

Which COVID vaccines have full approval? When could we see vaccines for the youngest kids?

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COVID vaccines have been available to adults in the United States for more than a year, but there are still a lot of questions. Which vaccines

have received full approval? When will we see vaccines approved for children under the age of 5? And are there any new vaccines forthcoming?

To learn more, we talked with Julie Swann. Swann is a systems engineer with expertise in public health and issues related to [contagious disease](#). In 2009, she served at the Centers for Disease Control and Prevention as a science advisor for the H1N1 pandemic response. Swann is the department head and A. Doug Allison Distinguished Professor of the Fitts Department of Industrial and Systems Engineering at NC State.

The Abstract: When people started getting COVID-19 vaccines in the U.S., it was done under an emergency use authorization (EUA). Which vaccines have now received full approval?

Swann: This information is changing all the time. As of today, both Moderna and Pfizer vaccines have received full approval from the FDA (respectively, for age 18 and up, and ages 16 and up). Just recently, Pfizer has added a request for full approval for adolescents age 12 to 15. One can find this information on websites from the FDA, the CDC, or [news organizations](#), although it can be difficult to keep up with it.

TA: Does this mean that we have more data on how safe they are and how well they work?

Swann: We have a lot of data about the [vaccine safety](#) and effectiveness. Full approval (or, a Biologics License Application) has standards that are even higher than for emergency use, which already has requirements on safety, effectiveness, and manufacturing quality. The manufacturer submits additional data and analysis on potential safety events,

distribution of the product, and studies after the EUA authorization. The FDA also does its own analysis of the vaccine for safety and effectiveness. For the EUA, we already had data from tens of thousands of participants who had received the vaccine, and now we have had it for millions and millions of doses in the U.S. and beyond.

TA: Where do things stand regarding vaccine approval for really young kids?

Swann: The Pfizer vaccine was approved for children aged 5 to 11 in October 2021. Many parents and caregivers are really looking forward to being able to vaccinate their younger children also. The Pfizer request for children under age 5 is currently anticipated in early April. This delay allowed Pfizer to give young children in the trial a third dose to increase effectiveness of the vaccine. We have not seen significant safety issues, but it appears a third dose is needed to ensure sufficient protection. Parents will need to hold on a little while longer, but this should also provide additional evidence that thorough reviews are being conducted.

TA: I saw that there's a new COVID-19 vaccine called Novavax coming out. How does it differ from the vaccines that have already been in use, like Moderna, Pfizer or Johnson & Johnson?

Swann: At a high level, the Moderna, Pfizer and J&J vaccines are all giving instructions to our cells to produce one of the SARS-CoV-2 proteins, the spike protein. Our immune systems then learn to target that spike protein as foreign. When the SARS-CoV-2 virus hits us, the [immune system](#) is already prepared with the tools for defense. It attacks the spike protein and keeps you from getting sick, or at least from getting as sick as you would have if you weren't vaccinated.

The Novavax is similar to more traditional vaccines in its technology, but it works along similar lines as the described COVID-19 vaccines. The key difference is the Novavax vaccine is the SARS-CoV-2 [spike protein](#) itself, not the instructions for how to make it. It is just the protein—not a live or inactivated virus. The vaccine is relatively easy to distribute, because the cold chain requirements are not as strict as for the mRNA and adenovirus-vectored vaccines [such as the Moderna, Pfizer and J&J vaccines]. If someone is allergic to the mRNA vaccines, they may not be to the Novavax, as it does not contain polyethylene glycol [an ingredient used as a stabilizing agent in some COVID-19 vaccines]. It appears to be highly effective against all the variants we've seen [so far](#).

(As a side note, the Novavax vaccine is made using moth cells to generate the protein and [tree bark](#) for an ingredient to boost immune response. There are other vaccines based on particles derived from tobacco plants. Nature is an amazing thing, and I think we will find the work on vaccines over the last couple of years will allow science to solve problems that we couldn't before.)

TA: Are there any other COVID vaccines forthcoming?

Swann: Absolutely! Some new vaccines will try to compete by having a [lower price](#), while others may strive for a manufacturing and distribution system that scales worldwide, including in low-resource settings. There are also companies testing a vaccine in pill form and nasal sprays. [This graphic](#) by a media organization is an overall summary of vaccines in various stages. It can be hard to keep up with it all, especially since some vaccines have been tested and authorized in other countries that we are not using here. I am particularly interested in ones that can help make sure we vaccinate people around the globe, as in places like India there is still a long way to go. Longer term, researchers are trying to determine

whether a vaccine could prevent severe disease not only from multiple variants, but even different types of coronaviruses. I also expect some of the technology will also advance our understanding of preventing other diseases. We should keep in mind that there are a number of diseases that kill many children (malaria) or affect the ability of humans to successfully reproduce (Zika), or cause lifelong effects (some tick-borne diseases). The advances in [vaccine](#) technology could also move forward treatments for cancer.

Provided by North Carolina State University

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