

# **POLICY BRIEF**

# Learning from each other: advancing RSV prophylaxis programmes for infants in Europe

September 2025

#### Context

This policy brief was developed to summarise and share the outcomes of the Focus Session 'Learning from each other: advancing RSV prophylaxis programmes for infants in Europe', which took place on 6 June 2025, in Rennes, France in the framework of the European Health Management Conference. Organised in response to the rising burden of respiratory syncytial virus (RSV) infections among infants across European countries, the session aimed to bring together professionals involved in various dimensions of immunisation delivery to exchange perspectives on overcoming common implementation challenges.

The session involved a presentation of the early findings from EHMA's ReSolVe II project, followed by discussions among participants, divided into two thematic tables: 'Health system integration' and 'Education and awareness'. Guided by tailored questions, participants shared real-world insights and proposed actionable strategies to overcome implementation barriers for RSV prophylaxis in infants.

# **RSV** and **RSV** prophylaxis

RSV constitutes a leading cause of lower respiratory tract infections in infants, responsible for approximately 6.6 million episodes annually, predominantly bronchiolitis and pneumonia, while accounting for roughly 1.4 million hospital admissions in their first year of life¹. Beyond acute illness, severe RSV in infancy have shown to predispose children to chronic respiratory issues such as recurrent wheezing and asthma, extending the impact on families and health services long after the initial infection¹. On top of that, the burden on healthcare systems has proven substantial: RSV-associated children infections generated an estimated €4.82 billion in direct medical expenditures worldwide, driving up spending on hospital, intensive care stays, and treatment during admission, as well as outpatient consultations, diagnostic tests, and prescribed medicines².

Long-acting monoclonal antibodies (mAbs) have emerged as a novel prophylactic approach to prevent RSV in infants, offering immediate, passive immunity that lasts approximately five to six months from a single intramuscular injection<sup>3</sup>. Clinical trials demonstrate that, in healthy infants entering their first RSV season, a single dose of nirsevimab led to an 82.7% reduction in hospitalisations

The European Health Management Conference is Europe's preeminent conference on health management. Each year it gathers the full healthcare ecosystem, including health managers and leaders, healthcare professionals, researchers, academics, industry representatives, and decision-makers from Europe, and beyond. The Conference provides a platform to discuss the latest health management research, tools and evidence from renowned researchers, academics and professionals. It is concerned on translating research into practice. It creates opportunities for dialogue and exchange on solutions to ensure the sustainability and resilience of health systems.

and a 75.3% reduction in very severe cases of lower respiratory tract infection, over a six-month follow-up period<sup>3</sup>. Unlike active vaccines, mAbs provide direct protection without requiring an immune priming period, making them particularly suited for protecting newborns at their most vulnerable age. Translating this evidence into real-world practice, various countries introduced universal infant immunisation programmes with RSV mAbs in the 2023/24 season, with early evidence from France, Spain and the United States showing a comparable 70-98% reduction in RSV-related hospitalisations<sup>4</sup>.

# Preliminary findings from the EHMA ReSolVe II study

Building on the foundation laid by the first edition of the ReSolVe project (2020–2022), which engaged healthcare professionals across 20 European countries through quantitative surveys and led to the publication of a white paper and policy recommendations welcomed by WHO and the European Commission, EHMA launched ReSolVe II to further explore the implementation landscape for RSV prophylaxis. The current study surveyed over 100 health and care professionals and administrators across Italy, Spain, Germany, and France to assess awareness, infrastructure readiness, and operational challenges around mAb prophylaxis. Early results indicate strong confidence in the clinical benefits of mAbs, but highlight gaps in logistics and public awareness, as well as significant variation in how national systems and regulatory bodies are equipped to support widespread rollout. The preliminary findings highlighted below will be expanded upon with the publication of the completed study in late 2025 at www.ehma.org.

# Clinical impact and health outcomes

All respondents (100%) agreed that mAbs reduce RSV related hospital and PICU bed occupancy and enable more efficient allocation of healthcare resources. A large majority (89%) observed shorter hospital stays for RSV cases when mAbs were used.

# **Operational readiness**

Countries scored highest on infrastructure and regulatory readiness (referring to the availability of storage, delivery capacity and formal inclusion of RSV mAbs in immunisation programmes) but lowest on logistics (referring to distribution, cold chain) and public awareness of mAbs. Education and training systems have yet to adapt fully, limiting the workforce's capacity to promote and deliver prophylaxis effectively.

#### Awareness and training gaps

Although healthcare professionals generally understand RSV burden, few have received specific training on mAb mechanisms, dosing schedules, or integration into routine infant care, which presents an obstacle for both uptake and equitable access.

# Key takeaways from EHMA 2025

#### Discussion group 1: Health system integration

The integration of RSV mAbs into infants' health services raises system-level challenges distinct from conventional vaccination, given their classification outside standard immunisation frameworks and the predominant reliance on both hospital- and- primary-care-based administration. In the absence of comprehensive digital registries and interoperable pathways, prophylaxis

delivery risks becoming disjointed, with infants discharged from maternity wards not systematically flagged for follow-up in primary care settings. This discussion therefore sought to identify pragmatic solutions for incorporating mAbs into existing care pathways, facilitating continuity across hospital, primary care, and pharmacy settings.

# Information systems and digital interoperability

In the absence of fully digitised, interoperable immunisation records able to track mAB administration, countries have adopted interim solutions:

- Italy maintains centralised vaccine centre registries, but hospital physicians
  often lack direct access to these immunisation pathways. To bridge the gap,
  regional health authorities issue monthly immunisation lists to paediatric
  wards, enabling manual reconciliation of paper charts with digital registers.
- Ghana uses patient held vaccine booklets as the primary record; pilot projects are exploring community health worker-led scanning of these booklets via mobile apps to create minimal electronic registries at the point of care.
- Sweden classifies mAbs outside traditional vaccine frameworks, recording them in hospital pharmacy systems rather than national immunisation databases. As an alternative, clinical sites attach pharmacy dispensing records to local electronic health records (EHRs) and deploy automated SMS reminders to families based on pharmacy logs.

#### Data-driven identification and recall

Where shared EHRs are incomplete, manual and semi-automated methods can ensure no infant is missed:

- Linking birth notifications from civil registries with primary care appointment schedules to flag eligible infants.
- Engaging community pharmacies to crosscheck dispensing data against local immunisation lists and to trigger outreach calls.

# Alignment with child health pathways

Embedding mAb administration into routine maternal and child health visits increases convenience and uptake:

- Co-location of prophylaxis delivery with six-week immunisation appointments in Italy, particularly for infants born prior to the RSV season, and with well-baby visits in Sweden has supported parental willingness to engage by minimising extra appointments.
- Partnerships with pharmacies in rural areas extend delivery beyond hospitals, leveraging existing immunisation days for influenza.

# Collaborative frameworks

Formal agreements between primary care networks and hospital maternity wards, as piloted in parts of Spain, establish coordinated procedures for referral, data sharing, and parental reminders. These arrangements aim to ensure that infants who do not receive mAb prophylaxis during their birth hospitalisation are systematically identified and followed up within community-based immunisation services. In this context, Maria State, Deputy Director of the National Board of Health and Welfare in Sweden, remarked during the group discussions: "All stakeholders in society – the government, healthcare organisations, patient associations, and pharmaceutical companies – have a shared responsibility to ensure equitable access to medicines that effectively reduce suffering, prevent unnecessary deaths, and free up hospital beds in inpatient care".

#### Discussion group 2: Education and awareness

The novelty of RSV prophylaxis inevitably introduces communication and training needs not addressed by current vaccine-oriented frameworks, not least in clarifying the choice between maternal vaccination and direct infant prophylaxis. Parents require clear information on passive immunity, seasonality, and expected protection, while health and care professionals need targeted training to deliver consistent and accurate guidance. This discussion aimed to define strategies for equipping both the workforce and the public with the knowledge required to support timely and equitable uptake.

#### Role of public health authorities

Consistent leadership and endorsement by national agencies are central:

- Centralised messaging from ministries of health lends legitimacy, while delegating local rollout to family doctors and nurses fosters trust.
- Spain's coordinated cascade model, where national guidelines inform regional health board toolkits, ensures unified communications adapted to local languages and contexts.

# **Messaging strategy**

While sharing public health objectives, prophylactic mAbs differ mechanistically and operationally from conventional active vaccines. As such, public-facing communication must clearly convey:

- The concept of passive immunity, emphasising immediate protection during the RSV season.
- Safety and efficacy data from clinical trials and real-world evidence, including the six-month duration of protection, to set accurate parental expectations.
- RSV seasonality framed alongside familiar seasonal campaigns such as those for influenza, to underline the optimal timing for immunisation.

#### Stakeholder engagement and channels

A multipronged approach maximises reach:

- Health and care professionals (paediatricians, neonatologists, GPs, nurses, midwives) deliver technical messaging, including passive immunisation mechanisms, protection duration, risk reduction, at clinical touchpoints such as pre- and post-partum checkups and maternity-clinic visits.
- Digital media campaigns, including social media Q&A sessions with trusted clinicians, address parental queries and dispel misinformation.
- Community champions such as parent advocacy groups reinforce official messages in grassroots settings.

# **Workforce training**

Targeted training modules, delivered in parallel with seasonal vaccination cycles, equip providers with the knowledge and tools they need without overburdening their schedules:

- E-learning sessions on mAb pharmacology and scheduling, funded through public health budgets or industry grants, can be completed asynchronously.
- Short, case-based workshops embedded in routine continuing-medicaleducation not only support practical skill transfer but also guide clinical professionals on navigating parental concerns and immunisation conversations.

#### Recommendations

Based on the early findings from Resolve II and the discussions observed at the EHMA2025 Focus Session, we recommend that health and care professionals, health administrators, policymakers, and regulatory authorities at both national and regional levels the following concepts when working to improve access and uptake to RSV prophylaxis within their respective health systems:

# • Mandate interoperable immunisation tracking

Issue national directives to integrate mAb records into existing EHRs or immunisation registries, with clear data sharing agreements between hospitals and community providers.

# Embed RSV prophylaxis into routine child health services

Align communication efforts and mAb delivery with standard pre- & postnatal and early childhood visits, leveraging maternal health clinics and community pharmacies to broaden access.

# • Launch coordinated, multi-channel awareness campaigns

Develop a harmonised RSV mAb messaging toolkit covering passive immunity, seasonality, real-world evidence and safety, endorsed by ministries of health and delivered consistently through clinicians, digital platforms, and parent champions.

# • Implement targeted workforce training

Integrate succinct RSV mAb modules into existing vaccination training programmes, funded through public health channels, and accessible via elearning to accommodate provider time constraints.

## Facilitate EU level knowledge exchange

Create a peer learning network, for example using the <u>ECDC Lighthouse</u> <u>platform</u>, of national RSV leads to share best practices, host annual workshops, and maintain a repository of implementation tools and data dashboards.

The ECDC Lighthouse is an online collaboration space where professionals working in the prevention of infectious diseases come together, driven by the shared goal of integrating social and behavioural sciences in their public health work. The platform provides resources and opportunities to learn, connect and collaborate.

The ECDC Lighthouse welcomes people who are interested, experienced, or currently involved in the prevention of infectious diseases through use of social and behavioural sciences, and who work for or are affiliated with organisations and institutions in the EU/EEA.

#### References

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