



RSV IMMUNISATION FOR INFANTS IN EUROPE: ARE OUR HEALTH SYSTEMS READY?





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EXECUTIVE SUMMARY

Respiratory syncytial virus (RSV) is an **urgent and immediate threat** to all infants and leads to significant burden to health systems. Nearly every child is infected with RSV by the age of 2, it accounts for 63% of acute lower respiratory tract infections in infants, and it is the most common cause of bronchiolitis and pneumonia in infants. RSV is also a **leading cause** of hospitalisations for infants in their first year of life and is responsible for a significant outpatient burden. The natural course of RSV infection is also highly unpredictable in infants, as an estimated 72-98.3% of infants hospitalised for RSV were previously healthy and born at term. Symptoms range from mild flu-like presentations to severe lower respiratory tract infections that might require acute care admissions and mechanical ventilation.

Specifically, the seasonality of RSV is a major factor in its negative impact on health system performance. The peak rise in RSV infections between October and March results in **acute pressure** on primary care providers, emergency services and paediatric care services. EHMA survey respondents in outpatient settings reported a median increase of 30% for primary care office visits for respiratory illnesses, a 20% increase for follow-up on RSV-related complications, and a 52.5% increase in daily visits to emergency departments.

Despite this clear burden on health systems, for many years the only approved agent for RSV prophylaxis in Europe was the anti-RSV monoclonal antibody (mAb) Palivizumab, which is typically reserved for a small population of infants at high risk of developing severe RSV disease. However, the monoclonal antibody nirsevimab received approval from the European Medicines Agency (EMA) in 2022 to **immunise all infants** against medically attended RSV-LRTI (lower respiratory tract infection) during their first RSV season. Although nirsevimab is a monoclonal antibody, its use in public health pursues the same primary prevention goal as vaccines, requiring its robust implementation into immunisation programmes to **guarantee equitable access** to infants.



With the arrival of this new option for RSV prophylaxis, there are compelling reasons to prioritise RSV prevention and raise public awareness about the public health impact of RSV in Europe. Initial positive national recommendations for nirsevimab have already been made by the Haute Autorité de Santé in France and the Ministerio de Sanidad in Spain, meaning European health systems are now in a critical period where a stronger understanding of how they might implement prophylactic mAbs can help to ensure equity of access for infants.

With the aim of developing a deeper understanding of how health managers can successfully implement an RSV mAb, EHMA conducted 27 interviews with experts from 10 European countries (Austria, Belgium, Finland, France, Germany, Italy, Netherlands, Norway, Portugal, Sweden) who possess expertise in RSV prevention, paediatric healthcare, and health system management. EHMA also hosted 12 of these experts, representing 8 of the observed countries, to a closed-door roundtable discussion on the topic of RSV mAb implementation at its annual conference. Through analysis of the insights gathered, this EHMA white paper provides an **in-depth understanding** of the challenges and opportunities associated with implementing prophylactic monoclonal antibodies for infants during their first RSV season.

Our analysis identified 6 key themes for consideration when developing an RSV immunisation strategy.



Each of these themes also highlights existing challenges and potential opportunities for integrating an RSV mAb into our health systems:

+ Timing of RSV immunisation

+ Regulation and the use of Existing Vaccination Infrastructure

+ Coordination between Hospital and Primary Care Settings

+ Data Collection and Surveillance Mechanisms

+ Interdisciplinary Collaboration

+ Comprehensive Education

Based on these themes, EHMA has developed country-specific fiches outlining the challenges and opportunities present in the 10 observed countries, as well as **8 widely applicable recommendations** for health managers and policymakers across Europe, providing actionable guidance to support the implementation of RSV immunisation programmes using prophylactic monoclonal antibodies. By embracing these recommendations, stakeholders across Europe can advance health system resilience through effective RSV prevention and **improve the health outcomes of vulnerable infants.**



RECOMMENDATIONS

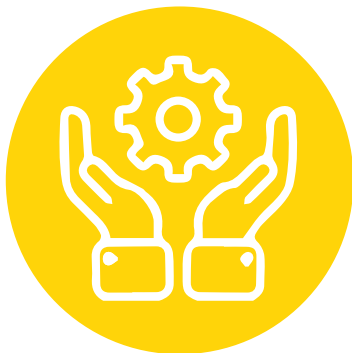
1. Establish Collaborative Networks on RSV Prevention: Through the development of regular forums on RSV prevention, health managers working within relevant health authorities should foster active collaboration and engagement from stakeholders involved in RSV immunisation.



2. Conduct Targeted Awareness Campaigns: Local policymakers and health managers should work with regional and national health authorities to develop comprehensive awareness campaigns targeting healthcare professionals, parents, and caregivers to increase understanding of RSV, the benefits of immunisation, the seasonal nature of the virus, and the functional nature of prophylactic monoclonal antibodies.

3. Develop Clear Guidelines for Implementing RSV Immunisation: Based on national regulatory recommendations, national and regional health authorities should establish clear guidelines and protocols to direct health managers and healthcare providers on the implementation of RSV immunisation both in hospitals and primary care settings.





4. Support Adequate Surveillance and Monitoring Systems: Policymakers should collaborate with public health agencies, healthcare providers, and researchers to establish comprehensive national RSV surveillance systems, leveraging existing immunisation information infrastructure.

5. Create Capacity Building and Training Programmes specific to RSV: Health authorities should create capacity building and training programmes to provide specialised training on RSV prevention, diagnosis, immunisation techniques, and public education strategies for healthcare providers.



6. Ensure health equity at population level: RSV infection does not discriminate between infants from different population groups, so policymakers must ensure that implemented RSV immunisation programs do not either.

7. Facilitate Knowledge Exchange and Best Practice Sharing: The EU should support and incentivise the use of platforms, networks, conferences and workshops promoting knowledge exchange and best practice sharing between member states regarding RSV immunisation.



8. Support the Development of Data Analytics and Digital Health Solutions: EU investment in data analytics and digital health solutions to support member states, such as the envisioned European Digital Health Space, will enhance RSV immunisation monitoring and evaluation.

BACKGROUND

Respiratory syncytial virus (RSV) is an urgent and immediate threat to all infants and leads to significant burden to health systems. Nearly every child is infected with RSV by the age of 2, it accounts for up to 81% of all viral lower respiratory tract infections causing hospitalisation in infants and young children (1), and it is the most common cause of bronchiolitis and pneumonia in infants. (2) As RSV is also a leading cause of hospitalisations for infants in their first year of life, it is responsible for a significant outpatient burden. (3) The real burden of RSV is likely to be even higher than is currently observed, as RSV infection is widely underreported in many EU countries and existing data systems are not always equipped to effectively monitor the disease. (4,5)

Like influenza, RSV is a seasonal virus, with a season that varies geographically but generally occurs during the colder months, starting in late autumn and lasting through early spring. This prolonged seasonal pattern can complicate immunisation efforts for infants, as aligning the immunisation schedule with the RSV season requires careful coordination across the health system so that infants born both during and before the season receive appropriately timed prophylaxis.

The natural course of RSV infection is also highly unpredictable in infants, as an estimated 72–98.3% of infants hospitalised for RSV were previously healthy and born at term. (6–8) Symptoms range from mild flu-like presentations to severe lower respiratory tract infections, such as bronchiolitis and pneumonia, that might require acute care admissions and mechanical ventilation.

(9) In the long term, previous RSV-LRTI is a significant risk factor for respiratory morbidity, characterised by early transient or recurrent wheezing, asthma and impaired lung function. (10) In addition to the acute demands that RSV places on health systems, RSV-associated hospitalisation in the first year of life is correlated with increased stress on healthcare service utilisation as affected children get older, with observed increases in paediatrician and emergency department visits. (11)



THE IMPACT OF RSV ON HEALTH SYSTEM PERFORMANCE

Between August 2021 and January 2022, the European Health Management Association (EHMA) conducted a survey to document the health system burden and impact of RSV infection and the actions required to mitigate the effects of RSV-associated health system disruptions. The survey provided clear evidence that paediatric RSV heavily disrupts health systems, with 89% of respondents considering this disruption to be moderate to extreme. (12)

Specifically, the seasonality of RSV was found to be a major factor in its negative impact on health system performance. The peak rise in RSV infections between October and March results in acute pressure on primary care providers, emergency services and paediatric care services. Survey respondents in outpatient settings reported a median increase of 30% for primary care office visits for respiratory illnesses,

a 20% increase for follow-up on RSV-related complications, and a 52.5% increase in daily visits to emergency departments. (12)

Overall, increased demand for health care services due to RSV infection impacts health system performance in both inpatient and outpatient settings, leading to reduced bed capacity, severe disruptions to patient flow, and delays to elective surgeries.

The study also revealed that many infants in care for RSV are not managed optimally, leading to unnecessary testing and treatments that represent an avoidable burden to infants, their families, and the wider health system.

The primary takeaway from the survey was that RSV prevention programmes using new immunisation options should be made a major priority for health policymakers in Europe.



The complete findings are published in the white paper [‘The health system burden of respiratory syncytial virus in Europe’](#).



PURPOSE OF THIS EHMA WHITE PAPER

For many years, the only approved agent for RSV prophylaxis in Europe was the anti-RSV monoclonal antibody (mAb), Palivizumab, which is typically reserved for passive immunoprophylaxis in a small population of infants at high risk of developing severe RSV disease due to associated cardio-pulmonary comorbidities and prematurity. However, the monoclonal antibody Nirsevimab received approval from the European Medicines Agency (EMA) in 2022 to immunise all infants against medically attended RSV-LRTI (lower respiratory tract infection) during their first RSV season, and is administered through a single intramuscular (IM) dose. (13).

With the arrival of this new option for RSV prophylaxis and given the findings from EHMA's earlier work about RSV's health system burden, there are compelling reasons to prioritise RSV prevention and raise public awareness about the public health impact of RSV in Europe. Initial positive national recommendations for nirsevimab have already been made by the Haute

Autorité de Santé in France (14) and the Ministerio de Sanidad in Spain (15), and European health systems are now in a critical period where a stronger understanding of how they might implement prophylactic mAbs can help to ensure equity of access for infants. This improved understanding will also support health managers as they navigate the specificities of an RSV mAb, including considerations of seasonality, the coordination of administration between primary and hospital care settings, and the training needs of health professionals.

In this context, this EHMA white paper builds on both existing knowledge and new insights from health managers and policymakers across Europe to develop comprehensive recommendations for the effective implementation of prophylactic monoclonal antibodies as a preventive measure specifically for infants during their first Respiratory Syncytial Virus (RSV) season.

OBJECTIVES

This white paper aims to offer actionable guidance to EU, national and local-level policymakers, health managers, and healthcare providers involved in implementing RSV prevention strategies by fulfilling three core objectives:

1. Synthesizing expert insights on implementation of a prophylactic monoclonal antibodies for infants' first RSV season.

2. Presenting a comparative analysis of health system contexts in 10 observed countries.

3. Formulating set of both broad and context - specific policy recommendations to guide health managers and policy makers in the implementation of a prophylactic mAb for RSV.



METHODOLOGY

EHMA conducted 27 interviews with experts from 10 European countries (Austria, Belgium, Finland, France, Germany, Italy, Netherlands, Norway, Portugal, Sweden) who possess expertise in RSV prevention, paediatric healthcare, and health system management. EHMA also hosted 12 of these experts, representing 8 of the observed countries, to a closed-door roundtable discussion on the topic of RSV mAb implementation at its annual conference in Rome, Italy on 5 June 2023.

These experts represent a combination of health managers working at national or regional health authorities, health managers working in hospital settings, and health managers working in primary care settings. By analysing and synthesizing the insights gathered through the interviews and the closed-door roundtable discussion, this paper provides an in-depth understanding of the challenges and opportunities associated with implementing prophylactic monoclonal antibodies specifically for infants during their first RSV season in a variety of European contexts.

As the factors influencing the implementation of an RSV mAb vary greatly across individual health systems in the 10 observed countries, this white paper adopts a comparative analytical framework using the collected expert insights to explore how different health system characteristics such as funding models, infrastructure, workforce capacity, and regulatory frameworks may impact the implementation of prophylactic monoclonal antibodies. By considering these contextual variations, the paper provides both a broad set of policy recommendations for health managers in Europe, but also tailored, country-specific information on how an RSV mAb could be optimally implemented.

These recommendations offer an evidence- and experience-based resource for health managers looking to develop effective policies and practices related to implementing a prophylactic RSV mAb and aim to promote successful and context-sensitive approaches to RSV prevention for all infants during their first RSV season.



A pair of white sneakers with white laces is positioned at the top left. Below them is a white baby bottle with a white cap and a measurement scale on the side showing 60, 80, 100, and 125 ml. At the bottom left is a colorful rattle with yellow, purple, blue, pink, and red rings.

IS EUROPE PREPARED TO IMPLEMENT RSV IMMUNISATION?

The implementation of prophylactic monoclonal antibodies as a preventive measure for infants during their first Respiratory Syncytial Virus (RSV) season presents both challenges and opportunities for European countries. This section discusses the insights gained from both the expert interviews and the in-person roundtable discussion focused on implementing a prophylactic monoclonal antibody for RSV immunisation. Based on these data, our analysis has identified 6 key themes that require consideration when developing an RSV immunisation strategy. Each of these themes also highlights existing challenges and potential opportunities for integrating an RSV mAb into our health systems.

TIMING OF RSV IMMUNISATION

Timing is crucial when it comes to RSV immunisation with an mAb if infants are to be protected throughout the period when they are most vulnerable to infection, the RSV season. As the duration of protection offered by nirsevimab covers at least 5 months, which is the approximate length of the season of peak viral transmission, the timing of immunisation is a critical component for the mAb's effectiveness at reducing the risk of severe RSV disease among infants.⁽¹⁶⁾ For infants born during the RSV season, immunisation immediately at birth in hospitals or within a few days of birth through primary care channels becomes paramount, as these newborns are immediately at risk of exposure. Any delays to immunisation for these infants could potentially lead to missed opportunities for protection, as the virus could infect them before they receive the antibody. On the other hand, infants born before the start of the RSV season should receive immunisation during a time window before the RSV season starts, creating a need for health managers and policy makers to consider **dual immunisation pathways**, through both hospital and primary care settings, to navigate the timing considerations for these two groups of infants.

REGULATION AND THE USE OF EXISTING VACCINATION INFRASTRUCTURE

Of these two pathways for RSV immunisation, European health systems are currently best equipped to leverage existing resources and care schedules towards reaching infants born before the RSV season.

All of the countries observed in this paper have well-established childhood immunisation programmes with comprehensive schedules in place that bring infants into contact with the health system at routine intervals (often at 1-2 weeks and 1, 2, 4, and 6 months of age), virtually guaranteeing that all infants will have the chance to receive an RSV mAb with the correct timing without the need to introduce potentially burdensome additional care visits.

Tie-ins to existing immunisation systems for infants born during the RSV season are less clear, as immunisations are not routinely administered to infants in hospital settings in Europe, apart from those in Portugal.

Finding ways to leverage existing infrastructure for both RSV mAb immunisation pathways allows healthcare systems to capitalize on well-established networks, distribution channels, and trained personnel. This can significantly reduce the logistical and resource burdens associated with introducing a new preventive option, enabling a more efficient and rapid implementation process. In some of the observed countries, however, an RSV mAb may be subject to a distinct regulatory and access pathway compared to traditional prophylactic vaccines that could create difficulties for implementation. As the use of monoclonal antibodies for passive immunisation pursues the same primary prevention and public health goals as vaccines, policy makers should re-evaluate existing regulations governing immunisation programme delivery when introducing an RSV mAb to allow for seamless integration with existing resources, thereby reducing avoidable added stress on financial and human resources.⁽¹⁷⁾

COORDINATION BETWEEN HOSPITAL AND PRIMARY CARE SETTINGS

Given the need for dual immunisation pathways for RSV, and the clear benefits of leveraging existing health system resources, coordinating the administration of prophylactic mAbs between hospital and primary care settings becomes crucial to ensure timely protection for all infants. Hospital and primary care settings often operate with distinct healthcare infrastructures and management, which can present challenges in coordinating prophylactic mAb administration. Bridging the gap between these settings requires a well-coordinated referral system, clear communication channels, and budgetary flexibility. Additionally, a high level of coordination is necessary to support a resilient logistics and administration system that can effectively manage supply chain and workforce challenges.

Many European health systems will face challenges in implementing comprehensive RSV immunization initiatives with their

current capacity for coordination across care settings. Further complicating matters is how responsibility for preventative, primary and hospital care is often fragmented across different levels of health system governance, ranging from municipal to regional to national. As an example, the health system in France has separately managed budgets for prevention and for hospital care, potentially leading to inconsistencies in funding allocation or programme prioritization in the case of an RSV mAb. Similarly, countries like Norway and Finland may face challenges due to the absence of established mechanisms that facilitate coordination between health managers in hospital and primary care settings.

As immunisation against RSV requires seamless implementation across health system settings to reach all infants, leaders will have to re-imagine the way that immunisation programmes have traditionally been administered.

DATA COLLECTION AND SURVEILLANCE MECHANISMS

Accurate and accessible data are essential to support the collaborative efforts in monitoring RSV infection rates, identifying high-risk periods such as the start of epidemics, and sharing immunisation records facilitate proactive planning for prophylactic mAb administration. Real-time information exchange enhances preparedness for seasonal outbreaks and ensures that immunisation programmes can be updated based on high-quality evidence.

Approaches to the collection and use of immunisation data varies significantly across the countries observed in this paper. Several, including Portugal, Germany, Finland, Belgium, The Netherlands, and France, have established advanced electronic vaccine registries and employ

sentinel surveillance systems within primary care specifically for RSV, but there is substantial variation on how these systems are managed, at which level of governance, and which professionals have access to which information. Sweden, while having a national vaccine registry in place, opts for a voluntary surveillance system when it comes to RSV, while Norway, Italy, and Austria focus their sentinel surveillance in primary care on influenza-like illnesses, without specific targeting for RSV. Given the diversity in capacity, governance, interoperability, and infrastructure related to immunisation data across Europe, a combination of EU and national-level support may be most effective in ensuring that health systems are equipped with modern systems that meet the specific practical needs of managing RSV immunisation programmes.

INTERDISCIPLINARY COLLABORATION

Collaboration between different groups of healthcare professionals will play a critical role in the successful implementation of RSV mAb immunisation programmes in European health care systems. Preventing RSV infections requires a coordinated effort from professionals at every level of our health systems, including hospital managers, paediatricians, primary care physicians, infectious disease specialists, pharmacists, nurses, midwives, paramedics, and public health experts. Effective mechanisms for interdisciplinary collaboration around RSV immunisation programmes can not only improve the design of these programmes from a practical standpoint, but also enhance their implementation through improved engagement. Allowing a wide range of care professionals a voice in the creation of implementation guidelines for RSV immunisation will help to ensure the consistent and optimal utilisation of RSV monoclonal antibodies throughout the health system.

The existing dynamics of interdisciplinary collaboration among in the observed countries vary considerably. In Finland, Norway, and Sweden, a strong emphasis on teamwork between professions is already ingrained into the delivery of immunisation programmes, with physicians and nurses often working hand in hand to enact a more holistic approach to patient care. Conversely, in Germany and Austria, the delivery of immunisation services is driven primarily by physicians, with delegation of responsibility to other professionals such as nurses or midwives being very rare. In Belgium, every nurse has the authority to administer immunisations, but only when prescribed by a physician. To enable the dual pathways essential for effective RSV mAb immunisation, policymakers and health managers will need to evaluate the state-of-play for interdisciplinary collaboration within their health systems and take steps to foster improvements where necessary.

Ensuring that healthcare providers have a thorough understanding about prophylactic mAb immunisation is essential in ensuring accurate knowledge of the product's mechanism of action, dosing, safety profile, and indications. Understanding the benefits and limitations of mAb immunisation also empowers healthcare professionals to confidently discuss and recommend the preventive option to the eligible population, who in turn will be empowered by improved access to this knowledge. Effective training for healthcare providers can be further supplemented by additional communication programmes educating the public about RSV, its potential complications, and the option of prophylactic mAb immunisation. Specific and easy-to-understand information about the nature of monoclonal antibodies could prove especially beneficial to building trust, as they are a new technology that may not be widely understood.

As noted in the other key themes in this section, there is notable variation in RSV awareness and education both among

healthcare professionals and the public between the observed countries. In Norway and Portugal, education and awareness surrounding RSV are relatively high among healthcare workers, and Norwegian parents appear to be particularly well-informed on the topic thanks to the prior development of numerous educational resources.

In contrast, citizens in Belgium and Austria tend to lack readily accessible, reliable information on RSV or immunisation in general. Just as it is important to leverage existing health system resources for RSV immunisation programmes, it is equally important to utilise proven communication and education strategies that can be adapted to the specificities of RSV. Notable examples of good practices in this regard come from France, with its efforts to conduct public information campaigns and annual promotions focused on influenza, and Finland, which places a significant emphasis on sophisticated immunisation education programmes for its healthcare workforce.



POLICY RECOMMENDATIONS

FOR THE LOCAL LEVEL:

Recommendations for the Local Level (municipal and regional health authorities, hospital managers, primary care managers):

1.

Establish Collaborative Networks on RSV Prevention: Through the development of regular forums on RSV prevention, health managers working within relevant health authorities should foster active collaboration and engagement from stakeholders involved in RSV immunisation, including healthcare providers, public health agencies, community organisations, and parents' associations. These forums can be online or in-person and should focus on facilitating the exchange of knowledge and resources, streamlining implementation processes, and building coordination between hospital and primary care settings to streamline logistics, supply chain, and workforce considerations.

2.

Conduct Targeted Awareness Campaigns: Local policymakers and health managers should work with regional and national health authorities to develop comprehensive awareness campaigns targeting healthcare professionals, parents, and caregivers to increase understanding of RSV, the benefits of immunisation, the seasonal nature of the virus, and the functional nature of prophylactic monoclonal antibodies. These campaigns should utilise diverse communication channels, tailored messages, and culturally sensitive approaches to effectively reach a wide variety of audiences.

POLICY RECOMMENDATIONS

FOR THE NATIONAL LEVEL:

1.

Develop Clear Guidelines for Implementing RSV Immunisation: Based on national recommendations, national and regional health authorities should establish clear guidelines and protocols to direct health managers and healthcare providers on the implementation of RSV immunisation both in hospitals and primary care settings. These guidelines should outline vaccination schedules, dosage, administration procedures, target populations, and post-immunisation monitoring protocols to standardize and simplify implementation. They should also elaborate on practical aspects of implementation such as the creation of interdisciplinary working groups and coordination channels between different care settings.

2.

Support Adequate Surveillance and Monitoring Systems: Policymakers should collaborate with public health agencies, healthcare providers, and researchers to establish comprehensive national RSV surveillance systems, leveraging existing immunisation information infrastructure. These systems should collect standardised and timely data on RSV cases, hospitalizations, and severity across all age groups as well as information about the uptake of immunisation, encompassing both hospital and outpatient settings. Integration with existing infectious disease surveillance networks will enable a more comprehensive understanding of RSV burden and support the identification and effective communication of the start of the RSV season.

3.

Create Capacity Building and Training Programmes specific to RSV: Health authorities should create capacity building and training programmes aimed at the widest possible range of healthcare professionals (e.g. nurses, midwives) who may be involved in RSV immunisation for infants. These programmes should provide specialised training on RSV prevention, diagnosis, immunisation techniques, and public education strategies to ensure that healthcare providers possess the necessary knowledge and skills to participate as empowered stakeholders in RSV immunisation programmes.

4.

Ensure health equity at population level: RSV infection does not discriminate between infants from different population groups, so policymakers must ensure that implemented RSV immunisation programs do not either.

Out of respect for ethical considerations and the need to support broader public health through herd immunity, immunisation programmes should be conscientiously designed to ensure that infants from all economic, social, and geographic backgrounds have equal access to an RSV mAb.

POLICY RECOMMENDATIONS

FOR THE EUROPEAN UNION:

1.

Facilitate Knowledge Exchange and Best Practice Sharing: The EU should support and incentivise the use of platforms for knowledge exchange and best practice sharing between member states regarding RSV immunisation.

This could include creating dedicated networks, organising conferences or workshops, and leveraging existing EU institutions and initiatives such as the European Health Data Space to promote collaboration and facilitate the dissemination of successful implementation strategies specific to RSV.

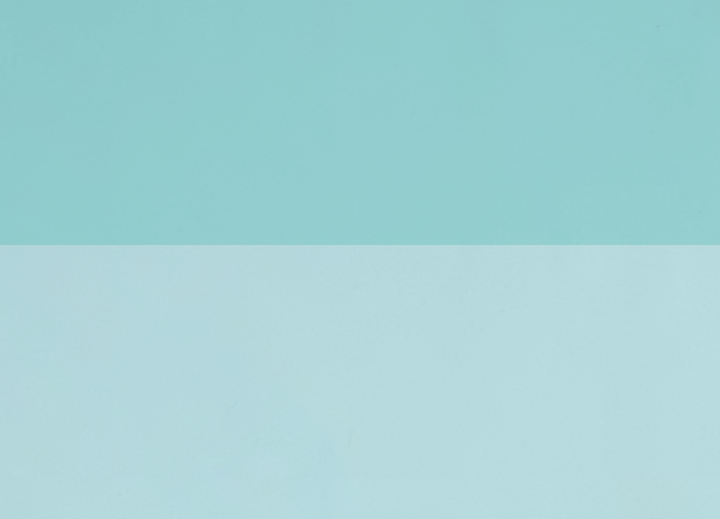
2.

Support the Development of Data Analytics and Digital Health Solutions: EU investment in data analytics and digital health solutions to support member states, such as the envisioned European Digital Health Space, will enhance RSV immunisation monitoring and evaluation. This includes utilising electronic health records, real-time data capture, and predictive analytics to identify vulnerable populations, monitor immunisation coverage, and assess the impact of preventive interventions. These tools can also enable evidence-based decision-making and facilitate targeted interventions.

These recommendations for health managers and policymakers at the local, regional, national, and EU levels provide actionable guidance to support the implementation of RSV immunisation programmes using prophylactic monoclonal antibodies for infants' first RSV season. By considering specific health system contexts across Europe and leveraging the insights presented in this paper, decision-makers can develop strategies that maximise the benefits of RSV immunisation while addressing the challenges unique to their respective settings.

By embracing these recommendations, stakeholders across Europe can advance health system resilience through effective RSV prevention and improve the health outcomes of vulnerable infants across the continent.





Appendix 1: Detailed Country Fiches



2023 RSV In-depth Research: Austria INSIGHTS FROM

AUSTRIA

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (1)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

The first scheduled examination for a newborn infant (using the Mutterkindpass) following hospital discharge takes place at 1 week, although this is usually done at a hospital. The next visit is typically once the infant is between 4 and 7 weeks old. (19)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Routine immunisations are not generally provided at hospitals. However, the regional health authorities are responsible for procurement and funding of medicines for hospitals through state health funds (LGFs). Supply and administration is then managed by individual hospitals. (20)

Administrative process for mAb access in hospitals

mAbs would need to be included in the annual vaccination plan as created by the national vaccination committee and the Ministry of Labour, Social Affairs, Health and Consumer Protection. Regional health authorities would then need to recommend the administration of mAbs in hospital. (20)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



An electronic vaccine registry was recently introduced (e-Impfpass), but there is not an integrated national approach and interoperability between hospital and outpatient systems is dependent on regional capacity. (21)

Budget for immunisations comes from a mix of general tax revenue and compulsory social health insurance. Providers under contract with social health insurance are paid a fee-for-service from this budget for delivering immunisations. (20)

Sentinel surveillance in primary care for influenza-like illness, not RSV-specific. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The national immunisation plan is a medical recommendation to all healthcare professionals who advise on or administer vaccinations. Regional health authorities (Landessanitätsdirektionen) established within the nine regional governments (nine Austrian provinces) implement joint vaccination programmes covering a number of vaccinations recommended in the national immunisation plan (i.e. not all recommended vaccinations are financed or offered by the public sector). In the regions, vaccination is carried out in different settings, e.g. in a doctor's surgery, by regional health authorities.

In Austria, generally only medical doctors administer vaccinations. Additionally, vaccines for children are mainly administered by specialized paediatricians. Vaccination fees (for the administration of vaccines) are paid to the doctor upon documentation (for free-of-charge vaccinations) by regional health authorities. For vaccinations that are not covered by vaccination programmes, vaccine administration fees as well as vaccine costs, which may both vary by region, are charged to the patient.

A medical doctor may decide to delegate the

administration of the vaccine to a nurse or emergency medical technician, provided that a medical doctor assumes responsibility for any effects of the vaccination and is on the premises where the vaccine is administered (e.g. in the nearby medical practice, vaccination centre, etc.). Technically, midwives are authorised to administer a limited range of vaccines to infants (e.g. MMR and Varicella). Despite the possibility for delegation, the administration of immunisation to a non-physician HCP is very rare.

Multi-annual tendering procedures are in place for the procurement of vaccines for the national vaccination programmes with price as the only criteria, if there are at least two existing competitors. The vaccines are then distributed to those administering the vaccinations (mainly paediatricians, outpatient doctors, vaccination centres). Some vaccination delivery points stock vaccines on their premises. If this is not the case, the patient has to obtain the vaccine from a pharmacy - with a prescription. In some cases, there is a voucher system (childhood vaccination programme) which enables the vaccines to be collected free of charge from the pharmacy. Vaccination delivery points often try to order or stock vaccines when the appointment for its administration is booked.



CHALLENGES

- ✦ Regional differences in vaccination costs and available subsidies could potentially add barriers (depending on regional variations). In addition, the density of vaccination delivery points and coverage with convenient opening hours may vary depending on the region (urban/rural area) and the regional implementation of the vaccination programme.
- ✦ Documentation of immunisation is largely still paper-based; meaning that reminder programmes and scheduling initiatives are sporadic.
- ✦ Official and reliable information on vaccinations tends to be scattered and difficult to find and access for much of the population (there are national, regional and local information websites offering different information).

OPPORTUNITIES

- ✦ In hospitals, some vaccines are administered, for example, to children who are born prematurely or who are staying in hospital for longer periods. Hospitals then order the vaccine but do not necessarily receive a vaccination fee from the regional health authority. This includes the mAb palivizumab which is not reimbursed if administered in a hospital setting, so the implementation of nirsevimab would benefit from a change in this policy.



COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Health managers at national level should consider developing a set of national implementation guidelines for an RSV mAb that offer standardized guidance to regional health authorities on how to best coordinate administration in hospital and primary care settings for infants born both during and before the RSV season.
- ✦ Training and education campaigns targeting physicians should be developed to improve knowledge and understanding of RSV and mAbs. Physicians have delegation authority to allow other health care professionals to administer the mAb, so engaging them on the topic of RSV is a critical step towards broader reach of RSV immunisation programmes at the implementation stage.

2023 RSV In-depth Research: Belgium INSIGHTS FROM

BELGIUM

Interviews

Hospital managers (0)

Care practitioners (1)

Health authorities (1)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

In all federated entities, new mothers have the option of receiving a home visit from a midwife within the first week after discharge from the hospital. The first official postnatal checkup including vaccination occurs at 2 months of age. (23)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Financing for immunisations is provided by the central government to the regional health authorities, who then manage procurement and recommended pathways for administration. The French and German federated entities share a common procurement process while Flanders has its own unique process. Hospital management is then responsible for supply and administration decisions. (23)

Administrative process for mAb access in hospitals

Following a positive recommendation for an RSV mAb by the federal scientific and economic advisory bodies, regional health authorities then decide how the mAb will be delivered to citizens. The process for including an mAb into hospital service delivery depends on the federated entity governing each hospital, as well as whether that hospital is private or public, and if it is owned by a municipality, province, or community association. (23)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



A functional electronic vaccine registry exists, but there is not an integrated national approach and interoperability between hospital and outpatient systems is dependent on regional capacity. (21)

Preventive care, including immunisations such as an RSV mAb, is funded by the federated entities (Flanders, Wallonia, German community). Their respective budgets for care service delivery come from the national statutory insurance scheme. In general, vaccinations provided to children via general practitioners or (hospital based) physicians (e.g. paediatricians) work on a fee-for-service basis (vaccines are free of charge, but a consultation fee has to be paid). A consultation at the office of a GP usually costs 18–30 euro, but this charge is mostly re-imbursed by the universal health insurance services (Mutualité), leading to a personal cost of 4–6 euro (in case of a licenced doctor, non-licenced doctors can ask a higher fee). (23)

Some vaccines can also be reimbursed by the social security system (NIHDI). In this case, the vaccines are reimbursed with a co-payment for the patient (e.g. HPV, Rotavirus, MMR, flu vaccines, etc.), as is the case for pharmaceuticals.

There is a sentinel surveillance in primary care and hospitals for RSV. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

At the national level, an established “permanente werkgroep ‘Vaccinatie’” (Belgium’s NITAG) under the Hoge Gezondheidsraad (Superior Health Council - SHC) provides independent scientific advice on vaccinations and formulates recommendations. These national recommendations serve as a basis for the vaccination programmes set up by the three Belgian federated entities. As a result, small differences between vaccination programmes are seen between the entities (e.g. timing and procured brands of vaccines, which vaccines are offered for free). The SHC is part of the “Federale overheidsdienst (FOD) Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu” (Federal Public Service (FPS) Health, Food Chain Safety and Environment).

Flanders

For the Flemish community (Flanders and Brussels), the Agentschap Zorg en Gezondheid (Agency for Care and Health) is responsible for the vaccination policy and a subnational vaccination plan is available online. The plan includes communication, training of healthcare workers, recommended vaccination schedules, administration, etc.

Kind en Gezin (K&G, Child and Family), offers free services equivalent to those of well-baby clinics as well as extensive support for health and upbringing to families with young children from pregnancy to toddlers (aged 2.5). The service consists of a combination of home visits and consults at K&G offices. During the basic consults at the K&G office, vaccinations are administered.

Besides the services of K&G, child vaccines (0-6 years of age) can be given by general practitioners and paediatricians.

Wallonia

In the French community (Walloon Region and Brussels), the responsibility for the vaccination policy is shared between agencies, based on location and/or population/age group.

The Office de la Naissance et de l’Enfance (ONE, Office of Birth and Childhood) which offers children and family services similar to well-baby clinics is responsible for managing the vaccination programme for children and adolescents (0-18 years of age) and pregnant women.

German Community

Kaleido-Ostbelgien is responsible for vaccination services for children up to 18 years of age. The German community uses the same tenders, vaccines, and vaccination schedule as the French community.

In general, all medical doctors are allowed to vaccinate in Belgium. In addition, since April 2016 nurses are allowed to administer physician-prescribed vaccines without the presence of a doctor in the case that they have a ‘standing order’ (a written instruction by a physician, authorising them to administer specified vaccines).

CHALLENGES

- Overall, vaccination coverage varies across the different regions of Belgium. This is likely related to a combination of factors, such as vaccine hesitancy and service issues (e.g. no parental authorisation available), varying vaccine registration systems, and different combinations of public and private services.
- Overall, there is still a lack of awareness on the importance of vaccination among the general public; and a lack of awareness on recommended vaccines and how to get them. This is probably due to different factors, e.g. not enough information about vaccination during school/education, not enough accessible information available or the information does not reach the public effectively (communication format/channel barrier etc.).

OPPORTUNITIES

- A large facilitator for the vaccination services in some regions is the existence of digital registration and ordering systems and a vaccine database. However, recording vaccine administration is not obligatory for all vaccines and is often incomplete.
- A widespread survey of health students showed that vaccinology in the curriculum for the health workforce is not well organised. Tailored training on vaccination and vaccine communication could provide value to all pre- and in-service healthcare professionals and be integrated into the existing curricula for nurses, MDs, pharmacists, and midwives.

COUNTRY-SPECIFIC RECOMMENDATIONS

- As healthcare providers remain the most trusted source of information for the public, they should be equipped with the appropriate training and education to allow them to effectively inform new parents about RSV and prophylactic mAbs both during pregnancy and following birth.
- Health managers in different Belgian regions should adopt a position supporting the creation of a national digital registration system that includes RSV mAbs. Such a system would provide all administrators of immunisation programmes with an enhanced ability to implement evidence-based practices.



2023 RSV In-depth Research: Finland INSIGHTS FROM

FINLAND

Interviews

Hospital managers (2)

Care practitioners (1)

Health authorities (0)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

Following discharge from hospital, the same nurse who oversaw the pregnancy will conduct a home visit to assess the health of the new mother and infant. (24) The first scheduled visit to a child health clinic for examination is at 4-6 weeks of age, which normally takes place with both a nurse and doctor. (24)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Immunisation does not normally take place in hospitals. However, the same wellbeing areas that are responsible for providing community child health services are also responsible for managing hospital services and conducting procurement activities as well. These wellbeing areas liaise with hospital service providers and hospital management to establish supply and administration procedures when appropriate. (26)

Administrative process for mAb access in hospitals

Once the RSV mAb is approved for inclusion on the national schedule, each wellbeing area will determine how to implement it into existing health services. For the mAb to be administered in the hospital setting these authorities will also need to collaborate with local hospital service providers to establish a financing and administration scheme. (26)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



An advanced electronic vaccine registry exists, with an integrated national approach encompassing hospital and outpatient systems (although it does not currently include mAbs). All municipal healthcare providers implementing the national vaccination programme are required to report these vaccinations to electronic monitoring systems, from which this data is collected in a national vaccination register. (21)

Financing for preventive care such as an RSV mAb comes from a combination of wellbeing areas, national, and social health insurance funding. Wellbeing areas get their funding from state budgets, which in turn finances the budget of municipal and county-level wellbeing services which are responsible for implementing the child health clinics where most immunisations take place. However, financing for immunisations covered under the national vaccination schedule comes directly from the national budget. (27)

There is a sentinel surveillance system in primary care for influenza-like illness, but it is not RSV-specific. However, RSV is a notifiable disease for national infectious disease registry when diagnosed. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

Under the Communicable Diseases Act 1227/2016, municipalities are responsible for making practical arrangements for vaccinations. Most municipalities provide these services themselves to their inhabitants, while still others have outsourced healthcare to private companies. As of 01.01.2023, the responsibilities of the over 300 municipalities have been shifted under new public entities, the 21 county wellbeing services.

Implementation of the national vaccination programme is a part of everyday healthcare in Finland. Childhood vaccinations up to the age of 7 are given in child health clinics as a part of regular health check-ups. Childhood vaccinations are the responsibility of child health clinics,

which typically have their own booking systems with some variance between different Finnish regions, although follow up appointments are typically booked at previous visits. Child health clinic services are voluntary, i.e., there is no requirement for anyone to use them. Despite this, these clinics are used by 99,6 % of families.

In Finland, all nurses (including midwives) with specific training in addition to all medical doctors, are authorised to vaccinate. Despite all doctors being authorised to vaccinate, vaccinations are predominantly administered by nurses and public health nurses and only rarely by doctors. Public health nurses are a subset of nurses who give vaccinations in child health clinics, schools and student healthcare services.



CHALLENGES

- ✦ The provision of immunisation services is currently undergoing a major shift, as it was previously the responsibility of municipalities to organise maternity and child health clinic services in Finland but as of January 2023 these services have become the responsibility of specific wellbeing services within counties.
- ✦ Alongside the ongoing reforms, it is possible that newly organised maternity and child health clinic services are centralised in some counties, meaning that small villages or municipalities no longer have a nearby child health clinic and people needing immunisation services would increasingly need to use public transportation or own cars to get to the clinic in the nearest town.

OPPORTUNITIES

- ✦ Vaccine education modules for medical and nursing students and health care professionals are highly developed. There are courses and study modules available for health care professionals as a voluntary continuing education such as an online 'Vaccination Competence Study Module' and an online study entity 'Vaccinations' which both include sections on how to discuss with vaccine-hesitant clients. These could be easily adapted to incorporate an RSV mAb.
- ✦ Finland has high levels of trust towards health care professionals and highly skilled public health nurses who have time to talk about the importance of vaccination with the parents during pregnancy, well before the childhood vaccinations begin.
- ✦ The population's general level of knowledge about the importance of immunisation is high. The information is widespread due to the good network of schools, child health clinics and healthcare centres.

COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Health managers at municipal health authorities should establish a forum for communication between themselves, hospitals, and wellbeing services with the aim of raising the profile of RSV and prophylactic mAbs. With the shift in immunisation implementation from municipalities to local wellbeing services, these activities are critical to ensuring that existing knowledge is effectively transferred between stakeholders.
- ✦ Nurses, as some of the most highly trusted and accessible healthcare professionals, should be equipped with the appropriate training and education to allow them to effectively inform new parents about RSV and prophylactic mAbs both during pregnancy and following birth.

2023 RSV In-depth Research: France INSIGHTS FROM

FRANCE

Interviews

Hospital managers (1)

Care practitioners (2)

Health authorities (0)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

The first compulsory medical examination for infants occurs within 8 days of giving birth, sometimes at Protection Maternelle et Infantile (PMI) centres. (28)

Main actors involved in immunisation at hospital (funding, supply/stock, administration ...)

The procurement and financing decisions for immunisation are made by the national health authorities, and hospital management is then responsible for supply and administration. (28)

Administrative process for mAb access in hospitals

The use of an mAb in hospitals could be introduced through ad-hoc decisions by hospital managers who can decide to stock and offer it to newborns, although this would likely be complicated by the systematic separation of hospital budgets from funds reserved for public health activities such as immunisation. (28)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



A functional electronic database of vaccinations exists, using an integrated national approach to merge health insurance claim data. However, this data is based on the dispensation of medications rather than their actual administration, immunisations in hospital are not monitored, and the system is not interoperable between hospital and outpatient settings. (21,29)

Budget for preventative immunisations such as RSV mAb comes from the mandatory social health insurance scheme. L'Assurance Maladie which is the national (public) health insurance system, reimburses the costs of purchase of vaccines and their administration. (28) However, budgets for prevention and hospitals are typically separate, meaning that mAbs administered at hospitals would likely come out of hospital budgets under the current funding structure. (30)

There is a sentinel surveillance system in primary care and hospitals for RSV. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

Regional health agencies (Agences Régionales de Santé, ARS) are responsible for implementing the national vaccination schedule and for adapting it to regional context and needs. They are also responsible for regional health policies on maternal and child health (so called 'Protection Maternelle et Infantile', PMI) which cover disease prevention and vaccination.

The national public health agency, Santé Publique France - conducts disease surveillance for diseases for which vaccines are available, measures vaccination coverage across the French territory and informs the public and health professionals about vaccinations.

Infants' vaccines against MMR, against DTP and against MenC can be administered in private practices, at the hospital or at a

Maternal and child protection Centre (Centre de protection maternelle et infantile; PMI) and at public vaccination centres.

Usually, 65% of costs of purchase of vaccines included in the national vaccination schedule (recommended and mandatory) are covered by the national health insurance system. 70% of costs of vaccine administration are covered by the national health insurance. The remainder of purchase and administration costs (called 'Ticket Modérateur') is reimbursed by the patient's complementary private health insurance (mutuelles). The vast majority in France has complementary insurance and amongst those that do not, the most economically vulnerable can benefit from the so-called supplementary health insurance for solidarity (Complémentaire Santé Solidaire (CSS)).



CHALLENGES

- ✦ An ongoing issue in France is that of the 'déserts médicaux,' i.e., an overall insufficient number of doctors per inhabitant, and their uneven distribution across regions, with scarcity especially in rural and disadvantaged urban areas. There are only 318 doctors per 100,000 inhabitants (compared to 328 ten years ago) and the number of doctors per inhabitant in the south-east of France is 1.6 times higher than in the Centre region.
- ✦ Depending on the patient's private insurance status, upfront partial payment for vaccine purchase and administration is required, and reimbursement from the national health system occurs at a later stage.
- ✦ In some cases the patient needs to (1) collect vaccine prescription from General Practitioners/healthcare professionals, (2) purchase it at a pharmacy, (3) have it administered at another location, or back at HC/GP (aside from public vaccination centres and Maternal and Child Protection Centres where prescription, delivery and the vaccination are done on the spot).
- ✦ Under current financing structures, the budgets for hospital care and prevention activities are managed separately, creating a barrier to the administration of immunisations in hospital settings.

OPPORTUNITIES

- ✦ Some vaccines can be dispensed free of charge at public vaccination centres, Maternal and Child Protection Centres ('Protection Maternelle et Infantile', PMI) (Centres gratuits d'information, de dépistage et de diagnostic (CeGIDD)), family planning centres (Centre de Planning Familial).
- ✦ Massive information campaigns were conducted to accompany the extension, in 2018, of mandatory vaccines to a total of eleven vaccines. Alongside more recent information campaigns conducted during the Covid-19 pandemic, and annual promotion campaigns for the influenza vaccine, the general population has an increased awareness of the importance of immunisation and may be more receptive to an RSV mAb.

COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Using successful techniques from earlier campaigns following the introduction of mandatory vaccination in 2018, health managers implementing immunisation programmes should develop targeted training and education programmes for midwives, nurses, physicians and the general public to improve understanding of RSV seasonality and prophylactic mAbs. This may help to improve trust and counteract any additional vaccine hesitancy arising out of the COVID-19 pandemic, as even though an mAb is not a vaccine it may be perceived in the same way due to the shared method of administration (injection).
- ✦ Health managers and policymakers should develop a mechanism for sharing budget items related to immunisations delivered in hospital, to ensure that financial and administrative obstacles do not prevent infants born during the RSV season from receiving immunisation at birth.
- ✦ Health managers should consider the implementation of a voucher programme to provide parents with free-of-charge, prescribed access to an RSV mAb for their infant. For children born out of season, this voucher could be mailed or sent digitally before the start of the RSV season. For children born in season, the voucher could be issued by the hospital of birth, if hospital administration is not possible, to prompt parents to obtain the immunisation for their child as soon as possible.

2023 RSV In-depth Research: Germany

INSIGHTS FROM

GERMANY

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (1)

Immunisation at birth

1st opportunity in primary care for immunisation after birth

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

HepB recommended at birth for risk groups only. (18)

Following discharge from the hospital, new mothers and infants are entitled to daily visits from a midwife until the infant is 10 days old, although midwives are not authorized to administer immunisations. The first scheduled visit to a paediatrician occurs at 4-6 weeks of age, and this is a good opportunity to schedule appointments for upcoming vaccinations. The first vaccination against rotavirus normally occurs at 6 weeks of age followed by a wider set of vaccinations at 2 months. (31)

In both hospital and primary care settings, paediatricians are the primary providers of immunisation services (although immunisation in hospital is rare), and often have responsibility for supply and administration decisions. (32) Funding is provided by state governments through social health insurance in case of a STIKO recommendation or when a sick fund decides to voluntarily reimburse the costs. Out-of-pocket payments are also possible if neither of the above options apply. Hospital managers are responsible for supply decisions. (32)

Administrative process for mAb access in hospitals

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

For mAbs classified as drugs, there is a standard process of procurement and distribution. Hospitals directly purchase from manufacturers through either the hospital pharmacy or a public pharmacy through a supply contract. The costs for this are borne by the health insurance companies. Germany provides a possibility for short-term, intermediate reimbursement for new and innovative technologies (NUB) to bridge the time while cost data is collected and analysed until they can be appropriately included in the national immunisation plan and the specific Diagnostic-Related Groups (DRGs).⁽³³⁾

An electronic vaccine registry exists in the form of the KV Surveillance tool. The data is based on compulsory provision of pseudonymized billing information from office-based physicians. For vaccination services and diagnoses of vaccine-preventable diseases, the data is transmitted to the RKI and processed there. These data, which reflect benefits paid by all statutory health insurers, can be used to estimate vaccination rates. The KV Surveillance tool represents a standardized national approach to vaccination data, making hospital and outpatient data available.⁽³⁴⁾

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



Funding for public health services such as immunisations comes from federal and state government budgets, which then transfer these allocated funds to social health insurance providers to reimburse these services. (32) German law does not currently allow for mAbs to be funded for a broad population of healthy infants, unlike for vaccines, following a STIKO recommendation.

There is a sentinel surveillance in primary care for RSV. (22) A legislative request to establish a compulsory register of RSV infections was approved by the Federal Council on 7 July 2023 and came into force prior to the 2023-2024 RSV season.(35)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The implementation and monitoring of the vaccination programme is the responsibility of the federal states. One federal state, the Free State of Saxony (Freistaat Sachsen), maintains its own vaccination commission, which consults the recommendations of the NITAG (STIKO) but works independently. All other 15 states rely only on the STIKO as source for recommendations, without having independent vaccination commissions. Likewise, they decide what the priorities are in vaccination campaigns, with some states undertaking additional communication campaigns for certain vaccines, based on the coverage rates for each vaccine across the different states (e.g. HPV). The local health offices then carry out the instructions of the federal state government, although their scope of action is limited due to the independence of medical doctors. This is because medical doctors ultimately decide which and how many vaccinations they recommend and administer to their patients. Paediatricians typically administer the MMR, the polio and the meningococcus vaccines to children as part of regular health examinations.

It is possible, although not routine, to receive vaccinations in hospitals, in doctors' practices, in care homes, at workplaces, in pharmacies (for influenza and COVID-19 only) and through official health authorities (e.g., in refugee camps or in asylum arrival centres). Not all these places typically offer the same vaccinations, as administration highly depends on physician's readiness and vaccine availability.

The different types of insurance follow different ways of financing. A person with statutory health insurance receives immunisations free of charge after showing their insurance card if the immunisation is recommended by STIKO or included as a voluntary benefit of their insurance provider. If there is neither a STIKO recommendation nor a voluntary reimbursement by the sick fund of the insured, then costs must be paid out-of-pocket. A privately insured person receives an invoice by post after the vaccination (and all other private medical services), which must initially be paid out-of-pocket and will be reimbursed thereafter.



CHALLENGES

- ✦ The lack of a centralised electronic vaccination pass based on standardized data collection may lead to knowledge gaps for doctors and patients: once a vaccination pass (in paper form) is lost, no one can retrieve the immunisation status of that person. There is no way to control the immunisation status of a person if they do not show their vaccination pass.
- ✦ The lack of digitalisation of the communication between patient and doctor (especially booking an appointment) leads to missed vaccinations and administrative obstacles. Although progress is being made, it still depends on the medical practice, if online appointment booking (in different languages) is possible or not.
- ✦ There is no national system of vaccine purchase. The purchase and distribution of vaccines is organized by private companies which supply pharmacies and doctors. Therefore, shortages can occur in one part of Germany while another part of Germany still has adequate supply, but there is no mechanism for stock transfer.
- ✦ There is a lack of equality between protective vaccination and measures of specific prophylaxis and therefore no adoption of recommendations of such measures (as a passive RSV prophylaxis) in the protective vaccination guideline. Hence, currently no compulsory reimbursement by the health insurance funds in the case of a successful STIKO recommendation.

OPPORTUNITIES

- ✦ Many health insurance providers offer immunisations not included in the national schedule as a voluntary benefit, such as the influenza vaccination for insured people who do not fall into the risk groups (pregnant women, those 60 years of age and older, and anyone whose health is at risk due to an underlying illness), in addition to those that are included in the guidelines. Health insurance providers can also provide voluntary reimbursement for measures of specific prophylaxis or passive immunizations for RSV respectively.
- ✦ Doctors are highly trusted and have great influence on the vaccination decision of their patients. If they receive proper training on motivation for immunisation and sufficient awareness of RSV, and the statutory health insurance providers reimburse costs, it will likely have a substantial positive impact on uptake.

The second dosage of the measles vaccine was moved from age 6 into the second year of life, and the immunisation schedule was synchronized with that of children's routine check-ups. This offers insight into the possible effectiveness of aligning RSV immunization with existing care visits.



COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Due to the status of the monoclonal antibody, a change of regulation is required to enable funding for healthy infants before implementation programmes for an RSV mAb for all infants can be foreseen. In the inpatient sector, regional health managers and physicians should consider apply for additional remuneration through New Examination and Treatment Methods (NUB).
- ✦ Training and education campaigns targeting paediatricians should be developed to improve knowledge and understanding of RSV and mAbs. Paediatricians have a substantial influence on which preventative treatments are implemented, and the opinions of patients, so engaging them on the topic of RSV is a critical step towards broader acceptance of RSV mAbs at both the regulatory and implementation stages.



2023 RSV In-depth Research: Italy INSIGHTS FROM

ITALY

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (1)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

In primary care settings all immunisations are delivered at vaccination centres by specifically trained care providers. The first scheduled visit is at 3 months of age for vaccines against pneumococcal pneumonia, meningitis B, rotavirus and DTaP/IPV/HepB/Hib. (38,39)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

In most cases the regional health authority will manage funding and procurement for immunisation services, with matters of supply and administration being delegated to the management teams at individual hospitals. (40)

Administrative process for mAb access in hospitals

Regional health authorities have to include RSV mAb in their individual Vaccine Prevention Plans, which also specify the health facilities where specific immunisations are delivered. (40)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



A functional electronic vaccine registry has been developed, but not implemented. Once functional, regions and autonomous provinces will enter information daily in the Anagrafe Nazionale Vaccini (National Vaccine Registry), which aims to ensure accurate assessment of vaccination coverage and provides information to national, EU and international health protection organisations. (21) It is unclear if immunisation against RSV will be incorporated.

Funding for public health services such as RSV mAb comes from a National Healthcare Fund pooling regional and national taxes, which is distributed to regional health authorities to use at their discretion. 5% of the budget for this fund is earmarked for prevention, under which an RSV mAb would likely fall. (40)

Some RSV infections are recorded through the influenza monitoring system, but overall there is no comprehensive surveillance system specifically for RSV. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The institution which designs vaccination programmes and makes recommendations (Italian National Plan for vaccinations) is the Conferenza Stato-Regioni (State-Regions Conference), through which national government, regions and autonomous provinces collaborate on common issues such as vaccination programmes. Every Region can adapt the implementation of the National Plan to local needs through regional resolutions approved by a Regional Council.

There are no national guidelines for booking and notification systems, so this differs from region to region and from one local health authority to another.

The National Vaccination Plan is the main planning instrument, but it does not cover this issue. Regions have a high level of autonomy in how they organise the enforcement of the national vaccine plan.

The healthcare professionals authorised to perform vaccinations are all physicians and nurses at vaccination centres and health assistants (“assistente sanitaria”, a health professional specialised in prevention). Physicians, general practitioners, and nurses administering vaccines all require institutionally provided specialist training (provided by the National Institute of Health).



CHALLENGES

- Family paediatricians only provide vaccination in some regions (e.g. Apulia, Tuscany), with high regional variability in general regarding where parents need to go to receive immunisation services. As vaccination coverage rates are currently high this represents more of an administrative and logistical challenge than a sociological barrier.
- Currently, the national online Vaccination Registry is yet to be implemented. The Registry is only formally available but currently it cannot allow each individual to move and register previous vaccinations from one LHA to another because of interoperability issues between hospital and primary care settings.

OPPORTUNITIES

- The Board of the Calendar for Life and the Italian Society of Neonatology (SIN) have officially recognized the nirsevimab as a novelty of considerable importance and potentially great impact for public health, as well as a universal preventive possibility that responds to a medical need. Their joint statement calls for this novelty to be promptly recognized and for regulators to consider its classification not as a therapeutic aid (as has always happened for monoclonal antibodies), but a preventive option, with a view to consider an evolution of the 'National Vaccine Prevention Plan' towards a more comprehensive 'National Immunisation Plan'. (41) This position offers a strong foundation for political support for the introduction of an RSV mAb in the NIP.
- The most recent National Vaccination Plan released August 2 2023 introduced, for the first time, mAbs as possible prevention tools to be considered in the future. (42)

COUNTRY-SPECIFIC RECOMMENDATIONS

- Through the Italian National Agency for Regional Healthcare Services (AGENAS), health managers at regional health authorities should work with national agencies to ensure that RSV immunisation is included in the implementation of the national vaccine registry. This would allow for evidence-based immunisation programme development based on improved data around RSV.
- Health managers at regional health authorities should consider working with HCP organisations to adopt and promote a set of national guidelines for implementing an RSV mAb. This would facilitate collaboration between health care settings upon eventual implementation.

2023 RSV In-depth Research: Italy INSIGHTS FROM

NETHERLANDS

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (0)

Immunisation at birth

1st opportunity in primary care for immunisation after birth

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Administrative process for mAb access in hospitals

HepB recommended at birth for risk groups only. (18)

Pregnant women sign up for a post-natal in-home care service called kraamzorg prior to giving birth, through which a postnatal care nurse comes frequently to the home over the first 8 days after the mother and infant's discharge from hospital. (36)

Hospital care is delivered under a network of agreements between the Ministry of Health, individual health insurance providers, and hospital management. In general, products used in the scope of public health are procured by the national institute for public health and distributed to municipal and community health facilities for administration. (37) Currently, the mAb palivizumab is only reimbursed outside of hospital settings and not through public health programs.

Immunisations are generally not delivered in hospitals. This would require a specific recommendation through the National Institute of Public Health and the Environment (RIVM) which organises immunisation services in collaboration with municipal health authorities. (36)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



An advanced electronic vaccine registry exists, with an integrated national approach encompassing hospital and outpatient systems. Each vaccination in the National Immunisation Programme is registered in the national database for vaccinations (Præventis). Præventis is connected to the Dutch population register (Basisregistratie Personen, BRP). (21)

All children under 18 are provided free access to care services deemed 'essential' through the national Health Insurance Act. This statutory coverage is financed through general taxation and managed by the Ministry of Health, Welfare and Sport. RSV mAb would be funded through this channel once approved as an 'essential' service by the ministry. (37)

Sentinel surveillance in primary care for RSV. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The National Childhood Immunisation programme (Rijksvaccinatieprogrammema) is organised by the National Institute of Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu, RIVM). The actual administration of the vaccines is carried out at a local level by the Municipal Health Services through baby well clinics.

There are 25 municipal health services in the Netherlands and most municipalities have organised their immunisation services collectively. The actual organisation may differ among these services, although childhood vaccination services in all regions are provided through well-baby clinics and the youth healthcare services departments of said Municipal Health Services. Well-baby clinics provide regular health check-ups for all children up to the age of 4 years old. There are no options to modify or tailor the vaccinations at this level, other than shifting the exact timing of the vaccinations, such as postponing a vaccination if a child is sick or has missed the vaccination for other reasons.

The invitation for childhood vaccinations (polio, meningitis, measles, mumps, and rubella (MMR), and vaccines against HPV for adolescents) is organised by the National Institute of Public Health and the Environment (RIVM) and conducted by the local municipal health services. Invitations are sent by mail to parents based upon information in the Dutch population registry. Up to the age of 4, children receive their vaccinations at well-baby clinics during their regular check-ups.

Vaccination locations (in addition to well-baby clinics) could include health centres, community houses, and/or other publicly accessible premises. In general, vaccination hours correspond with office hours, although some vaccination events may be organised on Saturdays; however, this differs according to the municipal health service organising the event. There is a good geographical coverage of well-baby clinics, although in some rural areas, people may have to travel to another village or city. Immunisations are usually administered by a youth physician or youth nurse from the municipal health services.



CHALLENGES

- ✦ For childhood vaccinations (0-4 years): a shortage of youth physicians leading to less contact in well-baby clinics or the closure of some of these clinics. This then causes longer travel times for parents and fewer options when it comes to changing appointments or providing a vaccination during another planned visit e.g., in the event of a child being ill.

OPPORTUNITIES

- ✦ Vaccination coverage may increase if a user-friendly system for making and changing appointments is implemented. This can be combined with existing invitations (with a pre-set appointment) stating that the immunisation is readily available along with a declaration that immunisation is voluntary, which seem to contribute positively to uptake rates.
- ✦ Personal invitations by trusted care providers (such as GPs in the case of the influenza vaccination) has been proven to contribute to willingness to have a vaccination.
- ✦ In addition to childhood vaccinations, the National Childhood Immunisation Programme has provided a booster vaccination for pregnant women at 22 weeks of gestation for tetanus, diphtheria, and whooping cough since 2020. This offers a valuable opportunity to raise awareness and build trust for an RSV mAb with expectant mothers.

COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ As GPs remain a highly trusted source of information for the public, they should be equipped with the appropriate training and education to allow them to effectively inform new parents about RSV and prophylactic mAbs both during pregnancy and following birth. Incentivizing GPs to extend personal invitations for RSV immunisation to parents could provide additional benefits for uptake rates.
- ✦ Health managers at the national and municipal levels should work to collaborate on a standardized system for making and changing appointments for immunisation, and for extending invitations to receive an RSV mAb. Developing a national set of guidelines that can be implemented by municipalities will streamline the pathway to immunisation for parents and likely improve acceptance.

2023 RSV In-depth Research: Norway INSIGHTS FROM

NORWAY

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (0)

Immunisation at birth

Vaccination at birth is not recommended. (18) Hexavalent vaccination is provided at 3,5 and 12 month, including Hep B.

1st opportunity in primary care for immunisation after birth

Several local authorities offer home visits by midwives 1-3 days after giving birth and returning home from the hospital. In all cases a health nurse will visit the home 7-10 days after birth. (43)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Funding for immunisation at hospital level would be provided by the hospital's associated regional health authority, which delivers case-based payments to hospitals based on established DRGs. The regional authorities also manage procurement, while supply and administration is managed by hospital management teams. (44) Hospital administration falls outside of the national paediatric vaccination programme and is funded through hospital budgets.

Administrative process for mAb access in hospitals

Immunisations are not routinely delivered at hospitals. Delivering an mAb at hospital would require a specific recommendation from governing regional health authorities and the agreement of a DRG financing model with management at the relevant hospitals through following the initiation of a pharmaceutical pathway process. (44)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



An advanced electronic vaccine registry exists (SYSVAK), with an integrated national approach encompassing hospital and outpatient systems. SYSVAK makes vaccination coverage information available to HCPs and the public. (45)

All health care services, including immunisations, are financed through the National Insurance Scheme which is funded by general taxation. Funding is delegated to regional authorities for the procurement of immunisations and as block grants to local authorities for their administration. (44)

Sentinel surveillance in primary care for influenza-like illness, not RSV-specific. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The childhood immunisation programme begins 2 months after delivery and continues up until 15 years of age. Initial vaccinations are scheduled in week 6 and are normally done in community settings such as child and health care centres, but they are often administered at the hospital for premature infants. The child and health units are administered by regional health authorities and are largely responsible for implementing the national vaccination programme. All babies are offered the full series of immunisations and parents receive automatic reminders when an appointment is needed.

The majority of paediatric care at child and health centres is provided by nurses, which is also true of immunisation administration. This creates a high level of trust between nurses, parents and children and the advice of nurses often has the most influence on parental decision-making. In addition to advice from nurses, a standard maternal information package given to expecting mothers, along with a visit from specialist nurses who provide specific information about the childhood vaccination schedule and related logistical considerations.



CHALLENGES

- ✦ Within the current structure of the health care system, hospitals are generally not able to offer immunisations to infants. Substantial efforts may be needed to shift policy and narrative around immunisation administration to reach infants with an RSV mAb in hospital who are born in-season.

OPPORTUNITIES

- ✦ There is a very high level of awareness of RSV, as nurses and doctors are educated in recognising RSV, parents know a lot about it, and many digital resources on the topic are widely accessible. There is also demand among leading HCPs, including the director of paediatric immunisation, for the inclusion of an RSV immunisation in the national programme.
- ✦ Hospitals may have the staffing available to administer immunisations to children, as maternity wards have not undergone the same challenges to capacity and workforce as other areas of the hospital system.
- ✦ There is a high level of trust in the government's administration of the health system, with a byproduct being a low level of vaccine hesitancy and misinformation. These conditions may be ideal for the implementation of a new RSV mAb.

COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Health managers at regional health authorities should establish a forum for collaboration between health managers and HCPs in hospitals and primary care settings, with the aim of reducing compartmentalisation in immunisation services and exploring possibilities for administration of an RSV mAb in hospital settings.
- ✦ Nurses, as some of the most highly trusted and accessible healthcare professionals, should be equipped with the appropriate training and education to allow them to effectively inform new parents about RSV and prophylactic mAbs both during pregnancy and following birth.



2023 RSV In-depth Research: Norway INSIGHTS FROM

PORTUGAL

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (0)

Immunisation at birth

1st opportunity in primary care for immunisation after birth

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Administrative process for mAb access in hospitals

Yes, Hep B is recommended at birth for all infants. (18)

For infants born during the RSV season, the best opportunity for immunisation is before postpartum discharge from hospital, alongside the administration of the Hep B vaccination in the National Immunisation Programme.

After discharge from hospital, standard practice is that parents bring their infant to the health centre to see if everything is well (feeding, weight, heel prick test - if it was not done at the hospital). Some families will receive a home visit from a nurse depending on regional programming, but this is not instituted at national level. (46)

The central NHS is responsible for financing and procurement for immunisation services across the country. Hospital managers rely on administration and clinical guidelines from the NHS to determine how to implement immunisations, but they are responsible for supply considerations. (47)

Once an RSV mAb is approved for inclusion in the National Immunisation Programme, the NHS would need to determine that the most effective pathway for its implementation is through hospitals. Clinical administration guidelines would then be developed to standardize this implementation. (46)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

The base for all computation of VCRs is the RNU – Registo Nacional de Utentes. RNU operates as a Master Patient Index. It is a national record of all persons registered in the NHS. Each person has a unique NHS number that identifies them in all interactions with the healthcare system, recording the clinical data generated for each patient in an electronic platform – the RSE (Registo de Saúde Eletrónico). This platform is accessible to all HCPs and patients in the country, including those in the private sector. As part of the RSE, there is a dedicated platform for recording vaccination data – VACINAS (which could be used to monitor prophylactic mAbs). When an individual receives a vaccine, the information is registered in this platform and automatically integrated in the national registry. (21)

Funding for vaccines is secured by the National Agency for the Administration of the Health System (Administração Central do Sistema de Saúde, I.P. – ACSS). The ACSS manages the funding for the NHS and transfers the necessary amounts to pay for the acquisition of vaccines. Acquisition of vaccines is managed centrally by the Shared Services of the Ministry of Health (Serviços Partilhados do Ministério da Saúde- SPMS) in conjunction with regional health authorities (ARS). The ARS in the different regions stipulate the amounts of vaccines needed and request that amount from the SPMS. Funding to pay for the purchase of vaccines (and prophylactic mAbs) is transferred to the ARS of each region by the ACSS. (47)

Established RSV surveillance system

Sentinel surveillance in primary care for RSV. (22)

National RSV Surveillance System (VigiRSV). A Hospital surveillance network to report RSV cases with 2 years and 20 hospitals involved, with national representativity. VigiRSV is implemented by the National Institute of Health (INSA), which performs analysis on samples from hospitals to identify which viruses circulate and create reports, including for RSV.

The Portuguese Society of Paediatrics (SPP) helps to identify the right hospitals and departments within the hospitals who will send samples to INSA. Selected hospitals then provide the RSV samples to INSA.



HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The coordination of the Programme Nacional de Vacinação (PNV) in Portugal follows a mixed method of central and regional coordination and currently follows the governance model last revised in 2017 (Portaria 248/2017). The Directorate-General for Health (Direção-Geral de Saúde - DGS) is the national authority in charge of coordinating the PNV. The DGS has a mandate to design the vaccination programme and to issue recommendations in related matters. It operates in close collaboration with other central governmental bodies for the acquisition of vaccines, management of vaccine stocks, the registry of vaccination information, monitoring of vaccination coverage and epidemiological surveillance. Acquisition of vaccines is centrally managed. Vaccines are distributed nationally under the coordination of the DGS.

Regional authorities are primarily in charge of the logistics of PNV implementation and have some leeway to adjust their models of operation according to the region's demographic characteristics. For example, they can take decisions about the location of vaccination points. Regional authorities oversee managing the administrative procedures required to guarantee the acquisition of vaccines, identifying the needs of their region.

They are also in charge of managing vaccine storage and regional distribution. They have the responsibility to secure a permanent stock of 25% of needs for each vaccine. Regional authorities also have the responsibility for collecting regional data and provide reports on regional vaccination coverage that are sent to DGS to feed national reporting.

Regional authorities cannot modify the PNV in matters related to included vaccines or schedules. There is also no room to modify eligibility criteria or technical protocols concerning the administration of vaccines (except for the autonomous islands, Madeira and Azores).

Vaccination will typically start immediately after birth if birth takes place at a hospital or maternity ward. Newborns receive the first dose of the hepatitis vaccine at the hospital or maternity ward. It is then that their vaccination booklet (Boletim de Saúde) is created, in paper format. Children born in locations where vaccines are unavailable receive the first dose of the hepatitis vaccine when they go to the healthcare centre for the New-born Bloodspot Screening Test during the first week of life. This is when most children are officially registered at the local healthcare centre and receive an NHS number. This is a unique personal number that will be used for all healthcare matters. Information systems that support the collection of data to monitor and evaluate the PNV are centrally administered, but monitoring for RSV is fragmented and done sporadically at local and regional level, meaning many cases are not reported and prevention responses may lack an evidence base. National reports on vaccination coverage are issued by the DGS yearly.

Education and awareness of RSV is generally high among paediatricians and HCPs but low among parents and the general public.

Vaccines for infants can be provided in various community and hospital settings, and routine maternity care visits align with delivering RSV immunisation to children born both in- and out-of-season.

CHALLENGES

- ✦ The existing clinical guidelines for Palivizumab are very restrictive to a specific set of pulmonary co-morbidities. Based on considerations of cost-effectiveness and existing disease burden, it is possible that any new treatment prophylactic mAb for RSV would likely be reimbursed only under a similar set of specific clinical guidelines.
- ✦ Only certain pharmaceuticals are fully reimbursed in both public and private settings for all people (e.g. certain medications for rheumatoid arthritis), so there is not a strong precedent for a prophylactic RSV mAb to be given this status unless it is classified under the same category as vaccines.
- ✦ There is a large degree of inequality among primary and maternity care centres throughout the country regarding their capacity to screen for RSV, train staff in treatment administration, and effectively manage the procurement and storage of pharmaceuticals.

OPPORTUNITIES

- ✦ Reimbursement decisions can come down to how effective the civil society response around a given topic or issue is. The time window for public consultation on reimbursement decisions is typically very short, so if relevant civil society groups do not have their positions prepared to actively participate in focus groups or stakeholder consultations it may be the case that the decision is made with a lower level of citizen participation and input.
- ✦ RSV is primarily perceived to threaten the health of infants, and parent groups are some of the most politically powerful entities in Portugal when it comes to influencing policymakers.
- ✦ Many parents choose to have children in private maternity clinics, which are paid for largely out-of-pocket and can offer many additional services and treatments not reimbursed by public health insurance, such as an mAb for RSV.

COUNTRY-SPECIFIC RECOMMENDATIONS

- ✦ Hospital managers in PT rely on administration and clinical guidelines from the NHS to determine how to implement immunisations. Updated NHS guidelines specific to an RSV mAb would ensure standardized implementation across the country for health managers, clinicians, and parents.
- ✦ Identify and work with relevant civil society groups, especially those that include parent voices, to establish a stakeholder network that advocates for access to an RSV mAb for all infants. This network should be supported with training and education to improve its ability to engage with government agencies responsible for RSV mAb implementation.



2023 RSV In-depth Research: Sweden INSIGHTS FROM

SWEDEN

Interviews

Hospital managers (1)

Care practitioners (1)

Health authorities (1)

Immunisation at birth

HepB recommended at birth for risk groups only. (18)

1st opportunity in primary care for immunisation after birth

For the first 2 weeks of an infant's life, the mother and infant have free access to care visits on demand at the hospital maternity ward and midwife home visits as desired. (48)

Main actors involved in immunisation at hospital (funding, supply/stock, administration...)

Regional and municipal health authorities are ultimately the stakeholders responsible for the funding and procurement of immunisations. They also work with providers to determine standards for administration, while hospital managers are responsible for managing supply. (48)

Administrative process for mAb access in hospitals

The Swedish Public Health Agency creates the national vaccination schedule that all regions are encouraged to follow, and the logistics of implementation for immunisation services are left up to the regions. For an RSV mAb to be administered in hospital the regions would need to determine that this is the best pathway for administration and work with hospitals to develop the necessary guidelines. (49)

Existing electronic registry to monitor immunisation coverage (encompassing interoperability between hospital & outpatient systems)

Origin of budget & insurance coverage to cover RSV mAb

Established RSV surveillance system



The Public Health Agency of Sweden keeps a national register of vaccinations and vaccination coverage in Sweden. As of January 1st, 2013, healthcare providers are obliged to report all vaccinations administered within the Swedish vaccination programme to the national vaccination register. (21)

Preventive health services, likely including a prophylactic RSV mAb, are financed through a pooled fund created from general taxation at municipal, regional and national levels. This financing is managed through the budget of the regions or municipalities that deliver immunisation services for their respective territories. (48)

A voluntary surveillance system through laboratory testing is in place for RSV. (22)

HEALTH SYSTEM: RELEVANT CHARACTERISTICS

The Swedish healthcare system is decentralised, which means that healthcare is provided either by regions or municipalities. Both health and medical care is divided into public and private sectors. Despite this, healthcare in Sweden is state-funded and free for all citizens. To make sure the healthcare system functions properly, the Swedish Public Health Agency (Folkhälsomyndigheten) draws up guidelines for different forms of healthcare; this includes vaccination schedules that healthcare providers are required to follow. These guidelines and recommendations need to be in line with the national Communicable Diseases Act, but ultimately regional and municipal authorities then choose how they implement these guidelines, and no region has the exact same organization for vaccination services.

Therefore, it is hard to generalize about the Swedish vaccination programme for children overall.

General practitioners are all authorised to vaccinate 1-7 (polio, meningitis, MMR, HPV, tetanus booster, influenza, and COVID-19). Mother and child health services are authorised for three diseases: polio, meningitis, and MMR. Health centres can provide vaccinations for tetanus boosters, influenza, and COVID-19. Pharmacies are authorised for general vaccinations (travel vaccines and other vaccines that are not generally recommended for the public but can be important for some), tetanus boosters, influenza and COVID-19 but only if they are in partnership with private medical centres. All vaccination can also be done in private vaccination clinics, but this service must be paid out-of-pocket by patients.



CHALLENGES

- Regions have a high level of autonomy when it comes to implementing immunisation programmes/recommendations, but best practices (tested strategies that work) are usually used, which means that the implementations look quite similar in most regions across the country.
- Healthcare professionals are also not able to access individuals' vaccination history as it is protected by privacy laws. Individuals are however able to see their own (and their children's) vaccination history. The registry is also accessible for research and education purposes.

OPPORTUNITIES

- The booking system for child vaccines is, in general, simple. Parents are notified when it is time for the child to be vaccinated and they can then decide if they want their child to receive the vaccine or not. Parents will receive an invitation from the child healthcare service when it is time for vaccination.
- Sweden has a very high Vaccination Coverage Rate for its child vaccination programme (98%), and this programme enjoys very high levels of public trust. If an RSV mAb is effectively implemented into this program it would virtually guarantee high levels of uptake and equitable access for all infants.



COUNTRY-SPECIFIC RECOMMENDATIONS

- As the administration of prevention programmes lies with the Swedish regions, and regions tend to share best practices through The National Board of Health and Welfare (Socialstyrelsen), a successful pilot implementation of an RSV mAb in individual regions may lead to effective implementation throughout the country. Pilots should take place in regions that are identified as leaders in the implementation of preventative care programmes.
- Health managers at the regional and national level should adopt a clear position statement supporting the expansion of the definition of 'vaccination' for the purposes of funding, data collection and administration to also include prophylactic RSV mAbs. This position statement should be communicated to relevant policymakers at the national level to encourage any necessary changes to legislation and the administration of vaccine registries.

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