FSS Sláinte Poiblí: Chosaint Sláinte
HSE Public Health: Health Protection

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

Evaluation – Executive Summary

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Programme Partners

FSS Sláinte Poiblí: Chosaint Sláinte
HSE Public Health: Health Protection

National Immunisation Office

National Women & Infants Health Programme

National Clinical Programme for Paediatrics and Neonatology

PAEDIATRICS

FSS Rochtain agus Comhtháthú
HSE Access and Integration

National Immunisation Advisory Committee
An Coiste Comhairleach Náisiúnta um Imdhíonadh

Sláinte Leanaí Éireann
Children's Health Ireland

Irish College of GPs

RHA Dublin and North East

RHA South West

Cuidiú
Caring Support for Parenthood

RHA Dublin and Midlands

RHA Mid West

Irish Neonatal Health Alliance

RHA Dublin and South East

RHA North and North West

The Rotunda Hospital Dublin

The National Maternity Hospital
Vita Gloriosa Vita – Life Glorious Life

The Coombe Hospital

Ospidéal Máithreachais na hOllscoile Corcaigh
Cork University Maternity Hospital

Louth Hospitals
OLOL | LCH | Cottage
RCSI Hospital Group

Galway University Hospitals

University Hospital Kerry
Ospidéal na hOllscoile, Ciarraí

Tipperary University Hospital
Ospidéal na hOllscoile Thiobraid Árann
Teaching | Understanding | Healing

St. Luke's General Hospital
Carlow - Kilkenny

Regional Hospital Mullingar

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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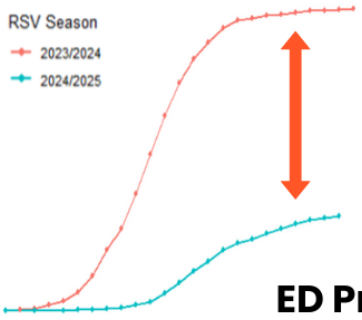
hpsc

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!

Executive Summary

1. 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.

Nirsevimab

Nirsevimab 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, 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]

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.).[12] 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. 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.

Evaluation Aim

To assess the effectiveness and efficiency of the RSV Immunisation Pathfinder Programme in Ireland, to inform future programme delivery and RSV immunisation policy.

2. Evaluation Methods

A mixed-methods evaluation was conducted. Quantitative data on immunisation uptake were collected from maternity hospitals, CHI and TCP Homecare. Impact was assessed using surveillance data for RSV-related outcomes requiring secondary care (ED presentations, hospitalisations and ICU admissions) and statistical modelling, including estimation of averted outcomes. Qualitative data were obtained from parent and staff surveys, focus groups, and stakeholder interviews to explore implementation experiences, barriers and facilitators.

Further detail on methodology is described in the full technical report for reference.

3. Outcomes

Immunisation Uptake

Between 1st September 2024 and 28th February 2025, a total of 22,444 infants were immunised with nirsevimab by maternity hospitals, CHI, and TCP Homecare. The overall cumulative uptake for the period was **83%**. Uptake among maternity hospitals was 82%, 96% in CHI and 99% among those offered the immunisation by TCP Homecare. **Table 1** shows regional uptake and **Figure 1** shows weekly uptake for 2nd September 2024 to 28th February 2025. Reliable denominator data was not available for 1st September 2024.

Table 1. Uptake of Nirsevimab by Regional Health Area (maternity hospitals only), between *2nd September 2024 and 28th February 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

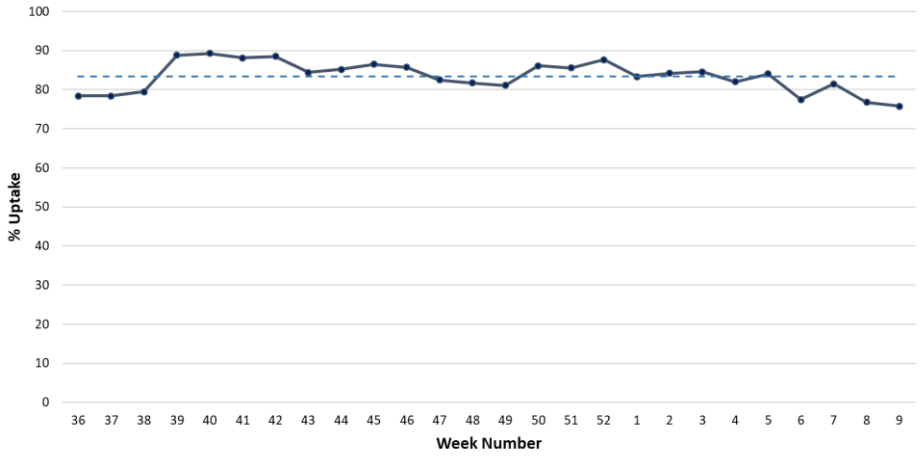


Figure 1. Percentage uptake rate in maternity hospitals and CHI by week, between 2nd September 2024 and 28th February 2025 (dotted line = average uptake)

Surveillance Data

Routine surveillance data of RSV among infants born between September and February was notably altered compared to previous years, reflecting the impact of the national RSV Immunisation Programme. **Table 2** illustrates a **significant decrease** in the number of cases in this cohort in 2024/2025 for all outcomes.

Table 2. 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).

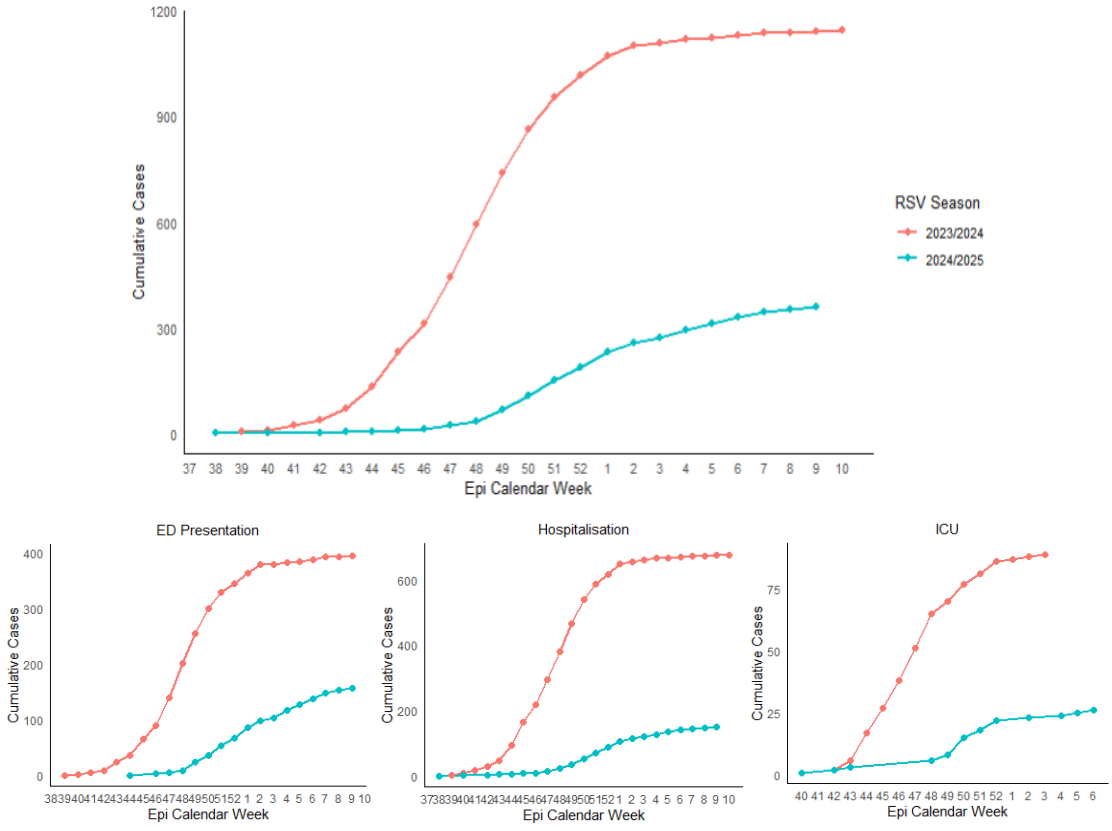


Figure 2. Cumulative laboratory confirmed RSV notified cases born between 1st September and 28th February in Ireland during the 2023/20204 and 2024/2025 RSV seasons, disaggregated by outcomes of interest; ED presentations, hospitalisations and ICU admissions

Critical Care Transfers and ICU Admissions

The number of paediatric transfers with RSV bronchiolitis for this birth cohort 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 ICU 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.

The HPSC is aware of 31 RSV-related ICU admissions among those born from 1st September to 28th February 2025 notified since 01/09/2024 (as of Week 16 2025). Of those, 11 (35%) received nirsevimab while 20 (65%) did not. 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. It was observed that those who did not receive nirsevimab were younger (≤2 months) at the time of ICU admission (p = 0.115).

Modelling Data: Estimated Impact on ED Presentations, Hospitalisations and ICU Admissions

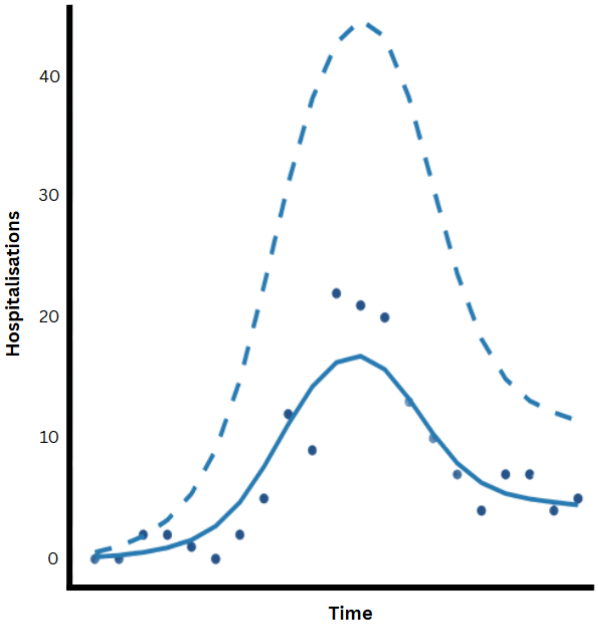
Method 1: Based on observed events and the reported effectiveness of nirsevimab, it is estimated that the RSV immunisation programme averted 1,030 laboratory-confirmed cases (74% of expected), 440 non-hospitalised ED presentations (74% of expected), 433 hospitalisations (74% of expected), and 79 ICU admissions (75% of expected) in infants born between 1st September 2024 and 28th February 2025.

Table 3. 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.

Method 2: Figure 3 focuses on observed data in this season's nirsevimab eligible cohort of infants born between 1st September 2024 and 28th February 2025 and compares to predictions based on previous RSV seasons and trends observed in older age cohorts this season. The difference between the two curves visualises the effect of nirsevimab. Based on this 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-related hospitalisations averted for this group, in this season.



The solid line reflects the predicted values for the immunised birth cohort model
The dashed line reflects the the predicted values if there had been no RSV immunisation programme
The dots reflect the observed number of hospitalisations during the 2024/2025 season

Figure 3. Models showing predicted number of hospitalisations among infants born between 1st September 2024 and 28th February 2025 with and without an RSV Immunisation Programme

4. Qualitative Evaluation

Feedback obtained from **surveys, focus groups and interviews** can be summarised according to the following themes:

- **Welcomed Programme:** All stakeholder groups welcomed the initiative, stating that it "it's a good measure to protect babies" and staff were "proud to promote it". One of the key motivations for staff delivering the programme was the knowledge of the positive impact it would have on preventing RSV among young infants.
- **Impact:** Paediatricians and General Practitioners (GPs) described the RSV immunisation as "a game changer". They noted that they saw fewer children present with RSV-related symptoms, and those that did have RSV and were immunised were "turning around quicker and needing less support".
- **Parental Reasons for Declining Nirsevimab:** According to our survey of parents, the reasons for refusing nirsevimab were: concerns about safety (64%), lack of information (33%), belief that it was unnecessary (30%), and perceived lack of time to make a decision (21%).
- **Groups less likely to Accept Nirsevimab:** Feedback from our staff survey and focus groups suggested that the following groups were less likely to accept nirsevimab for their child: Those who were unaware of the immunisation prior to delivery, Eastern European ethnicity, Irish Traveller/Roma ethnicity, those who didn't have English as a first language, younger parents, lower socioeconomic groups, and those with two or more previous children
- **Programme Criticisms:** Criticisms of the programme reflected the speed at which the programme was implemented. The main criticisms were regarding insufficient staffing/resources to deliver the programme, lack of information among parents, the general public and other healthcare professionals (e.g. GPs) about RSV Immunisation.

5. 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 proving 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 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.

6. Conclusion

This RSV Immunisation Pathfinder Programme, which involved offering nirsevimab to newborn infants in maternity hospitals as well as clinically high-risk infants at home and in CHI, has proven to be a successful delivery model. It was also the first time that midwife vaccinators had been central to a completely innovative neonatal vaccination programme. A key finding of our evaluation of this programme was the high uptake that was achieved (83%), representing the value of the trust placed by parents in midwives as vaccinators.

There has been a significant reduction in RSV-related ED presentations, hospitalisations and ICU admissions in this cohort, and this has reduced the burden on health services, which are already at peak demand during winter. Those who do present with RSV are not as sick, turn around quicker and require less support. GPs and Paediatricians have called this a “game changer”.

Learnings from this evaluation has informed the second RSV Immunisation Pathfinder Programme to be delivered in winter 2025/26, which, in addition to the existing delivery model, aims to include a catch-up programme for infants ≤6 months at the start of the RSV season, with a different delivery model for that cohort, utilising paediatric services. The findings of the evaluation will inform the full Health Technology Assessment (HTA) on RSV immunisation programmes and on the RSV immunisation policy by the DoH.

7. Steering Group and Evaluation Group Members

Programme Steering Group Members:

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Sue Jameson	Patient Partner, Cuidiú
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