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National real-life impact of prevention with nirsevimab on infants' RSV hospitalizations in Belgium

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Real-life impact of prevention with nirsevimab on infants' RSV hospitalizations in Belgium. Results of a National survey

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Abstract

Background

Since 2023, two preventive tools (monoclonal antibodies, nirsevimab, and preF maternal vaccine) were approved to protect infants against severe RSV infections. During winter 2024-2025, nirsevimab started to be administered in Belgium to infants <6 months old encountering their first RSV season. We aim to evaluate on a national scale the impact of RSV prevention in the pediatric hospital setting.

Method

This survey pooled data from two surveillance systems: the prospective SARI (Severe Acute Respiratory Infection) surveillance (6 hospitals) and the retrospective RSVPed study (25 hospitals). Both used the same case definition and clinical questionnaire to record RSV hospitalizations in children <5 years. Seasonal incidences and clinical data were compared between seasons 2023–2024 (pre-prevention) and 2024–2025 (first year of prevention).

Results

Our study covered 47% of all pediatric beds in Belgium. We demonstrated a reduction of 39% in pediatric RSV-related hospitalizations and of 57% in RSV-related admissions to intensive care units during 2024–2025 compared to 2023-2024. Incidences decline mainly concerned infants <6 months, without changes in older age groups. Furthermore, savings in health care resources were observed through shorter length of stay and significantly less use of non-invasive ventilatory support and nutritional support among hospitalized cases in 2024-2025.

Conclusion

Following implementation of nirsevimab a substantial reduction in RSV paediatric burden was observed in Belgium. However, efforts should be made to increase the uptake of preventive tools in our country to achieve better effectiveness. This study also highlights the major role of a national network to monitor efficacy of prevention over time.

Background

Respiratory Syncytial Virus (RSV) is one of the most important causes of respiratory infections in infants globally [1]. In low- and middle-income countries, RSV-related acute lower respiratory tract infections (ALRTIs) cause more than 100.000 deaths yearly [2], whereas in high-income countries they are responsible for a substantial number of hospitalizations and paediatric intensive care unit (PICU) admissions, especially amongst young infants [3]. Until recently, prevention was limited to non-pharmaceutical isolation measures to reduce spread of this contagious virus [4] and to administration of short-acting monoclonal antibodies (palivizumab) to very high-risk infants. From 2023 onwards, the

monoclonal antibody nirsevimab (Beyfortus®) as well as the maternal vaccine (pre-fusion F protein vaccine, Abrysvo®) were approved by EMA and FDA to prevent RSV-related ALRTIs in young infants, based on convincing data from clinical trials [5,6]. The availability of these preventive tools has drastically changed the strategy to decrease RSV burden, in addition to new vaccines dedicated to older adults with or without comorbidities [7,8].

Real-life impact and safety data after the implementation of RSV preventive tools are at present of utmost importance and need to be compared with results from clinical trials. The first season of prevention by implementation of nirsevimab took place in 2023-2024 in a limited number of European countries and in the USA, and demonstrated a dramatic decline in hospitalization rate among young infants [9-14]. However, differences in national regulations and organizational procedures render results not fully generalizable due to the variability in access to preventive tools, strategies of immunization applied (e.g. seasonal or year-round program, age of eligibility), reimbursement criteria, availability of catch-up programs and people vaccine hesitancy.

In Belgium, yearly more than 10.000 children under 5 years (2% of this age group, with almost 7.000 below the age of 1 year) are hospitalized due to a proven RSV infection and 400 infants require PICU admission [15,16]. The disease burden is much higher when accounting for ambulatory care and the total (direct and indirect) cost of RSV in children has been estimated to be at least 43 million euros annually in our country [16]. At the end of 2023, official recommendations about RSV prevention

supporting the use of either monoclonals or maternal vaccine on a seasonal basis for all infants were published by our National Immunization Technical Advisory Group [17]. In the 2024-2025 season, both preventive tools were available on the Belgian market but only nirsevimab was reimbursed on a national scale, so that the vast majority of infants eligible for prevention were immunized with monoclonal antibodies during that season. Eligibility to receive near-free immunization was based solely on age and available for every infant aged under 6 months at the start of the season or birth during the season, regardless of prematurity or comorbidity.

To overcome the lack of an adequate surveillance network specifically dedicated to paediatrics ALRTIs and to thoroughly monitor the impact of RSV prevention, the national SARI (Severe Acute Respiratory Infection) surveillance system was adapted in 2023. In parallel, an extra survey (RSVPED) was launched to broaden data collection of paediatric RSV-related hospitalizations. Combining both systems, data covering the 2023–2024 (pre-prevention) and 2024–2025 (first year of prevention) seasons could be captured and analysed, providing a reliable assessment of impact of RSV prevention on a national scale. Furthermore, in this report, we discuss some operational hurdles that could have partly hindered the success of the campaign, in order to help other colleagues and authorities to optimize their future RSV prevention strategy.

Methods

Study design

The study was conducted by combining 2 surveys. The distribution of centres according to their survey network and contribution is displayed in **Figure 1**. Specific analyses were carried out using either one dataset or combining both.

Firstly, the RSV Paediatric Survey (RSVPED) retrospectively collected data from all RSV-related paediatric hospitalizations meeting the case definition below and admitted during either the 2023-2024 or 2024-2025 RSV season (from October 1st to February 28th). Numerous hospitals distributed all over the country were invited to participate through various national networks. Twenty-five hospitals were included and enabled incidence calculation, out of which 15 additionally provided clinical data.

Secondly, 6 hospitals contributed through the Belgian SARI surveillance network (BELSARI-NET), conducting a prospective surveillance of adult and paediatric patients admitted for SARI, and coordinated by the National Institute of Public Health (Sciensano) [18]. Detection of RSV was assessed through systematic multiplex in-house RT-qPCR of a respiratory swab, taken for each recruited patient [19].

For both studies, eligible cases were identified based upon exhaustive laboratory database and/or computerized file summaries. Inclusion was performed by a dedicated study nurse or by the local primary investigator himself to ensure correct cases ascertainment.

The SARI case definition for children was aligned with that of the RSVPed survey on mid November 2023, hence patients from the SARI surveillance

were only included from that time in the whole study cohort and not involved in incidence calculation.

Study population and case definition

All children <5 years of age meeting the case definition below, and for which RSV acute respiratory illness was the main reason of hospitalization were included.

Children infected with RSV but hospitalized for another clinical reason or admitted for < 24 h were excluded, as well as nosocomial acquisitions of RSV. If a child was hospitalized twice, the second hospitalization was considered as a distinct episode if both events were separated from each other for ≥ 1 month.

A proven RSV related hospitalized case was defined as a child:

- presenting with a respiratory illness with **an acute onset**
- **requiring hospitalization** > 24h for this specific reason.
- **presenting with ≥ 2 following signs**:
  - Cough
  - Signs of respiratory distress
  - Fever ≥ 38°C
  - Abnormal pulmonary auscultation
  - Apnea/cyanosis
- in which **RSV was identified in the respiratory tract** by rapid antigen detection or PCR from nasopharyngeal swabs, nasopharyngeal aspirates or bronchoalveolar lavage within 48h after admission.

Questionnaire

Both surveys used a common clinical questionnaire expressly developed for this survey (**Supplemental appendix 1**) and collected pseudonymized data on a secure electronic platform.

Ethics

The whole study was conducted in compliance with the principles of ICH-GCP and in accordance with all applicable laws and regulatory requirements.

Both study protocols were approved by ethics committees of participating hospitals. The SARI study was conducted in liaison to the trial Surveillance of severe cases of influenza through a sentinel network of hospitals (B.U.N. 143201215671) and was further approved by a central medical ethics committee (O.G. 016) under the case number 2012/310. Patient informed consent (oral or written) is part of B.U.N. 143201215671.

For the RSVPed study, the need for consent to participate was deemed unnecessary due the retrospective study design and the absence of additional sampling performed in the purpose of the study. However, parents were informed about the participation of their hospital to the national survey through posters displayed in all pediatric and emergency wards.

Statistical analysis

R software version 4.4.3 was used to analyse the data.

Differences between groups have been assessed by chi-square test for non-continuous variables and by Mann-Whitney U-test for continuous variables. Furthermore, p-values were adjusted for multiple comparisons using the

Bonferroni method. For all statistics, a p-value of <0.05 was considered as statistically significant.

Seasonal comparisons of disease counts were performed assuming a Poisson distribution, using either raw case counts or incidence rates when available.

Incidences of paediatric RSV hospitalizations were calculated using exclusively RSVPed data, using as denominator the paediatric catchment population of the RSVPed network. To determine this catchment population, we summed the paediatric catchment populations of all participating hospitals across all Belgian municipalities. A hospital's catchment population for a given municipality was calculated by multiplying its paediatric market share in that municipality by the municipality's paediatric population (according to data from the Federal Public Service Health Belgium 2025). A hospital's paediatric market share in a given municipality represents the proportion of all-cause paediatric (0–16 years) admissions of residents of that municipality that took place in that hospital.

To calculate the incidence of PICU admissions, the paediatric catchment population of the six participating hospitals was estimated by multiplying the Belgian paediatric (0-5year-old) population by the proportion of national PICU beds located in these six hospitals.

Results

1) Study cohort

Data from 31 centres covering 47% of the entire Belgian paediatric population were analysed in this study (**Figure 1**). The paediatric catchment population of the RSVPed network used for incidence calculation represents 38% of the Belgian paediatric population. Moreover, 6 PICU centres among the 10 existing Belgian PICUs contributed to the study, corresponding to a coverage of 67% of the Belgian PICU beds.

Figure 1 : Repartition of hospitals according to their contribution to the whole study network. Legend: ** One hospital participated consecutively to both surveys and is counted here in RSVPED cohort; **Main clinical data consist at least in demographic characteristics (including age), length of stay, need for respiratory support +type/duration, transfer to ICU/tertiary hospitals, immunization status (monoclonal antibody) and status at discharge.*

2) Epidemiological features

In 2023-2024, we recorded 3448 paediatric admissions related to RSV in children <5 years-old among the 25 RSVPed hospitals, corresponding to a seasonal (October-February) incidence rate of 15.4/1000 children <5 years. During 2024-2025, 2055 admissions were recorded, corresponding to a seasonal incidence of 9.4/1000 children. This indicates a significant decrease of 39% (95% CI, 36%–43%) compared to the previous season, corresponding to a reduction of 3641 (95% CI, 3259–4023) cases at the population level. The difference in incidence was the greatest at the peak of the epidemic, with a reduction of 41% (95% CI, 36%–46%) of RSV-related admissions, representing 1731 (95% CI, 1475-1987) fewer cases (**see Figure 2a/2b**). Seasonality was slightly different with an earlier start in 2023-2024 while the typical pattern of RSV circulation was again observed in 2024-2025.

Figure 2 : Comparison of incidence of RSV-related hospitalizations among children under five years of age, by season of survey *(A) Number of cases per month, by season of survey. (B) Cumulative monthly incidence per 1,000 children <5 years, by season of survey.*

The decrease in the number of hospitalizations mostly concerned children <6 months (66%; 95% CI, 62%–69%), leading to a significant change in age distribution among children hospitalized for RSV (**Figure 3,** global X^2 p<0.001). Children <6 months of age represented only 32% of the cohort in 2024-2025 compared to 54% in 2023-2024 (p<0.001). No increase in number of hospitalized cases was seen in older age groups.

Figure 3 : Number of RSV-related hospitalizations among children under five years of age, stratified by age group, by season of survey.

RSV-related PICU admissions also significantly declined from 228 in 2023-2024 to 97 in 2024-2025, corresponding to a RSV-related PICU-admission incidence of 0.58/1000 and 0.25/1000 children in 2023-2024 and 2024-25, respectively. When extrapolated to the whole country, we can estimate that 195 PICU cases were avoided (a 57 % reduction).

Concordantly, the absolute number of transfers from general paediatric wards (secondary care setting) to tertiary hospitals also decreased. Out of the 15 hospitals from which the information was available, 75 transfers were recorded in 2023-24 compared to 35 in 2024-2025. The percentage of transfers among total admissions was however not significantly different (4.8% vs 3.4%, not significant (ns)).

3) Clinical pattern of RSV disease

The main clinical features of children hospitalized for RSV according to the season of infection are shown in **Table 1**. As expected, the major part of children requiring hospitalization had no medical condition whatever the study period. The rate of children with at least one comorbidity represented maximum 20% of the cohort, being significantly higher during the second season (**Table 1**). The main comorbidities reported during both seasons were prematurity, asthma, congenital cardiopathy and neurological disorders. Children for whom a previous history of hospitalization for bronchiolitis was reported represented a significantly higher proportion of the cohort in 2024-2025, likely reflecting the greater proportion of older children. The median length of stay was significantly reduced by 1 day during 2024-2025 (**Table 1 and Supplemental appendix 2**, Kaplan-Meier plot), whether considering the entire cohort ($p<0.001$) or only infants < 6 months ($p<0.001$). Savings of health care resources was also marked by significantly fewer children needing non-invasive ventilatory support and nutritional support (i.e. gastric feeding or total parenteral nutrition) (**Table 1**). By contrast, once hospitalized, the proportion of children presenting with pneumonia or receiving antibiotics did not differ between both cohorts. However, because of the decrease of the hospitalization incidence, the absolute number of cases for which antibiotics was administered was reduced, especially among children <6 months (**Table 1**). The median duration of antibiotic therapy remained stable between seasons (7 days) as well as the main reasons for prescriptions (pneumonia, acute otitis media and fever of unknown origin) and rate of proven invasive bacterial infection (8.5% vs 6.7% in 2023-2024

and 2024-2025; respectively, ns). Finally, less children with RSV—related neurological complications (including febrile seizures) were recorded in 2024-2025, and number of encephalitis were very low during the study period.

Table 1 : Main clinical features of children hospitalized with RSV disease according to season of survey (N= 20 centres*) Legend: *The analysis includes the 20 centres for which main clinical data from both seasons were available (see figure 1). ** The analysis is based on 15 centres (out of the 20 previous ones) for which all clinical data from both seasons were available (see figure 1). ***This analysis was done on a subset of patients for which the complete information was available (1258 in 2023-2024 and 838 in 2024-25). Comorbidities recorded consisted in: prematurity, severe atopic dermatitis, poly-malformative syndrome, non-malignant haematological disease, neurological disorders (encompassing congenital neuromuscular disease, cerebral palsy and epilepsy), metabolic disease, kidney congenital disease, intrauterine growth retardation, congenital immunodeficiency, congenital malformative cardiopathies, asthma/chronic wheezing, malignancies, other pulmonary chronic disease, acquired immunodeficiency (HIV, immunosuppressive therapy), Down syndrome. **** This analysis was done on a subset of patients for which information on previous hospitalization for bronchiolitis was available. NS= not significant

	2023-2024		2024-2025		
	n	%	n	%	p-value
Part 1: data from 20 centres*					
N of admissions	1912		1220		
Median age in months (IQR)	5.0 (2.0-12.0)		10.0 (3.0-17.0)		p < 0.001
Median length of stay in days (IQR)	5.0 (3.0 - 6.0)		4.0 (3.0 - 5.0)		p < 0.001
N (%) children needing respiratory support	1221	64	671	55	p < 0.001
Oxygen goggles only	787	41	469	38	ns
Non invasive ventilatory support	415	22	191	16	p < 0.001
Invasive ventilatory support	10	1	2	0,003	ns
N (%) of death	0	0	0	0	
Part 2: Data from 15 centres**					
N of admissions	1338		859		

N (%) children needing nutritional support	435	33	197	23	p < 0.001
median duration in days (IQR)	3.0 (2.0 - 5.0)		4.0 (2.0 - 5.0)		ns
N (%) children treated by antibiotics	475	36	320	37	ns
median duration in days (IQR)	7.0 (6.0 - 10.0)		7.0 (6.0 - 9.8)		ns
N (%) children with pneumonia	224	17	172	20	ns
N(%) children with neurological complications	11	1	2	0,002	ns
N (%) children with any comorbidity***	192/1258	15	164/838	20	p < 0.05
N (%) prematurity	137	11	99	11	ns
N (%) asthma	21	2	41	5	p < 0.001
N (%) children with cardiopathy	15	1	10	1	ns
N (%) children with neurological disorder	10	1	12	1	ns
N (%) children with previous hospitalization for bronchiolitis ****	112/1328	8	116/827	14	p < 0.001

Among the PICU cohort, infants were older in 2024-2025 (median age 1 month vs 3 months in 2023-2024 and 2024-2025, respectively, p<0.001) but showed same rate of comorbidities (29% vs 26%, ns). All received respiratory support, consisting of invasive ventilation for 11 of them in 2023-2024 and 6 of them in 2024-2025 (7% and 8% of the PICU cohort, respectively). No children needed extra-corporeal membrane support and no death was recorded because of RSV disease. Median length of PICU stay tended to be shorter in 2024-2025 (5 days, IQR 3-7, in 2023-2024 vs 4 days, IQR 3-6, in 2024-2025; ns) and less children needed nutritional support (88% vs 67%, p<0.001). The rate of antibiotic prescriptions was similarly high during both seasons (48% vs 49%, ns).

4) Immunization status

Out of 1096 children hospitalized in 2024-25 for which the information was available, 429 were eligible for prevention according to the age-based reimbursement rules in our country. Out of them, 131 (31%) were immunized (66% at the maternity, 34% through catch-up program), representing 12% of the whole cohort that season. Among them, information on dosing date or dose received was available for 25 individuals only. Within this subset, 19 had received a dose of 50 mg before 1 month of life, likely consistent with recommendations (weight at immunization's time not available). The median interval from immunization to hospitalization was 40 days, suggesting that waning of antibody levels was unlikely to be the primary driver of breakthrough hospitalization in these cases.

A comparison of clinical features between immunized and unimmunized RSV infected children is provided in **Table 2**. Of note, 10 children hospitalized in 2024-2025 were born from vaccinated mothers (vaccine only reimbursed since the end of the season) which were excluded from the comparison. Whereas infants hospitalized, despite having been immunized, were younger, their need for respiratory support was less frequent compared to unimmunized age-eligible children. Length of stay, rate of pneumonia, antibiotics use and need for nutritional support did not differ significantly between both groups. Rate of transfer to tertiary hospital was also similar (7% vs 8 %, ns). Sensitivity analyses adjusting for age yielded similar results, confirming that the observation between immunised and unimmunised children was robust. Similar adjustment could unfortunately not be done for socioeconomical status (data

unavailable). Inside four participating PICU centres for which detailed information was available, age-eligible infants represented 46% (37/80) of all RSV-related PICU admissions this season, among which 30% were immunized (11/80, 14% of total RSV PICU admissions). Once admitted to PICU, the pattern of infections did not significantly differ for the main studied parameters according to immunization status (data not shown).

Table 2 : Main clinical features of eligible infants hospitalized with RSV disease according to monoclonals' immunization status (N= 20 centres*).

Legend: *The analysis includes the 20 centres for which main clinical data from both seasons were available (see figure 1). ** The analysis is based on 15 centres (out of the 20 previous ones) for which all clinical data from both seasons were available (see figure 1). ***Comorbidities recorded consisted in: prematurity, severe atopic dermatitis, poly-malformative syndrome, non-malignant haematological disease, neurological disorders (encompassing congenital neuromuscular disease, cerebral palsy and epilepsy), metabolic disease, kidney congenital disease, intrauterine growth retardation, congenital immunodeficiency, congenital malformative cardiopathies, asthma/chronic wheezing, malignancies, other pulmonary chronic disease, acquired immunodeficiency (HIV, immunosuppressive therapy) , Down syndrome. ****Immunization with nirsevimab only, the 10 infants born from vaccinated mothers were excluded from the analysis. NS= not significant

	Immunized****		Not immunized		
	n	%	n	%	p-value
Part 1: data from 20 centres*					
N of admissions	131		288		
Median age in months (IQR)	1.0 (1.0 - 3.0)		2.0 (1.0 - 5.0)		p < 0.01
Median length of stay in days (IQR)	4.0 (3.0 - 5.0)		4.0 (3.0 - 6.0)		ns
N (%) children needing respiratory support	60	46	182	63	p < 0.01
Part 2: Data from 15 centres**					
N of admissions	100		166		
N (%) children with any comorbidity***	14	14	17	10	ns
N (%) prematurity	11	11	14	8	ns
N (%) children needing nutritional support	29	29	56	34	ns
median duration in days (IQR)	4.0 (2.0 - 5.0)		4.0 (4.0 - 6.0)		ns
N (%) children treated by antibiotics	21	21	40	24	ns
median duration in days (IQR)	7.0 (4.5 - 8.5)		7.0 (3.0 - 8.0)		ns

N (%) children with pneumonia	12	12	19	11	ns
N (%) children with neurological complications	0	0	0	0	

5) Co-detection of other respiratory viruses with RSV

Out of 434 patients tested, a third presented with at least one other respiratory virus co-detected with RSV. This rate remained stable between both study seasons (**Figure 4**). The distribution of viruses was globally similar, except that more coronaviruses and bocavirus were isolated in 2023-2024. Multiples (≥2) co-detected viruses accounted for 17 % of co-detections in 2023-2024 and for 12 % in 2024-2025 (ns). No difference in severity pattern of RSV infection could be observed for the main studied parameters in case of co-detection of another virus (data not shown). Of interest, the rate of co-detection between RSV and rhino/enterovirus tended to be higher among immunized infants compared to non-immunized ones (22% vs 13.5%, ns), but this observation, made on a small subset of patients, needs to be further investigated on larger cohorts.

Figure 4: Rate of co-detection of RSV and other respiratory viruses, by season of survey. Legend: N=434 patients recruited through the SARI network. Presence of respiratory viruses was systematically assessed by in-house multiplex RT-qPCRs which detect type A and B influenza viruses; type 1, 2, 3, or 4 parainfluenza viruses; type A and B respiratory syncytial viruses; human metapneumoviruses; adenoviruses; picornaviruses (Rhinovirus and Enterovirus genera); specific enterovirus D68; parechovirus; bocavirus; and seasonal hCoVs OC43, 229E, and NL63 as well as SARS-CoV-2, as already described elsewhere [19].

Discussion

Our results corroborate findings from other countries by showing substantial reduction of RSV burden of disease in the hospitals setting,

after one year of seasonal prevention by nirsevimab [10-14]. Impact of prevention was important not only because of decrease of number of RSV-related hospitalizations, but also by the savings in healthcare resources during the hospital stay (i.e. less need for respiratory assistance or nutritional support and shorter length of stay) and a lower number of referrals to tertiary hospitals or PICU admissions. Another major benefit was the reduction in antibiotics consumption, a crucial point in this era of threatening increase in bacterial resistances. Of note, the rate of antibiotics prescriptions among children hospitalized with RSV in our general paediatric wards was in line with reports from other European countries [20]. The reduction in RSV burden observed here is most consistent with the implementation of prevention, rather than with natural variation in virus circulation alone, given that the impact was concentrated in the youngest infants — the direct recipients of nirsevimab — without a parallel decline in older children or adults [21]. Nevertheless, as this remains an ecological comparison, a contributory role of inter-seasonal variability cannot be formally excluded. The same picture was however reported by neighbouring countries that have implemented RSV prevention but not by others [22]. Furthermore, the magnitude of impact in terms of incidence decline was in accordance with the uptake of nirsevimab in our country and with the effectiveness estimated by a parallel case-control study run on Belgian, Spanish and Portuguese SARI data [23]. Whereas our study only focused on the hospital setting, other have shown a reduction of RSV burden in ambulatory care as well [24]. Impact of prevention on long-term complications of RSV disease in infancy

(i.e. chronic wheezing and asthma) would also certainly deserve future evaluation and should be included in cost-benefit analysis [25].

However, benefits of prevention were lower than described by Spanish colleagues for example, since only suboptimal uptake of the monoclonals was achieved in Belgium. Indeed, according to data on reimbursed healthcare benefits from the Inter Mutualistic Agency, only 62% of children eligible for prevention were immunized in 2024-2025. An independent study estimated that this corresponded to an 85% immunization of newborns in maternity wards and a 55% immunization rate for infants through the catch-up campaign (*Raes et al, unpublished data*). Under a hypothetical 90% coverage scenario, our framework suggests that an additional ~20% of hospitalisations in infants <6 months might have been prevented, yielding reductions comparable to high-coverage settings. Reasons underlying such a mitigated success of the first year of prevention could be the heavy administrative workload linked to the reimbursement procedure for monoclonals, the short delay between communication for reimbursement and the start of the season leaving limited time to organize the catch-up campaign, the delivery of the product after the season had already started, the late reimbursement of maternal vaccine (from January 2025 onwards), the absence of extra resources to support implementation of the program and the lack of an informative campaign dedicated to the general public organized by the national authorities. To tackle all these hurdles, a task force was set up, initiated by the Belgian paediatricians themselves, bringing weekly together stakeholders from various institutions and healthcare structures involved in RSV paediatric

prevention. Nonetheless, the importance of a proactive public educational campaign preceding implementation of a new immunization program, even in a country with a low rate of vaccine hesitancy, has been well demonstrated, and illustrated by the successful approach of Galician colleagues who were able to achieve a very high uptake (>90%) after 3 weeks of nirsevimab hospital-based administration program [10]. Given the increase in vaccine hesitancy in Europe following the COVID-19 pandemic, efforts must be made to improve global acceptability to prevention by parents and health care workers (HCWs). A previous study of acceptability of RSV prevention conducted in our country showed that parental awareness of RSV burden was low but their acceptance to prevention increased after being better informed [26]. A quarter reported having generally lost confidence in vaccination after the pandemic. A similar study is currently ongoing to compare results after one year of prevention and better identify strength and caveats of the first campaign, as well as parents and HCWs expectancies.

The current survey underlines the need of a specific network to monitor RSV (and other respiratory viruses) paediatric burden and efficacy of preventive strategies over time. The RSVPED network was specially built for this purpose, after the need was deemed urgent because of arrival of preventive tools on the market [27]. At the same time, the SARI survey – which has the advantage to provide active surveillance enabling timeline decision making- was adapted to provide an integrated respiratory surveillance and better include the paediatric population, in line with international discussions [28]. The case definition used to recruit patients

in the SARI survey was therefore widened, e.g. through removal of fever as *sine qua non criterion* and, for youngest children, by including extra possible qualifying signs and symptoms. Thanks to a fruitful collaboration, an appropriate composite network could be built to offer a quite representative picture of RSV burden on a national scale, with high coverage of paediatric wards. Since other preventive tools are currently or will soon be available, it is of the utmost importance to continue surveillance over time, paying attention to the prevalence of RSV infection in toddlers and older children. Indeed, age shift after universal vaccination has been observed with other infectious diseases (*H. influenzae* or whooping cough) [29]. Moreover, since monoclonals are specifically directed against a single epitope of the protein F, monitoring genomic evolution of the virus is crucial, to ensure absence of selection of escaping mutants [30]. The availability and use of numerous preventive tools, each targeting different epitopes of the protein, could help to prevent this threat.

In both seasons of our study, a third of patients presented with a co-detection of RSV with at least one other respiratory virus. Co-detection did not correlate with severity in our study, but further investigation of each combination and on larger cohort are needed, considering both synergy and antagonism between RSV and other viruses (notably with rhinovirus) have been described [31]. Furthermore, primary data on impact of RSV prevention on dynamic circulation of respiratory viruses, and in particular human metapneumovirus, are currently discordant [32,33]. In depth follow-up on longer period of time, in hospital and community settings,

should be carried out to monitor potential changes on global viral ecology, as observed during and after the pandemic [34]. However, prevention with monoclonals only targeted a small part of the population, so that the pressure on the ecosystem should be minimal for the moment, even if adding RSV vaccination for at risk adults.

Our study has some limitations. First, although we covered >40 % of paediatric beds in Belgium, full representativity could not be guaranteed because participation was done on a voluntary basis. However, all types of institutions (private/public, academic/non-academic) were included and participating centres were distributed over the three regions. Secondly, there is no standardized criterion for hospitalization and management of RSV disease in Belgium, particularly for the sampling strategy to detect infectious agents in infants presenting with ALRTIs. Some hospitals only performed testing in case of severe respiratory illness, especially during the season 2023-2024 when the PCR was not reimbursed. This might lead to underestimation of the RSV burden, and interfere with the evaluation of the impact of prevention. Thirdly, because several clinical data were retrospectively collected, some variables were unknown in a subset of patients. Destination was for example undetermined in case of transfer to tertiary hospitals, meaning that several children had to be excluded from some analysis to avoid overestimation. Also, among infants hospitalized despite having been immunized, information on dosing date and dose received was available for a few of them only, precluding robust characterization of breakthrough infections as a group. Systematic collection of these variables in future surveillance will be of importance.

Fourth, the adapted SARI survey started after the epidemic peak in 2023 which might induce a bias in some indicators. Finally, we did not collect patients' socio-demographic characteristics. Often, infants living in less favourable conditions are more prone to severe infections s and hospitalization [35]. However, in Belgium, like in many places, they also suffer from a lower vaccine coverage [36]. Immigrant infants and infants without social insurance were not eligible for reimbursement of RSV prevention during this first year, but fortunately equity was established for the second year.

Conclusions

Following implementation of nirsevimab a substantial reduction in RSV paediatric burden was observed in Belgium. However, efforts should be made to increase the uptake of preventive tools in our country.

This study highlights the importance of having a reliable network to monitor the epidemiology of RSV on a national scale in order to assess the efficacy of preventive tools, guide policy makers in defining the best strategy and follow consequent changes on global ecology of RSV and other respiratory viruses over time.

Declarations

Abbreviations

ALRTI: Acute Lower Respiratory Tract Infection
ECMO: Extracorporeal Membrane Oxygenation
GCP: Good Clinical Practice

HCW: Health Care Worker
IQR: Interquartile Range
NITAG: National Immunization Technical Advisory Group
PCR: Polymerase Chain Reaction
PICU: Pediatric Intensive Care Unit
RSV: Respiratory Syncytial Virus
SARI: Severe Acute Respiratory Infection

Ethics approval and consent to participate

Both study protocols were approved by ethics committees of participating hospitals. For the SARI surveillance, approval from a coordinating central ethical committee was also obtained (Ref : B.U.N. 143201215671). No informed consent was requested for the RSV Ped survey due to its retrospective design.
The whole study was conducted in compliance with the principles of GCP and in accordance with all applicable regulatory requirements.

Consent for Publication

Not Applicable" (no identifying images or other personal or clinical details of participants that compromise anonymity in our survey).

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Data availability

The datasets generated and analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.
Our surveillance data may be made available upon request for a reasonable research purpose, subject to the approval of more than half of the participating hospitals, as stipulated in our study contract. In addition, if case-based data are needed, the request must be formally submitted to and approved by the National Sectoral Committee for Social Security and Health (Information Security Committee), which ensures compliance with data protection regulations. This committee granted authorization for the SARI surveillance in its Decision 15/043 of 16 June 2015.

Clinical trial number: not applicable

Competing of interest

AL, MV, YL, YD, SD, AW, AN, AT, CM, DT, HR, IM, JV, JH, JD, KC, KVH, KV, LW, MB, MP, MU, OC, SD, ST, SVS, TV, VSK, XH, and YB have no conflict of interest to declare. SB has taken part to one advisory board of VIATRIS (outside the scope of this work). MR and TG have received honoraria from Sanofi, MSD and GSK for taking part in advisory boards and expert meetings and for acting as a speaker in congresses outside of the scope of the submitted work. DVB has received honoraria from Sanofi, MSD and Pfizer for taking part in advisory boards and expert meetings. TG has been clinical investigator in a nirsevimab clinical trial. N.D had honoraria from MSD for advisory board; speaker fees from Abbvie and Astra Zeneca (outside the scope of this work), travel fees and research grant from MSD, travel fees from Gilead. WEB is MSD global international speaker outside of the scope of the submitted work and participated to MSD EMA HPV advisory board. MRE has received travel grant from Pfizer.

Use of AI

ChatGPT was used to generate portions of the code for data management and statistical analysis (R Software). After using this tool, AL reviewed and edited the content as needed and takes full responsibility for the final version of the article.

Authors' contributions

The corresponding author attests that all listed authors meet authorship criteria. SB and MR designed and coordinated the RSVPED study. LD coordinated the SARI survey. YD curated the data of the SARI survey. AL, MV, YL, and LD analysed the data. SB, AL and LD reviewed and guided data analysis. SB, AL, LD and MR wrote the first draft of the manuscript. AW, AN, AT, CM, DVB, DT, HR, IM, IV, JV, JH, JC, KC, KV, KM, KV, LW, LS, MP, MR, ND, OC, RN, SD, ST, SV, TG, TV, VS, WE, XH, YM collected the data and samples. MU prepared data from the Belgian national health insurance institute (IMA). SDN coordinated the microbiological testing of SARI samples. All co-authors contributed to the establishment of this manuscript. SB finalized the manuscript.

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