

COVID-19 VACCINE NEWS YOU CAN USE

December 8, 2020
Issue 1

New Perspective

The recent news about the COVID-19 vaccines has us excited about the future. We're looking forward to providing as much information about how this will impact our residents and team members. To keep you well informed, every couple days over the coming weeks, you can expect to receive an issue of Vaccine News You Can Use from us. We'll be sharing the latest vaccine news and updates, answering your questions, and dispelling myths and rumors about the vaccines. We'll also be sending around letters, videos, tips, and answers to frequently asked questions as we orchestrate vaccination for our residents and team members.

For this first issue, we want to take the opportunity to describe where the country is at in the vaccine timeline.

THE HEADLINE

Pfizer/BioNTech and Moderna vaccines are being evaluated for FDA approval on December 10 and December 17.

ANSWERING YOUR QUESTIONS

What's happened so far?

- February: Moderna and BioNTech begin developing a COVID-19 vaccine.
- March–May: Moderna and Pfizer/BioNTech began working on a Phase 1 trial of vaccines.
- May: Moderna and Pfizer/BioNTech launch a Phase 1/2 trial of vaccines.
- July: Moderna and Pfizer/BioNTech complete Phase 2 trials of the vaccines.
- August: Moderna and Pfizer/BioNTech begin Phase 3 trials of the vaccines.
- November: Preliminary data indicates the Moderna vaccine is 94.5% effective.
- November: Final data from clinical trials show the efficacy rate of the Moderna vaccine at 94.5% and the Pfizer/BioNTech vaccine at 95%.
- November 20: Pfizer requests an emergency use authorization (EUA) from the FDA.
- November 30: Moderna requests an emergency use authorization (EUA) from the FDA.

What's still to come?

- December 10: The FDA will review authorization of the Pfizer/BioNTech vaccine.
- December 17: The FDA will review authorization of the Moderna vaccine.
- December 31: Pfizer/BioNTech and Moderna expect to produce up to 60 million doses by the end of the year, and more than 1 billion doses in 2021. Each vaccinated person will require two doses.
- Spring 2021: Vaccines by Pfizer/BioNTech and Moderna (and other vaccine developers) are expected to reach large-scale distribution in the spring.

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What does EUA even mean?

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of vaccines pending full approval to prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives. A declaration of a public health emergency is required for an EUA.

Why is the FDA using emergency powers to approve a vaccine?

Such authorizations require less data and can be done more rapidly than full approvals. Since February, the FDA has used this power to authorize hundreds of COVID-19 tests and a few treatments. The director of the FDA center that oversees vaccines has vowed to insist on an emergency standard for a vaccine that is roughly equivalent to what's needed for a full licensure.

I'm concerned vaccines were made so fast. Have the vaccines been tested enough?

Developing messenger RNA vaccines like the Pfizer and Moderna candidates has been fast because scientists were able to start their work before there was a known case of the novel coronavirus in this country, using the viral genome shared online as a template. Making messenger RNA vaccines does not require time-consuming steps, such as growing ingredients in chicken eggs.

Clinical trials of COVID-19 vaccines must first show they are safe and effective before any vaccine can be authorized or approved for use. The known and potential benefits of a COVID-19 vaccine must outweigh the known and potential risks of the vaccine for use under what is known as an Emergency Use Authorization (EUA).

WHAT'S IN THE NEXT ISSUE

The next issue we send of Vaccine News You Can Use will answer the question "When will the vaccine be available?" by addressing:

- Who will get the vaccine first?
- Will there be enough vaccine for everyone?
- Should a person with COVID-19 get the vaccine?

If you have questions about Vaccine News You Can Use, please reach out to your executive director.