

8 things physicians and patients need to know about the Pfizer vaccine

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Editor's note: *The FDA has granted full approval to the Pfizer-BioNTech COVID-19 vaccine for ages 16 and older. This is the first COVID-19 vaccine to receive full approval and will be marketed as Comirnaty. Learn more from a joint statement from the AMA, American Hospital Association and American Nurses Association that applauds FDA full approval of the Pfizer COVID-19 vaccine.*

The U.S. Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) to Pfizer-BioNTech's COVID-19 vaccine on Dec. 11. The vaccine is given in two doses that are 21 days apart from each other and is reported to be 95% effective at preventing COVID-19.

The authorization and distribution of the vaccine has raised a number of questions among physicians and the public. To help offset vaccine hesitancy, three AMA experts recently sat down to try and answer these questions during a two-part AMA COVID-19 Update. The panelists were:

- Sandra Fryhofer, MD, internal medicine physician, adjunct associate professor of medicine at Emory University School of Medicine, AMA Board of Trustees member, and AMA Liaison to the Advisory Council on Immunization Practices (ACIP)
- Shannon Curtis, assistant director, Federal Affairs for the AMA
- Marcus Plescia, MD, chief medical officer, Association of State and Territorial Health Officials (ASTHO), ASTHO Liaison to ACIP

The three discussed what physicians need to know about the Pfizer vaccine and how to counsel patients on vaccine allocation.

Pfizer's vaccine is the first mRNA vaccine that received EUA by the FDA. What is different about an mRNA vaccine?

Although mRNA vaccines — also known as messenger RNA vaccines — are now being approved for the first time, they have been a topic of study by researchers for decades. The difference between mRNA vaccines and more traditional ones comes down to what is contained within the vaccine.

“MRNA vaccines do not contain live virus, so they cannot cause an infection,” Dr. Fryhofer said. “They cannot give someone COVID. MRNA vaccines do not affect or interact with our own DNA in any way. The messenger RNA never enters the nucleus of the cell and it doesn't hang around. The body breaks it down with hours.”

What's different about an EUA compared with the normal vaccine approval process?

An EUA is different than approval of a vaccine. According to the FDA website, an EUA “is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies.” A product can receive EUA if it meets an effectiveness standard and an assessment of its benefit compared with its risk is favorable.

“It's very important that everybody knows that (EUA) is not necessarily cutting corners or short-cutting FDA's review,” Curtis said. “Really, we just cut out a little bit of the bureaucracy, some of the paperwork, and the time that it takes to do that instead of cutting any corners on the safety and efficacy or short-cutting the process.”

The FDA has been transparent in its review process and expects any manufacturer that receives EUA to continue its clinical trials and eventually pursue official FDA approval, Curtis said.

Pfizer's COVID-19 vaccine earns FDA nod. Here's what comes next.

If you've already had COVID-19 or received monoclonal antibodies, should you still get the vaccine?

Yes, said Dr. Fryhofer, although people who received monoclonal antibodies or convalescent serum should wait at least 90 days before getting the vaccine.

Should pregnant women get the vaccine?

Pregnant or lactating women may receive the vaccine if they choose, however, safety data is not known about this population at this time. A woman who is pregnant or lactating should consult with her physician about what is best for her and her baby.

Is there anyone who should not get the vaccine?

According to ACIP, people who have a history of allergic reactions to any vaccine should not get vaccinated at this time. Dr. Fryhofer said. There were no signs of allergic reactions during the Pfizer

trials, she said, but several people in the United Kingdom had severe allergic reactions to the vaccine earlier in the month.

Dr. Fryhofer also warned about getting the vaccine at the same time or soon after a flu shot.

“The COVID vaccine should not be given in combination with other vaccines right now,” she said. “The study protocol for these vaccines did not allow co-administration with other vaccines, so don't do it. We want this vaccine to do its best job.”

The Centers for Disease Control and Prevention (CDC) recommends at least a two-week window between getting Pfizer's COVID-19 vaccine and any other vaccine.

Are there any expected side effects to the vaccine?

As with any vaccine, patients may experience some side effects, and it is important for physicians to make sure their patients understand the side effects, which include pain or swelling at the site of the shot, as well as fever, chills, tiredness or headache.

“The symptoms are usually worse after the second dose, and they're usually worse in younger as compared to older patients,” Dr. Fryhofer said. “But you can think of these symptoms as a sign that the vaccine is working.”

What other information should physicians and patients know about the vaccine?

Dr. Plescia called the development of COVID-19 vaccine a wonder of science, but he also shared a reminder that the vaccine will not make COVID-19 disappear by itself.

“The vaccine is one tool in the toolkit that we have right now,” he said. “It's important that people continue to practice the social distancing interventions that we've had in place so far, particularly wearing a mask.”

What resources has the AMA created for physicians to get more information about COVID-19 vaccines?

The AMA has created a COVID-19 vaccine resource center that features an array of information relevant to physicians about the development and distribution of COVID-19 vaccines. The AMA also partnered with the CDC and FDA to provide a series of educational webinars that help explain the process of vaccine development and offer a deeper dive into the data to understand safety and efficacy results. These webinars are also available on the AMA COVID-19 vaccine resource center.