RSV prevention finally in reach after 20 years of research

August 23 2022

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World-first immunizations providing protection against deadly respiratory syncytial virus (RSV) could be just months away thanks to global research efforts spanning multiple decades.

The latest research published in *The Lancet Infectious Diseases* has revealed a long-lasting monoclonal antibody treatment for babies is likely to be accessible on the market within 12 months, followed closely by the approval of a maternal vaccine given in pregnancy to provide newborns with protection against the virus.

Responsible for more than 100,000 deaths and 3.6 million hospitalizations in children each year, RSV infects the airways and lungs and is a key contributor to the global mortality burden due to life-threatening complications such as bronchiolitis and pneumonia.

Professor Peter Richmond, Head of the Vaccine Trials Group at the Wesfarmers Center of Vaccines and Infectious Diseases, based at the Telethon Kids Institute, Head of Pediatrics at The University of Western Australia and Perth Children's Hospital Pediatrician, said researchers are now completing the final stages of development for numerous preventative antibody treatments and RSV vaccines.

"Observations from multiple studies conducted worldwide have shown there are nine potential candidates in Phase 3 clinical trials—the final stage prior to licensing for use—including two antibody immunization treatments for prevention in babies and two maternal vaccines designed to be given to pregnant mothers," said Professor Richmond.

"This is an especially exciting time for us—we started our first Phase 1 and 2 studies looking at RSV vaccines all the way back in 2000 and it has been a long journey to get to this point.

"Unfortunately, some of the early studies were unsuccessful and ceased in the development stages, but in 2016 we began to see positive results for a Phase 2 study looking at a monoclonal antibody treatment called Niversimab.

"We recently completed Phase 3 studies on Niversimab here in Perth, and there have been positive results reported from the northern hemisphere pre-COVID-19, so it is expected to be licensed for use as the very first RSV prevention treatment in the U.S./Europe by late 2022 or early 2023.

"This week we began a Phase 3 study on the second potential antibody treatment, which hopes to provide long-lasting protection for babies at highest risk of being hospitalized with RSV, including those born prematurely, or those with congenital heart disease or chronic lung disease," said Professor Richmond.

Telethon Kids Institute is also the lead site in Western Australia for global studies finalizing development of a maternal vaccine for pregnant mothers, with enrollment now complete and results expected in the coming months.

"I am very keen to make the most of this opportunity here in Australia, as I believe the potential burden of disease we may be able to prevent will be even greater than first thought, including decreasing the amount of antibiotics that are prescribed, reducing ear infections in young babies and decreasing more serious bacterial pneumonias that are associated with RSV infection. There is also the potential benefits of preventing longer-term complications such as chronic lung infections and asthma.

"As a pediatrician who has looked after sick babies with RSV for over 30 years, the idea that we could prevent a large proportion of these illnesses is fantastic and I feel privileged to have been involved in the process.

"In the next 10 years I hope to see licensed vaccines and preventative drugs being given to mothers, babies, toddlers and older adults, with multiple vaccine and monoclonal antibody platforms available that could

even be combined with COVID and influenza vaccines, keeping our hospitals and GP surgeries much quieter over winter.

"The biggest challenge will be ensuring these vaccines are accessible and affordable in low- and middle-income countries where more than 99% of RSV deaths occur, especially given the effectiveness shown in the large Phase 3 trials included countries across Africa, Latin America and Asia.

"I am also concerned that parents may not be aware of RSV and the pivotal role it plays in serious infections in young children, and whether this may reduce the uptake of highly effective monoclonal antibodies or maternal vaccinations when they become available," said Professor Richmond.

Associate Professor Hannah Moore, Epidemiologist from the Wesfarmers Center for Vaccines and Infectious Diseases and the School of Population Health at Curtin University, is preparing for a future vaccine roll-out by assessing parental awareness of RSV.

"We're conducting a survey to gauge knowledge of RSV throughout the community and ask pregnant families and parents of young children how they would feel about these vaccines being given to their newborn babies or in pregnancy," said A/Prof Moore.

"This information will help us plan larger studies around community awareness and guide the development of educational materials for the general public, which will help parents feel confident about the vital importance of these long-awaited vaccines."

"We are also closely analyzing the data we have collected about RSV in Western Australia to help shape vaccination policy and ensure the programs put in place have maximum impact. After many years working

in this space, I can't wait to see a safe and effective vaccine program for RSV implemented in our community, significantly reducing hospitalizations and longer-term effects of the virus," concluded A/Prof Moore.

More information: Natalie I Mazur et al, Respiratory syncytial virus prevention within reach: the vaccine and monoclonal antibody landscape, *The Lancet Infectious Diseases* (2022). DOI: 10.1016/S1473-3099(22)00291-2

Provided by Telethon Kids Institute