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Modelled Impact of Nirsevimab for all Infants in the Prevention of Respiratory Syncytial Virus (RSV)-Related Hospitalizations and Its Predicted Cost to the Brazilian Public Healthcare System

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BACKGROUND

- Respiratory syncytial virus (RSV) is a major cause of lower respiratory tract infection (LRTI) in young children and poses a significant burden for Brazil's public healthcare system (SUS).
- Palivizumab is the sole preventive intervention for early preterm infants (<29 weeks), or those with comorbidities, and is reimbursed by the Public Healthcare System since 2013.
- Nirsevimab is a single-dose monoclonal antibody for passive immunization, with an extended half-life which has 70-80% efficacy for the prevention of RSV-LRTI in broad infant populations, regardless of gestational age.

OBJECTIVES

- This study aims to model RSV-related hospitalizations and costs of the impact of Nirsevimab on SUS population, compared to Standard of Practice (SoP).

METHODS

- A decision analytic model was developed to estimate RSV-LRTI events in a Brazilian birth cohort during their first year of life.
- Parameters were derived from published literature and Brazilian open-source databases (**Table 1**). Hospitalization rate and risk of intensive care unit (ICU) admission were based on Hospital Information System from Department of Informatics of the Brazilian Unified Health System (SIH/DATASUS),[1] adjusted for gestational week at birth according to published literature (**Figure 1**).[2]
- Based on Brazilian market data we assumed a prophylaxis coverage rate of 70% with Nirsevimab and 59,5% with Palivizumab (corresponding to a mean of 4,25 doses received by 70% of infants). To be conservative the risk reduction for hospitalization for Palivizumab was assumed as the same as Nirsevimab achieved at published studies.

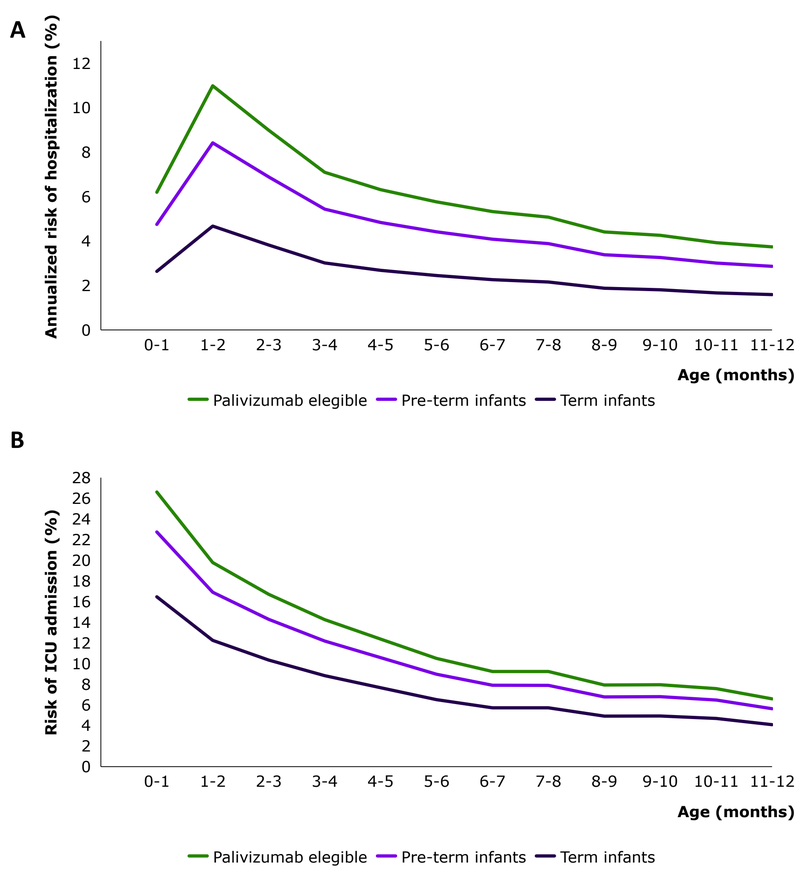
Table 1: Model parameters.

Parameter	Value	Source
Individuals < 12 months covered exclusively by public healthcare (Brazil 2024)	2.182.446	IBGE [3]
Palivizumab eligible infants (< 29 weeks or those with comorbidities)	0,84%	SINASC/DATASUS [4]
Late pre-term infants (29-36 weeks)	10,45%	SINASC/DATASUS [4]
Term infants	88,71%	SINASC/DATASUS [4]
Palivizumab: Risk reduction for hospitalization	86,20%	Simões et al., 2023 [5]
Nirsevimab: Risk reduction for hospitalization (palivizumab-eligible infants)	86,20%	Simões et al., 2023 [5]
Nirsevimab: Risk reduction for hospitalization (pre-term and term-infants)	74,50% **	Simões et al., 2023 [5]
Palivizumab coverage	59,5%	Model assumption
Nirsevimab coverage	70%	Model assumption
Hospitalization costs (medical ward)	R$1.333,14	SIH/DATASUS [1]
Hospitalization costs (intensive care unit)	R$16.948,89	SIH/DATASUS [1]

IBGE: Brazilian Institute of Geography and Statistics (Instituto Brasileiro de Geografia e Estatística), SINASC: Information System on Live Births (Sistema de Informações sobre Nascidos Vivos), DATASUS: Department of Informatics of the Brazilian Unified Health System (Departamento de Informática do Sistema Único de Saúde), SIH: Sistema de Informações Hospitalares.

** The risk reduction hospitalization with preterm and term infants was conservative, new studies show even higher rates [6]

Figure 1: Annualized RSV-related hospitalization rate by gestational age (A) and risk of intensive care unit admission among hospitalized patients (B).

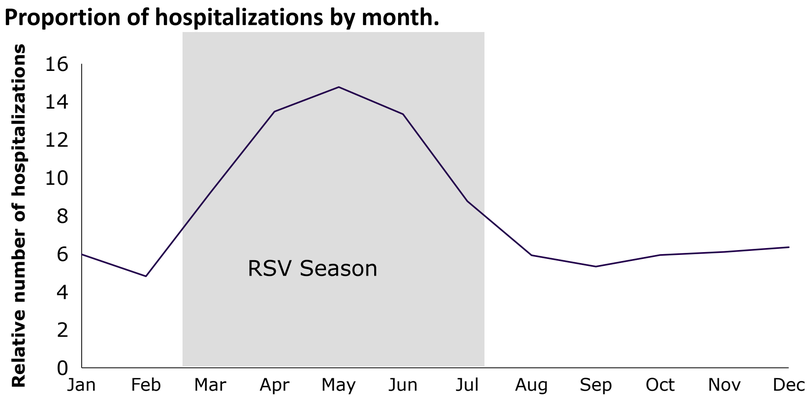


ICU: intensive care unit.

RESULTS

- The model shows that 58.1% of the RSV-related hospitalizations occur during the RSV season, while 41.9% of hospitalizations occur outside the season (**Figure 2**).

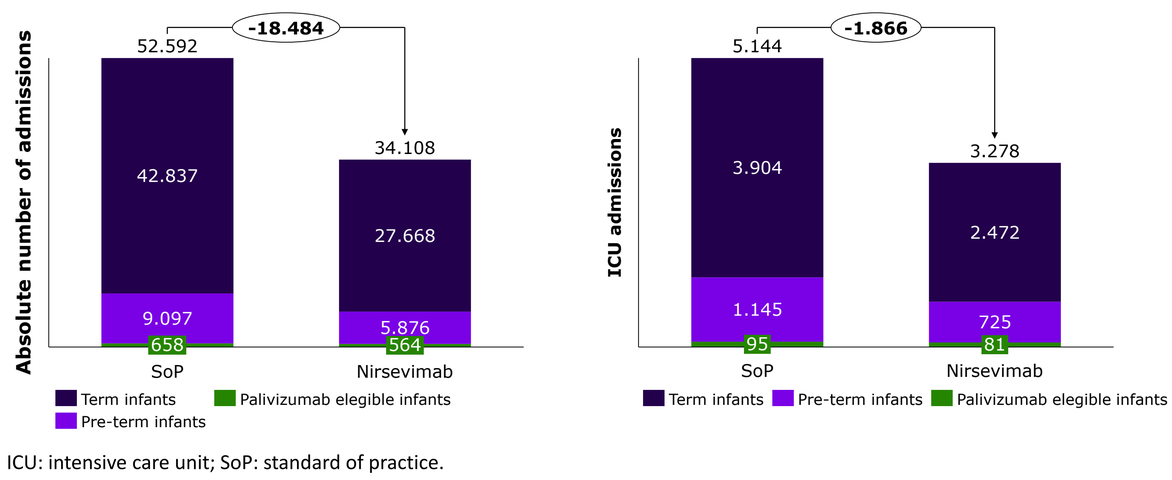
Figure 2: Proportion of hospitalizations by month.



In Brazil, the RSV season typically runs from March to July for most regions, with the exception of the North and South regions. The data has been adjusted so that all regions are represented by the same months on the graph. .

- Estimates for RSV-related hospitalizations under SoP are 658 for Palivizumab eligible, 9,097 for late preterm, and 42,837 for term infants, including 5,144 hospitalizations in ICU.
- In the modeled scenario, Nirsevimab would have prevented 18,484 hospitalizations (94, 3,221, and 15,169 for Palivizumab eligible, late preterm and term infants, respectively), including, 2,081 ICU hospitalizations (**Figure 3**).

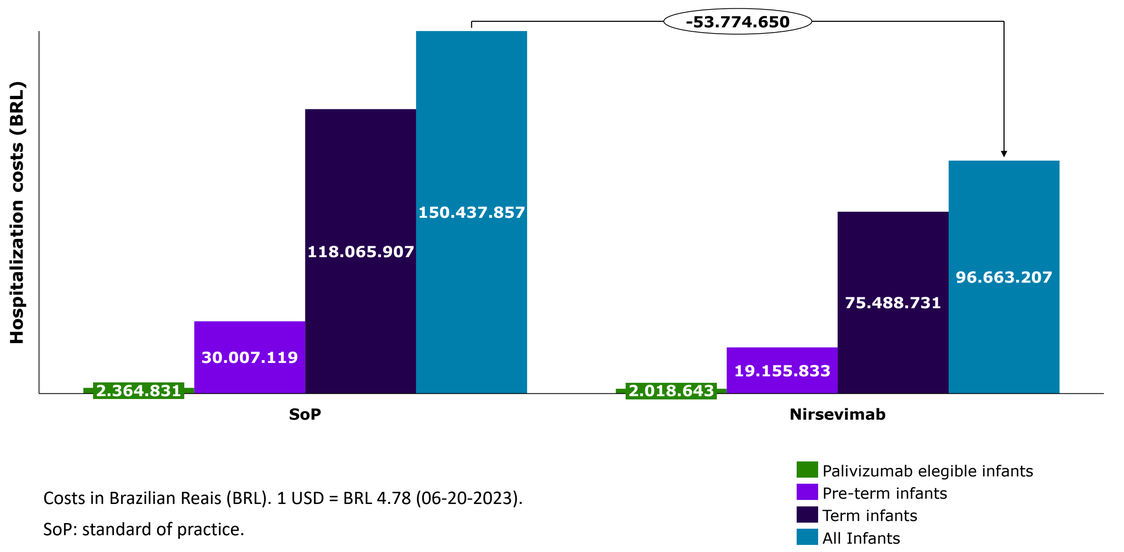
Figure 3: Number of hospitalized patients (A) and number of ICU hospitalized patients (B) by gestational age.



ICU: intensive care unit; SoP: standard of practice.

- Estimated savings, in Brazilian Reais (BRL) by preventing hospitalizations in the modeled scenario with Nirsevimab are BRL 53.8 million (BRL 0.35 million, 10.9 million and 42.6 million for palivizumab eligible, preterm, and term infants, respectively), not accounting for outpatients' care and social costs (**Figure 4**).

Figure 4: Hospitalizations costs by gestational age (BRL).



Costs in Brazilian Reais (BRL). 1 USD = BRL 4.78 (06-20-2023).
SoP: standard of practice.

CONCLUSIONS

- RSV is a leading cause of hospitalizations in all infants. Nirsevimab is designed to provide protection for all infants
- While preterm infants have a higher individual risk of hospitalization, term infants account for 80% of the total number of RSV-related hospitalizations. This underscores the importance of strategies to prevent RSV in the broader population. After the development of this analysis, other studies were published confirming that Nirsevimab has superior efficacy results in reducing the risk of hospitalization.
- Our findings indicates that Nirsevimab could substantially reduce RSV-related hospitalization burden and costs. This study offers valuable information for policymakers evaluate the benefits of Nirsevimab coverage in SUS for RSV prophylaxis.

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CONFLICTS OF INTEREST:
SW, JS, KR, AT, AK: Sanofi — employee, may hold stock and/or stock options in the company.
MF, NBS, MAPS and RTS: received professional service fees from Sanofi for conducting this research.

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