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EDITORIAL

Nirsevimab in Madeira: a first step towards reshaping respiratory syncytial virus prevention in Portugal

Nirsevimab na Madeira: primeiro passo para remodelar a prevenção do vírus sincicial respiratório em Portugal

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Respiratory syncytial virus (RSV) has long imposed a substantial burden on infants, families, and health systems at all levels of care. For decades, preventive options were limited to selected high-risk infants, leaving the majority of RSV-related hospitalisations occurring in previously healthy children without a broadly applicable preventive strategy. The arrival of nirsevimab, a long-acting monoclonal antibody administered as a single dose before or during the RSV season, has changed this landscape.

The study from Madeira, published in this issue of the *Portuguese Journal of Pediatrics*, captures an important moment in that transition.[1] In the 2023-2024 RSV season, Madeira became the first Portuguese region, and one of the first regions worldwide, to recommend universal immunoprophylaxis with nirsevimab for all infants. The campaign included both infants born during the season and a broad catch-up group born between April and October 2023. This regional experience was especially valuable because it provided a concrete example of how universal infant RSV prevention could be operationalised in our country.

The results are striking and consistent with the growing body of international real-world evidence from different countries and health care settings.[2] Among 1756 eligible infants, immunisation coverage reached 97.4%, with similarly high uptake in the seasonal and catch-up groups. More than 90% of the catch-up group was immunised within the first month, further suggesting strong engagement by primary care teams. The implementation message from Madeira is very important, because the effectiveness of an immunisation programme is not determined only by the performance of the product. It depends on timing, accessibility, engagement, communication, parental confidence, and integration into existing care pathways. A delayed or uneven campaign risks missing the narrow window during which the youngest infants are most vulnerable.

Effectiveness against hospitalisation was 94.6%, at the upper end of published real-world estimates.[2] Compared with previous seasons, the authors estimated 45 averted hospitalisations and a relative reduction in hospitalisations of 79.6%. Supplemental oxygen therapy duration was significantly lower. The number needed to immunise to prevent one hospitalisation was 25. These numbers should be interpreted with some caution, given the small number of events and the very small non-immunised group, resulting in wide confidence intervals that also limit the precision of subgroup and severity analyses. Furthermore, historical comparisons are imperfect, because RSV circulation varies between seasons, was disrupted during and after the COVID-19 pandemic, and RSV testing practices may have led to underestimation of hospitalisations in earlier seasons.

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These findings should now be read in the context of the following seasons. In 2024-2025, Portugal implemented nirsevimab prophylaxis nationwide, although with a more restrictive catch-up policy than that adopted in Madeira. The national recommendation included infants born between August 2024 and March 2025, in addition to at-risk infants. This represented a decisive step towards a national prevention policy, while also showing how eligibility criteria may vary according to operational and resource considerations.

The Portuguese VigiRSV test-negative case-control study for the 2024-2025 season provides important confirmation of the effectiveness of this strategy at the national level.[3] Among 341 hospitalised children under 24 months eligible for immunisation, 137 tested positive for RSV. Most participants were young infants, with a median age of two months, and 91.2% had no known chronic condition. Adjusted nirsevimab effectiveness against RSV-related hospitalisation was 78.5%, with sensitivity analyses showing consistent results. These national findings are consistent with real-world evidence from other countries and settings.

The difference between the Madeira estimate of 94.6% and the national estimate of 78.5% should not be interpreted as contradictory, as the studies used different designs, populations, settings, and eligibility policies. The Madeira study was a population-based longitudinal observational study in a small region with exceptionally high coverage with an exceptionally broad catch-up campaign. The national study used a test-negative case-control design within a sentinel hospital network, during the first season of nationwide implementation, and under more restrictive eligibility criteria. Despite the limitations, both estimates point in the same direction: nirsevimab substantially reduces RSV-related hospitalisation in infants.

The more restrictive catch-up approach used nationally deserves careful evaluation. A narrower catch-up policy may be operationally simpler and less costly, but it may leave some infants entering their first RSV season without protection, particularly those born earlier in the year but still at meaningful risk during winter. The Madeira experience suggests that broader catch-up can be implemented successfully when supported by strong primary care coordination. In the 2025-2026 season, eligibility criteria were adapted to cover all infants born between June 2025 and March 2026.[4] At the time of writing, we are awaiting the most recent VigiRSV case-control study results, which will help assess the impact of this change, as well as the decisions regarding the 2026-2027 campaign.

The national 2024-2025 experience also highlights the importance of monitoring coverage. In the VigiRSV study, 77.9% of RSV-negative controls had received nirsevimab, compared with 44.5% of RSV-positive cases. However, official population coverage data were not available during the season, which is a key gap. To guide future policy, Portugal needs timely national and regional coverage estimates, ideally linked to birth cohorts, primary care records, and hospital surveillance. Without such data, it is difficult to distinguish between true programme limitations, recruitment bias in surveillance studies, regional inequalities, delayed administration, and parental refusal. Also, there is a need to look beyond hospitalisation alone as RSV burden includes emergency department visits, primary care consultations, parental work absenteeism and antibiotic exposure, amongst other relevant endpoints.

It is important to emphasise that nirsevimab does not encompass all available approaches to preventing RSV disease. Clesrovimab, another long-acting monoclonal antibody targeting the RSV F protein, has emerged as an additional option for passive immunisation of infants during their first RSV season, with single-dose administration and the potential operational advantage of fixed dosing irrespective of body weight. Clinical trials demonstrated clesrovimab's significant efficacy in reducing RSV-associated hospitalisations by 84.3% and medically attended lower respiratory infections by 60.5%, with a safety profile comparable to existing prophylactic treatments.[5,6] Maternal immunisation with the RSVpreF vaccine represents a different approach, promoting transplacental transfer of neutralising antibodies and providing protection from birth, when infants are particularly vulnerable.[7] It has been introduced in the United Kingdom, but equitable access and affordability must be prioritised, particularly in resource-limited settings.[8,9]

All these interventions should be incorporated into a coherent prevention strategy tailored to product availability, national recommendations and family preferences, while maintaining universal measures such as hand hygiene, reduction of exposure to respiratory infections and avoidance of tobacco smoke. Integrated respiratory surveillance should also monitor possible shifts in RSV and other pathogens, such as human metapneumovirus or rhinovirus, as RSV prevention changes the seasonal respiratory landscape.[10]

These questions require integrated surveillance. Portugal would benefit from harmonised national data collection on RSV disease burden and preventive

interventions, linking birth cohorts, immunisation records, laboratory-confirmed infection, hospital admissions, intensive care use, and safety reporting. Such systems would allow more robust estimates of effectiveness and support careful evaluation of equity, safety, and cost-effectiveness. They would also help detect regional differences in uptake or impact and support timely adjustments to future campaigns. But the direction is now clear. RSV prevention has become a real and actionable public health strategy. Madeira opened the path; national data confirm that the path is worth following.

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