

REPORT OF THE 2022 WORKING GROUP ON RSV BURDEN AND PREVENTION STRATEGIES

Conclusions of the 2022 EIP Annual Conference RSV Working Group Meeting

INTRODUCTION

Respiratory Syncytial Virus (RSV) Infections are a major global health priority and are increasingly seen as a major health burden on over-stretched healthcare systems across Europe. Most hospitalisations happen in otherwise healthy infants, highlighting the need

to protect all infants against RSV. However, the elderly (65+) can also present a high-risk infection, especially with underlying diseases, as RSV can cause respiratory exacerbations.

RSV is the primary cause of lower respiratory tract infections and illnesses in infants and young children that may lead to hospitalisations and a substantial number of outpatient visits, which result in a huge economic and healthcare burden. The impact on healthcare systems, including hospitals, ICUs, primary care settings and healthcare workers, is massive, as documented by the EHMA in its 2022 survey on the Health System Burden of RSV in Europe, especially during the peak Winter season of respiratory infections (Generally October to April).

With this in mind, developing prevention strategies against RSV for all infants entering their first RSV season constitutes a large unmet medical need. Coupled with this is an unmet need to educate healthcare professionals on the

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nature of RSV circulation and to increase disease awareness and knowledge among the healthcare communities and the patients of RSV in general.

Finally, there is a high medical need for a prevention solution that is easy to administer in the current settings and cost-effective compared to the overall disease burden. Prevention is essential to decrease RSV's burden on European healthcare systems.

BURDEN ON HEALTHCARE SYSTEMS

Healthcare systems are already stretched to their limits during the peak season due to admissions from respiratory infections. Hospitals are overwhelmed with admissions for infants with bronchiolitis, most of which is caused by RSV. Equally, ICU units are overstressed by admissions caused by RSV infection. This is a massive burden for hospitals trying to cope with the flood of admissions with their limited capacity.

Most children with bronchiolitis-related intensive care admission require prolonged ICU stays with a mean duration of around seven days in intensive care and, in many cases, another seven days in the hospital afterwards. This reality is that the overall demand exceeds the capacity of the settings with the hospitals, resulting in patients being transferred to another hospital, usually away from the place the family lives.

Staff are severely impacted across care settings, especially when operating at overcapacity with a high number of staff sickness absences in addition to the high direct demand for care. RSV has a domino effect across hospitals and health systems that push them to their limits. To estimate the overall burden and impact of RSV Infections on the healthcare systems, it is essential to incorporate outpatient visits before

the hospital admission and the visits to manage the long-term consequences and the rehabilitation period after the admission.

A similar impact in the broader healthcare systems is caused by the admissions of older people with RSV infection, especially considering the long-term consequences of chronic co-morbidities.

RSV INFECTIONS DRIVE ANTIMICROBIAL RESISTANCE

Bronchiolitis and RSV infections are the leading cause for healthcare professionals and pediatricians to administer unnecessary antibiotics to young children, contributing significantly to antimicrobial resistance, the recent antibiotic supply shortages across European countries, and the health systems' cost increase. This status quo must be changed through the education of HCPs, demonstrating the importance of effective prevention strategies against RSV infection in the first place.

CHALLENGES CAUSED BY SEASONALITY

The seasonality of RSV has been a decisive factor in impacting health system performance, usually with infection peaks in the Winter months, contributing to a significant patient surge to the hospitals, ICUs, and Emergency Departments when the healthcare systems are already operating at their maximum capacity. The seasonality of RSV must also be taken into serious consideration when planning efficient and effective prevention strategies.

The ability to immunise patients before the start of the infection season in the already existing settings could significantly contribute to a successful prevention program.

This flexibility will also be of value if the dynamics of RSV infections continue to change, as observed this year.

AWARENESS - EDUCATION

There's a significant discrepancy between the high prevalence of RSV infections and the lack of awareness and knowledge among parents, elders, and healthcare professionals. All groups are not sufficiently informed about this infectious disease, the short-term risks, and the potential long-term consequences associated with RSV infections.

The same applies to the infection's epidemiology and transmission cycle, especially between family members, children, adults, and elders. There is an urgent need to educate and train healthcare providers, including pharmacists and nurses, and offer parents more information on RSV.

SOCIOECONOMIC IMPACT ON FAMILIES

Apart from the disease burden on the healthcare systems, the already stressed capacity of the healthcare providers, and the health systems' cost, RSV Infections are a significant burden to families, often underestimated or ignored. Healthcare professionals often underestimate RSV infection prevalence and the associated risks causing confusion, stress and anxiety among parents who are not sufficiently informed or aware of the disease.

The toll on families and the disruption to families' social and economic life from a lengthy hospitalisation of a child in a hospital ward or ICU is tremendous. Apart from the stress and uncertainties during the hospitalisation, parents are stressed about the long-term consequences of the infection while being unprepared for the very long rehabilitation period needed after the discharge from the hospital, which could stretch to months or even years.

THE TRANSMISSION CYCLE WITHIN FAMILIES DRIVES RSV EPIDEMICS

Herd immunity is essential to combat RSV epidemics. When a child presents with typical signs and symptoms of RSV lower respiratory tract infection, there is already a significant spread of RSV among the family members. In most cases, an older sibling or the parent is the most likely source of a young child with an RSV infection. There is a group critical in triggering RSV epidemics. It's considered to be mainly children younger than ten years, particularly those between the age of 3 to 6 years.

The impact of RSV on different age groups remains underestimated. The spread of RSV within the family is pivotal for severe infection in infants, younger children, and older adults, especially those with underlying conditions. Paediatricians must become aware of the RSV burden in infants and toddlers and the primary and secondary cases within the families and the whole community.

PAN EUROPEAN APPROACH

Our recent experiences with the COVID pandemic have shown that addressing an infection epidemic at a national level is insufficient, especially in regions where people often travel between countries, such as Europe. Whatever happens in one country affects the rest of the countries across the region. A pan- European coordinated approach is needed to prevent RSV infections across all European countries.

There are significant discrepancies between European healthcare systems and inconsistencies in surveillance and reporting. With open borders between European countries and frequent travel from one country to another, only a European-wide consensus on prevention could efficiently reduce RSV infections across the region.

IMPLEMENTATION OF THE PREVENTION POLICY

With most hospitalisations from a previously healthy group of children, prevention strategies targeting high-risk children won't be successful. In addition, identifying at-risk patients differs from country to country and sometimes from region to region in the same country.

Therefore, there is a need to protect all children under 5 years of age and all adults over 65 against RSV infections to tackle the high burden of RSV.

However, to achieve this, Policymakers need concrete evidence and data to prioritise and implement new prevention policies in times of budget constraints and financial challenges.

Potential Prevention approaches for infants and young children include maternal immunisation, immunisation of infants with vaccines, immunisation of infants with licensed mAbs, and immunisation of infants with long-acting mAbs. In particular, the expected new prevention solution using monoclonal antibodies (the most advanced ones being long-lasting monoclonal antibodies for all infants' protection, with EMA marketing authorisation granted for one of them already) could help address the problem if implemented successfully.

Monoclonal antibodies don't interfere with the scheduled routine vaccinations making the prevention strategy easier to implement since the frontline paediatricians could administer the monoclonal antibodies during the regular visits. In

addition, they could be administered before the peak season starts, allowing easy adjustment based on the virus seasonality's dynamics. Based on current data, immunisation of infants with long-acting mAbs might represent the most effective approach for protecting all infants entering their first RSV season.

The medical community must demonstrate the current constraints to hospitals, primary care, and health workers from RSV infections in children and elders and the immediate savings from a prevention strategy to the healthcare systems cost from visits, hospitalisations, ICU admissions, materials, and antibiotics.

The medical community must also provide evidence to demonstrate the long-term consequences of RSV infections and their associated costs to the healthcare systems so that they are considered in the cost/benefit analysis when evaluating the prevention strategy. While budget constraints often drive short-sighted actions to address the problem, the long-term consequences of RSV Infections are too important to ignore and cause a significant economic burden to healthcare systems.

Finally, the medical community must work with civil and patient groups to demonstrate the tremendous socio-economic impact RSV infections have on families, not only from the numerous visits to primary care physicians and the hospitalisation but also from the rehabilitation period, which could last for many weeks or months after the infection.

RECOMMENDATIONS FROM THE RSV WORKING GROUP

SUGGESTED ACTIONS FOR HEALTHCARE PROFESSIONALS (HCPs) & HCP ASSOCIATIONS TO LEAD IN THE FIGHT AGAINST RSV

- 1) **HCPs IMPROVING HCP's RSV AWARENESS & EDUCATION**
- 2) **HCPs ENGAGING PATIENTS' GROUPS IN RSV PREVENTION AND ADVOCACY**
- 3) **HCPs INFORMING THE DECISION-MAKING PROCESS FOR RSV PREVENTION POLICIES**

HCPs IMPROVING HCP AWARENESS & EDUCATION

1. Understanding frontline HCPs' level of awareness and perceptions about RSV Infections.

HCPs' engagement is crucial for a successful prevention program implementation. First, we need to establish the level of awareness, the education gaps and any false perceptions related to the prevalence and the risks of RSV infections.

EIP ACTION - An online RSV Awareness Survey to EIP's 46,000+ network

2. Apply HCPs' experiences, ideas, and suggestions for a successful RSV prevention policy.

HCPs need to know that they are heard and need to be involved from the initial stages of implementing the prevention program. We must hear and share their experiences, ideas, suggestions, educational needs, and patient concerns.

EIP ACTION – Online Suggestion Box for HCPs to submit personal experiences and ideas.

3. Update HCPs with the latest surveillance data and RSV epidemic dynamics.

Frontline and primary care HCPs cannot access the latest evidence easily. We must ensure that they are informed on trends and shifts in the dynamics of RSV epidemics.

EIP ACTION - Monthly/quarterly newsletters on the latest RSV trends so that they are prepared ahead of the peaks and have RSV infections in mind.

4. i) Educate HCPs on Monoclonal Antibodies administration and safety profile.

The public's immunisation literacy has improved in recent years. Still, Monoclonal Antibodies are a relatively new term. It is essential that paediatricians have the knowledge to provide the correct information on the safety and the benefits versus the associated risks of an infection.

ii) Paediatricians explaining the potential risk of RSV infections to Parents.

It must be the paediatrician's role and duty to explain to parents the potential risks associated with a usually perceived mild infection. But we must first ensure that the healthcare professionals know the epidemiology and associated risks with the disease in-depth.

EIP ACTIONS - Plenary and parallel conference sessions at the 15th EIP Conference in Paris in December 2023. Free-to-attend online training and HCP Awareness and Information Campaigns.

5. Cross-speciality collaboration and education on the RSV disease burden.

Cross-speciality collaboration is needed to understand the broader consequences of RSV infections and establish the actual extent of the burden. Prevention of RSV infections shouldn't be an issue just for infectious disease specialists and should include many other specialists

EIP ACTION - Cross-specialty Free-to-view Online Training programs.

6. Clear guidelines and recommendations on managing RSV infections.

Paediatricians need to feel more confident in avoiding the use of antibiotics, corticosteroids, and bronchodilators when they are not needed. Clear guidelines and recommendations are required from medical associations on the use of antibiotics to manage RSV infection.

EIP ACTION - An educational program to train paediatricians on identifying and managing an RSV infection in a hospital or primary care setting.

HCPs ENGAGING PATIENTS' GROUPS

1. Work with Patient Groups to help all understand the position of patients and parents.

There is a need to share personal stories and experiences from families with policymakers and HCPs. To equip paediatricians, family physicians and general practitioners to inform and advise the whole family, including older members, on RSV risks and prevention

EIP ACTIONS - Patient Group-led conference sessions at the 15th EIP, free-to-attend online education and an HCP-led social media campaign.

2. Work with Patient Groups to prepare 'ready to use' materials that HCPs share with their patients.

There's a need to mobilise physicians to disseminate the communication materials to families and through social media using their accounts to their colleagues, friends, and patients.

EIP ACTIONS - Fact sheets, patient/parent checklists, infographics, and short videos (parents' talks) with experts answering the most common questions asked by patients.

HCPs INFORMING THE POLICY DECISION MAKERS

1. i) Present solid evidence on the cost/benefit of the prevention policy.

Policymakers operating in times of budget constraints need evidence of the cost avoidance and cutting that the new policy will achieve compared to the cost of implementing the prevention policy. Experts and medical associations must work with health managers and public health experts to quantify the overall burden of RSV in Hospitals, ICUs, and Primary care settings.

ii) Work with hospital facilities and primary care managers on the RSV infection burden.

Health managers and HCPs are best positioned to speak about the RSV burden on their already stressed facilities. For a prevention policy to be adopted, it is crucial to demonstrate immediate benefits to healthcare systems and workers' capacity.

EIP ACTIONS - RSV Working Group at the 8th Life Course Immunisation Summit in 2023 with a dedicated Implementation section of the Working Group led by EHMA. Share the outcomes in a position paper and with policymakers.

2. Collect and share personal stories from frontline HCPs from the RSV epidemic.

Making decision-makers fully understand the experiences paediatricians, neonatologists, and adult physicians have from the seasons when admissions from RSV infections surge is crucial in terms of action change.

EIP ACTION - Share the outcomes and materials collected with policymakers and hospital managers to demonstrate the impact on the organisational level and the individuals working there.

3. Communicate the fact that RSV infections heavily contribute to antimicrobial resistance.

Showcase to policymakers that RSV infections are one of the most important reasons for administering unnecessary antibiotics in-patient and out-patient. This heavily contributes to the antimicrobial resistance problem and its increased costs.

EIP ACTION – A round table discussion at the 15th EIP with experts to examine the issue and provide recommendations on how using antibiotics for RSV patients could be minimised.