Bronchiolitis: Two French studies demonstrate the effectiveness of nirsevimab to protect infants

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After a 2022–2023 season marked by a severe epidemic of bronchiolitis due to respiratory syncytial virus (RSV), in particular in terms of

emergency department visits and hospital admissions, on September 15, 2023 the French Government launched a preventive immunization campaign, administering nirsevimab (Beyfortus), to protect infants and reduce the circulation of the virus.

To assess the effectiveness (real-world efficacy) of administering the monoclonal antibody nirsevimab (Beyfortus), in combating the epidemic of RSV bronchiolitis during the 2023–2024 season, two complementary studies were conducted as a collaborative effort by the Institut Pasteur and Santé publique France: one to estimate the effectiveness of nirsevimab against cases of RSV bronchiolitis admitted to intensive care units, and the other to model the impact of the drug in terms of the number of hospital admissions prevented.

The results of both studies confirm the positive impact of nirsevimab on the bronchiolitis epidemic, showing a significant reduction in the number of infants hospitalized and an estimated effectiveness of 76% to 81% for the prevention of RSV bronchiolitis-related hospitalizations in intensive care. In addition, the administration of nirsevimab prevented around 5,800 hospitalizations for bronchiolitis following emergency department visits between September 15, 2023 and January 31, 2024 in mainland France.

The effectiveness of nirsevimab (Beyfortus) in preventing cases of RSV bronchiolitis admitted to intensive care is estimated to be between 76% and 81%

Every year, Santé publique France monitors epidemiological trends in bronchiolitis. For the 2023–2024 season, a pilot surveillance program for severe cases of bronchiolitis in children under the age of two was set up in cooperation with the PICURe (Pediatric Intensive Care Unit Registry) network, with the participation of pediatric and neonatal intensive care units that volunteered to take part.

The surveillance program is run in each region by the regional units of Santé publique France. In particular, it has made it possible to describe the viruses involved in severe cases of bronchiolitis, as well as severe cases of RSV bronchiolitis that have benefited from preventive immunization with nirsevimab (Beyfortus).

Based on these indicators, nirsevimab's effectiveness against RSV bronchiolitis-associated hospitalization in intensive care was estimated using a test-negative, case-control design by Santé publique France.

The results of the study, conducted in mainland France from September 15, 2023 to January 31, 2024 in 288 infants, confirm the effectiveness of nirsevimab in preventing severe cases of RSV bronchiolitis hospitalized in intensive care units, which is estimated to be 75.9% (95% confidence interval: 48.5-88.7) and 80.6% (61.6–90.3) depending on the assumptions made. These findings are in line with the results of an international clinical study of 8,058 infants.

"Surveillance is at the heart of our professional work; it is carried out by an extensive network of partners and highly motivated health care professionals. Today, thanks to our bronchiolitis surveillance system and the involvement of intensive care physicians, we have been able to evaluate the positive effects of nirsevimab (Beyfortus) on infants' health within a very short time frame and under real-world conditions, with treatment efficacy estimated at between 76% and 81%.

"These results have been passed to the relevant authorities to help inform decision making and public action on the prevention of RSV bronchiolitis," said Isabelle Parent du Chatelet, Head of the Respiratory Infections and Vaccination Unit, Infectious Diseases Department, Santé publique France.

5,800 hospital admissions for RSV bronchiolitis were

prevented, according to modeling data

To assess the impact of nirsevimab administration on the bronchiolitis epidemic, researchers at the Institut Pasteur and epidemiologists at Santé publique France developed a mathematical model of RSV transmission among different age groups, as well as plausible scenarios for the administration of nirsevimab doses, based on data on the number of treatment doses supplied to maternity hospitals and pharmacies. They calibrated their model using hospital and virological surveillance data for the period from mid-2017 to February 4, 2024, as well as serological data.

They estimate that administration of nirsevimab prevented 5,800 (95% confidence interval: 3,700-7,800) hospitalizations for RSV bronchiolitis after a visit to the emergency department, of which 4,200 (2,900-5,600) were among children aged 0 to 2 months, between September 15, 2023 and February 4, 2024, in mainland France.

This corresponds to a 23% (16%–30%) reduction in the total number of hospitalizations for RSV bronchiolitis following a visit to the emergency department [35% (25%–44%) in the 0-2 months age group], compared with the non-administration scenario. In the baseline scenario, with 215,000 doses administered by January 31, 2024, the efficacy of nirsevimab against hospitalizations for RSV bronchiolitis was estimated to be 73% (61%–84%), corresponding to one hospitalization prevented for every 39 (26–54) doses administered.

"With one hospitalization for RSV bronchiolitis prevented for around 40 children treated, our study highlights the value of administering nirsevimab to reduce hospitalizations due to RSV. The two studies use different approaches. One analyzes real-world data from pediatric intensive care units, while the other models population-based surveillance data; but they give similar estimates of nirsevimab efficacy.

"Modeling also provides additional information, for example, on the number of hospital admissions prevented. This demonstrates the value of using these complementary approaches to assess the impact of public health measures," said Simon Cauchemez, Head of the Mathematical Modeling of Infectious Diseases Unit at the Institut Pasteur.

A viral respiratory infection, bronchiolitis (mainly caused by respiratory syncytial virus, or RSV) is a highly contagious disease that affects infants and young children under the age of two, especially in autumn and winter. Although bronchiolitis is common and usually benign, in some cases, particularly in infants under two months of age, it can lead to severe complications and hospitalization.

In France, it is estimated that bronchiolitis affects almost 30% of infants under two years of age every winter, i.e. some 480,000 cases a year. 2%–3% of infants under one year of age are thought to be hospitalized each year with more severe bronchiolitis.

More information: Nirsevimab effectiveness against cases of respiratory syncytial virus bronchiolitis hospitalised in pediatric intensive care units in France, September 2023 -January 2024, April 26, 2024

Estimates of effectiveness and impact of nirsevimab on hospitalisations for RSV bronchiolitis in metropolitan France, 2023-2024 : a modelling study, April 26, 2024

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