

Getting Closer to a Much-Needed RSV Vaccine



By Julianna LeMieux — May 15, 2018



Baby with RSV infection [1]

We may be one step closer to saving thousands of newborns from a potentially nasty illness and death. A press release this month from Novavax, a clinical-stage biotechnology company, states that they have reached a milestone in their clinical trial for the highly anticipated vaccine for respiratory syncytial virus (RSV.)

What is RSV?

Although you may not have heard of it, the Centers for Disease Control and Prevention (CDC) states that almost all children have had RSV in the first two years of life. To put it into perspective, the numbers of the morbidity and mortality of RSV are nearly identical to influenza virus. Indeed, more than 57,000 children under the age of 5 in the United States require hospitalization for RSV each year.

It is common for symptoms to be mild with a runny nose, coughing, sneezing, fever, wheezing, and decreased appetite. However, more severe cases can result in bronchiolitis or pneumonia, which could have serious implications for young infants or older adults.

Although RSV infections may not be a top worry of every new parent in the United States, globally, RSV is the second leading cause of infant death (second to malaria) making vaccination an urgent global unmet need.

Therefore, a vaccine is critical for the health of babies around the world. However, there are a few reasons why vaccination for this particular virus is trickier than others. Perhaps the biggest challenge is time. Because RSV is a disease of infants, and an infant's immune system is immature, several vaccine doses would be needed in order to have an effective immune response. By the time the boosters are given, it may be too late.

Because of this, the vaccination strategy is to vaccinate the pregnant mothers who would pass on the antibodies to the developing fetus through the placenta. This concept is used for other infectious diseases and is known to be effective against tetanus, pertussis, and influenza.

Clinical Trial Advances Bring a Vaccine in Sight

Novavax is developing an RSV vaccine candidate and has recently reached a significant enrollment milestone for their clinical phase 3 trial, called Prepare, which was started in December 2015. [We first wrote about this trial in 2015, when it was in phase II.](#) ^[2] The Prepare trial will assess the safety and efficacy of maternal immunization with the RSV vaccine.

A total of 4,600 healthy, pregnant women in their third trimester have been enrolled in the global Prepare trial. This enrollment is significant because that is the total number of women who will be enrolled. To date, at least 3,000 of participants have received the RSV vaccine. Once the last infant born to all 4,600 women turns 6 months old, the data will be analyzed and, if the results show that the vaccine is safe and effective, Novavax can then move to a license application with the US Food and Drug Administration (FDA). In addition, the vaccine had already been granted Fast Track Designation by the FDA which would potentially make it eligible for priority review of the Biologics License Applications (BLS) process, cutting the standard FDA review process by 4 months.

Although there are still multiple hurdles to jump over, the idea that a safe and effective RSV vaccine may be available in the future is a huge step forward in the health of infants worldwide.

Sources:

[Novavax Press Release](#) ^[3] (<http://ir.novavax.com/news-releases/news-release-details/novavax-reaches...> ^[3])

COPYRIGHT © 1978-2016 BY THE AMERICAN COUNCIL ON SCIENCE AND HEALTH

Source URL: <https://www.acsh.org/news/2018/05/15/getting-closer-much-needed-rsv-vaccine-12963>

Links

[1] <https://www.flickr.com/photos/34547181@N00/11627677596>

[2] <https://www.acsh.org/news/2015/08/12/rsv-the-devil-you-dont-know>

[3] <http://ir.novavax.com/news-releases/news-release-details/novavax-reaches-significant-enrollment-milestone-preparetm-phase>