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Respiratory Syncytial Virus (RSV) Immunisation Pathfinder Programme 2024-2025

Evaluation – Technical Report

Version date: 17th December 2025

Report written by: **Dr Michael Hanrahan**, Specialist Registrar in Public Health Medicine

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Senior Editor: **Dr Éamonn O'Moore**, Director of National Health Protection

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National Clinical Programme for Paediatrics and Neonatology

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University Maternity Hospital, Limerick

Cavan General Hospital

Midlands Regional Hospital, Portlaoise

Wexford General Hospital

Portiuncula University Hospital

University Hospital Waterford

Letterkenny University Hospital

Mayo University Hospital

Sligo University Hospital

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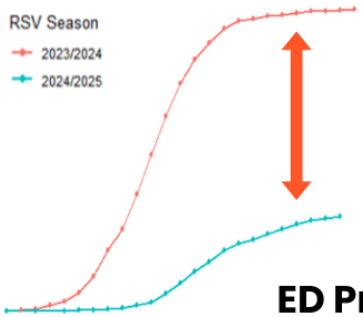
22,444
Infants immunised

UPTAKE
83%

Nirsevimab, a monoclonal antibody, was offered to all children born from 01/09/2024 to 28/02/2025 in all maternity hospitals in Ireland. In accordance with national recommendations, Children's Health Ireland and TCP Homecare also offered nirsevimab to high-risk infants

RSV IMMUNISATION PATHFINDER PROGRAMME 2024/25



IMPACT

Infants born Sept-Feb 2024/25 compared to 2023/24

Total cases -65%
ED Presentations -57%
Hospitalisations -76%
ICU Admissions -65%

AVERTED OUTCOMES

Estimated
433 - 532
Hospitalisations Averted

Est. **440** **Emergency Department Presentations Averted**

Est. **79** **ICU Admissions Averted**

POSITIVE FEEDBACK

Parents described the programme as a **"good measure to protect babies"**. Paediatricians described it as a **"game changer"** and commented that they saw fewer kids in A&E, and the ones they did see **"seemed to be turning around quicker and needed less support"**.

TRANSFERS

Neonatal transfers **-86%**
Paediatric transfers **- 74%**

Huge thank you to all the staff, especially midwives, who delivered this successful programme!

Contents

Abbreviations

ADOM	Assistant Director of Midwifery
CAR	Contract Approval Request
CCO	Chief Clinical Officer
CHI	Children's Health Ireland
CI	Confidence Interval
CIDR	Computerised Infectious Disease Reporting System
CMO	Chief Medical Officer
CSO	Central Statistics Office
DoH	Department of Health
DOM	Director of Midwifery
DPIA	Data Protection Impact Assessment
ED	Emergency Department
EMA	European Medicines Agency
EU	European Union
FAQ	Frequently Asked Questions
GDPR	General Data Protection Regulations
GP	General Practitioner
HERA	Health Emergency Preparedness and Response Authority
HIQA	Health Information and Quality Authority
HP	Hasse-Pratschke
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
HTA	Health Technology Assessment
IC	Immunisation coverage
ICU	Intensive Care Unit
IE	Immunisation effectiveness
IQR	Interquartile range
LOS	Length of stay
MN-CMS	Maternity & Newborn Clinical Management System
NAAT	Nucleic acid amplification testing
NAE	Number of averted events
NGO	Non-Governmental Organisation
NIAC	National Immunisation Advisory Committee
NICU	Neonatal Intensive Care Unit
NHPO	National Health Protection Office
NSIO	National Social Inclusion Office
NWIHP	National Women & Infant Health Programme
OVD	Operational vaginal delivery
PICU	Paediatric Intensive Care Unit
RCPI	Royal College of Physicians Ireland
RDPH	Regional Director of Public Health
REO	Regional Executive Officer
RSV	Respiratory Syncytial Virus
SD	Standard deviation
SOP	Standard operating procedure
SVD	Spontaneous vaginal delivery
TCP	Temperature Controlled Pharmaceuticals
USA	United States of America

1

Introduction

Introduction

RSV

Respiratory Syncytial Virus (RSV) is a very common and highly contagious winter virus and is a major cause of respiratory tract infections. It has the most severe impacts on the very young, older people, and people who are immunocompromised.[1] During the 2023/2024 RSV season, 1,431 children aged <1 year were hospitalised with RSV. This equates to almost 2.5% of all children aged <1 year in Ireland. Of those, 118 children aged <1 year were admitted to Intensive Care Units (ICU) due to RSV. Children <1 year accounted for 78% of all RSV-related ICU cases in 2023/2024. No children died from RSV in 2023/2024.

What is Respiratory Syncytial Virus (RSV)?

Incidence

RSV is ubiquitous, affecting nearly all children by the age of two. It typically spreads during the autumn and winter months, with peak infections usually occurring in December and January. Without immunisation, 1-2 out of every 100 children younger than 6 months with RSV infection may need to be hospitalised.

Transmission

The virus spreads through respiratory droplets when an infected person coughs or sneezes. It can survive on surfaces for several hours, facilitating transmission through contact with contaminated objects.

Clinical Presentation

- Cold-like symptoms: runny nose, coughing, sneezing, fever
- Wheezing
- Decreased appetite and irritability
- May progress to more severe symptoms requiring hospitalisation – bronchiolitis, pneumonia, respiratory distress, death

High Risk Groups

- Infants under 6 months
- Premature infants
- Children under 2 years with congenital heart or lung disease
- Older adults, particularly those with comorbidities or who are immunocompromised

Diagnosis

Diagnosis is typically based on clinical presentation and can be confirmed through various methods, primarily nucleic acid amplification testing (NAAT) using a multiplex platform.

Treatment

Treatment is generally supportive, focusing on symptom management, as there is no specific antiviral treatment for RSV.

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Nirsevimab

Nirsevimab (Beyfortus ®) is a monoclonal antibody which provides passive immunity and immediate protection against RSV, lasting for approximately 150 days.[2,3] It was authorised by the European Medicines Agency (EMA) in 2022. In October 2023, the National Immunisation Advisory Committee (NIAC) recommended the passive immunisation of all infants against RSV during their first RSV season.[4] International evidence shows that nirsevimab is over 80% effective in preventing RSV-associated lower respiratory tract infections and has a very favourable safety profile.[2,3] Nirsevimab also replaces an existing monoclonal antibody, palivizumab (Synagis ®), which was previously offered to infants identified as high-risk of severe RSV, because nirsevimab can be given as a single dose for season-long protection, while palivizumab required five monthly injections. A number of other countries have also introduced nirsevimab for infants, including Spain, France, Luxembourg, the United States of America, Canada, Chile and Australia.[5-11]

Nirsevimab Overview

Description

Nirsevimab is a monoclonal antibody, which means that it provides near-immediate passive immunity against RSV.

Indication

Nirsevimab is indicated for the prevention of RSV in:

- Neonates and infants during their first RSV season
- Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season

Timing of Injection

Administered shortly after birth, before discharge from the maternity hospital.

Duration of Protection

Nirsevimab has an extended half-life greater than 3 times that of typical monoclonal antibodies. One dose is sufficient to cover 150 days, equalling the entire RSV season. Nirsevimab begins to provide protection against RSV immediately after the injection is administered.

Side Effects

- Mild to moderate rash within 14 days after injection – 0.7%
- Fever within 7 days of injection – 0.6%
- Tenderness at the site of injection within 7 days of injection – 0.4%
- Allergic/hypersensitivity reaction – rare

Effectiveness

70-80% effective in preventing RSV-associated lower respiratory tract disease requiring hospitalisation.

Benefits compared to Palivizumab

Single dose provides season-long protection, whereas palivizumab requires monthly injections throughout the RSV season. Nirsevimab is indicated for all infants in their first RSV season, not just high-risk groups.

Real-world evidence from countries that have already implemented nirsevimab indicates that it is effective in reducing the burden of RSV hospitalisation and ICU admissions in infants aged under 8 months. In France, there was a 73% (95% CI: 61–81%) reduction in hospitalisations and a 76% (95% CI: 48.5–88.7%) reduction in ICU admissions for infants aged under 3 months.[12] Luxembourg saw a 69% reduction in RSV cases in infants aged under 6 months and a reduction in hospital length of stay - 2.2 days less in hospital for infants aged under 6 months.[13] In the USA, nirsevimab was 90% (IQR: 75–96%) effective against RSV hospitalisations in infants in their first RSV season.[14] In Spain, one of the first countries to recommend nirsevimab for the 2023/2024 season, more than 200,000 doses of nirsevimab were administered, achieving an average coverage rate of 91.9% (range 85.7–96.7%) in infants aged under 6 months.[15]

RSV Immunisation Pathfinder Programme

On 18th June 2024, the Department of Health (DoH) announced that at the request of the Chief Medical Officer (CMO), the Health Service Executive (HSE) had established an RSV Immunisation Pathfinder Programme – a pilot programme to offer nirsevimab to all infants born between 1st September 2024 and 28th February 2025, as well as other clinically high-risk infants less than 12 months of age (e.g. infants born before 30 weeks gestation, hemodynamically significant heart disease, chronic lung disease of prematurity, immunocompromised, etc.).[16] A pathfinder explores innovative ways to improve health outcomes and, if successful, can be scaled up and replicated. The aim of the programme was to reduce RSV-related illness (including emergency department (ED) presentations, hospitalisations and ICU admissions) among young infants. During the summer of 2024, a multidisciplinary team from the HSE, led by the National Health Protection Office (NHPO), worked quickly to organise the rollout of the programme in time for 1st September. As a result, nirsevimab was made available in all 19 maternity units in Ireland, in Children's Health Ireland (CHI) and was administered to clinically high-risk infants at home by Temperature Controlled Pharmaceuticals (TCP) Homecare.

The initiative follows advice from the National Immunisation Advisory Committee (NIAC) to the CMO and (DoH) who required HSE to look at the feasibility of delivering an RSV immunisation programme by winter 2024/25 and ahead of a formal decision by the DoH on a national programme, which was awaiting the outcome of a Health Technology Assessment (HTA) by HIQA.[4,17] The NHPO convened a Working Group to consider the feasibility of an RSV Immunisation programme for 2024–25. This working group included representatives from Access & Integration, National Women & Infant Health programme (NWIHP), National Social Inclusion Office (NSIO), National Clinical Programme for Paediatrics and Neonatology, the Royal College of Physicians Ireland (RCPI) Faculty of Paediatrics and the newly formed Regional Health Areas (RHAs). The proposed RSV Immunisation Pathfinder Programme was expected to immunise approximately 28,000 infants using nirsevimab.

The DoH has emphasised the urgency of this programme, noting the unprecedented number of RSV hospitalisations observed during the 2023/2024 winter season. By implementing this pathfinder programme, the aim was to alleviate pressure on healthcare services while also gathering data to inform future RSV immunisation strategies. The DoH requested that a detailed review of the effectiveness and efficiency of the programme be carried out within three months of the end of the programme.

Aims and Objectives

Aim

The primary aim of the evaluation is to assess the effectiveness and efficiency of the RSV Immunisation Pathfinder Programme in Ireland, in order to inform future RSV immunisation policy.

Objectives

1. **Describe the RSV Immunisation Pathfinder Programme**
   a) Document the steps that were taken to establish and run the RSV Immunisation Pathfinder Programme.

2. **Reach and Uptake**
   a) Measure the proportion of eligible infants who received nirsevimab, by week (and for the entire period of the programme), setting, geographical area and other factors.
   b) Analyse demographic factors influencing immunisation uptake.

3. **Impact**
   a) Assess the programme's overall impact on RSV-related ED presentations, hospitalisations and ICU admissions among infants eligible for nirsevimab.

4. **Implementation Assessment**
   a) Evaluate the programme's implementation across various maternity hospitals, paediatric sites and immunisations delivered at home.
   b) Describe the experiences of staff delivering the immunisation.
   c) Explore parental perspectives regarding the RSV Immunisation Pathfinder programme.
   d) Identify facilitators and barriers to the successful delivery of the immunisation.

5. **Costs**
   a) Describe the costs associated with the delivery of the RSV Immunisation Pathfinder Programme (this information is provided in a separate, confidential document).

2

Evaluation Methods

Evaluation Methods

Framework

This evaluation follows the Centre for Disease Control and Prevention Program Evaluation Framework to assess the implementation and outcomes of the RSV Immunisation Pathfinder Programme.[18] It includes six steps: assessing context, describing the program, focusing the evaluation design, gathering credible evidence, generating and supporting conclusions, and acting on findings. The framework also emphasises five standards (relevance and utility, rigour, independence and objectivity, transparency, ethics) and three cross-cutting actions (collaboration, advancing equity, learning from and using insights).

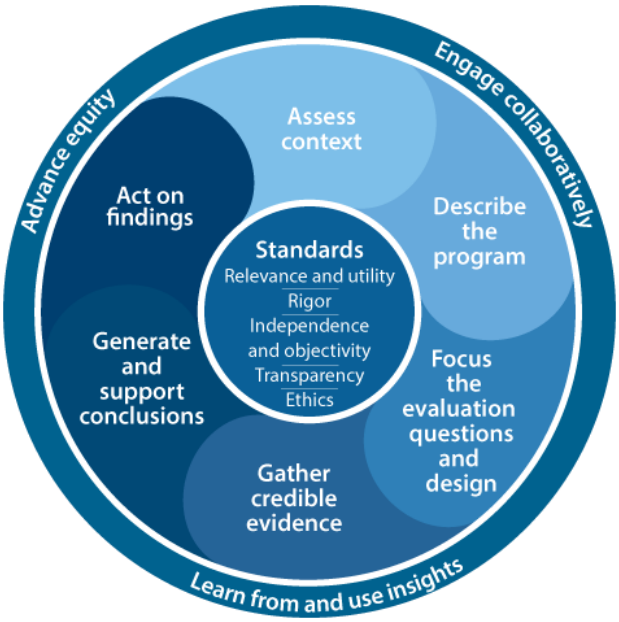


Figure 2.1 Centers for Disease Control and Prevention Program Evaluation Framework

Describing the RSV Immunisation Pathfinder Programme

The RSV Immunisation Pathfinder Programme has been described by summarising the publicly available information regarding the programme as well as reviewing the related training materials, standardised operating procedures, frequently asked questions documents, meeting minutes and consultation with the steering committee/working group members that organised the programme.

Uptake

National Uptake of Nirsevimab

For the duration of the programme, each site reported uptake of nirsevimab in their setting on a weekly basis to HPSC using an online survey. For maternity hospitals, this was calculated as *(number of infants immunised during week X) ÷ (number of live births during week X)*. For CHI and TCP Homecare this was calculated as *(number of infants immunised during week X) ÷ (number of eligible infants offered immunisation during week X)*. Data collection for maternity hospitals, CHI and the TCP Homecare programme began during week 36, 37 and 39 of 2024, respectively. The percentage

uptake for week 35, 2024 is not reported as it only included one day (1st September). A nominated person from each hospital/site was responsible for reporting these data each week to HPSC. HPSC reported the uptake of nirsevimab on a weekly basis. This evaluation report provides the weekly and overall uptake of nirsevimab nationally. The weekly uptake for each site involved in administering nirsevimab is included in the supplementary material.

Some paediatric units that were co-located with maternity units administered nirsevimab to high-risk infants. It is unknown whether or not all of these administrations are included among the uptake figures returned by data providers. Therefore, the reported figures in this report may under-represent the true number of immunisations administered.

Factors associated with the Uptake of Nirsevimab

A subgroup analysis exploring factors associated with the uptake of nirsevimab was conducted in the National Maternity Hospital and the Rotunda Hospital. A summary of their combined results is provided in the Appendix. A detailed document outlining individual hospital findings is also available in the Supplementary Materials.

Impact

The deadline for this evaluation report was soon after the end of the programme, and some analysis was conducted before the end of the RSV season. As a result, the full benefits of the programme may not be evident at the time of writing this report.

RSV Surveillance Data

Surveillance data relating to RSV notified cases, hospitalisations, and PICU admissions among those born between 1st September 2024 and 28th February 2025 were extracted from the Computerised Infectious Disease Reporting System (CIDR). Descriptive analysis was conducted, comparing the 2024/2025 RSV season to the previous five RSV seasons for similar birth cohorts.

Estimated Number of Hospitalisations Averted

Method 1:

The number of outcomes (ED presentations, hospitalisations and ICU admissions) averted by the RSV immunisation in Ireland was estimated using a published method previously used both nationally and internationally to assess the impact of influenza and COVID-19 vaccination and, more recently, internationally for RSV in other contexts.[19,20,21,22]

The impact of RSV immunisation on each outcome was estimated using the formula:

$$\text{NAE} = n \times \frac{\text{IC} \times \text{IE}}{1-(\text{IC} \times \text{IE})}$$

- NAE = the number of averted events
- n = number of observed cases with the outcome of interest (e.g. hospitalisation)
- IE = the immunisation effectiveness for the outcome of interest (for this analysis the same IE value was used for all outcomes)
- IC = the population immunisation coverage (i.e. the uptake rate)

It was not possible to calculate nirsevimab immunisation effectiveness in Ireland because linked immunisation status data for RSV cases were not available at the time this study was being

undertaken. Therefore, an estimate of immunisation effectiveness for nirsevimab was used, taken from a recent and robust systematic review and meta-analysis that gathered available evidence on the effectiveness of nirsevimab in children and newborns. The meta-analysis included 45,238 infants from 19 series and documented a pooled immunisation effectiveness of 88.4% (95% CI: 84.7–91.2%).[23]

Method 2:

An alternative method was used to understand the reduction in RSV-related hospitalisations among the birth cohort this season compared to predictions made based on previous RSV seasons. These models were informed by RSV surveillance data for this and four previous RSV seasons (excluding the 2020/2021 and 2021/2022 seasons). The observed number of hospitalisations was compared to the predicted number for those born between 1st September 2024 and 28th February 2025 to estimate the number of hospitalisations averted. A full description of the methods and results are available from the following pre-print article.[24]

Intensive Care Unit Admissions

Nirsevimab immunisation status of infants notified with RSV infection was verified (by contacting hospitals to confirm) to determine what proportion of those admitted to the ICU due to RSV were immunised compared to those who were not immunised. Information gathered on enhanced surveillance forms submitted to the HPSC was summarised and analysed. A selection of this analysis is provided in this report.

Number of In-Patient Bed Days Avoided

The number of in-patient bed days avoided was calculated based on multiplying the average length of stay (LOS) by the estimated number of hospitalisations averted (as determined by method 1 and 2). The average LOS was 4.3 days (95% CI 3.4-5.2) for infants aged <1 year hospitalised (including ICU admission), with a primary diagnosis of RSV. This figure was taken from the HIQA rapid HTA, which included an analysis of Hospital Inpatient Enquiry (HIPE) data for 2013 to 2022.[17]

To calculate the cost savings from averted hospitalisations, an average cost of a hospital episode was estimated to be €9,739 (95% CI 8,615-10,931). This estimate is also based on the HIQA rapid HTA. This was applied to the estimated number of hospitalisations averted due to method 1 and 2.[17]

Number Needed to Immunise

The number needed to immunise was calculated by dividing the total number of infants immunised by maternity hospitals and CHI by the estimated number of hospitalisations averted according to method 1.

Critical Care Transfers

Information on critical transfers conducted between 1st September 2024 and 28th February 2025 was received from the Irish Paediatric Acute Transport Service for children aged >4 weeks. Information was also received from the National Clinical Programme for Paediatrics and Neonatology regarding the number of neonatal (infants aged <4 weeks) critical care transfers for the same time-period.

Qualitative Evaluation

Parent Survey

Parents were invited to participate in an online survey to provide their feedback in relation to the RSV Immunisation Pathfinder Programme. The survey was active between 20th January 2025 and 9th March 2025. All parents who were offered the immunisation for their child during the immunisation programme were eligible to participate. Information regarding the survey was distributed via leaflets given to mothers during the survey period. Perspectives of parents who gave birth to infants earlier in the programme were gathered by promoting the survey via parent advocacy groups, Pavee Point and within the outpatient departments of maternity hospitals and CHI.

Staff Survey

Staff involved in the delivery of nirsevimab were invited to participate in a survey to gather feedback on how they perceived the implementation of the RSV Immunisation Pathfinder Programme. The survey was distributed to relevant staff via the Directors of Nursing/Midwifery in each of the hospital sites participating in the RSV Immunisation Pathfinder Programme. The survey was active from 20th January 2025 to 9th March 2025.

Additional Stakeholder Feedback

Several focus groups and one-to-one interviews were conducted with Directors and Assistant Directors of Midwifery, Pharmacy Leads, Paediatricians, Regional Directors of Public Health, GPs and Practice Nurses, Community Public Health Nurses and Steering/Evaluation Group Members to gather more detailed feedback on the implementation and impact of the programme.

Data analysis

Qualtrics, a secure online survey instrument, was utilised for both the parent and staff surveys. Descriptive statistics were used for multiple-choice questions and Likert scale responses from surveys and were summarised as counts and percentages.

Thematic analysis has been conducted on data from free-text questions in surveys and focus group and interview transcripts.

3

Programme Description

Programme Description

Overview

The RSV Immunisation Pathfinder Programme is a pilot initiative launched in Ireland to address the significant burden of RSV infections among infants. This programme, which ran from 1st September 2024 to 28th February 2025, aimed to protect infants during the critical early months of life when they are most vulnerable to severe RSV-related illness.

Programme Need

In the winter of 2023/2024, Ireland experienced a record number of RSV-related hospitalisations, particularly among children under one year. The programme seeks to reduce illness, hospitalisations, and strain on the healthcare system during the peak RSV season.

Expected Effects

The programme aimed to:

- Provide immediate protection against RSV for approximately 150 days after immunisation.
- Reduce RSV infections, severe illness and hospitalisations among infants.
- Prevent up to an estimated 453 hospitalisations and 48 ICU admissions during the pilot phase (uptake rates similar to what was observed in Galicia, Spain, with an 89% overall reduction in hospitalisations and ICU admissions).[15]

Activities

The programme involves:

- Administering a single dose of nirsevimab to all eligible newborns before discharge from all maternity hospitals and selected high-risk infants aged less than 12 months at the start of the RSV season.
- Educating parents about RSV and the benefits of immunisation through antenatal clinics and postnatal counselling.
- Coordinating with healthcare professionals, including midwives, neonatologists, and pharmacists, for seamless delivery.

Resources

Key resources include:

- Funding provided by the Department of Health.
- Collaboration between the HSE and other stakeholders.
- Training materials for healthcare staff.
- Public information campaign.
- Additional staffing – midwives, informatics pharmacists, pharmacy technicians, programme manager.

Stage of Development

This pathfinder programme is a pilot initiative designed to evaluate the feasibility and impact of widespread RSV immunisation. The findings will inform a longer-term national strategy in addition to the HIQA HTA currently underway.

Context

The programme was implemented in all maternity hospitals across Ireland during the winter months when RSV rates are highest. It builds on evidence from similar initiatives in Spain, where immunisation led to an 89% reduction in infant hospitalisations due to RSV. The programme also replaces the previous palivizumab programme that was in place to provide RSV Immunisation to high-risk infants. This part of the programme was delivered by CHI and TCP Homecare.

Logic Model

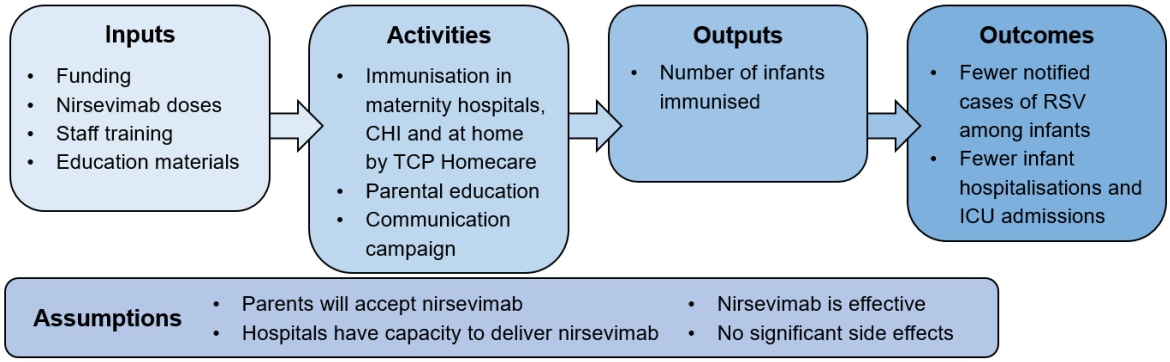


Figure 3.1. RSV Immunisation Pathfinder Programme Logic Model

Programme Governance

The programme was governed by a programme steering group (membership listed on page iii) which oversaw the activities of the following subgroups:

- Programme Enablement
- Operations Management
- Data Subgroup
- Evaluation Subgroup

Anyone who had queries about the programme was able to contact a dedicated email address, rsvpathfinderprogramme@hpsc.ie, for direct responses from the programme co-ordinators.

Eligibility

NIAC recommended nirsevimab for all healthy term infants born in the RSV season, from September to the end of February inclusive.[4] NIAC also recommended nirsevimab for all high-risk infants aged ≤12 months at the start of their first RSV season. The recommendation was for these infants to receive nirsevimab prior to the start of the RSV season. Due to some delay in the initiation of the programme to immunise high-risk babies at their homes, the RSV season had already begun when

immunisation was being offered, but every effort was made to immunise this cohort early in the RSV season, and this is reflected in the uptake data presented later in this report.

High-risk infants include:

- Infants born before 30 weeks, 0 days' gestation.
- Preterm infants with chronic lung disease of prematurity (defined as birth at <32 weeks' gestation and a requirement for >21% oxygen for at least 28 days after birth).
- Certain infants with hemodynamically significant heart disease, specifically those with acyanotic heart disease requiring medication for congestive cardiac failure and/or moderate to severe pulmonary hypertension, and infants with cyanotic heart disease (in consultation with a cardiology specialist).
- Infants with a pulmonary abnormality or neuromuscular disease that impairs their ability to clear upper airway secretions may be considered for prophylaxis.
- Children younger than one year who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.

Nirsevimab was also recommended for all ex-preterm infants aged under 24 months with chronic lung disease in their second RSV season. The NIAC also recommended nirsevimab for all infants aged ≤6 months at the start of the RSV season. However, due to programmatic limitations and supply chain constraints, this cohort was not offered the immunisation as part of this Pathfinder Programme.

The NIAC recommendations can be accessed here.[4]

Nirsevimab Administration

Nirsevimab was administered in maternity hospitals, CHI and at home by TCP Homecare. For those in maternity hospitals, nirsevimab was administered soon after birth, either in the delivery suite, theatre or post-natal ward. Those identified as being at high risk of severe RSV were offered nirsevimab by CHI and TCP Homecare. A small number of high-risk infants were immunised early in the programme by maternity units, where feasible, ahead of the TCP Homecare programme commencing.

Nirsevimab is administered to infants intramuscularly in the anterolateral aspect of the thigh.

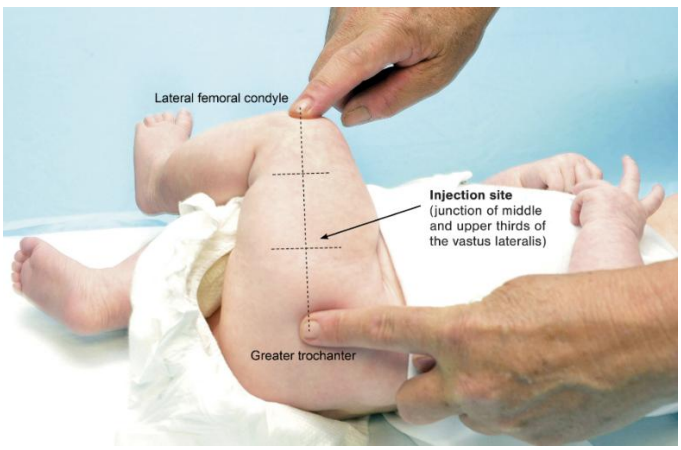


Figure 3.2. Nirsevimab injection site

Dose:

- Infants <5kg birth weight: A single dose of 50mg (0.5ml)
- Infants ≥5kg birth weight: A single dose of 100mg (1.0ml)

Both the 50mg and 100mg doses were provided in pre-filled syringes.

A medicines protocol was developed to allow nurses, midwives and student midwives (under supervision) to administer nirsevimab without a prescription.

It was advised that verbal consent was sufficient for Nirsevimab, in line with other immunisation programmes. Written consent was not recommended.

Data Collection Methods

Paper-based data collection forms

The majority of maternity sites used paper data collection forms to record information relevant to nirsevimab acceptance, refusal and administration (if relevant). A copy of this data collection form can be found among the supplementary material. This was a duplicate record with one copy kept in the patient chart and another kept aside for eventual upload to a national data repository. Unfortunately, a mechanism to collate the data from these data collection forms at a national level has not been established at the time of writing this report. In addition, due to time constraints, the necessary data sharing agreements and Data Protection Impact Assessments (DPIAs) that were required to centrally store and process this data were not devised and approved in time for publication of this evaluation report.

MN-CMS hospitals

The National Maternity Hospital, Rotunda Hospital, Cork University Maternity Hospital and University Hospital Kerry use the MN-CMS electronic record system.[25] This allowed them to record nirsevimab immunisation data electronically. Informatics pharmacist posts were granted for the Rotunda and National Maternity Hospital to provide them with the analytic capacity to report on the determinants of nirsevimab uptake. Due to the HSE Pay and Numbers Strategy, Cork University Maternity Hospital and University Hospital Kerry had vacant informatics pharmacist posts and were unable to contribute to the project.

TCP Homecare

TCP Homecare also utilised an electronic record system to record all the relevant data required by the paper-based form.

Procurement

As the value of the contract exceeded €10m, the Contract Approval Request (CAR) document had to undergo the HSE approval process: sign-off by Budget Holder → Head of Procurement → Senior Leadership Team, led by the Chief Financial Officer → Audit & Risk Committee → HSE Board. This was challenging given the short turn-around time for the request.

A Voluntary Ex-Anti Transparency Notice was also published on the eTenders website for additional transparency and is available to any supplier/interested parties, including outside Ireland.

Extracts from the CAR

1.0 Procurement Process Type: Direct Negotiation

- Issues encountered: Sole Supplier. Very short timeline due to sign off from DoH for budget approval which was received on 18th June 2024 and the commencement of the contract 1st August 2024.
- Value for money: HSE Procurement achieved a cost avoidance on the original proposed price submitted by Sanofi-Aventis Ireland Ltd following direct negotiations.

2.0 Procurement Market

- Sanofi-Aventis Ireland Ltd is the sole supplier of nirsevimab (Beyfortus®) which is the only drug with marketing authorisation for use in all neonates and infants for the prevention of RSV disease and requires one (1) dose. As a result, the HSE entered in to Direct Negotiations with Sanofi-Aventis Ireland Ltd to secure supply for this pathfinder programme pending the HTA assessment due in 2025.

3.0 Procurement Strategy

- There is one sole supplier for this drug and as a result, Negotiated Procedure under Article 32(2) (b) of the EU Procurement Directives as there is only one supplier (sole supplier confirmed by Public Health).
- Ireland expressed an interest to participate in a Joint Procurement with EU Health Emergency Preparedness and Response Authority (HERA). However following discussions with HERA and Sanofi-Aventis, this confirmed Sanofi-Aventis did not wish to participate in a Joint Procurement with HERA EU level at this stage. Ireland will continue to be part of the Joint Procurement HERA to procure maternal and vaccines for over 65 on a non-committal basis.

4.0 Procurement Process

- Negotiated Procedure under Article 32(2) (b) of the EU Procurement Directives as there is only one supplier (sole supplier confirmed by Public Health).

Logistics and Storage

Funding for nirsevimab was provided centrally by the HSE. No charges were incurred by hospital pharmacies for the product or deliveries through the pharmaceutical wholesaler. Based on the volume of births, each hospital estimated its likely weekly nirsevimab stock ordering levels. To prevent hospitals from holding excessive amounts of stock, the maximum weekly orderable amount of nirsevimab 50mg formulation for a hospital was limited to 150% of their anticipated normal weekly usage figure.

Nirsevimab must be stored in a refrigerator at +2°C to +8°C and protected from light at all times. It may be kept at room temperature (below 25°C) for a maximum of 8 hours. After removal from the medication fridge, nirsevimab has an in-use time limit of eight hours.

Staff Training

A detailed standard operating procedure (SOP) was developed to act as a training resource for all staff involved in the programme (see Supplementary Materials). This was adapted to align with local protocols by several sites.

Training Slides were presented to staff via an online webinar on 31st July 2024 and a recording of the training session was made available on YouTube. An additional information briefing was held on 8th August 2024 for staff to ask additional questions. Extra meetings with Directors of Midwifery were held during the programme once it was up and running to address further queries and provide feedback on implementation and uptake.

Maternity Units and CHI were encouraged to conduct additional on-site training with staff involved in the programme. This included medical, nursing, midwifery, pharmacy and admin staff.

Additional educational materials were also developed for internal use. For example, the "Talking to parents about nirsevimab" poster, developed by the Irish Medicines in Pregnancy Service at the Rotunda Hospital, has also been adapted by other units (Figure 3.2).

Weekly Uptake Reports

Every week throughout the programme, the HPSC produced and circulated an updated progress report that included uptake of nirsevimab in each of the maternity hospitals, CHI and TCP Homecare. These were circulated to Regional Executive Officers (REOs), Regional Directors of Public Health (RDPHs) and hospital management in addition to members of the Steering Group, senior HSE leaders and the CMO and officials at the DoH.

Communications

Communication Plan

In late August, a targeted communication campaign was launched, aimed at promoting the availability of nirsevimab for babies born in maternity units from 1st September 2024. The objective of this campaign was to promote nirsevimab to eligible expectant parents and parents of newborn babies born between 1st September 2024 and 28th February 2025. The campaign directed them to the HSE's webpage, where further information on nirsevimab is available. Hospitals were asked to conduct internal promotion through posters, leaflets, and education sessions. Additional information about RSV and nirsevimab was available on the HPSC website also. The targeted campaign included promotion via established social media platforms such as Meta, Pinterest, and TikTok to expectant parents of eligible infants. Analysis of this campaign showed a high click-through rate compared to industry standards, indicating a very effective targeted campaign.

There was a decision by the RSV Pathfinder Programme Steering Group not to widely publicise the RSV Immunisation Pathfinder Programme. We thought that a broad communication campaign would do more harm than good, and it was felt that a direct communication campaign to eligible parents would be sufficient, given the targeted nature of the programme to newborns who were most at risk and the exclusion of older and catch-up cohorts.

On 10th December 2024, an Epi Insight article was released with interim updates on RSV epidemiology and nirsevimab uptake. This was followed by a Press Release by the HSE on 16th December 2024.

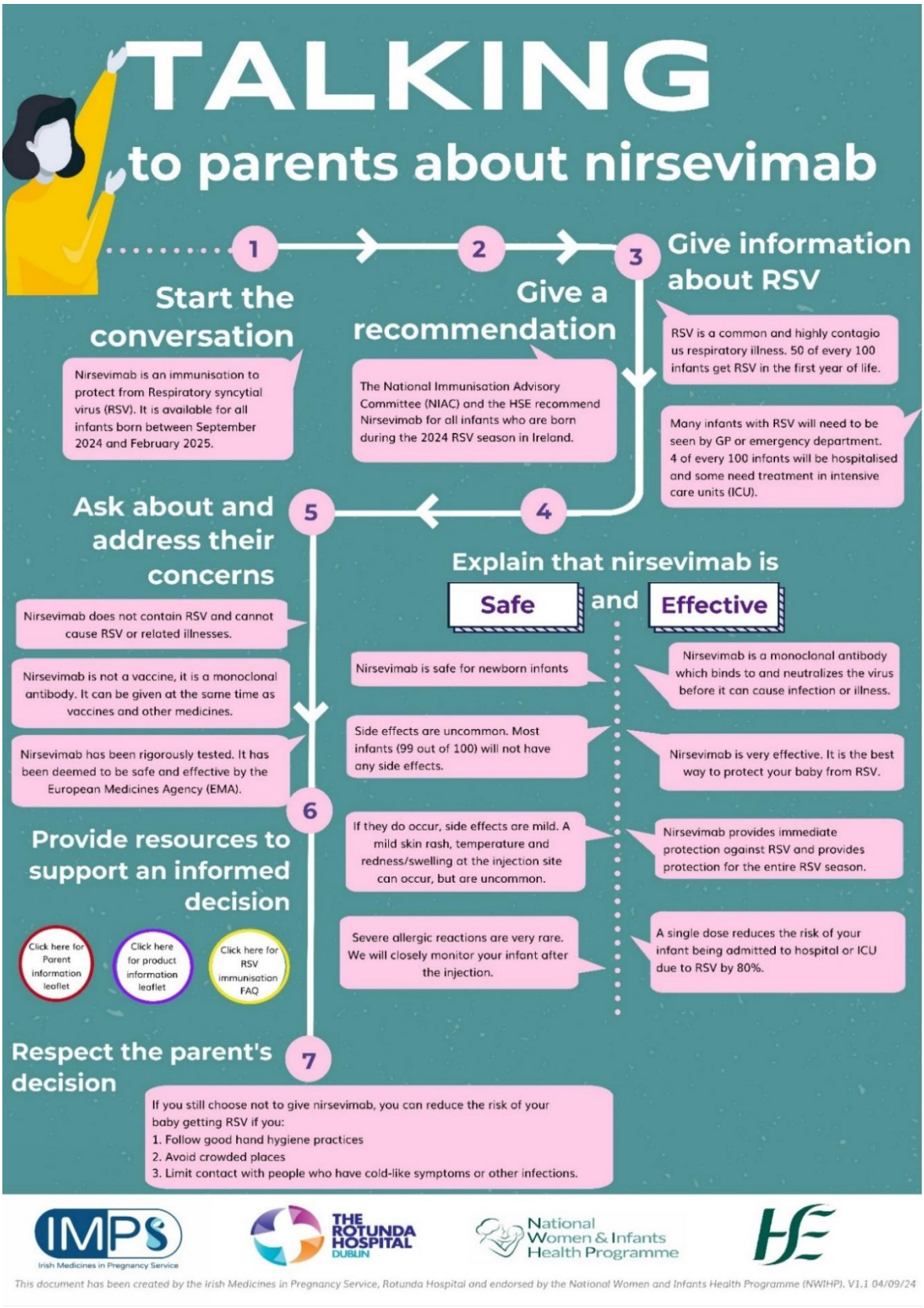


Figure 3.2. Talking to parents about nirsevimab poster

Figure 3.3. RSV Immunisation Information Leaflet for Parents

Consideration towards underserved groups

Information Leaflets & resources

The HSE National Communications team recommended that, in addition to English and Irish, the RSV patient information leaflets be translated into various languages to ensure equitable access to information. The HSE RSV Parent Leaflet was translated into the following languages: Ukrainian, Russian, Romanian, Portuguese, Polish, Chinese, Arabic, Georgian, Somali and Urdu.

All the resources, including patient information leaflets, posters and a resource for staff giving advice on "Talking to parents about nirsevimab", were made available online. A dedicated Frequently Asked Questions (FAQ) page was also launched, which provided further information for parents and staff.

Engagement and bespoke resources

On the 3rd of September 2024, the NSIO facilitated a meeting with Traveller, Roma and migrant representations with the DOM and Obstetrician in the Rotunda Hospital. It was agreed at this meeting that:

- The Rotunda Hospital staff would give a presentation to Traveller and Roma networks.
- Pavee Point Traveller and Roma Centre, Cairde and NSIO, would help promote the information leaflet via their channels and develop a video to engage Traveller and Roma parents, and share it via Non-Governmental Organisation (NGO) and NSIO social media channels.

Figure 3.4. The RSV Immunisation Programme has featured on the front page of the Pavee Mothers website for the duration of the programme

Ethnicity Equality Monitoring

Ethnicity information (in line with CSO ethnicity categories) was included in the immunisation administration form. Ethnicity information was also requested as part of the Parent Survey. Pavee Point Traveller and Roma Centre shared the details of the survey through their networks to reach Traveller and Roma parents who would be eligible. Staff were also asked to identify if any ethnic groups were more likely to refuse nirsevimab from their perspective as part of the staff survey.

Media Coverage

Despite the HSE not running a national media campaign, Figure 3.5 illustrates the volume of traditional and social media items that centred around the RSV Immunisation Pathfinder Programme that took place between June 2024 and February 2025. Much of the social media that took place was from individual hospitals/health regions and the DoH.

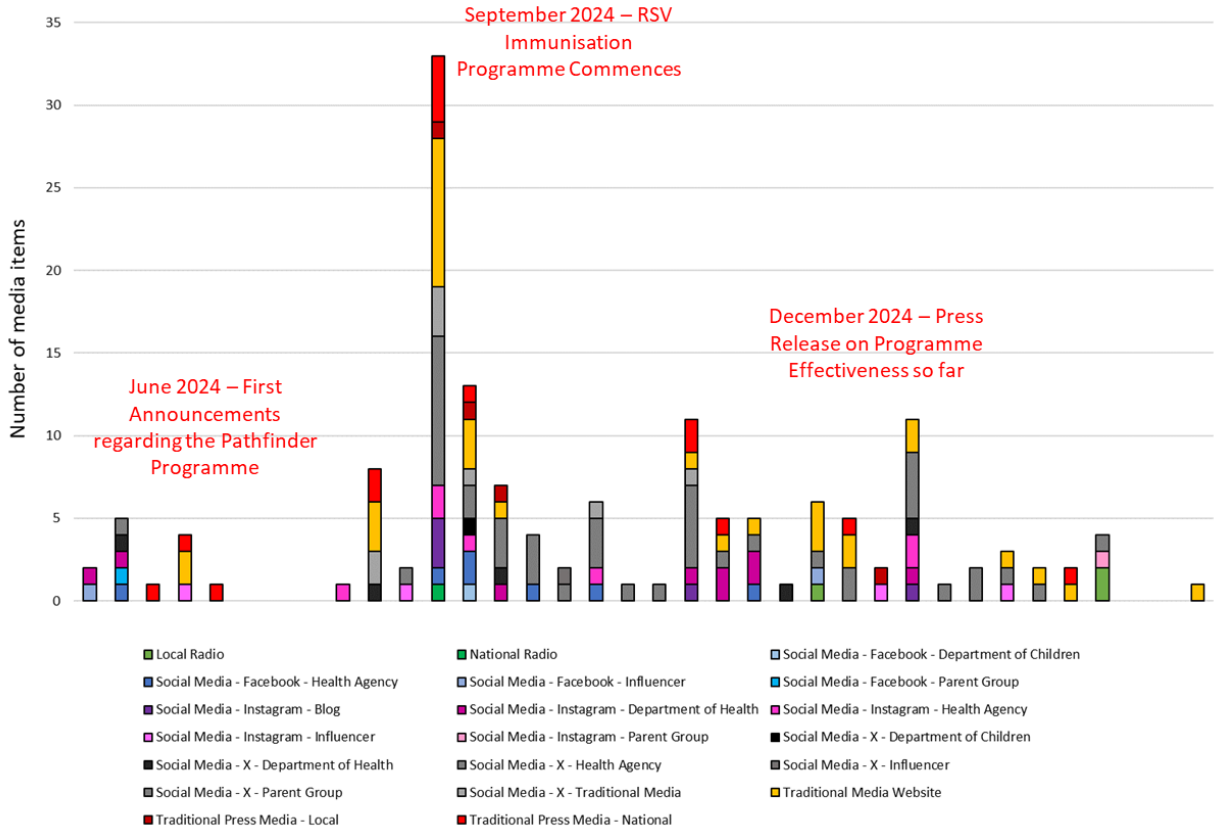


Figure 3.5. Number of Traditional and Social Media Items Related to the RSV Immunisation Programme over time, June 2024 to February 2025

Positive Media Coverage

Media coverage regarding the RSV Immunisation Programme was generally positive. Media Items generally focused on the following topics:

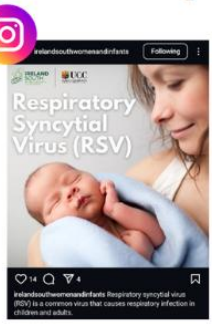
- Sharing awareness about the programme
- Advocating parents to accept nirsevimab
- Sharing preliminary uptake and effectiveness data

LEINSTER Express

New programme at hospital to protect babies against RSV

The Journal

RSV cases in infants have dropped massively since vaccine programme started in September



Irish Independent

Large take-up of RSV jab for babies in hospital on day one of rollout

EILISH O'REGAN

Almost all parents accepted the new jab for their newborns to protect them from the potentially serious respiratory syncytial virus (RSV) on the first day of its rollout in the busiest maternity hospital in the country.

Professor Sean Daly, Master of the Rotunda Hospital in Dublin, said 76 of the 80 babies born last Sunday, the first day the new jab was offered, were immunised.

"It is very encouraging. Some of our midwives came in on their own time to administer the injection," he said.

The new jab, known as nirsevimab, will be offered to all newborns until the end of February.

He said it is not a vaccine but can give antibodies directly to the baby to provide protection for 150 days.

Just one dose is needed and it is administered into the baby's thigh, providing protection straight away.

Over 1,000 children had to be hospitalised with the virus in this country last winter and, depending on take-up, the injection could lead to 453 fewer having to be admitted.

He said the hospital contacted all expectant mothers due to give birth in the hospital last weekend in advance to advise them around the injection.

'In Spain 90pc of newborns got the jab and hospitalisations fell by over 80pc'

A group of anti-vaccination protesters held a demonstration outside the hospital yesterday before being asked to leave by gardaí.

The Rotunda rolled out the jab from last Sunday along with all other maternity hospitals.

Prof Daly said the newborns are administered the injection in the labour ward and they are also offered a vitamin K injection.

Babies who get the RSV jab must be observed for 15 minutes. Babies # who need intensive care receive it later.

"RSV can be a very nasty virus for some children in their first year," he added.

A number of European countries have already rolled out the jab since it was approved two years ago. In Spain 90pc of newborns were immunised against RSV. The hospitalisation rate among this group fell by over 80pc.

The HSE said some babies get mild side effects from nirsevimab but this is not common. Side effects may include redness of the skin where your baby got the injection, a temperature or rash.

Health Minister Stephen Donnelly. Photo: Gareth Chaney

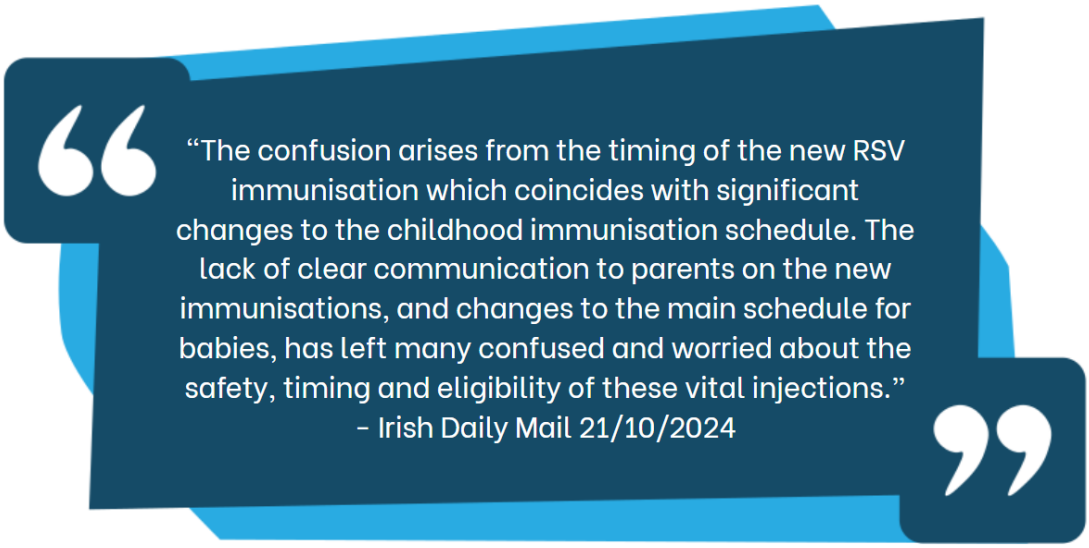
MIDLANDS 103

New RSV Immunisation More Direct Than Vaccine Treatment

Criticism in the Media

The only negative comments in the media surrounding the RSV Immunisation Pathfinder Programme were that there wasn't enough promotion and that children aged ≤6 months at the start of the RSV season were excluded despite NIAC recommendations. No Irish-based anti-vax information relating to nirsevimab in traditional media or social media was found, although international examples were seen, particularly from the United States of America (USA), targeting their programme.

Confusion – Parents have expressed confusion in relation to the RSV Immunisation Programme due to its timing – coinciding with other changes made to the Primary Childhood Immunisation Schedule.



Not far enough – There have been several articles in Irish Media from a pharmacist that the programme was not going to go far enough by limiting eligibility to those born from 1st September 2024.

Other notes

Terminology – The terms vaccine and immunisation are used interchangeably by the media. This probably means little to the general public, but it may be important to always refer to nirsevimab as an immunisation or medication and not a vaccination, where possible, to reduce the risk of this being confused with other anti-vax sentiments.

4

Uptake

Uptake

Nirsevimab Uptake

Between 1st September 2024 and 28th February 2025, a total of 22,444 infants were immunised by maternity hospitals, CHI and TCP Homecare with nirsevimab.

Maternity hospitals and CHI have reported a total of 22,049 infants immunised during the period 01/09/2024–28/02/2025. Overall cumulative uptake for the period 02/09/2024–28/02/2025 was 82.6% (21,913/26,522 infants immunised).

Maternity Hospitals

Overall cumulative uptake for the period 02/09/2024–28/02/2025 in maternity hospitals only was 81.8%, ranging from 69–91% by hospital site. Uptake of nirsevimab according to RHA is provided in Table 4.1. Weekly and total uptake for each maternity hospital and CHI are provided in the supplementary material.

Table 4.1. Uptake of Nirsevimab by Regional Health Area (maternity hospitals only), 02/09/2024–28/02/2025*

HSE Health Region	Number of live births	Number of infants immunised	% Uptake
HSE Dublin & North East	6,075	4,643	76.4%
HSE Dublin & Midlands	4,857	3,963	81.6%
HSE Dublin & South East	5,866	4,983	84.9%
HSE South West	3,726	3,060	82.1%
HSE Mid West	1,869	1,552	83.0%
HSE West & North West	4,129	3,487	84.5%
Total	26,522	21,688	81.8%

*1st September 2025 not included in this data

Children's Health Ireland

Overall cumulative uptake for the period 09/09/2024–28/02/2025 in CHI was 95.7% (225/235 eligible infants were immunised).

TCP Homecare programme (High Risk infants)

Overall, the cumulative uptake for the period September 2024–February 2025 in the TCP Homecare programme was 99.0% (395/399 eligible infants were immunised who were offered immunisation via TCP Homecare).

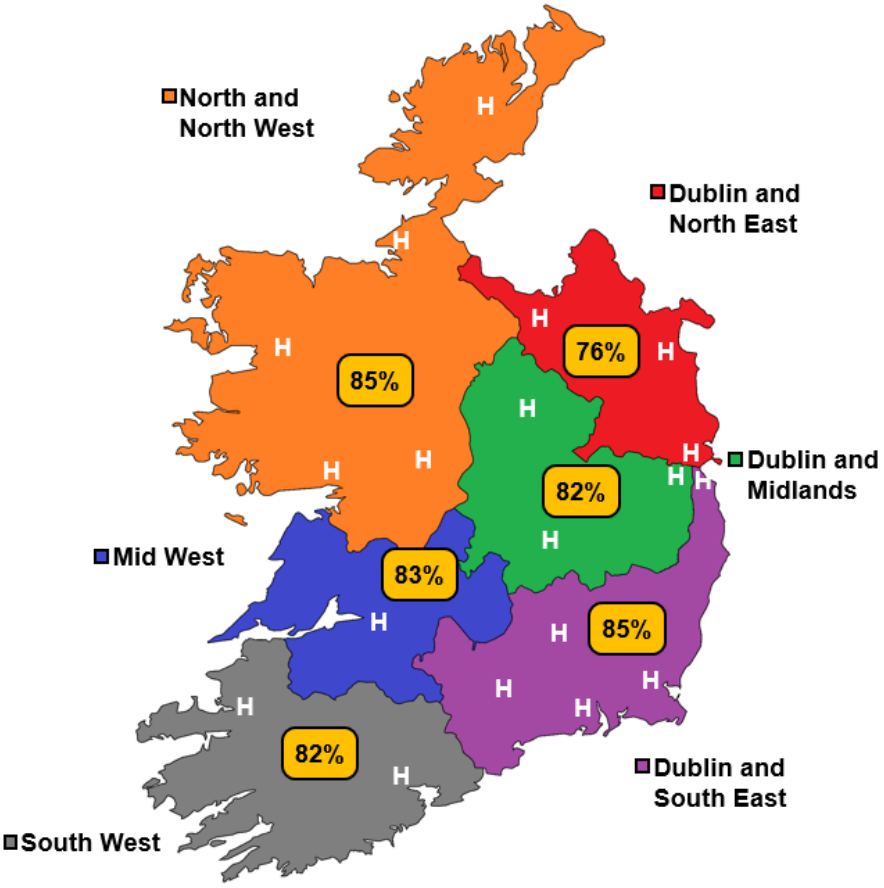


Figure 4.1. Maternity Hospital Uptake of Nirsevimab by Regional Health Area

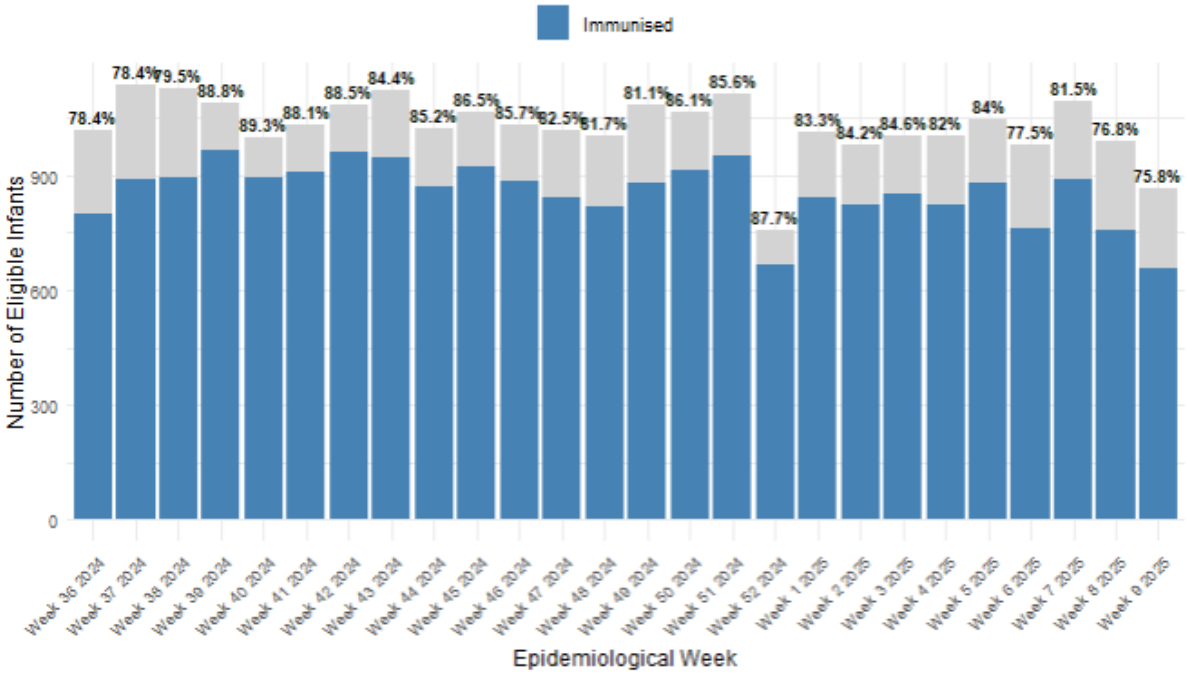
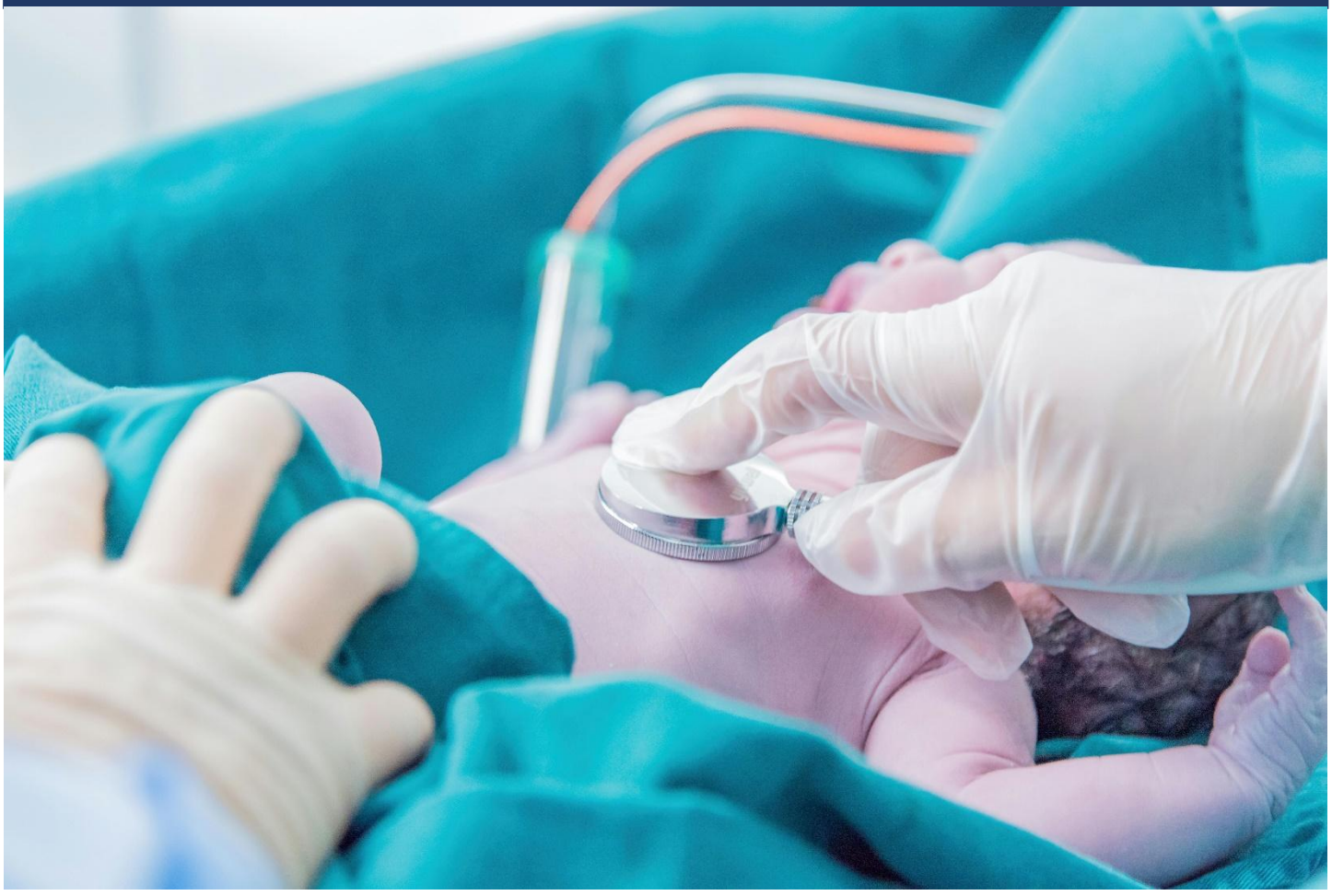


Figure 4.2. Number of infants immunised and uptake rate in maternity hospitals and CHI by week, Ireland, between 2nd September 2024 and 28th February 2025

5

Impact



Impact

Epidemiological Impact

RSV Epidemiology

The 2024/2025 RSV season in Ireland, as characterised by a total number of reported cases, was broadly similar to the 2023/2024 season. However, the timing of the epidemic curve has shifted, with the onset, peak, and decline of RSV cases aligning more closely with pre-pandemic seasonal patterns, as observed in the 2018/2019 and 2019/2020 seasons. Specifically, the epidemic peak occurred earlier in the epidemiological year, and the return to a more typical seasonal distribution is evident when compared to the atypical patterns seen during the pandemic and immediate post-pandemic years (Figure 5.1).

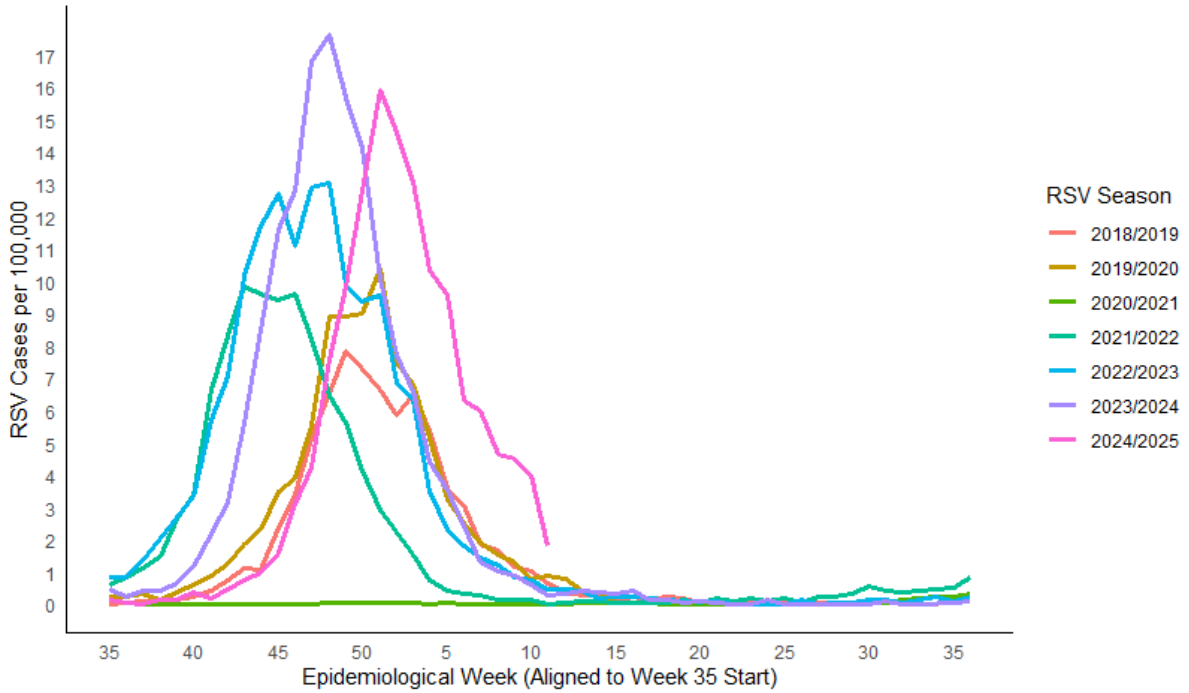


Figure 5.1. Weekly incidence rates (per 100,000 population) of RSV notifications for all ages by RSV season (epi-week 35-34 following year), Ireland, 2018/2019 - 2024/2025

This overall trend masks important differences by age group. The epidemiology of RSV in infants aged less than six months was notably altered, reflecting the impact of the national RSV Immunisation Programme. Table 5.1 summarises RSV cases notified among infants born between 1st September and 28th February, including those presenting to the ED, hospitalisations, and ICU admissions, compared across different RSV seasons from 2018/2019 to 2024/2025. Here, one can observe a significant decrease in the number of cases in this cohort in 2024/2025 for all outcomes.

Table 5.1. Summary of RSV cases notified among those born between 1st September and 28th February by RSV season, Ireland, 2018/2019 – 2024/2025

RSV season	ED Presentation	Hospitalised	Non-ICU	ICU[a]	Total cases[b]
2018/2019	240 (24%)	501 (52%)	-	-	967 (100%)
2019/2020	263 (26%)	573 (58%)	-	-	996 (100%)
2020/2021	2 (100%)	0 (0%)	-	-	2 (100%)
2021/2022	340 (42%)	400 (50%)	-	-	801 (100%)
2022/2023	468 (47%)	488 (49%)	-	-	997 (100%)
2023/2024	395 (35%)	676 (59%)	587 (51%)	89 (8%)	1142 (100%)
2024/2025[c]	169 (42%)	164 (41%)	133 (33%)	31 (8%)	398 (100%)

a) Surveillance of RSV in ICU began in October 2023
b) All laboratory confirmed RSV notifications (including primary care and outpatients)
c) This data only covers up to Week 16, 2025

During the **2023/2024 RSV season**, 395 ED presentations and 676 hospitalisations, of which 89 ICU admissions were notified among children born between 1st September 2023 and 28th February 2024. **In 2024/2025**, ED presentations dropped to 169 (57% reduction), hospitalisations to 164 (76% reduction), and ICU admissions to 31 (65% reduction), indicating a substantial decline in severe RSV cases following the introduction of the nirsevimab immunisation programme.

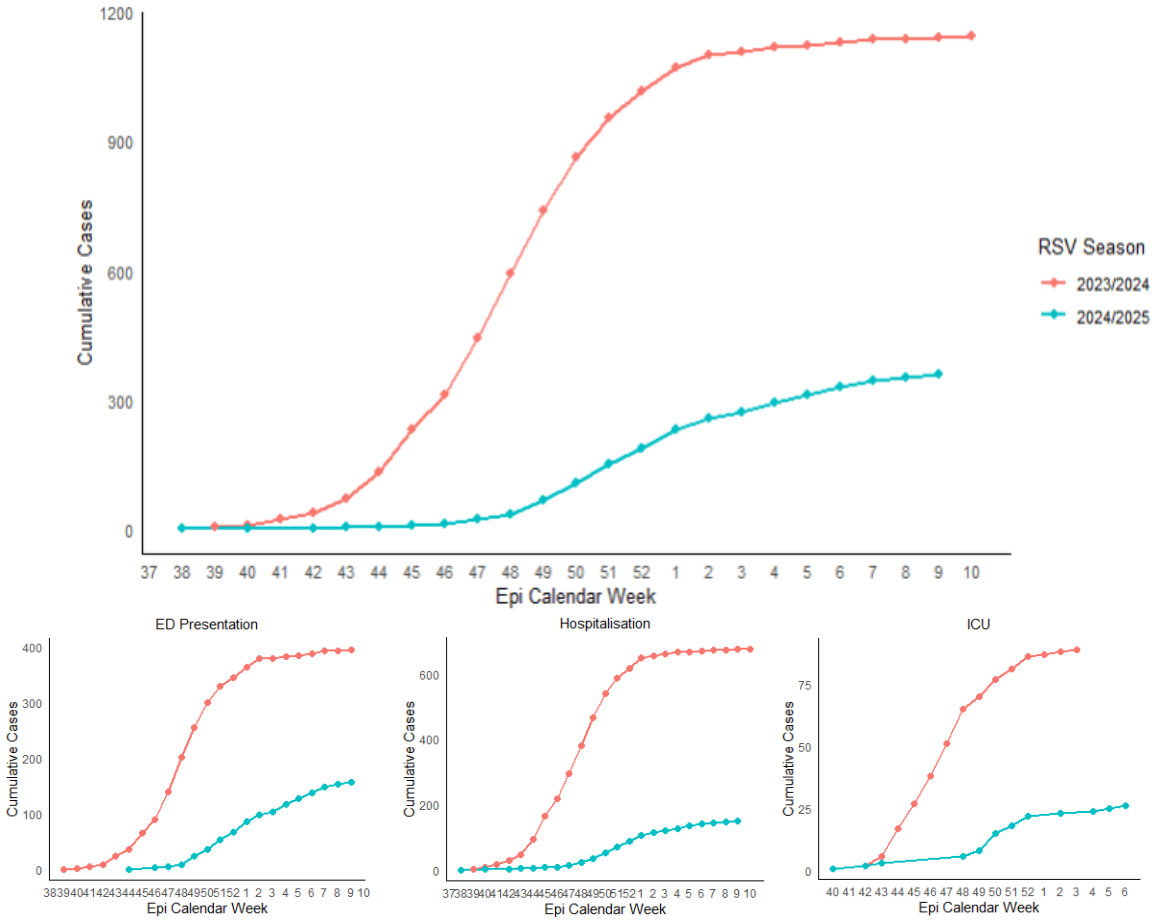


Figure 5.2. Cumulative laboratory confirmed RSV notified cases born between 1st September and 28th February in Ireland during the 2023/20204 and 2024/2025 RSV seasons, disaggregated by outcomes of interest; ED presentations, hospitalisations and ICU admissions

Averted Hospitalisations

Method 1:

Based on observed events and the reported effectiveness of nirsevimab, it is estimated that the nirsevimab immunisation programme averted 1,030 laboratory-confirmed cases (74% of expected), 440 non-hospitalised ED presentations (74% of expected), 433 hospitalisations (74% of expected), and 79 ICU admissions (75% of expected) in infants born between 1st September 2024 and 28th February 2025. The estimated hospital-related costs avoided from hospitalisations (including ICU admissions) were €4.2 million (95% CI: 3.7–4.8).

Table 5.2. Estimated number of RSV cases averted by health outcome among infants born between 1st September 2024 and 28 February 2025

Outcome	Observed	Expected	95% CI	Averted	95% CI
ED Presentations (non-hospitalised)	157	597	586–606	440	432–447
Hospitalisations (including ICU)	149	582	573–592	433	426–440
ICU admissions	26	105	103–108	79	77–81

*Note: These estimates are based on data extracted on 3rd March 2025. Based on this method, the estimated number of averted outcomes would increase if all observed cases in this birth cohort is used to estimate impact after the end of the RSV season.

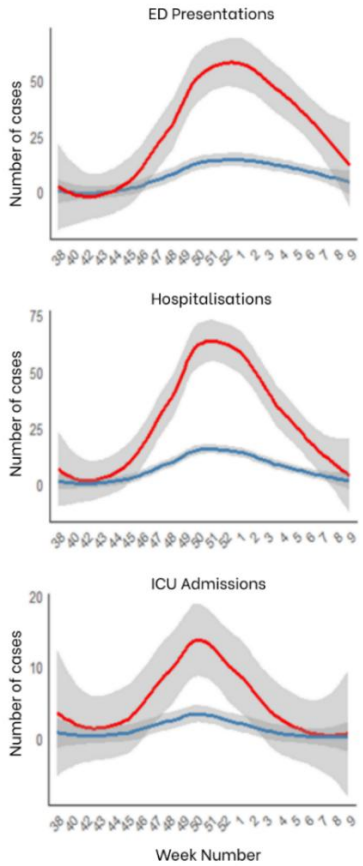


Figure 5.3. Expected (red) and observed (blue) laboratory confirmed RSV cases and outcomes of interest (ED presentations (non-hospitalised), hospitalisations, and ICU admissions) among infants born between 1st September 2024 and 28 February 2025 by week

Method 2:

Figure 5.4 focuses on observed data in this season's nirsevimab eligible cohort of infants born between 1st September 2024 and 28th February 2025 and compares predictions from the base model to those of the RSV Immunisation model. The difference between the two curves, each representing the respective models' predictions, visualises the effect of nirsevimab. Based on the RSV Immunisation model, there was a 75% reduction in the incidence rate for nirsevimab-eligible infants born this season. This corresponds to an estimated 532 (95% CI: 369–695) RSV hospitalisations averted for this group, in this season. The estimated hospital-related costs avoided from hospitalisations (including ICU admissions) using this method was €5.2 million (95% CI: 3.6–6.8).

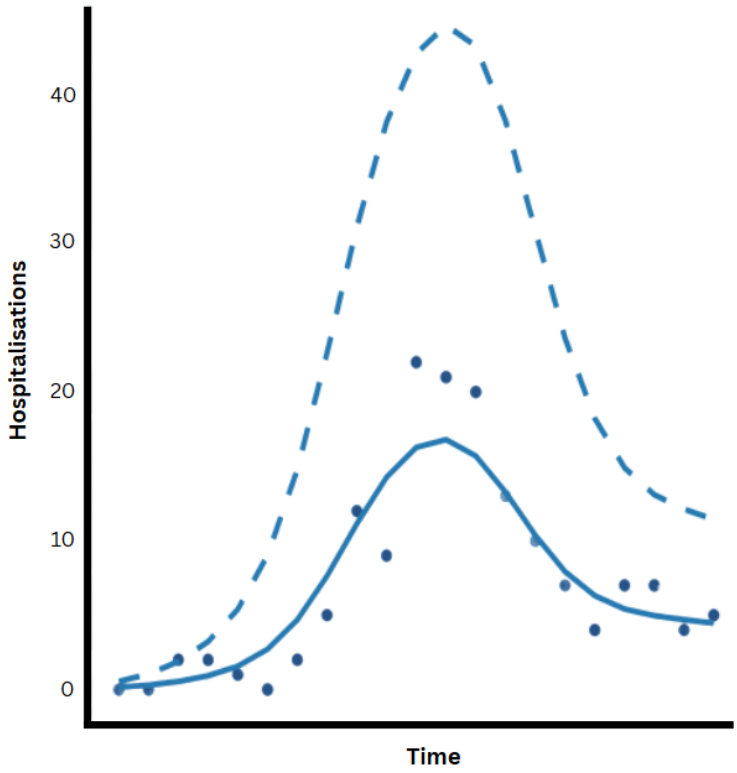


Figure 5.4. Models showing predicted number of hospitalisations among infants born between 1st September 2024 and 28th February 2025 with and without an RSV Immunisation Programme

ICU Admissions

A total of 31 infants eligible for nirsevimab (born since 1st September 2024) were admitted to ICU during the 2024/2025 season to date (up until week 12 2025). Of those, 11 (35%) received nirsevimab while 20 (65%) did not. The median time between immunisation and ICU admission was 64.5 days with an IQR of 50.5–78.5 and a range of 29–131. The median length of stay in ICU was 3 days (range 1–7 days) for those who received nirsevimab and 3 days (range 0–9 days) for those who did not receive nirsevimab.

Due to the small number of infants involved and for confidentiality reasons, further specific details regarding these infants will not be published here. However, it was observed that those who did not receive nirsevimab were younger (≤2 months) at the time of ICU admission (p = 0.115). Interestingly, those who received nirsevimab and were admitted to the ICU were more likely to be male (p = 0.035).

Compared to the 2023/24 season, there was a 67% decrease in ICU admissions for the similar age cohort. There were 89 PICU admissions for children born between 1st September 2024 and 28th February 2025 last season.

Number of In-Patient Bed Days Avoided

The number of bed days avoided (including ICU bed days) using estimates from method 1 was 1,861.9 days (95% CI: 1,445–2,293.2). The number of bed days avoided (including ICU bed days) using estimates from method 2 was 2,287.6 days (95% CI: 1,586.7–2,988.5).

Number Needed to Immunise

Using data from method 1 to calculate the number of hospitalisations averted, the number needed to immunise to prevent one hospitalisation was 51 (95% CI: 50–52).

Critical Care Transfers

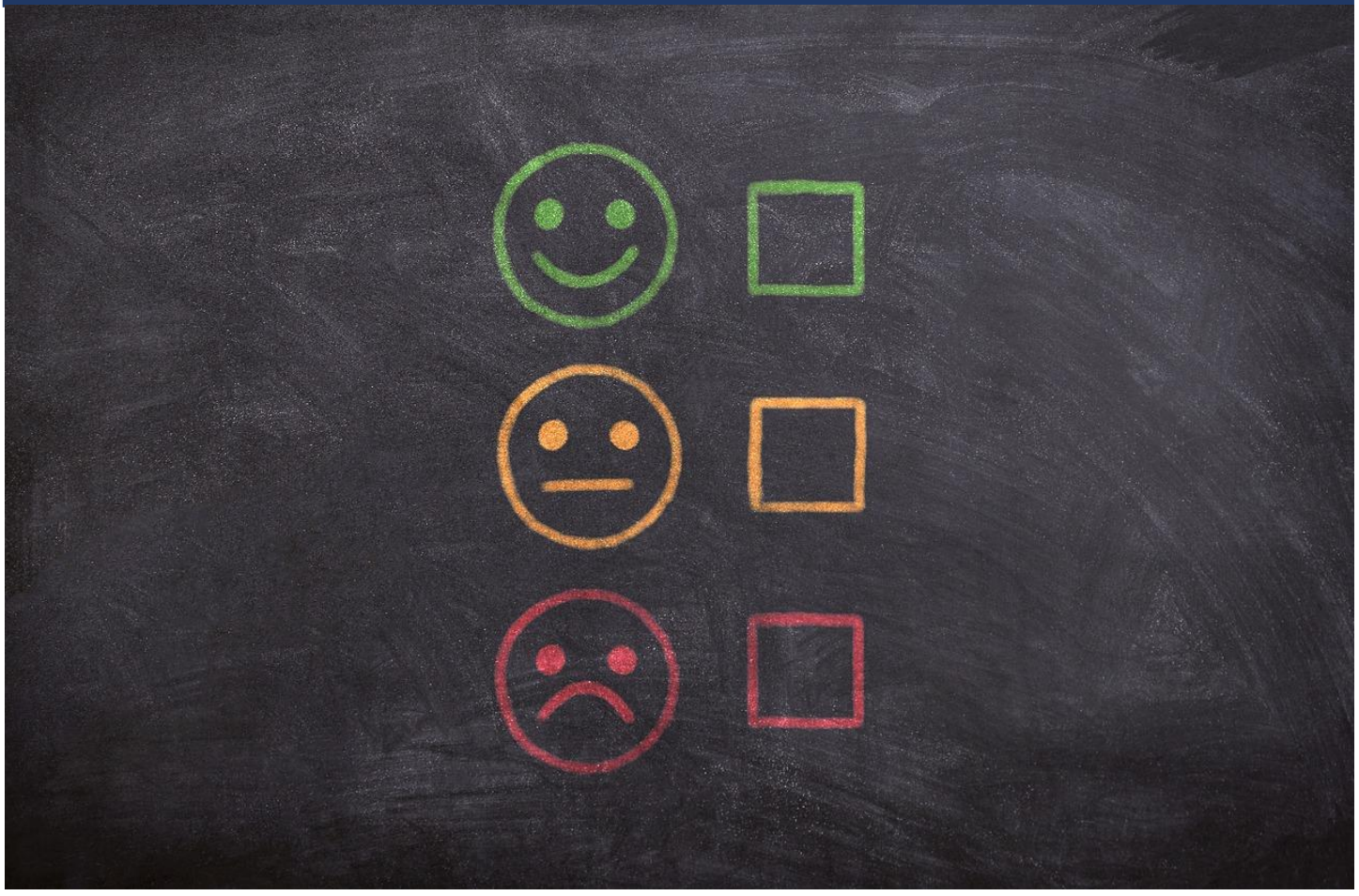
Critical care transfers – paediatric and neonatal – are complex procedures requiring meticulous planning and skilled staff. These transfers involve navigating logistical challenges and ensuring the infant receives the appropriate level of care, often moving them from smaller units to larger neonatal/paediatric intensive care units (NICUs/PICUs). The complexity stems from the need to coordinate resources, transport the infant safely, and maintain continuity of care in the new environment. Anecdotally, these transfers utilise significant resources.

The number of paediatric transfers for this birth cohort with RSV bronchiolitis decreased from 19 in 2023/24 to five in 2024/25. Of these five, three were not immunised. Of the two infants immunised, neither required intubation (required high flow oxygen only) and were discharged from PICU after a short length of stay.

The number of neonatal transfers between hospitals due to RSV dropped from 35 in 2023/24 to just five in 2024/25. Of those five, four neonates were not immunised with nirsevimab.

6

Qualitative Evaluation



Qualitative Evaluation

This section describes the findings from the parent survey, staff survey and wider stakeholder feedback sessions that were held to inform this evaluation. This section describes the participants involved and then summarises the feedback from all groups combined according to common themes.

The quotes presented in the following sections are colour-coded according to Figure 6.1.

Figure 6.1. Legend for interpreting source of quotes

Parent Survey Participation

There were 370 valid responses to the Parent Survey. Overall, 91% of respondents accepted Nirsevimab for their child. Further details describing the participants are included in Table 6.1.

Table 6.1. Characteristics of Parent Survey Participants

Characteristic	Number	% *	Characteristic	Number	% *
Age Group			**Location where Nirsevimab was Offered**		
18-29 years	50	13.5%	HSE Dublin & North East	91	24.6%
30-39 years	270	73.0%	HSE Dublin & Midlands	51	13.8%
40+ years	50	13.5%	HSE Dublin & South East	89	24.1%
Baby's Month of Birth			HSE South West	42	11.4%
Before September 2024	42	11.4%	HSE Mid West	20	5.4%
September 2024	41	11.1%	HSE West & North West	42	11.4%
October 2024	44	11.9%	Children's Health Ireland	20	5.4%
November 2024	41	11.1%	TCP Homecare	8	2.2%
December 2024	33	8.9%	Didn't Specify	7	1.9%
January 2025	57	15.4%			
February 2025	112	30.3%			

*Percentages do not add to 100% due to rounding

Staff Survey Participation

There were 402 valid responses from healthcare workers to the staff survey. All sites that provided Nirsevimab participated. The role and work location of the participants are included in Table 6.2.

Table 6.2. Characteristics of Staff Survey Participants

Characteristic	Number	%	Characteristic	Number	%
Work Location			**Role**		
HSE Dublin & North East	64	15.9%	Midwife	200	49.8%
HSE Dublin & Midlands	21	5.2%	Nurse	82	20.4%
HSE Dublin & South East	106	26.4%	Student nurse/midwife	56	13.9%
HSE South West	37	9.2%	Director/Assistant Director of Midwifery	24	6.0%
HSE Mid West	18	4.5%	Doctor	16	4.0%
HSE West & North West	54	13.4%	Pharmacist/Technician	11	2.7%
Children's Health Ireland	99	24.6%	Other	9	2.2%
National	1	0.2%	Not Specified	4	1.0%
Not Specified	2	0.5%			

Focus Groups and Interview Participation

Three focus groups, which included 15 DOMs/Assistant Directors of Midwifery (ADOMs), were conducted to gather feedback relating to the programme.

Additional interviews and focus groups were conducted with a broader range of stakeholders. These included seven Paediatricians, 14 GPs, three GP Practice Nurses, one GP Practice Manager, seven Hospital Pharmacists involved in the programme, two Regional Directors of Public Health and one Community Public Health Nurse.

Feedback Themes

A Very Welcomed Initiative

The feedback from all groups (parents, staff, DOMs and wider stakeholders) was generally positive as most people viewed the RSV Immunisation Pathfinder Programme as a very welcomed initiative. 91% of parents who responded to the survey reported accepting nirsevimab for their child. Several parents said that they thought the Immunisation was “amazing” and that they were “very grateful”. Some parents noted that they previously had children very sick with RSV so were keen to get nirsevimab for this baby. Others noted that their child still got RSV but they believe the illness was less severe thanks to nirsevimab.

DOMs recognised the potential benefits of the RSV immunisation programme to reduce infant morbidity and hospital admissions due to RSV. There was consensus that the initiative aligns with broader public health goals and supports the well-being of both mothers and infants. Some staff expressed excitement about being part of the RSV Immunisation Programme.

Concerns Regarding Nirsevimab

While acceptance of nirsevimab was very high for this programme and among parents who responded to the Parents Survey, it is noted that many parents had some concerns regarding the safety of nirsevimab. Figure 6.2 shows that approximately half of parents who accepted nirsevimab for their child had no concerns about nirsevimab, but more than one-third were worried about side-effects/adverse reactions. Fourteen percent worried about giving the immunisation to their child at such a young age and 11% were concerned about the effectiveness of nirsevimab.

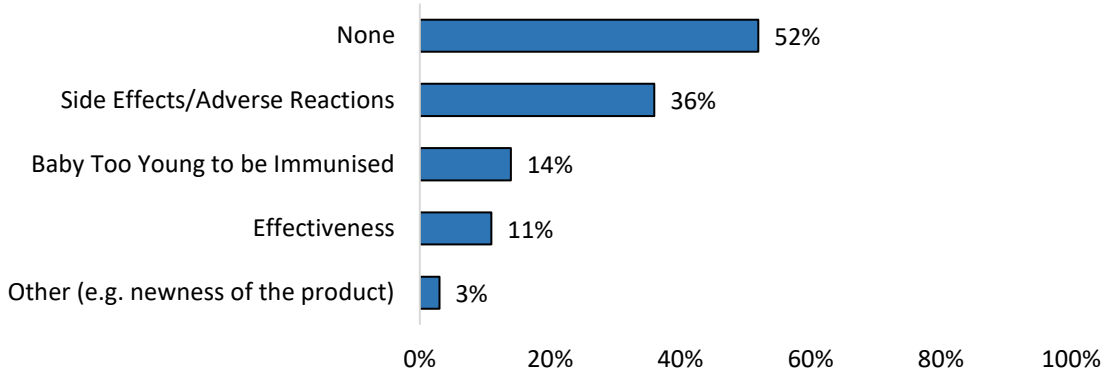


Figure 6.2. Concerns regarding nirsevimab among those who accepted it for their baby

Just 33 (9%) of parents who responded to the survey reported declining nirsevimab for their child. The reasons for declining nirsevimab are outlined in Figure 6.3.

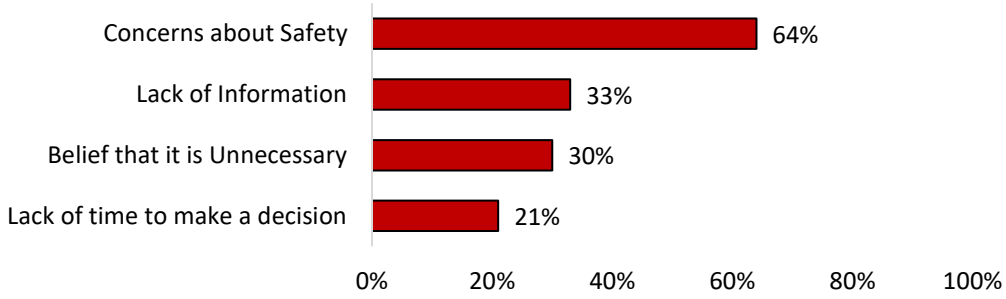


Figure 6.3. Reasons for declining nirsevimab

Similar reasons for parents declining nirsevimab was gleaned from the Staff Survey. From the perspective of staff, the common reasons for declining of nirsevimab were:

- Concerns about safety/Fear of side-effects
- Lack of information
- Fear of giving it so soon after birth
- Anti-vax sentiments

When asked about factors associated with declining nirsevimab, staff reported that, in their experience, the following groups were more likely to decline:

- Those who were unaware of the RSV Immunisation Programme prior to delivery = 29%
- Eastern European Ethnicity = 23%
- Irish Traveller Ethnicity = 23%
- Those who did not have English as their first language = 19%

> Some of the Mums are coming back from the hospital panicked. In fairness, I don't know what the mums are told. It was sprung on them with no warning, they had to decide there and then. Two said no because of lack of knowledge. And then they came back from hospital panicked looking for it. If they'd had the time to think about it, they would have loved to have gotten it.

Nirsevimab Safety & Incidents

Just 1% of doctors and midwives reported observing any adverse reactions in infants after administering nirsevimab. These reactions were described as rashes, with no other serious adverse events mentioned. Pharmacists reported not being aware of any adverse reactions

The Health Products Regulatory Authority were just aware of one adverse reaction relating to nirsevimab (source: email correspondence dated 29/01/2025) – erythema following double administration.

Two medication safety incidents have been reported to the central programme team to date relating to the double administration of nirsevimab. This was likely due to a breakdown in communication between teams when the infants were transferred between wards, and it was unclear if the child had already received nirsevimab or not.

There was at least one incident where the incorrect dose was given to an infant (i.e. 100mg given to a child <5kg). No adverse reaction occurred, and the parents were informed of the error.

Awareness & Communication

Most parents who responded to the Parent Survey were aware of RSV and the potential seriousness of the infection for newborn babies.

83%

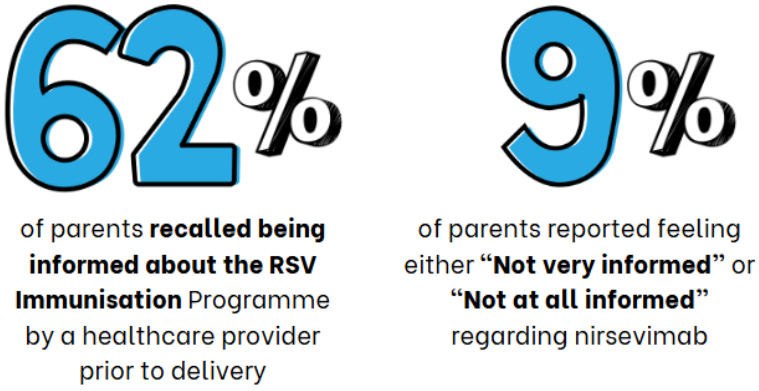
of parents reported being **"Somewhat aware"** or **"Very Aware"** of RSV prior to this programme

91%

of parents believed that RSV is either **"Very serious"** or **"Extremely serious"** for newborn babies

6% of parents believed that RSV was either **"Moderately serious"** or **"Not at all serious"**

Just under two-thirds of parents recalled being informed about the RSV Immunisation prior to delivery. Almost one-in-ten parents said they were not informed about the immunisation.



Even among those informed about the programme, some parents felt that they did not receive adequate information.

Figure 6.4 presents how parents learned about the RSV Immunisation Pathfinder Programme.

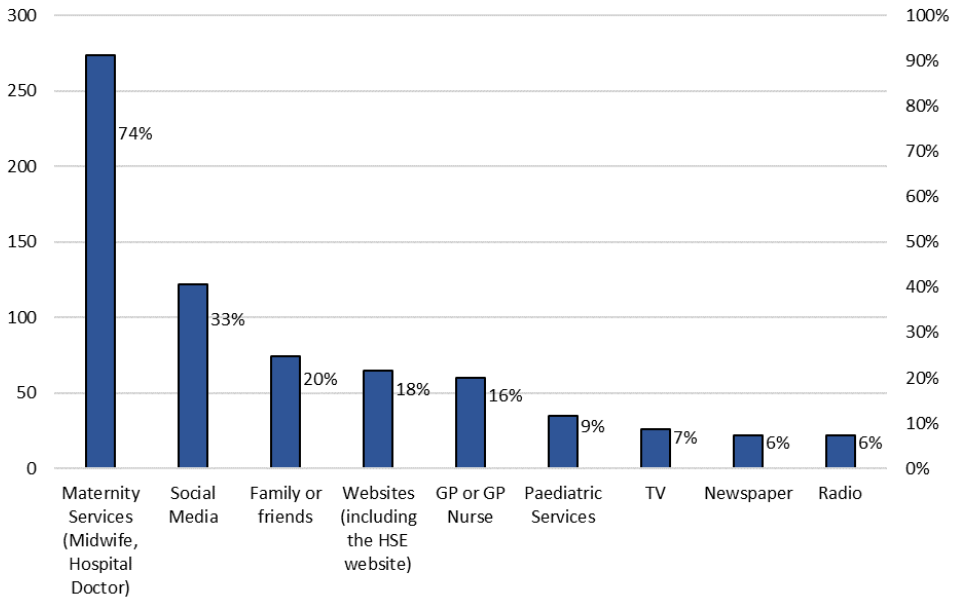
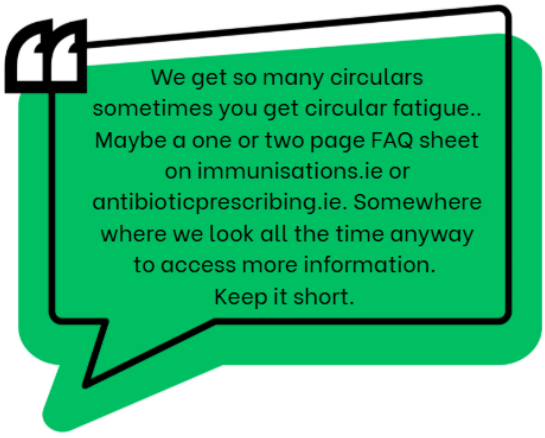


Figure 6.4. How parents learned about the RSV Immunisation Programme based on responses to the Parents Survey

Many parents suggested that there should be more antenatal education and awareness about the programme. Some felt they were making a last-minute decision once the baby was born. Some parents said that they would have liked to have had more discussion about the programme with a healthcare professional during outpatient appointments. Respondents from all groups mentioned the potential power of using real stories and voices from parents of children who had RSV as well as parents of children who have received the immunisation. This would assist with communication campaigns to increase acceptance of nirsevimab.

There may have been some confusion among parents about the RSV Immunisation Programme. GPs commented that the relative lack of national communications from the HSE, tied with communications about a new primary childhood immunisation schedule, some awareness of a maternal vaccination programme for RSV in the UK and news of a new RSV vaccine for older adults, may have caused confusion among parents.

Perceived lack of a national communications effort was noted by many respondents. Some parents said that they had to do a lot of their own research about nirsevimab. One parent commented that their GP did not know anything about the RSV Immunisation. GPs also admitted that they knew very little about the RSV Immunisation which caused difficulties when patients were asking them about it. Most GPs commented that they did not receive formal communication about the RSV Immunisation Pathfinder Programme. A circular from the Irish College of General Practitioners was sent to GPs to inform them of the programme, however, it is possible that not everyone read the email.



Most GPs said that they would not be confident in discussing nirsevimab with patients. However, GPs would know where to source information if asked (e.g. NIAC guidelines, HSE websites). GPs have requested more information and a concise FAQ document to help them promote it. They have also asked for leaflets to be made available to them to give to pregnant women and prompt discussion.

Similarly, RDPHs said that it would have been useful for them to be kept more informed of overall RSV immunisation policy so they are up-to-date when speaking with senior decision makers in the HSE and external stakeholders (e.g. politicians in the Regional Forum where queries had arisen).

Among hospital staff, after additional staffing, more education and training was the second most requested thing staff asked for in order to improve the programme implementation. Staff asked for

earlier, more practical and ongoing training, with protected time and adequate staffing, clear leadership, and resources tailored for both clinical and communication needs.

Additionally, as a result of the limited levels of national communication about the RSV Immunisation Programme, maternity hospital staff felt under greater pressure to do all of the education to parents around the immunisation.

Spotlight on the Rotunda Hospital Experience

The Rotunda hospital took a unique approach to proactive antenatal engagement with parents and gathering consent pre-delivery. Staff used phone calls and digital tools to send information and consent forms, which proved efficient and effective. No additional staff were available, so existing staff worked overtime, often from home, to deliver antenatal education and obtain consent. Overtime and remote working were used as incentives for staff to promote the initiative. This was only possible due to existing technological infrastructure (e.g. MN-CMS).

Immunisation was primarily administered in the labour ward/theatre, with a daily “mop-up” on the postnatal ward for women who had not been informed about nirsevimab antenatally. The hospital’s electronic whiteboard system was used to enable real-time tracking of immunisation status, minimising missed cases.

The hospital also credited the appointment of a dedicated RSV co-ordinator with driving the programme’s success, enabling efficient internal operations, staff education, and liaison with pharmacy.

Not Far Enough

Unprompted, several parents expressed their opinion that the programme should have been available to all children <6 months or <12 months at the start of the RSV season. Paediatricians are also saying that it needs to be available to more infants. However, DOMs in hospitals where maternity units and paediatric sites are co-located say there is no way the acute hospitals could deliver a catch-up programme for nirsevimab without being adequately resourced.

Staff widely supported extending RSV immunisation to older infants and making it available beyond the immediate newborn period, both for reasons of equity and practicality. There was a clear call for future iterations of the programme to include catch-up opportunities and community delivery to ensure no infants are left unprotected due to narrow eligibility or timing constraints. Some of the GPs and Practice Nurses who took part in interviews said that it makes sense that it would be offered in Primary

Care. They want to be able to offer it to their patients, and some had parents requesting it from them this year.

The Programme Felt Rushed

One of the main criticisms about the programme was that staff felt that it was very "rushed" and "fragmented". There was a very short period of time between when DOMs were informed about this programme and 1st September 2024 and many of the resources that were promised to them did not materialise in a timely way (e.g. staff, additional fridge, information leaflets).

Education for staff was also introduced very quickly. There was also not much time to raise awareness among parents about the programme. Because of this lack of awareness, more time was needed for midwives to inform parents of the benefits of nirsevimab. There was a strong sentiment from DOMs and Midwives that the programme was "dumped" on maternity units on "staff who were already understaffed and overworked".

Immunisations was a new task for midwives. Most staff had no experience in providing a mass immunisation programme. This was seen as a challenge and added complexity to the roll-out.

In the Staff Survey, 49% of DOMs and Midwives felt that the overall programme implementation was "Very Good", 35% said it was "Good", 9% were "Neutral", 6% said it was "Poor" and 2% said it was "Very Poor".

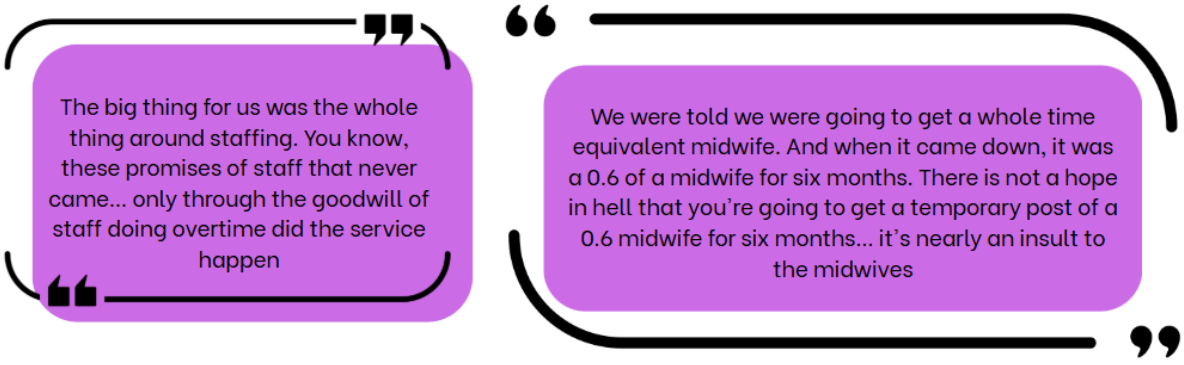
Programme Staffing

DOMs highlighted logistical challenges, particularly regarding staffing and workload. Many noted that the current workforce is already stretched, and the introduction of the immunisation programme exacerbated existing pressures. DOMs were generally dissatisfied with the staffing situation for this programme, 66.6% of DOMs and ADOMs reported that there was not adequate staffing resources provided to implement this programme. This sentiment was shared by 39% of Midwives.

Recruitment of additional staff promised (midwives, pharmacists and admin) was impacted by:

- Pre-existing vacancies
- Ongoing HSE and Regional Health Area reform
- HSE Pay and Numbers policy – Recruitment Embargo
- Long lead-in time for recruitment
- Lack of attractiveness of a part-time position for less than 1 year, especially in areas outside cities

Instead of recruiting, some maternity units used the funds intended for additional staff to pay for overtime related to the programme for existing staff. DOMs noted variability in infrastructure and resources across different sites, which could affect equitable implementation.



53% said it has added <2 hours extra to their working week, 18% reported 2-4 additional hours per week, 4% said 4-6 hours and 3% said they worked 7 or more additional hours per week due to this programme. 22% of Midwives reported that the programme added no additional hours of work to their week.

Participants called for dedicated funding to support the programme's rollout, including resources for training, additional staff, and educational materials. DOMs have said that staffing positions for the RSV immunisation Programme should be year-round and not limited to six months. This is because there is work that can be done outside of the RSV season to prepare and educate parents and staff about the immunisation.

Fewer Cases of RSV Bronchiolitis

The benefits of the immunisation programme have been apparent to paediatric teams managing infant cases of RSV. Paediatricians have called this programme "A Game Changer" for paediatric services this past winter. Midwives in maternity units knew how much benefit this programme could bring to babies and families, and ultimately, this is what motivated them to "get on with" rolling out the programme despite not feeling adequately resourced or prepared.

Another secondary benefit that was expressed by stakeholders was the effect on families. One respondent said that "Approximately 85% of the kids who were admitted last year (2023/24) had siblings. So you are taking a parent away from a family. You were sending kids to ICU. There is this whole second victim thing of a traumatic experience". Many of these second victim experiences were avoided this past season due to the effectiveness of RSV immunisation.

The difference was also noticed in primary care. Many respondents commented on a significant reduction in bronchiolitis among the infant cohort eligible for nirsevimab.

Multidisciplinary Team Approach

Several participants described how local working groups or committees were established to deliver the programme, often including neonatologists, pharmacists, midwives, nursing managers, and administrative staff. Participants noted that support from neonatologists and pharmacists was particularly valuable for both clinical decision-making and troubleshooting. Not all sites experienced the same level of multidisciplinary engagement. Some reported that medical colleagues were less involved, with the burden of implementation falling mainly on midwifery staff.

Pharmacists played a central role in the design, logistics, implementation and ongoing support of the RSV Immunisation Pathfinder Programme. Their early and ongoing involvement was highlighted as a key factor in the programme's success, especially for practical aspects such as stock management, ordering, SOP development and troubleshooting. The inclusion of pharmacists from the outset was seen as a positive departure from previous national programmes, where pharmacy expertise was often underutilised. This multidisciplinary approach was credited with smoothing the rollout and supporting midwifery and nursing teams.

Data Collection

Data collection was a major challenge, particularly for paper-based sites. Pharmacists and DOMs described the process as labour-intensive, prone to missing or misfiled forms and difficult to reconcile retrospectively.

Participants strongly recommended moving towards an electronic consent and documentation system. They noted that electronic platforms would be intuitive, quick and allow easy data extraction for monitoring and evaluation. Some hospitals already had electronic maternity information systems (e.g., MN-CMS) that integrated consent and immunisation records, making the process smoother.

From a Regional Department of Public Health perspective, RDPHs said that it would have been useful to be able to cross-check the immunisation status of notified RSV cases. However, this was not possible due to the lack of an accessible database.

The weekly uptake reports, which included a league table of nirsevimab uptake, were reported to be very useful to DOMs. They reported that they helped motivate staff to increase uptake. Unfortunately, it was discovered through feedback sessions that not all DOMs were receiving the uptake reports. This is because the communication chain for the uptake report relied on hospital management to forward the email to DOMs rather than going directly to them. This meant that some DOMs were unaware of their individual hospital's performance until the end of the programme.

Pathway Back

Respondents were clear that the absence of a defined, accessible pathway for parents who changed their mind about RSV immunisation after discharge was a significant gap in the pathfinder programme. Although national guidance suggested that arrangements could be made, in practice this was rarely feasible, and families had no routine way to access immunisation after leaving hospital. The majority of maternity units did not have the resources or capacity to maintain a pathway back for parents who changed their minds. Respondents strongly recommended that future programmes include a formal, well-communicated process - potentially involving community services or designated clinics - to ensure all families have equitable access, even if they initially decline in hospital.

Home Births

Whilst some community midwives were able to provide nirsevimab at home, with support from local neonatologists and pathways for administration, other regions did not have this benefit. Babies who did not receive nirsevimab soon after birth at home were offered nirsevimab at their baby check appointment in hospital. For the 2025/2026 RSV season, clarification is required on the pathway and governance for community midwives to administer nirsevimab in the home birth setting. The RSV Immunisation Pathfinder Programme delivered mixed messages to community midwives, resulting in inequity of access to immunisation due to regional variations in practice.

Variations in Practice

a. Consent

The SOP advised that verbal consent was acceptable, and many sites followed this approach. However, DOMs expressed concerns about the vulnerability of relying solely on verbal consent, especially when nirsevimab was declined or questioned later. The absence of written documentation made it difficult to verify consent status, which is particularly important in maternity services where thorough documentation is standard practice.

There were incidents where babies received double doses of nirsevimab because consent documentation was not clearly visible or accessible across different units (e.g., labour ward and neonatal unit). Midwives highlighted the need for clear, accessible records to prevent such errors.

b. Prescribing

In some maternity units, DOMS reported that there was reluctance of paediatricians to facilitate a standard order, which resulted in midwives having to rely on individual prescriptions. This meant that, instead of a streamlined protocol, each administration required a separate prescription, adding to the workload of staff. The requirement for individual prescriptions was seen as a bottleneck, particularly when paediatricians or non-consultant hospital doctors were unavailable, potentially delaying administration and affecting timely uptake.

c. Best Location to Provide Nirsevimab

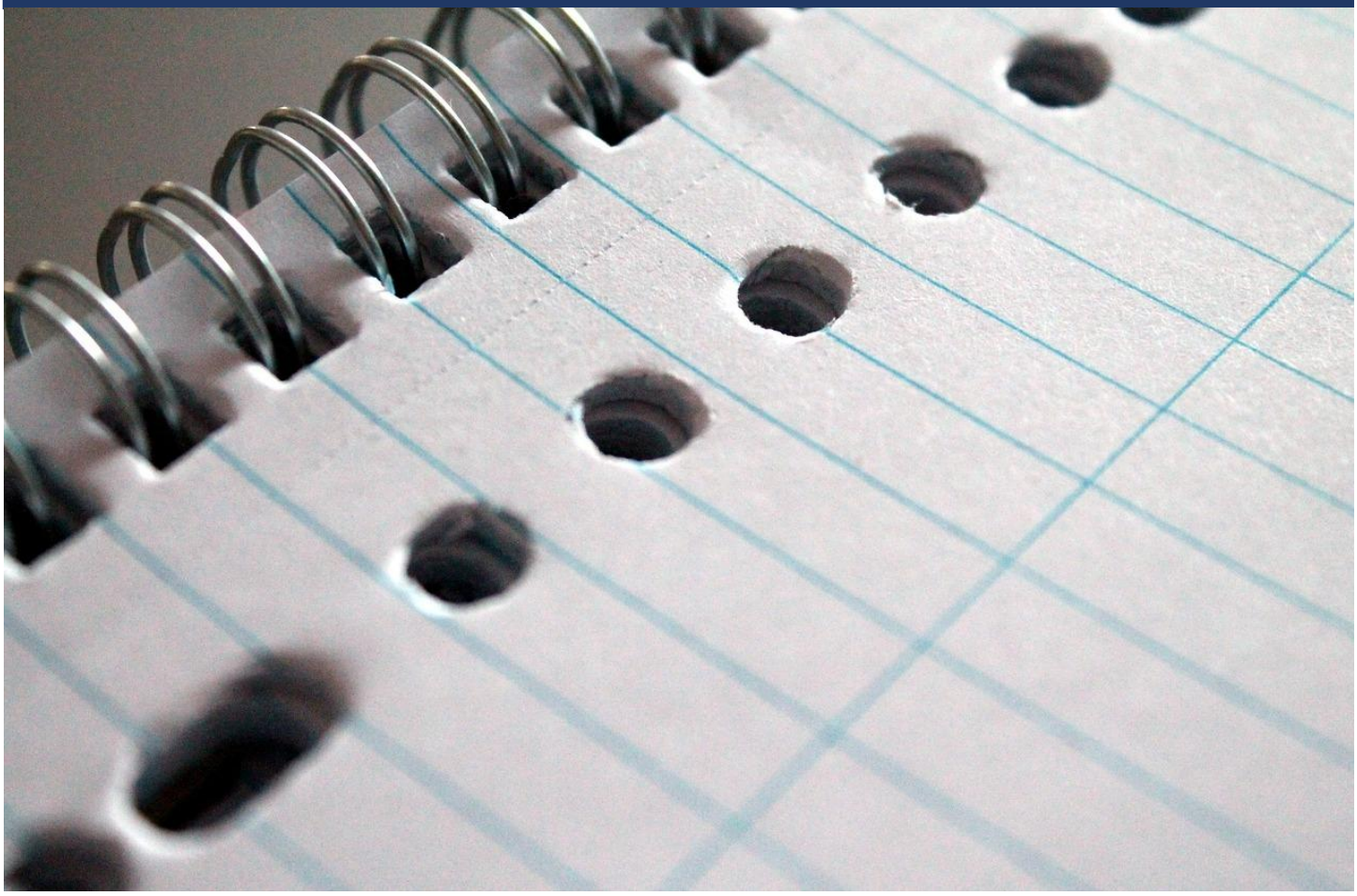
Many participants favoured administering the immunisation in the delivery suite or labour ward, especially soon after birth, as this allows timely protection and capitalises on the mother's presence in a clinical setting. Midwives supported giving the immunisation in the labour ward and theatres but only if parents have been adequately informed in advance. One DOM said: "The reason we chose not to give it in theatre at the beginning was lack of information (among) parents... if we're rolling it out again in September, it's going to be given in the labour and birthing unit and our theatre because those nurses and midwives are very familiar with giving (vitamin K)".

However, the postnatal ward was also an important location, especially when immediate post-birth administration was not feasible due to clinical or consent reasons - "We started off giving the immunisation in the delivery suite, but a recommendation from the postnatal ward and delivery suite was that probably in the postnatal period is the better time to give it... so they felt supported."

Early antenatal information provision and dedicated follow-up were critical enablers to maximise timely immunisation and uptake.

7

Discussion



Discussion

Programme Success

The programme's success in achieving high uptake of nirsevimab immunisation across all maternity hospitals is a testament to the collaborative efforts and strategic planning involved. The fact that all maternity hospitals were able to provide RSV immunisation is a major success of the programme. It was not guaranteed that all hospitals would participate. Regional reform of the health service and staffing issues could have served as an obstacle to the programme. The national lead midwife and lead neonatologist at the NWIHP played a valuable role in engaging with DOMs and hospital management directly to ensure all sites provided nirsevimab. Although one site started a couple of weeks later, they were able to come fully on-stream. This ensured that the pathfinder programme offered protection to all babies born in Ireland during the RSV season. RDPHs played a valuable role in advocating for and supporting the programme at a regional level and were advocates for immunisation in the REO's executive teams.

The success of the RSV Immunisation Programme is also evident in its profound impact on the health outcomes of the target population. By achieving 83% uptake of nirsevimab, the programme has significantly reduced ED presentations, hospitalisations, and ICU admissions among infants during the RSV season. In the 2024/2025 RSV season, ED presentations (non-hospitalised) dropped by 57%, hospitalisations by 76%, and ICU admissions by 65% compared to the previous season. Based on the observed number of cases, nirsevimab uptake and presumed immunisation effectiveness, we estimate that the RSV immunisation programme averted 440 (95% CI: 432–447) non-hospitalised ED presentations, 433 (95% CI: 426–440) hospitalisations, and 79 (95% CI: 77–81) ICU admissions. Using an alternative statistical method based on modelling informed by RSV surveillance data from previous seasons, we estimated that there were 532 (95% CI: 369–695) fewer hospitalisations among the infant cohort born between 1st September 2024 and 28th February 2025 compared to what was predicted in the absence of an RSV immunisation programme. Based on these figures, it is estimated that the number of bed days avoided (including ICU bed days) was 1,861.9 days (95% CI: 1,445–2,293.2). The estimated hospital-related costs avoided from hospitalisations (including ICU admissions) was €4.2 million (95% CI: 3.7–4.8 million). The estimated number needed to immunise to prevent one hospitalisation was 51 (95% CI: 50–52). The decrease in severe cases requiring intensive medical intervention highlights the programme's effectiveness in mitigating the adverse effects of RSV and providing a safer, healthier start for newborns.

Understanding the factors associated with nirsevimab uptake is crucial for the ongoing success and improvement of the RSV Immunisation Pathfinder Programme. By identifying demographic characteristics such as maternal age, patient type, ethnicity, parity, socioeconomic status, and breastfeeding, the programme can tailor its strategies to address specific barriers and enhance acceptance rates. For instance, targeted education and outreach efforts can be developed to ensure equitable provision of information across different ethnic groups, particularly those with lower acceptance rates like Irish Traveller and Roma communities. Additionally, recognising the influence of social deprivation on uptake allows for more focused interventions to support mothers from disadvantaged areas. This comprehensive understanding will enable the programme to refine its approach. The MN-CMS data from the Rotunda and National Maternity Hospital have demonstrated the possibility of producing information-rich, timely reports with granular information on the

determinants of uptake. Next year, it may be possible to use data from six MN-CMS hospitals (Cork University Hospital, University Hospital Kerry, University Maternity Hospital - Limerick, the Coombe Hospital, the Rotunda and the National Maternity Hospital) and enable interactive dashboards to provide public health insights in real-time.

The insights gained from the Parents Survey, Staff Survey, focus groups and interviews with stakeholders will inform the future directions of the RSV Immunisation Programme. For example, addressing the common concerns about nirsevimab (informed by the Parent Survey) through effective communication campaigns may improve uptake further.

Hypotheses

Prior to this evaluation, several hypotheses were made about RSV Immunisation Programme. This section presents the originally stated hypothesis and the relevant evidence generated in this programme evaluation.

Hypothesis: Uptake of nirsevimab may be low initially but improve over the six-month period as awareness increases.

Findings: National weekly uptake of nirsevimab in maternity hospitals and CHI ranged from 75.8% to 89.3% throughout the programme. Uptake in the first and last months of the programme was slightly lower, but uptake was relatively consistent throughout the middle four months of the programme.

Hypothesis: Infants from lower socio-economic or marginalised groups would have lower uptake of nirsevimab compared to the general population.

Findings: Data from the Rotunda and National Maternity Hospital support this hypothesis as correct.

Hypothesis: Multiparous mothers are more likely to accept nirsevimab for their child compared to primiparous mothers.

Findings: Surprisingly, this hypothesis was refuted by the evidence from the Rotunda and National Maternity Hospital. Multiparous women, particularly those with two or more prior deliveries, were less likely to accept nirsevimab. This may be due to a belief that the immunisation was not necessary (as their previous children may not have been severely impacted by RSV), alternatively, it may be due to the association of higher parity and lower socioeconomic status or other factors yet unknown.

Hypothesis: Hospitalisations and PICU admissions for those born during September 2024 to February 2025 will be lower compared to previous RSV seasons.

Findings: The programme significantly reduced RSV-related ED presentations, hospitalisations and ICU admissions among infants. In the 2024/2025 RSV season, ED presentations dropped by 60%,

hospitalisations by 78%, and ICU admissions by 71% compared to the previous season. This substantial decline in severe RSV cases highlights the programme's effectiveness in mitigating the adverse effects of RSV and providing a safer, healthier start for newborns.

Differences in Operational Delivery of Nirsevimab

Location of Administration

There was a variation in the process for administering nirsevimab across different hospitals. Some hospitals provided nirsevimab in the delivery suite or theatre, while others administered it only in post-natal wards. This was due to logistical factors within hospitals. Delivery of nirsevimab was preferred in the delivery suite, labour ward or theatre, but only if parents were adequately informed of the immunisation prior to delivery.

Prescriptions

Some maternity units required the use of individual prescriptions rather than allowing midwives to follow the medicines protocol. This is unnecessary and burdensome given the safety profile and public health importance of the intervention. DOMs described it as administratively cumbersome, a source of delays, and an area where greater autonomy would improve workflow, uptake and staff satisfaction.

Consent

The process of obtaining consent for the RSV Immunisation Pathfinder Programme varied across different maternity hospital sites. For instance, the Rotunda Hospital adopted a proactive approach by engaging with parents antenatally through phone calls and digital tools to send information and consent forms. Other sites obtained consent to administer nirsevimab around at the time of delivery or on the post-natal ward. Additionally, some sites accepted verbal consent, while others opted for formal written consent.

Comparison to other countries

The United Kingdom (UK), USA, Canada, Spain, France, Luxembourg, Chile, and Australia have each adopted distinct approaches to infant RSV immunisation, reflecting variations in health policy, epidemiology, and available products, but all with the shared goal of reducing severe RSV disease in infants.

UK and Northern Ireland

In the UK, an RSV immunisation programme for pregnant women was implemented from September 2024, following advice from the Joint Committee on Vaccination and Immunisation. The strategy is based on maternal vaccination, with RSVpreF (Abrysvo®), during pregnancy, aiming to confer passive immunity to newborns through transplacental antibody transfer. Pregnant women from 28 weeks of gestation up until delivery are eligible for this programme.[26]

The most recent official data for England, covering December 2024, indicate that 47.6% of women who gave birth that month had received the RSV vaccine during pregnancy. This figure is based on data from 40.4% of General Practices across England. This is up from 33% of pregnant women who gave birth in September 2024.[27] Uptake data for Northern Ireland is not publicly available.

Since the approach to RSV immunisation differs fundamentally between Ireland and the UK, this creates somewhat of a natural experiment on the island of Ireland. This divergence, maternal versus infant-focused approaches, will allow for comparative analysis of real-world effectiveness, coverage and equity outcomes across two populations with shared geographic and demographic characteristics but differing interventions. Key metrics for comparison include RSV-related hospitalisations, immunisation uptake rates, and ethnic or socioeconomic disparities in access and outcomes. Collaboration with public health colleagues in Northern Ireland will be required to make these comparisons, as routinely published data does not provide enough insight to compare the two approaches at present.

United States of America

The USA introduced both infant and maternal immunisation options for RSV in the 2023–2024 season. Nirsevimab was recommended for all infants under eight months of age during the RSV season, while the RSVpreF vaccine was offered to pregnant women at 32–36 weeks of gestation. Despite strong efficacy, overall uptake was limited, with coverage for nirsevimab at 44% and maternal vaccine at 33%. Implementation challenges included logistical barriers, supply constraints, and disparities in access across states, which impacted the overall effectiveness at a population level.[14]

Canada

Canada, specifically Ontario, expanded its RSV immunisation programme for the 2024/2025 season to include all infants born in 2024 and throughout the RSV season, not just those at high risk. The programme uses nirsevimab for infants, with RSVpreF available for pregnant individuals who opt not to use nirsevimab for their infant. The programme also covers high-risk children up to 24 months of age and allows co-administration with other vaccines.[9]

Spain

Spain was among the first countries to implement a universal infant RSV immunisation strategy using nirsevimab during the 2023–2024 season. Coverage was high, with 91.5% of infants born during the season immunised. The campaign targeted all infants under six months of age, preterm infants up to 34 weeks gestation, and children with specific risk conditions. Rapid immunisation was achieved, and the programme demonstrated high uptake and operational feasibility, although coverage was somewhat lower among children of immigrant origin.[15]

France

France launched a national nirsevimab immunisation campaign in September 2023, prioritising neonates in maternity wards due to limited dose availability. By January 2024, approximately 232,000 doses had been delivered. Studies indicate a substantial reduction in RSV-related hospitalisations among infants aged 0–2 months, with an estimated effectiveness of 70–83% against hospital admissions for RSV lower respiratory tract infection. Modelling suggests that one hospitalisation was averted for every 40 children treated, highlighting the significant impact of the programme.[6]

Luxembourg

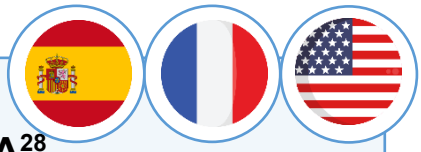
Luxembourg also introduced nirsevimab immunisation in 2023, achieving an estimated neonatal coverage of 84%. Paediatric RSV-related hospitalisations, particularly among infants under six months, dropped markedly compared to the previous year – a 69% reduction in this age group.[7] The mean age of hospitalised children increased, and the length of hospital stay decreased, suggesting that nirsevimab prophylaxis not only reduced the incidence but also the severity of RSV infections.

Chile

Chile became the first Southern Hemisphere country to implement a universal, nationwide nirsevimab immunisation strategy for RSV prevention during the 2024 winter season. Coverage reached 98% for in-season newborns and 83% for the catch-up infant group by mid-June 2024. Effectiveness was estimated at 86% against paediatric intensive care unit admissions and 75% against overall RSV-associated hospitalisations. No RSV-related deaths were reported among immunised infants, compared to 13 deaths in the previous year, and no serious adverse events were observed. The programme's rapid rollout and high coverage demonstrate the feasibility and impact of universal immunisation in a national context.[10]

Australia

In Australia, record RSV case numbers in 2024 has prompted the government to include the RSV vaccine RSVpreF on the National Immunisation Program for pregnant women, starting February 2025.[11]



Lessons learned from Spain, France and USA[28]

- Reviewing and funding nirsevimab using the same pathways that are used for all other childhood immunisations.
- Ensuring nirsevimab could be accessed at no cost at the point of service.
- Public awareness campaigns that were tailored to the knowledge and perceptions of different populations.
    - Recognising the seriousness of RSV was an important predictor of accepting nirsevimab.
    - Framing nirsevimab as a preventative treatment rather than a vaccine was important in France.
- Clear logistical plans that were suitable within the existing systems.
    - In France and US, older infants were given nirsevimab during routine appointments in hospitals or Primary Care, reducing administrative burden.
    - In Spain, dedicated catch-up appointments were scheduled in hospitals and Primary Care.
- Proactive training and engagement with the relevant healthcare professionals.
- RSV surveillance and immunisation monitoring data that could be used to assess the uptake and impact of nirsevimab in preventing severe RSV and related hospitalisations.
    - Also needed to ensure equity.

Source: Morris T, Acevedo K, Alvarez Aldeán J, Fiscus M, Hackell J, Pérez Martín J, Sanchez Luna M, Weil-Olivier C, Tate J. Lessons from implementing a long-acting monoclonal antibody (nirsevimab) for RSV in France, Spain and the US. Discover Health Systems. 2025 Dec;4(1):1-7.

Collectively, these countries' experiences underscore the effectiveness of both infant-targeted monoclonal antibody strategies and maternal vaccination in reducing severe RSV outcomes. Universal immunisation programmes, particularly those employing nirsevimab, have achieved high coverage and substantial reductions in hospitalisations among infants. Maternal immunisation, as implemented in the UK, USA, and Australia, offers an additional or alternative approach, particularly where logistical or supply challenges limit direct infant immunisation. The diversity in policy approaches reflects both local epidemiological trends and health system capacities, but the overarching evidence supports the substantial public health benefit of widespread RSV immunisation.

Evaluation Strengths

The evaluation of the RSV Immunisation Pathfinder Programme was comprehensive, addressing multiple facets of the programme. This approach ensured that various aspects were examined, providing a well-rounded understanding of the programme's delivery and impact.

One of the notable strengths was the inclusion of a wide range of stakeholder feedback. By seeking insights from diverse participants involved in or affected by the programme, the evaluation could capture a broad spectrum of perspectives, enhancing the depth of the findings.

Additionally, despite the surveys being conducted in the months of January and February, it successfully garnered responses from parents whose babies were born throughout the RSV season. This allowed for a richer dataset, encompassing experiences and opinions from different stages of the RSV season, thereby providing a more comprehensive overview of the programme's reception and perceived effectiveness.

Limitations of this Evaluation

Due to the speed at which the RSV Immunisation Pathfinder Programme was set up, this evaluation protocol was not produced until after the programme had commenced. As a result, it was not possible to conduct parent surveys from the start of the programme. This may limit our understanding of early opinions of the RSV Immunisation Pathfinder Programme.

The evaluation report was produced shortly after the completion of the RSV Immunisation Pathfinder Programme. As such, long-term data on the programme's impact was not available. Due to the deadline for which this report was due, the full impact of the programme on cases and hospitalisations may not be fully known, as the benefits of the programme may not be seen for several months after the programme has ended.

This evaluation included a review of traditional and social media pieces about the RSV immunisation; however, detail regarding the paid-for promotion of the RSV Immunisation Programme is not included in this report.

Only laboratory-confirmed cases of RSV are notifiable in Ireland. Clinical cases (not laboratory tested) are not notified. This may include mild/moderate disease (those not hospitalised) or those with atypical symptoms. This evaluation does not assess the potential impact on other age groups also. This may impact the interpretation of the RSV programme's success.

Potential data quality issues, the pathfinder programme has been set up at speed, using paper records in most sites, with no way to validate paper records. Some paediatric units that were co-located with maternity units administered nirsevimab to high-risk infants. It is unknown whether or not all of these administrations are included among the uptake figures returned by data providers. Therefore, the reported figures in this report may under-represent the true number of immunisations administered.

The absence of a national data repository for immunisation records resulted in an inability to link immunisation status to surveillance notifications of RSV cases. Consequently, it was not possible to calculate the effectiveness of nirsevimab in Ireland. This limitation also means that our estimates of hospitalisations averted are based on either previously published effectiveness rates (method 1) or predictions based on previous RSV seasons (method 2). Therefore, these estimates should be interpreted with caution.

There are limitations comparing historical data (pre-COVID-19 pandemic) to 2024/2025, including improved testing capacity, increased use of multiplex NNAT, changes to health-seeking and testing behaviour, access to care, improved surveillance and reporting, the use of robotic process automation for RSV notifications on CIDR and overall better quality of data in 2024/2025.

8

Recommendations

Recommendations

Based on the feedback from parents, healthcare staff and wider stakeholders, in the context of a very successful Pathfinder Programme, the following are some recommendations intended to enhance further iterations of the RSV Immunisation Programme:

1. **Repeat the Existing Programme as a Minimum:** The delivery model for providing nirsevimab to newborns and clinically high-risk infants through maternity hospitals, CHI and TCP Homecare during the RSV season should be repeated on an on-going basis.
2. **Expand Eligibility**: Make nirsevimab available to all infants aged ≤6 months at the start of the RSV season. This would ensure broader protection for vulnerable infants.
3. **Provide Adequate Staffing**: Provide adequate and specific staffing resources to deliver the programme effectively. This includes recruiting additional midwives, pharmacists, pharmacy technicians, data analysts/data scientists and administrative staff.
4. **Enhance Data Management**: Establish or utilise a national data repository for immunisation information. For future iterations of the programme, RSV immunisation should ideally be incorporated into the Primary Childhood Immunisation Programme and data collected through the new National Immunisation Information System (NIIS) in primary care, with access to NIIS to record immunisation in hospitals and homecare teams also. This would streamline data collection and improve the accuracy of immunisation records. Ensure that data sharing agreements and Data Protection Impact Assessments (DPIAs) are in place to allow for centralised collation and analysis of patient identifiable information from all settings where nirsevimab is administered.
5. **Leverage Routinely Collected Data from Electronic Health Records:** Utilise electronic health records from six maternity hospitals (equipped with the Maternity & Newborn Clinical Management System) in real-time to produce interactive dashboards visualising determinants of uptake continuously throughout the RSV season, enabling tailored education and outreach.[13]
6. **Strengthen Communication**: Implement a widespread national communication campaign to raise awareness about the RSV Immunisation Programme. This should include targeted education and outreach programmes to ensure equitable provision of information across different ethnic and demographic groups.
7. **Address Concerns**: Develop strategies to address common concerns among parents regarding the safety and effectiveness of nirsevimab. This includes providing more detailed information about potential side effects and the benefits of immunisation.
8. **Provide Antenatal Education**: Offer comprehensive antenatal education about the benefits of RSV immunisation. This could include information sessions incorporated into existing antenatal clinics and additional resources for expectant parents. Specifically target groups known to have lower levels of uptake.
9. **Educate Healthcare Workers**: Provide more education and training to healthcare workers, including those not directly involved in administering RSV immunisation. This would ensure that all healthcare providers are well-informed and can effectively promote the programme.

a) **GPs, Practice Nurses and Public Health Nurses:** Promote the RSV Immunisation Programme through Primary Care and Public Health Nurses by ensuring these groups are informed of the programme and distributing promotional information that can be used to relay information to parents.

10. **Operational Improvements**: The role of hospital management in strengthening operational coordination must be recognised at regional and national level. Individual units should establish standard operating procedures (SOPs) to address operational challenges, such as prescribing, gaining/recording consent and location where nirsevimab is administered, which may influence the acceptance of nirsevimab, prevent incidents and avoid missed opportunities.

    a) **Home Births**: Develop clear pathways for midwives to administer nirsevimab to babies born at home. This would ensure that infants born outside of hospital settings are not excluded from the programme.

    b) **Provide Pathways Back:** Develop a pathway for parents who initially decline nirsevimab who may subsequently change their minds, to have their infants immunised at a later date.

    c) **Direct Updates**: Provide regular updates to Directors of Midwifery (DOMs) and other services administering nirsevimab directly, rather than relying on communication cascades from others. This would ensure that key partners are kept informed and can effectively manage the programme.

    d) **Multidisciplinary Team Approach**: At every hospital, foster a multidisciplinary team approach by ensuring support from neonatology, paediatrics, pharmacy and administrators for the smooth roll-out of the programme.

11. **Inclusion Health**: Design an Inclusion Health strand of work that coordinates with the National Social Inclusion Office (NSIO) and non-governmental organisations (NGOs) to increase uptake among underserved groups. This can be informed by analysis of the determinants associated with uptake of nirsevimab.

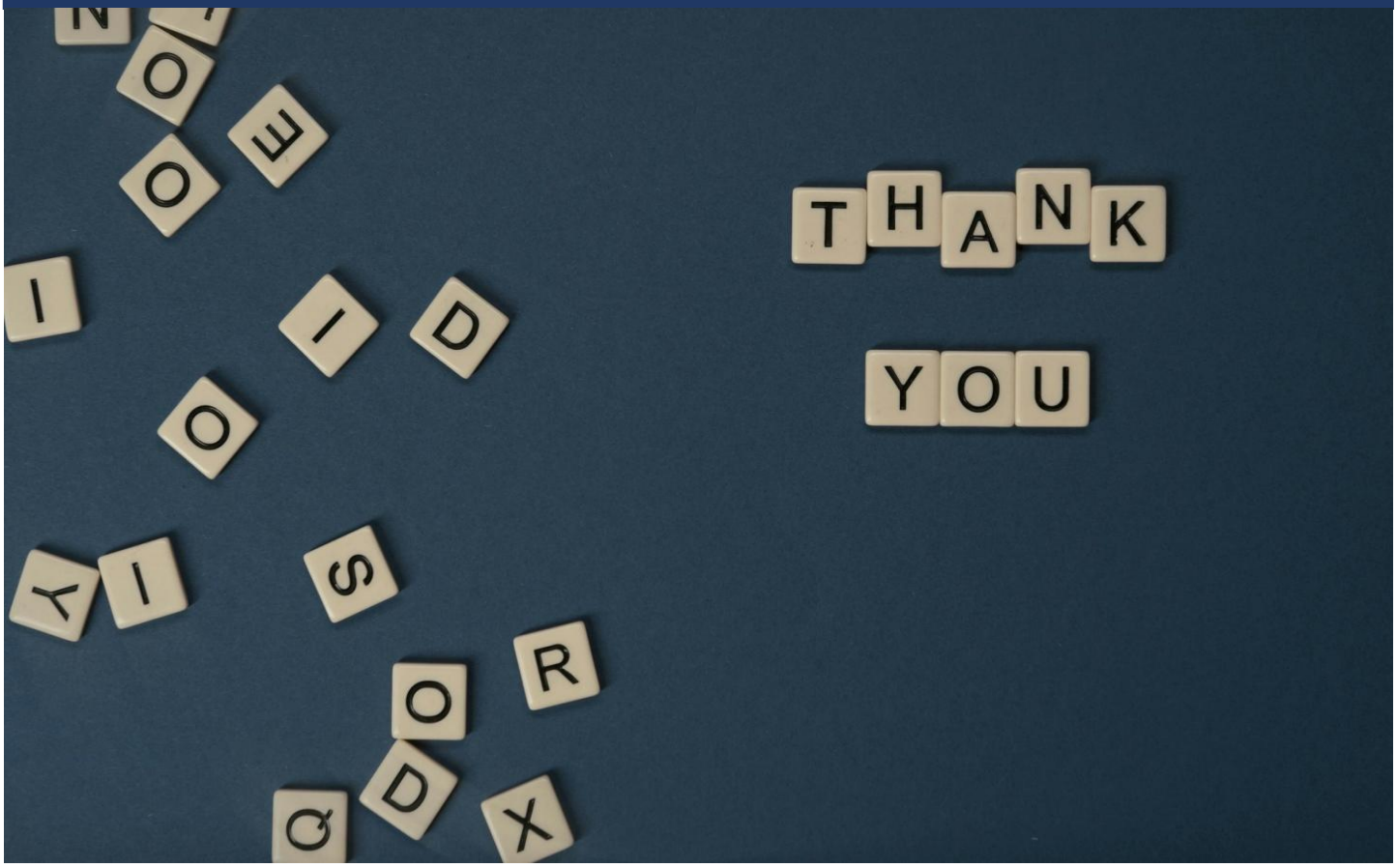
12. **Research on Clinical Impact**: Design a clinical research study to estimate the impact of nirsevimab on the improvements in quality of clinical care describes anecdotally during the evaluation of pathfinder version 1.0. This includes the impact across all settings including in maternity units, paediatric hospitals and primary care. This would help quantify the benefits of the programme in reducing winter pressures.

13. **Research on Immunisation Acceptance**: Conduct research to explore the factors influencing nirsevimab acceptance and strategies to increase uptake.

14. **Continued Evaluation**: Continue evaluating the RSV Immunisation Programme into its next iteration (pathfinder version 2.0), including additional epidemiological analyses of the impact and effectiveness of the programme. This would help identify areas for further improvement and ensure the programme's ongoing success.

9

Acknowledgements



Acknowledgements

Specific acknowledgement for components of the evaluation report are detailed in Table 9.1.

Table 9.1. Acknowledgements

Section	Contributors
Procurement Details	Marnie McDermott
Traditional Media Coverage	HSE Press Office
National Uptake of Nirsevimab	Adele McKenna
Factors Associated with Uptake of Nirsevimab	Brian Cleary, David Fitzgerald, Leon O'Hagan and Avril Dempsey
RSV Surveillance Data	Laura Paris, Maureen O'Leary and HPSC Respiratory Virus Unit
Estimated Number of Hospitalisations Averted (Method 1)	Laura Paris, Margaret Fitzgerald, Eve Robinson, Carina Brehony and Louise Marron
Estimated Number of Hospitalisations Averted (Method 2)	Darren Dahly and Katie O'Brien
Intensive Care Unit Admissions	Eva Kelly and Emma Coughlan
Critical Care Transfers	Cathy Gibbons and John Murphy
Interviews with GPs and GP Practice Nurses	Ciara Cunningham
Interviews with Paediatricians	Sean Fennessy

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- **Steering Group Members (listed on page iii):** Finally, we thank the Steering Group members for their guidance, oversight, and constructive input at every stage.

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10

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