

# Novavax: Early study indicates its vaccine effective vs. RSV

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Early research in older adults found an experimental vaccine prevented nearly two-thirds of serious cases of a common, seasonal respiratory virus that annually kills thousands of vulnerable Americans—babies and senior citizens.

If further testing by vaccine developer Novavax Inc. goes well, in a few years the biotech company's genetically engineered shot could become the first vaccine approved against respiratory syncytial virus, or RSV.

"It could be a major breakthrough," said Dr. Andrew Pavia, a spokesman for the Infectious Diseases Society of America, cautioning that the preliminary study's results must be duplicated in more people. "It's not time to break out the champagne."

There's no specific treatment for RSV, and drugmakers for the last half-century have unsuccessfully tried to create a vaccine. In the U.S., it infects virtually every child by age 2, is the top cause of infant hospitalizations and kills an estimated 11,000 to 14,000 people 60 and older each year. Worldwide, it causes more than 30 million lower respiratory infection episodes and kills roughly 175,000 children under age 5 annually.

The virus circulates each year from mid-fall through spring, usually causing mild cold symptoms or none at all in healthy adolescents and adults, who are mostly protected by immunity built up from childhood exposure.

It's a different story for those at the beginning or end of life, whose immune systems are just revving up or are sputtering out, and for others with weak immune systems, such as bone marrow transplant and cancer patients and people with uncontrolled HIV.

In the U.S., RSV only kills several hundred children each year because of widespread availability of

supplemental oxygen and other supportive medical care.

But by age 65, people often have other health problems, their immunity to RSV has mostly worn off and their immune system on average works roughly half as well as in their prime. So RSV lands up to 180,000 of them in the hospital with pneumonia and other dangerous respiratory problems, and kills nearly a tenth of them.

Novavax, based in Gaithersburg, Maryland, has been developing this vaccine for four years, testing it in animals and now people.

Past efforts by other companies didn't work because they were making vaccines either from killed RSV virus or a key protein on its surface, Dr. Gregory Glenn, head of research and development at Novavax, told The Associated Press. Those had membranes around them that made it very hard for the immune system to recognize the virus, allowing repeated infections over the years, including ones causing serious symptoms in about 5 percent of seniors each year.

By using recombinant technology—building genetic material into that key protein—Novavax made a vaccine that exposes the most vulnerable parts of the protein, without any protective membrane, to the immune system, Glenn said.

In the study announced late Monday, about 800 people aged 60 and over got the vaccine and another 800 got dummy shots.

The vaccine was 64 percent effective in preventing serious symptoms of lower respiratory tract infections: shortness of breath and other difficulty breathing, coughing and excessive sputum. It was 44 percent effective in preventing all symptoms of respiratory syncytial virus.

While the overall effectiveness rate appears low, it's

the same rate as for senior citizens getting Prevnar, the popular vaccine against pneumonia and other bacterial diseases. Like the immune system, vaccines don't work as well in the elderly.

"Moderate efficacy, which is the 40-60 percent range, could make a big difference," said Pavia, a professor of pediatrics at the University of Utah.

Meanwhile, Novavax is conducting early testing in children aged 2 to 5 years and pregnant women.

The goal with the latter group is to have the moms-to-be pass on antibodies against RSV to their newborns, the most vulnerable age group, Glenn said. That strategy is already successfully used with flu shots.

Novavax CEO Stanley Erck said the eventual vaccine may cost \$100 to \$200 for seniors and perhaps only \$50 for pregnant women.

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