for infants at increased risk of serious RSV disease. The timing for newborn RSV season programmes will generally run from September/October through to January, February, March or April. Twelve of the countries with funded programmes also plan to have a catch-up programme in place, mostly for those infants entering their first RSV season but who were born outside the RSV seasonal immunisation campaign (Belgium, Cyprus, Czechia, Finland, Germany, Iceland, Ireland, Latvia, Liechtenstein, Luxembourg, the Netherlands and Portugal).

RSV fully funded/reimbursed maternal vaccination programme

For RSV vaccination programmes for pregnant people, nine countries (Belgium, Cyprus, Denmark, France, Greece, Luxembourg, Poland, Romania and Slovenia) have recommended and implemented fully funded one-dose programmes. Four countries (Austria, Bulgaria, Czechia and Liechtenstein) have recommended but not funded programmes; three of these countries have RSV mAb funded programme. Belgium, Cyprus, Czechia, Denmark, France, Greece, Liechtenstein, Luxembourg and Poland, will have seasonal programmes, whilst Slovenia will have it year-round for now, and Romania is still under discussion. The timing of these programmes typically starts in September and runs until January, February, or March. The recommended gestational timing of vaccination during pregnancy differs between the countries, with vaccination offered at 24–36 weeks in Slovenia and Poland, 28–36 weeks in Belgium, and 32–36 weeks in Cyprus, Czechia, Denmark, France, Greece, Liechtenstein and Luxembourg.

Combined fully funded/reimbursed programmes of RSV long-acting mAbs and maternal vaccination

There are five EU/EEA countries who have introduced both mAbs for infants and vaccination for pregnant people to protect their infants (Belgium, Cyprus, France, Greece, Luxembourg). Pregnant people are given the choice of either taking the vaccine themselves or choosing instead for their newborn infant to receive the mAb after birth. However, countries did state that in certain circumstances mAbs may be considered for infants born to mothers that have already received maternal vaccination, such as when an infant is at higher risk of RSV infection disease (if born prematurely and/or not enough time has passed following maternal vaccination for complete transplacental transfer of maternal immunoglobulin G (IgG) before birth (at least 14 days following vaccination)).

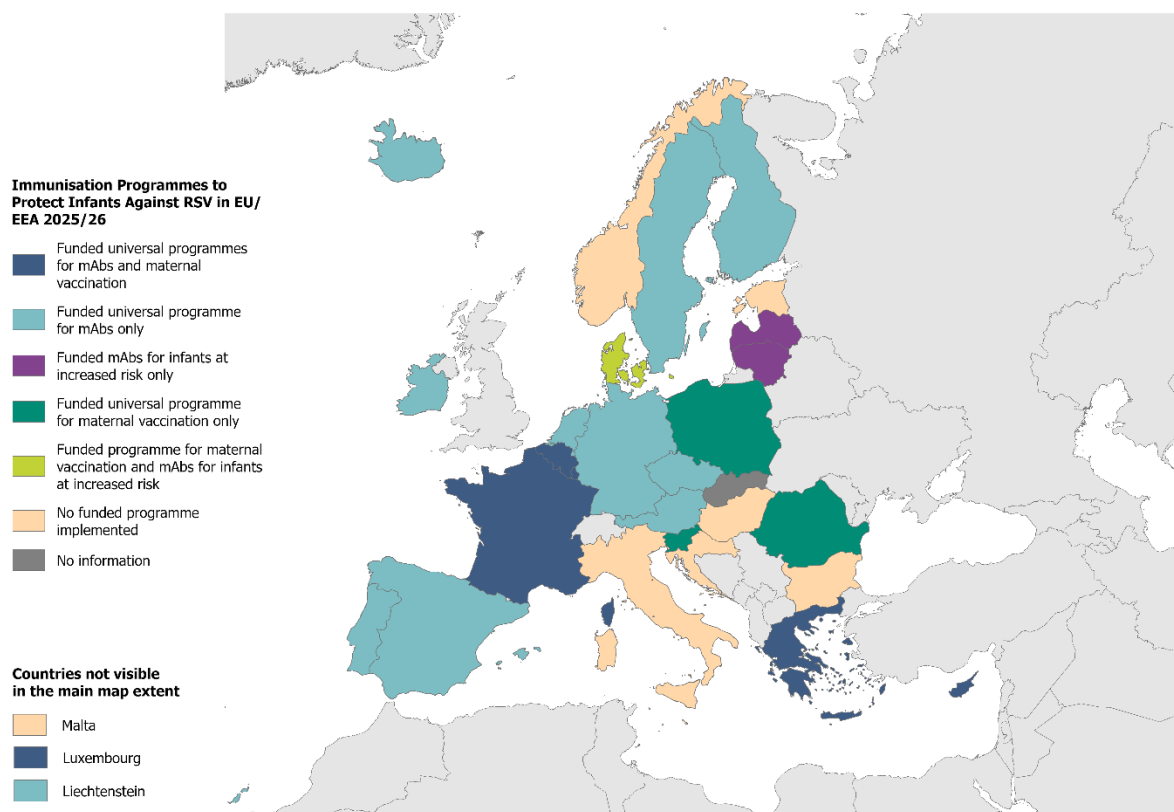
Table 2. Fully funded/reimbursed infant RSV immunisation programmes in EU/EEA countries 2025/2026 season (N: 30)

Fully funded/reimbursed infant RSV immunisation implemented programmes	Countries	N
Combined universal RSV long-acting mAbs and maternal vaccination programme RSV long-acting mAbs and maternal vaccination programme	BE, CY, FR, GR, LU	5
RSV long-acting mAbs universal infant programme exclusively	AT, CZ, FI, DE, IS, IE, LI, NL, PT, ES, SE	11
RSV long-acting mAbs for at-risk infants programme exclusively	LV, LT	2
RSV maternal vaccination programme exclusively	PL, RO, SI	3
RSV long-acting mAbs for at-risk infants and maternal vaccination programme implemented	DK	1
No funded programme for either long-acting mAbs or maternal vaccination implemented	BG, HR, EE, HU, IT, MT, NO	7
No information*	SK	1

***Note:** Information for Slovakia was not available through the survey nor identified during the desk review.

Notes

- Austria recommends maternal vaccination (not funded), for pregnant people if the due date is between October and March. If the due date is outside the RSV season (between April and September), mAbs is recommended.
- Bulgaria has recommended maternal vaccination only but not implemented a funded programme.
- Czechia recommends maternal vaccination but is not funded.
- Denmark vaccination programme runs from May to January (with due dates from July to March), although in 2025 it will run from October since it was only recently recommended.
- In Italy the RSV immunisation strategy at national level is under discussion.
- Latvia has an mAbs catch up programme only for infants at high risk or preterm.
- Liechtenstein recommends maternal vaccination but has a co-payment funded programme.
- In Norway the RSV immunisation strategy at national level is under discussion
- In Portugal, the fully funded RSV immunisation programme with mAbs includes all the infants born between 1 June 2025 and 31 March 2026.
- Spain has assessed the recommendation for maternal vaccination, and it was recommended that, given the results of the first campaign, the best strategy at this moment in their country is immunisation with mAbs in the infant population.
- For Germany, Luxembourg, and Slovakia, the information was obtained through a desk review.

Figure 2. Implementation of RSV immunisation programmes to protect infants in EU/EEA countries for the 2025-26 season

Map produced on: 22 Oct 2025. Administrative boundaries: © EuroGeographics © UN-FAO © Turkitat. The boundaries and names shown on this map do not imply official endorsement or acceptance by the European Union.

Annex 3. RSV immunisation in infants – brief evidence review

RSV-specific monoclonal antibodies for newborns and infants

Efficacy, safety and effectiveness

Based on clinical trials [15] nirsevimab demonstrated high efficacy of 79.5% (CI: 65.9 to 87.7) against medically attended RSV associated acute respiratory illness and 77.3% (50.3 to 89.7) efficacy against RSV associated hospitalisation in infants (using pooled analysis from both trials). Another trial conducted in conditions that approximated real-world settings across Europe, which included Germany, France and the UK, found high nirsevimab efficacy of 83.2% (CI: 67.8 to 92.0) against RSV-associated lower respiratory tract infection (LRTI) hospitalisation and found an efficacy of 75.7% (CI: 32.8 to 92.9) against very severe RSV-associated LRTI [16]. Nirsevimab showed a very good safety profile in clinical trials before and after receiving EMA recommendation for authorisation and there have been no substantial safety concerns in the three months post immunisation [16,28-30]. Long-term safety continues to be monitored.

There are now also real-world data available, showing strong effectiveness of nirsevimab against different outcomes. Similar to the results of efficacy shown through the clinical trials, a recent systematic review and meta-analysis on the real-world effectiveness of nirsevimab against RSV disease in infants which included a pooled analysis with 28 studies from five countries (France, Italy, Luxembourg, Spain and the United States) found that nirsevimab significantly reduced the risk of RSV related hospitalisation with a vaccine effectiveness estimate of 86% (CI 80% to 89%) [17].

Duration of protection

Based on clinical and pharmacokinetic data from the trials, the duration of protection of nirsevimab was estimated to be at least five months. A recent study looking at the 180-day endpoint analysis from a phase IIIb RCT of nirsevimab (HARMONIE) found that protection offered by nirsevimab was 82.7% (CI: 67.8 to 91.5%) against hospitalisation for RSV-associated LRTI for up to six months post-dosing [19]).

Overall impact

There are some EU countries, including Luxembourg, Spain, France and Italy, who have also provided real-world data on the significant impact of the nirsevimab immunisation campaign in preventing severe bronchiolitis and hospitalisation for immunised infants [11,31-34]. A study from Spain showed that for those infants in the first two weeks of life, nirsevimab prevented 78.1% (CI: 73.3 to 82.0) of hospitalisations among all children born during the campaign and catch-up immunisation prevented 67.8% (CI: 62.8 to 72.2) of hospitalisations for RSV infection among children born between 1 April 2023 and the onset of the campaign (the campaign started generally from 1 October) [35]. In an end of season analysis from Galicia, Spain, the study investigators found that nirsevimab contributed to reducing RSV-related LRTI hospitalisations in Galicia by a median of 89.2% (IQR 89.1 to 91.4) in the overall cohort and by 95.2% (94.8 to 96.2) in the seasonal cohort [18].

Maternal vaccination

Efficacy, safety and effectiveness

A systematic review and meta-analysis on the efficacy and safety of RSV maternal vaccination found that the vaccine reduced medically attended RSV-associated LRTI with a vaccine efficacy of 54% (CI: 28 to 71) (high certainty of evidence) and severe cases with a vaccine efficacy of 74% (high certainty of evidence) in infants within three months after birth. It also reduced hospitalisation due to RSV disease in infants with a vaccine efficacy of 54% (CI: 27 to 71) (high certainty of evidence) [20]. The systematic review also found that the maternal RSV vaccine is likely to have little to no difference in severe adverse events in both infants and mothers. However, earlier clinical trials showed a slight, though not statistically significant, numerical imbalance in premature births between those who were vaccinated and not vaccinated. Although data was insufficient to establish or exclude a causal relationship between preterm birth and Abrysvo, the US Food and Drug Administration (FDA) added in the prescribing information to administer Abrysvo in pregnant individuals at 32 through 36 weeks gestational age [36]. Based on this finding, a recent post-authorisation observational study was conducted during the 2023–2024 RSV season and showed no increased risk of preterm births or adverse perinatal outcomes associated with Abrysvo [23].

Post authorisation studies on RSV maternal vaccine effectiveness for infant outcomes are still limited at this stage, however recently published studies from Argentina [21,37] and the UK [22] have found similar strong estimates of effectiveness against severe disease in infants following maternal vaccination as was found in the clinical trials. In one study in Argentina for the 2024 season, vaccine effectiveness against RSV-associated LRTD leading to infant hospitalisation was 78·6% (CI 62·1 to 87·9) from birth to three months of age and 71·3% (CI 53·3 to 82·3) from birth to six months of age. Vaccine effectiveness against RSV-associated severe LRTD leading to hospitalisation was 76·9% (CI 45·0 to 90·3) from birth to six months of age [21]. Real-world estimates of RSV maternal vaccination in preventing infant hospitalisation in the UK was 58% (CI 28 to 75) for infants whose mothers were vaccinated at any time before delivery and 72% (CI 48 to 85) for infants whose mothers were vaccinated more than 14 days before delivery [22].

Duration of protection

The maternal vaccination induces maternal antibodies that cross the placenta and provide the neonate the most protection from birth until six months of age when given at least 14 days before birth [7,21]. At present, due to lack of data, the need for revaccination with subsequent pregnancies has not been established [7].

Annex 5. ECDC current and future activities to support EU/EEA countries with RSV infant immunisation decision-making

ECDC is committed to monitoring the evolving evidence on immunisation products to prevent severe RSV in infants and plans the following:

- Continuous RSV epidemiology monitoring in EU/EEA countries with summaries provided through the ECDC European Respiratory Virus Surveillance Summary ([ERVISS](#)) platform. The revised [list of diseases covered by EU surveillance list](#), which is planned to include RSV as a disease to be notified through indicator-based surveillance, is currently under consideration. This would provide more granular data to support the understanding of the epidemiology at EU level.
- Monitoring the efficacy, effectiveness and safety of RSV vaccines through updates to a systematic review and meta-analysis [20,38] with another update planned for publication on the ECDC website in early 2026.
- [A systematic review of the efficacy, safety and effectiveness of RSV mAbs](#) that have been authorised in the EU or have demonstrated efficacy and safety in completed phase three clinical trials for preventing RSV infections in infants and young children (1–24 months old) planned for publication on the ECDC website in early 2026
- A rapid systematic review is ongoing on the population level impact of RSV immunisation products in infants and older adults, plan for publication on the ECDC website in early 2026.
- Monitoring and reporting of RSV immunisation effectiveness estimates (of both maternal vaccines and mAbs) through the [ECDC VEBIS project](#).
- Assessment of priority questions including on RSV immunisation to be answered through generation of new evidence as part of the activities of the [Vaccine Monitoring Platform](#).
- Modelling various scenarios of RSV infant immunisation strategies through ECDC [RSV RespiCompass 2025/2026 Scenarios](#) with results available in 2026.
- Continue to update the ECDC [vaccine scheduler](#) tool with RSV vaccination recommendations and implemented programmes in EU/EEA countries.
- Monitoring of RSV immunisation recommendations, implementation of programmes and coverage in EU/EEA countries.

Annex 6. Links to country RSV infant immunisation recommendations

Country	Recommendation for infant RSV long-acting mAbs	Recommendation for RSV maternal vaccination
Austria	Vaccination plan Austria	N/A
Belgium	Belgium RSV Information	Preventive strategies against RSV disease in children
Bulgaria	N/A	N/A
Croatia	N/A	N/A
Cyprus	Vaccination Plan Against Respiratory Viruses and Introduction of Monoclonal Antibody in the Health System of Cyprus for Autumn – Winter, 2025-2026	Vaccination Plan Against Respiratory Viruses and Introduction of Monoclonal Antibody in the Health System of Cyprus for Autumn – Winter, 2025-2026
Czechia	Recommendation of the Czech Society of Vaccinology of the Czech Medical Society JEP on vaccination against infections caused by respiratory syncytial virus in adults	Recommendations of the Czech Vaccinological Society for Vaccination in Pregnancy
Denmark	Denmark RSV immunisation for infants	RSV vaccination for pregnant women
Estonia	Recommendations of the meeting of the Expert Committee on Immunoprophylaxis	Recommendations of the meeting of the Expert Committee on Immunoprophylaxis
Finland	National recommendation (in Finnish) English summary of above: Recommendation updates (in Finnish)	Announcement of start of evaluation
France	Vaccine recommendation against RSV infections in pregnant women	Vaccine recommendation against RSV infections in pregnant women
Germany	Recommendations of the Standing Committee on Vaccination at the Robert Koch Institute 2025	Recommendations of the Standing Committee on Vaccination at the Robert Koch Institute 2025
Greece	Greek Ministry of Health	Greek Ministry of Health
Hungary	N/A	N/A
Iceland	Iceland Directorate of Health	Iceland Directorate of Health
Ireland	Ireland RSV immunisation for babies	Immunisation Guidelines for Ireland
Italy	N/A	N/A
Latvia	Latvia Ministry of Health	N/A
Liechtenstein	Vaccination Schedule 2025	Recommendations for vaccination and immunization against respiratory syncytial virus (RSV)
Lithuania	National Immunization Programme	N/A
Luxembourg	Respiratory syncytial virus (RSV) infection - Health Portal - Luxembourg	Respiratory syncytial virus (RSV) infection - Health Portal - Luxembourg
Malta	N/A	N/A
Netherlands	Immunization against RSV in the first year of life	N/A
Norway	N/A	N/A
Poland	Prevention of RSV infections	Announcement of the Minister of Health of 17 September 2025 on the list of reimbursed medicines, foodstuffs for special nutritional purposes and medical devices as of 1 October 2025
Portugal	Seasonal Immunization Campaign against Respiratory Syncytial Virus (RSV) in Paediatric Age: autumn-winter 2025-2026	N/A
Romania	N/A	N/A
Slovakia	N/A	N/A
Slovenia	N/A	Vaccination of pregnant women against RSV
Spain	Recomendaciones de inmunización pasiva para la prevención de enfermedad grave por VRS en la población infantil	N/A
Sweden	Questions and answers about prophylaxis against RSV infection for children	N/A

*N/A - not available

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