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What to Know About the New R.S.V. Immunizations

New vaccines for older adults and pregnant women, and an antibody therapy for infants, provide options for preventing severe infection.

By Dana G. Smith

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Respiratory syncytial virus is the leading reason for hospitalization among infants in the United States. Between 58,000 and 80,000 children under the age of five, the majority of whom are less than a year old, are hospitalized for it every year.

R.S.V. also results in 60,000 to 160,000 hospitalizations and 6,000 to 10,000 deaths annually in Americans over the age of 65. (For comparison, flu caused about 171,000 hospitalizations and 16,000 deaths in older adults during the 2019-2020 flu season.)

Despite the harm caused by the disease, R.S.V. historically has not received as much attention as the flu or Covid-19. That's starting to change, in part because the serious consequences of R.S.V. were on full display last winter with the so-called "tripledemic," when the virus overwhelmed hospitals alongside the flu and Covid.

Coinciding with rising awareness about the risks of R.S.V., there are finally tools available to prevent severe infections in both infants and older adults. In May, the Food and Drug Administration approved two vaccines for adults 60 and up, in July it approved a monoclonal antibody therapy to protect infants and toddlers who are at high risk for severe disease, and in August it ruled that one of the vaccines could be given to pregnant mothers in order to protect their newborns.

Here's what to know about the different options, who should get them and when.

Vaccines for adults

The two adult vaccines, which were created by Pfizer and GSK, are very similar, both in terms of how well they protect against symptomatic R.S.V. infection and in their side effects. They also work the same way biologically — targeting a protein the virus uses to fuse to human cells — and were developed based on the same decade-old scientific discovery, which is why they've emerged at the same time.

In clinical trials, the Pfizer vaccine, called Abrysvo, was 89 percent effective at preventing lower respiratory symptoms (such as cough, shortness of breath or wheezing) in the first R.S.V. season after vaccination, while the GSK vaccine, called Arexvy, was 83 percent effective. There weren't enough people in either trial to determine whether the vaccines also helped reduce hospitalizations and deaths, but experts anticipate that they will.

The vaccines were somewhat less effective at preventing disease in the second R.S.V. season after people received a shot. However, experts say that R.S.V. doesn't mutate in the same way that influenza and SARS-CoV-2 do, so there shouldn't be a need to update the vaccine or re-dose people every year.

"At least in terms of the more severe symptoms from the infection, it did not seem to diminish over the two-year period appreciably," said Dr. Edward Walsh, a professor of medicine at the University of Rochester Medical Center, who led the Pfizer clinical trial. "This would suggest that right now, we're probably looking at a vaccine that is not given any more frequently than every two years."

Out of the roughly 38,000 people who received either vaccine, 20 experienced atrial fibrillation and six developed neurological complications, including encephalomyelitis and Guillain-Barré syndrome, in the weeks after vaccination. More common side effects were fatigue, fever and muscle pain at the site of the injection.

Rather than recommend the vaccines outright to everyone 60 and older, the Centers for Disease Control and Prevention advised that people talk to their doctors when deciding whether to get the shot. They included this extra step in part because of the potential for these severe, albeit very rare, side effects.

It's about weighing the benefit versus the risk, said Dr. Tochi Iroku-Malize, the president of the American Academy of Family Physicians. She and the A.A.F.P. support the federal recommendation that older adults get the vaccine after consulting with "their physician to make sure that this is the right thing for them."

“Most adults who get infected with R.S.V. usually have mild or no symptoms,” she added. “But some adults may have more severe symptoms,” usually because they have an underlying condition such as chronic obstructive pulmonary disease, asthma, heart disease, diabetes, kidney disease or a compromised immune system. People with these conditions may benefit more from receiving the vaccine.

The vaccines will be available at doctors’ offices and some pharmacies, including Walgreens and CVS, this fall. R.S.V. season typically begins in October, and people are encouraged to get the shot before it starts. The R.S.V. vaccine is safe to get at the same time as the flu shot, Dr. Walsh said, but there isn’t available data yet on receiving it and the Covid vaccine simultaneously.

Monoclonal antibodies for infants

While vaccines teach the immune system to produce antibodies against a specific disease, monoclonal antibodies provide an infusion of prefabricated antibodies — but their protection is more temporary. For babies whose immune systems are still developing, that temporary immunity could make a big difference.

A new monoclonal antibody therapy developed by AstraZeneca, called nirsevimab, was approved earlier this year to protect infants against severe R.S.V. In a clinical trial, the drug was about 77 percent effective against both hospitalizations and cases of R.S.V. requiring a doctor’s visit. Side effects were mild, with a rash at the injection site being the most common.

The C.D.C. recommended that all infants who are less than 8 months old at the start of R.S.V. season receive nirsevimab. Children between the ages of 8 months and 19 months are also recommended to get the shot if they have an increased risk for severe disease. That includes not only children who are immunocompromised or have pre-existing lung conditions, but also American Indian and Alaska Native populations. Babies should be able to receive the monoclonal antibody therapy at their pediatrician’s office, and some hospitals may offer the shot to newborns delivered during R.S.V. season.

Dr. Ruth Karron, a pediatrician and professor of international health at the Johns Hopkins Bloomberg School of Public Health, said that she “completely concurs with” the C.D.C. recommendations. “R.S.V. is the No. 1 cause of hospitalization for children under a year of age,” she said. “I think it will make a profound difference in the health and well-being of children.”

Babies over 8 months old can also become ill with R.S.V., but “they’re far less likely to have to be in the hospital or far less likely to get severely ill,” said Dr. Coleen Cunningham, the chair of pediatrics at the University of California Irvine and pediatrician in chief of Children’s Hospital of Orange County.

That’s because the youngest infants’ airways “are just smaller, so any little bit of swelling in that airway has a bigger impact on how well they can breathe,” Dr. Cunningham said.

A vaccine for pregnant women

The F.D.A.’s final R.S.V.-related decision this year was to approve giving the Pfizer vaccine to pregnant women so they will pass on antibodies to their babies through the placenta.

A clinical trial found that, for mothers who were vaccinated between weeks 24 and 36 of their pregnancies, the shot was 82 percent effective at preventing severe disease in infants in the first three months after birth. That dropped to 69 percent protection six months after birth.

The most common side effects of the vaccine were muscle pain, headache and nausea. Cases of severe side effects were slightly higher in the vaccine group compared to the placebo group, including pre-eclampsia in the mothers and low birth weight and jaundice in the infants. Preterm birth was also more common, occurring in 5.7 percent of the vaccine recipients compared to 4.7 percent of the placebo recipients. The F.D.A. stated that it couldn’t “establish or exclude a causal relationship between preterm birth and Abrysvo,” but they advised that the vaccine be given to women between 32 and 36 weeks of pregnancy to minimize any potential risks.

Now that both the monoclonal antibodies and prenatal vaccine are approved, pediatricians and obstetricians will have to work together to recommend which patient should receive which treatment. Dr. Karron said that healthy babies should not receive both the vaccine and monoclonal antibodies, “not for safety reasons,” but because it would be “a waste of resources.”

Dana G. Smith is a reporter for the Well section, where she has written about everything from psychedelic therapy to exercise trends to Covid-19. More about Dana G. Smith

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