

Nirsevimab: a change of paradigm in the prophylaxis of RSV disease among infants.

Dear Editor,

Garattini and Clavenna have recently suggested to policy makers to be very cautious in introducing new immunization products in public health strategies for the prevention of Respiratory Syncytial Virus (RSV) infections, affirming that this risk is overestimated and the choices could be even driven by a bunch of powerful multinational companies. These considerations were published after several countries, including Italy, Spain, Germany, and the United States, based on strong scientific evidence, included in their immunization schedules the administration of the monoclonal antibody (mAB) nirsevimab for all newborns. (.....)

REFERENCES

- [1] Garattini L, Clavenna A. RSV prevention options for infants and older adults: A specific expanding competitive arena. *Health Policy*. 2024 Oct 20;150:105187. doi: 10.1016/j.healthpol.2024.105187. Epub ahead of print. PMID: 39442242.
- [2] Shi T, McAllister DA, O'Brien KL, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in young children in 2015: a systematic review and modelling study. *Lancet* 2017; 390:946–58.
- [3] Hall CB, Weinberg GA, Iwane MK, et al. The burden of respiratory syncytial virus infection in young children. *N Engl J Med* 2009; 360:588–98.
- [4] Geoghegan S, Erviti A, Caballero MT, et al. Mortality due to Respiratory Syncytial Virus. Burden and Risk Factors. *Am J Respir Crit Care Med*. 2017;195(1):96-103. doi:10.1164/rccm.201603-0658OC
- [5] Hall CB, Weinberg GA, Blumkin AK, et al. Respiratory syncytial virus-associated hospitalizations among children less than 24 months of age. *Pediatrics*. 2013;132(2):e341-e348. doi:10.1542/peds.2013-0303
- [6] Meissner H. C. (2016). Viral Bronchiolitis in Children. *The New England journal of medicine*, 374(1), 62–72. <https://doi.org/10.1056/NEJMra1413456>
- [7] Stein RT, Bont LJ, Zar H, et al. Respiratory syncytial virus hospitalization and mortality: Systematic review and meta-analysis. *Pediatr Pulmonol*. 2017;52(4):556-569. doi:10.1002/ppul.23570
- [8] Li Y, Wang X, Blau DM, et al. Global, regional, and national disease burden estimates of acute lower respiratory infections due to respiratory syncytial virus in children younger than 5 years in 2019: a systematic analysis. *Lancet*. 2022;399(10340):2047-2064. doi:10.1016/S0140-6736(22)00478-0
- [9] Thomas E, Mattila JM, Lehtinen P, Vuorinen T, Waris M, Heikkinen T. Burden of Respiratory Syncytial Virus Infection During the First Year of Life. *J Infect Dis*. 2021;223(5):811-817. doi:10.1093/infdis/jiaa754
- [10] Scarpaci M, Bracaloni S, Esposito E, et al. RSV Disease Burden in Primary Care in Italy: A Multi-Region Pediatric Study, Winter Season 2022-2023. *Influenza Other Respir Viruses*. 2024;18(4):e13282. doi:10.1111/irv.13282

- [11] Vittucci AC, Antilici L, Russo C, et al. Respiratory syncytial virus: can we still believe that after pandemic bronchiolitis is not a critical issue for public health?. *Eur J Pediatr*. 2023;182(12):5303-5313. doi:10.1007/s00431-023-05201-y
- [12] Bozzola E, Ciarlito C, Guolo S, et al. Respiratory Syncytial Virus Bronchiolitis in Infancy: The Acute Hospitalization Cost. *Front Pediatr*. 2021;8:594898. Published 2021 Jan 18. doi:10.3389/fped.2020.594898
- [13] Antilici L, Vittucci AC, Cristaldi S, et al. High-flow nasal cannulas versus standard oxygen therapy for moderate bronchiolitis: a quasi-experimental analysis. *Pediatr Pulmonol*. Published online October 25, 2024. doi:10.1002/ppul.27358
- [14] Villani A, Vittucci AC, Antilici L, et al. Prevention of RSV Bronchiolitis: An Ethical Issue. *Pediatr Infect Dis J*. 2024;43(8):e296-e297. doi:10.1097/INF.0000000000004354
- [15] Ares-Gómez S, Mallah N, Santiago-Pérez MI, et al. Effectiveness and impact of universal prophylaxis with nirsevimab in infants against hospitalisation for respiratory syncytial virus in Galicia, Spain: initial results of a population-based longitudinal study [published correction appears in *Lancet Infect Dis*. 2024 Jul;24(7):e419. doi: 10.1016/S1473-3099(24)00355-4]. *Lancet Infect Dis*. 2024;24(8):817-828. doi:10.1016/S1473-3099(24)00215-9
- [16] Perramon-Malavez A, de Rioja VL, Coma E, et al. Introduction of nirsevimab in Catalonia, Spain: description of the incidence of bronchiolitis and respiratory syncytial virus in the 2023/2024 season. *Eur J Pediatr*. 2024;183(12):5181-5189. doi:10.1007/s00431-024-05779-x
- [17] Jimeno Ruiz S, Peláez A, Labourt A, et al. Evaluating the Effectiveness of Nirsevimab in Reducing Pediatric RSV Hospitalizations in Spain. *Vaccines (Basel)*. 2024;12(10):1160. Published 2024 Oct 11. doi:10.3390/vaccines12101160
- [18] Paireau J, Durand C, Raimbault S, et al. Nirsevimab Effectiveness Against Cases of Respiratory Syncytial Virus Bronchiolitis Hospitalised in Paediatric Intensive Care Units in France, September 2023-January 2024. *Influenza Other Respir Viruses*. 2024;18(6):e13311. doi:10.1111/irv.13311
- [19] Orsi A, Scarpaleggia M, Baldo V, et al. First real-world data on universal respiratory syncytial virus prophylaxis with Nirsevimab in infants. *J Prev Med Hyg*. 2024;65(2):E172-E187. Published 2024 Aug 31. doi:10.15167/2421-4248/jpmh2024.65.2.3329
- [20] Xu H, Aparicio C, Wats A, et al. Real-World Effectiveness of Nirsevimab Against Respiratory Syncytial Virus: A Test-Negative Case-Control Study. Preprint. *medRxiv*. 2024;2024.09.12.24313545. Published 2024 Sep 12. doi:10.1101/2024.09.12.24313545
- [21] Consolati A, Farinelli M, Serravalle P, et al. Safety and Efficacy of Nirsevimab in a Universal Prevention Program of Respiratory Syncytial Virus Bronchiolitis in Newborns and Infants in the First Year of Life in the Valle d'Aosta Region, Italy, in the 2023-2024 Epidemic Season. *Vaccines (Basel)*. 2024;12(5):549. Published 2024 May 17. doi:10.3390/vaccines12050549
- [22] Getaneh AM, Li X, Mao Z, et al. Cost-effectiveness of monoclonal antibody and maternal immunization against respiratory syncytial virus (RSV) in infants: Evaluation for six European countries. *Vaccine*. 2023;41(9):1623-1631. doi:10.1016/j.vaccine.2023.01.058

➤ Letter in press by Rezza G et al.