DRAFT REPORT

WORKING GROUP ON RSV PREVENTION

Observations - Challenges- Strategies

6th Life Course Immunisation Summit 2021-2022





Trends in Prevalence

- → There are an estimated 33 million new infections worldwide yearly, 10% severe enough for hospital admission. RSV is a significant problem globally and a considerable concern in the pediatric world, with 95% of children infected until the age of 5 years.
- → There is a significant increase in RSV admissions in developing countries, with very high mortality. Mortality and morbidity are higher in low and middle income countries.
- → RSV infections and admissions with bronchiolitis show a strong seasonality trend with a spike very concentrated every year during winter and in the period starting at the beginning of November and mid-December. Seasonality per country, though, can vary.
- → While RSV is the most common single cause of respiratory hospitalization in infants, it is the second-largest cause of lower respiratory infections and mortality worldwide. But although often characterized as a paediatrician disease, the burden of RSV in adults is also significant, with a mortality rate of 7 to 8% among all the adults.

- → Surveillance for RSV infections in many developed countries and mainly in the developing world is lacking, making it extremely difficult to know the exact burden of the infections. Very little has been done on tracing other infections and complications triggered by RSV infections which increasing the overall disease burden.
- → Regarding infection prevalence and mortality in the developing world, we are in uncharted waters, and better surveillance is needed to establish the burden's dimension considering that access to hospitals and health care systems in many countries is limited, with infections not always reaching hospitals.
- → There is a need to identify the mix of infections and conditions that stress the healthcare systems to their limit, considering their seasonality. A more targeted approach would allow us to prepare ahead, develop more clever strategies and relieve the health systems when most needed.
- → With most adult vaccine-preventable diseases not being a priority for most health care planners, the RSV infections in adults are mostly unchecked and uncontrolled. Moving towards a more meaningful life course approach, RSV should be included in the equation, and more studies are needed to provide evidence of the disease burden.

Trends in Prevalence

- → COVID pandemic, social distancing, and other restrictions impacted the prevalence of RSV infections. RSV infections can vary from year to year, and we experienced a massive spike in 2019, while infections significantly decreased in 2020-2021. A critical point around the social mixing patterns and how much social contact drives the epidemiology. It remains to be seen what will happen now that restrictions are gradually lifted, and the first indications show that infections are on the rise again.
- → We need more studies to get a complete picture of the RSV burden in the under five years. We know what is happening during the first year. Still, the RSV burden should not be studied as a single agent since its implications for triggering bacterial and other infections could be significant for all age groups up to 5 years. Therefore, it is essential to have the data that will allow us to design the most efficient immunization policy.
- → RSV has a high prevalence but a very different distribution. All children will have at least one infection in their lives. But this affects children from low-income, middle-income, high-income countries and developing countries differently. In developing countries, deaths outside of the hospital, we know, are approximately more than 50% of the burden. This is a hidden burden of the virus.

- → Close monitoring of the RSV infections after removing the COVID related restrictions is needed to see whether infections will return to the pre-COVID period and whether RSV epidemiology and seasonality have changed. It is also essential to see whether RSV infections will follow the same trend as other seasonal infections such as influenza, allowing us to develop cross-infection seasonal prevention strategies.
- → The cost versus benefit factor is critical, especially in this period when all healthcare systems' budgets are being strained and exhausted by the COVID pandemic. On the other hand, with the health systems preparedness better understood and the possibility of COVID becoming a seasonal infection, there is ground to discuss a more holistic approach to prevent RSV infections if the evidence supports it.
- → It is challenging to establish the burden and mortality of RSV infections outside hospitals, especially in the developing world, where access to healthcare systems is limited. It is critical to engage primary healthcare physicians and community pharmacists to help trace and report infections outside hospitals to better understand the problem's size.

Engaging not only the hospital facilities but also the primary care and community settings. We need to establish the burden of RSV infections not only on the secondary facilities but also on the broader socioeconomic effects associated with the disease.

We Must Improve Surveillance of RSV Infections to Understand the True Burden

We need better planning and prevention strategies for seasonable infections to protect our facilities and resources and ensure that quality of healthcare services delivered are not compromised during the winter peaks.

Improved Prevention Strategies That Take Seasonality into Account

STRATEGIES

Education Campaign for Community Physicians and HCPs in Developing Countries

They are the only ones who can contribute to improving surveillance in the developing world. An education campaign is needed with materials in various languages to increase their awareness and commitment.

HCPs Advocating Life Course Immunization Strategies

Healthcare professionals must advocate for a Life Course Immunization strategy that covers all ages against all vaccine-preventable diseases. We must work with civil and patient advocacy groups for the message to be clear that it is not acceptable anymore that otherwise preventable diseases remain uncontrolled.

Better surveillance is needed to establish the epidemiology of RSV infections compared to other seasonable infectious diseases. We must utilise our findings to design and implement effective prevention strategies for the expected seasonal peaks of RSV.

Surveillance to Establish the Epidemiology of RSV Infections Compared to Other Diseases

We can train primary care community healthcare professionals in the developing world to manage the infections better, volunteer to report the infections, and help establish the actual burden of the disease in countries with limited, or without any, central surveillance systems.

A Need to Train Community HCPs in the Developing World to Establish and Manage the Burden

STRATEGIES

Design and Implement New Seasonal Infection Strategies

We must design and implement new seasonal infection strategies that will allow us to better manage peaks in admissions and visits. At the same time, we won't need to stretch the systems beyond the limits or increase costs by expanding our capacity for the whole year, instead only focusing on busy periods.

RSV Implications

- → Data from the UK has shown that infections and hospital admission rates for bronchiolitis are increasing, while we know that 75% of all bronchiolitis is due to RSV infection.
- → Preterm infants and children with severe respiratory disease, congenital heart disease, cancer, cystic fibrosis, immunodeficiency, and Down syndrome are at increased risk for severe RSV infection. There is no doubt that morbidity and mortality in children with RSV infections are strongly related to existing comorbidities. But there is a significant proportion of children admitted to hospital and intensive care who do not have any recognized risk factor.
- → RSV Infection is not just a problem for the preterm infant. Even though prematurity is a significant risk factor, the commonality of admission is coming from normal, well-formed, well-grown children. The majority are actually from the full-term group.
- → In many cases, RSV bronchiolitis can trigger wheezing and asthma. Further studies are needed to demonstrate that if we prevent the infection, probably we will also prevent recurrent wheezing and Asthma. There is also a significant risk of a bacterial infection in babies with RSV infection with RSV looking like a precursor to invasive bacterial disease,

- → We must increase awareness among healthcare professionals and the decision-makers so that the infection prevalence and the size of the burden are understood for prevention will become a priority.
- → We must strongly advocate that a holistic approach is needed for RSV prevention, demonstrating that not only preterm infants or infants with serious conditions are at risk but all infants, even if they are well grown and healthy. A risk group addressing policy will not be sufficient, leaving many infants in danger unprotected.
- → It will be challenging to change the many years of existing perception of providers, planners and decision-makers that RSV is a problem that is not related only to the preterm infant. With more prevention solutions becoming available in the coming months and years, education must start to increase understanding and awareness among all stakeholders.
- → We suspect that RSV infection implications beyond the actual infection are profound and significantly increase the overall burden. Still, it will be challenging to make decisions, persuade the planners and prioritize the budget when we do not have enough evidence to demonstrate the benefit beyond doubt.

With prevention solutions being made available in the coming months, we must launch a campaign to increase awareness and change the narrative that RSV infections are not preventable and that there is nothing we can do.

RSV Awareness Campaign Considering New Prevention Solutions are on the Horizon

An educational campaign is needed for frontline paediatricians to understand the epidemiology of the disease across the various age groups and the various complications that are often associated with these infections. This will help them see the scale of the problem.

HCP Online Education Series - Part 1 on RSV Epidemiology Across Childhood

STRATEGIES

HCP Online Education Series - Part 2 on New Prevention Tools and Approaches

Changing perceptions and established practice is challenging, and broad training will be required for healthcare professionals to understand the full extent of a previously under-recognised and underreported problem for which the reality was that they had very few tools available to use for prevention.

Cross Specialty Collaboration on Disease Burden

Cross specialty 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 diseases specialists and should include many other specialists, including those responsible for the management and the planning of healthcare facilities.

Burden to Hospitals and Healthcare Systems

- → The number of hospitalizations is increasing each year, which is probably multifactorial. Increased RSV infection prevalence, increased number of children with underlying conditions, increased number of at-risk children, and more preterm infants could be factors contributing to the admissions rise.
- → The seasonality of RSV infections is a decisive factor impacting health system performance. With RSV infections picking in the winter when health systems are already operating at maximum capacity, it exhausts the facilities and the staff's ability to deliver quality care.
- → Winter admissions of infants with RSV bronchiolitis are often complex and co-exist with other viruses, including rhinovirus, adenovirus, metahuman virus and flu, although flu is rare. These patients often require more extended hospitalizations and increased attention to their care.
- → RSV infections are a significant cost burden to parents and health systems even without or before hospital admission. Parents with an infant with RSV can spend lots of healthcare resources on call centres, visits to private practices followed by visits to primary care facilities, often going back and forth many times before they end up at the hospital.

- → Suppose the trend of increased hospitalizations caused by RSV infections continues in the years to come; it will add additional stress to the already stressed systems. We must change the way we are planning our capacity to take action and prepare early, considering the clear trends in disease prevalence.
- → We now know that better planning and preventive strategies are needed for hospitals and resources not to be exhausted and remain ready to address other threats that we can't predict. The challenge here is not to forget the lessons learnt when the imminent danger from COVID has passed away.
- → Eliminating hospitalizations that can be prevented by other means (with vaccination being one of the main tools) must now become a top priority. We now know that new infection pandemics will be a constant threat in the years to come, while we have realized that there are limits to expanding our capacity and resources to address existing and new threats.
- → The cost burden of RSV to healthcare systems, excluding hospitals, is challenging to estimate and measure. RSV infection costs to all three levels of the healthcare systems, namely primary care, hospitals and PICUs, must be considered for our benefit-cost analysis when evaluating prevention strategies to be accurate.

Burden to Hospitals and Healthcare Systems

- → RSV infections are a significant cost burden for hospitals and PICUs. The average length of stay at the hospital for an infant with bronchiolitis is five to seven days. If admitted to the PICU, the stay is extended to one month, resulting in extremely high costs for the healthcare systems.
- → ICU beds and staff capacity have been the most crucial element during the COVID pandemic. Therefore avoiding unnecessary admissions to the ICUs is extremely important because of the related cost and the limited availability we have. We must ensure that it will take into consideration when evaluating prevention strategies.

- → Apart from the RSV infections burden on health systems and hospitals, families have a significant social and economic burden. Parents lose time from work, and children lose time from school.
- → With the RSV burden extending far beyond the hospitals stressing out the families, we must make sure it is understood that RSV is a multidimensional problem having a serious social and economic toll on hospital budgets and societies. It is essential to persuade planners to incorporate all factors when deciding on a prevention strategy.
- → Health care personnel across all care settings report extended work hours significantly increased stress, exhaustion, and burnout during the ICE season. In the previous seasons, the large majority of the occupancy of the bed in the wards was due to respiratory patients, and more than half of these cases were due to RSV.
- → Seasonality is not taken seriously under consideration when planning our capacity and resources. Since increasing capacity for a specific season is difficult, if not impossible, we must utilize other tools to reduce needs so that our systems are not stressed and the quality of care will remain intact.

We need to change the narrative on how we plan our capacity, how we use the available prevention tools and how we are prepared for the upcoming challenges. Healthcare professionals must sound the alarm to the decision-makers to prepare healthcare systems to become a priority.

New RSV Tools and Health System Preparedness

Healthcare professionals must advocate for more efficient prevention strategies to improve their facility's performance during the seasonal infection period protecting their resources and ensuring a better quality of services delivered in periods of constraint and high demand.

HCP Advocacy for Efficient Prevention Strategies

STRATEGIES

Engaging HCP in the Planning of RSV Resource Allocation in Hospital Facilities

Healthcare professionals must actively engage in the planning for healthcare facilities, ensuring that the epidemiology and management requirements of infections and other conditions will be factored in as the most crucial factor when designing capacities and resource needs..

Primary Care Physicians Informing Decision-Makers on RSV Health Policy

Primary care physicians must step in and make their voices heard, helping decision-makers understand the burden of RSV infections on hospitals,, primary care facilities and private practices. Especially during the seasonal peaks of infections.

Hospital and ICU physicians must advocate the importance of prevention strategies in reducing unnecessary hospitalisations. Expanding capacity in infrastructure and human resources is unsustainable financially and extremely difficult, especially in finding sufficiently trained personnel.

Prevention Over Expanding Treatment Capacity and Infrastructure

Healthcare workers must advocate for changes to the planning and prevention strategies to minimise delivery services under pressure and with limited resources, which affects the quality of the care they provide and proves dangerous when factoring in the experience of the recent pandemic.

Minimising the Impact on Healthcare Systems Already Under Immense Pressure

STRATEGIES

Establishing a True Estimate of All Undetected Social and Economic Costs Related to RSV Infections

It is time to establish all hidden social and economic costs related RSV infections, ensuring that these costs will be seriously factored into the decisions made when planning prevention strategies. Primary care physicians and national medical associations need to help establish the real burden.

Time and Range of Intervention

- → There's a high burden of the disease and a real need to invest in prevention. The available today prevention tools are only used on very select children—some studies advocate for the inclusion of all children due to the burden caused to health systems by RSV.
- → The consensus is that the focus should be placed on infants, especially in the first six months of life, when a severe risk associated with respiratory disease is high. But we must consider that children under five years of age are the group predominantly responsible for transmission, suggesting that by vaccinating this age group, it is likely that we will see a considerable reduction in disease in unvaccinated age groups.
- → More evidence of protection for early infantile RSV prevention through maternal vaccination and the benefits of maternal immunisation versus direct protection of the infant is needed to help us define the best immunization strategies to follow.
- → Careful consideration is needed to decide which optimum intervention we could have based on cost effectiveness. There is no doubt that infections are higher, and the most severe cases appear in the 0-6 months age group. Then we must examine what we will do with the next group 6-12 months and whether the epidemiologic data support a decision from a cost-benefit point.

- → With the focus now on investing in capacity and resources to overcome the recent pandemic, decision-makers often overlook prevention as a luxury for better times. The COVID experience has highlighted the importance of vaccinations in maintaining capacity and protecting resources.
- → Even though vaccination under six months is considered essential by all experts, we must persuade policymakers to think broader and plan wider to reduce infection rates among all children, including the unvaccinated ones. The challenge here is, again, budgets and cost-effectiveness.
- → Vaccination during pregnancy is lacking behind for the already approved and recommended vaccinations. Pregnancy is a very sensitive period, and women are reluctant to get vaccinated, as the recent pandemic and COVID vaccinations have shown.
- → In periods of budget constraints, especially today after the COVID pandemic, cost-effectiveness will be one of the main elements that decision-makers will consider. It is possible that the contribution to the systems and resources availability and capacity will not be incorporated into the equation and will be ignored.

Healthcare professionals to help policymakers understand that the importance of prevention exceeds COVID and is essential for all infections that are causing unnecessary hospitalisations since all of them significantly contribute to the exhaustion of the available resources.

HCPs Informing Policy Makers on the Importance of Prevention in Post-COVID Times

Vaccination during pregnancy could become a choice only when we have more evidence of its benefits. More studies are needed before the healthcare professionals decide to advise RSV prevention during pregnancy.

The Need for Further Information and Studies on the Potential of RSV Vaccination During Pregnancy

STRATEGIES

A More Holistic Approach to Preventing and Managing Seasonal Infections

We must advocate a more holistic approach to preventing and managing seasonal infections protecting against the challenges of acquiring hospital capacity and experienced personnel. With resources needed for emerging new infections, eliminating existing infections through prevention must become a priority.

Communicating the Limited Resources and Changing Realities to Policy Makers

Healthcare Professional organisations must reach out to policymakers pointing out that expanding resources has limits and finding trained and experienced personnel will become increasingly difficult, as proven during the pandemic. Therefore it is not only cost-benefit that should define decisions but also the realities of the real world.

How to Better Communicate the RSV Burden

- → RSV is one of the most critical pediatric infectious diseases and a significant global burden for healthcare systems, with serious social and economic costs to families. We need to work together and make parents, care providers, and policymakers aware of the prevention tools available and the disease burden.
- → Bronchiolitis is underrepresented to policymakers and health service planners. It doesn't seem to be a clear understanding of the burden and the considerable pressures the infection applies to the already stressed health systems during the Winter. Primary, secondary and tertiary care can be completely overwhelmed by the massive surge of Bronchiolitis cases.
- → There is an interesting comparison with meningococcal disease. All are aware that meningococcal disease can be terrifying. Because RSV will infect most kids at some stage without further implications, everyone is missing the point that the disease will be critical for a significant percentage of infected children, almost as the meningococcal disease is.
- → When new prevention solutions are available, it will be challenging to communicate the benefits of an antibody instead of a conventional vaccine. We must start building an understanding among parents early and increase knowledge among healthcare providers on antibodies' role, mechanism, and benefits.

- → Awareness of RSV infections is low among the policymakers, the healthcare professionals and the families. With all being tired from the recent pandemic, it will be challenging to speak and be heard about the risks associated with already existing infections that are considered common until now.
- → Policy planners have little understanding of the overall seasonal strains on the healthcare systems. Planning for capacity and resources doesn't consider the infections winter picks. On hand prevention strategies are fragmented and incomplete. With COVID probably becoming a more seasonal infection, more constraints will be added to the systems.
- → As proven by the COVID pandemic, perceptions that an infection is mild and easy for a child to overcome, changes the risk assessment made by parents when considering the risk of vaccination using new and perceived as not sufficiently tested technology. We will face the same as COVID challenges when introducing the RSV prevention tools.
- → The usual reluctance of new technologies for children's prevention has intensified during the pandemic with the introduction of mRNA vaccines for children. The introduction of another technology different to vaccines for children could be challenging.

A campaign is needed to increase awareness among policymakers, healthcare professionals, and patients on the real burden of the infection and the possible short and long term risks associated. RSV infections must be at the top of the mind ahead of the next Winter season.

A Campaign to HCPs and Policy Makers on the Real RSV Burden Before Next Winter

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 make sure that the healthcare professionals know in-depth the epidemiology and the associated risks with the infection.

The Role of the Pediatrician is to Explain the Potential Risk of RSV Infection to Parents

STRATEGIES

Education on Healthcare Professionals to Advocate for More Holistic Prevention Strategies

Education of healthcare professionals to understand the epidemiology and the prevention tools is necessary for them to advocate prevention in every consultation. New prevention tools for RSV should be aligned with the universal immunisation program for children.

Training of Pediatricians and GPs on New RSV Tools Available

We must train the frontline paediatricians and GPs to understand the technology and become sufficiently equipped to address parents' concerns. In the end, they are the most trusted source of information and advice, and they must step in to persuade parents to make the correct decisions.