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CDC committee OKs COVID-19 vaccine, discusses guidance for clinicians

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Update 12/13/20: *CDC Director Robert R. Redfield, M.D., announced he has signed off on ACIP's recommendation. For the latest news on COVID-19, visithttps://www.aappublications.org/news/2020/01/28/coronavirus.*

Another national group of vaccine experts gave the green light to the first COVID-19 vaccine Saturday, and federal officials provided guidance for clinicians on vaccine administration, which could begin Monday.

The Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted 11-0 Saturday in favor of recommending Pfizer-BioNTech's COVID-19 vaccine for people ages 16 and older. The CDC director will consider the recommendation when making his own determination.

"This vaccine and future vaccines do provide a promise of a lot of progress in the future," ACIP member Beth P. Bell, M.D., M.P.H., said after the vote. "… I do believe the process we have used here in ACIP to reach this decision is transparent, is science-based, keeps equity in mind and it is, for this moment, the absolute best we can do."

The Pfizer-BioNTech vaccine is a messenger RNA (mRNA) vaccine. Clinical trials that included more than 40,000 participants showed it is 95% effective in preventing symptomatic COVID-19, and it did not present serious safety concerns. Some of the most common reactions were typical of an immune response, including injection site reactions, fatigue, headache, muscle pain, chills, joint pain and fever.

ACIP's vote comes as the number of infections in the U.S. since the start of the pandemic topped 15.8 million and deaths have surpassed 295,000, according to Johns Hopkins University. The vote followed months of discussion about issues around potential benefits and harms, feasibility, equity and resource use related to any potential vaccine.

ACIP's decision came one day after the Food and Drug Administration (FDA) issued an emergency use authorization (EUA) upon a recommendation from its own advisory group.

Clinical considerations

CDC experts on Saturday provided clinicians with extensive guidance on administering the vaccine, including to pregnant women.

Studies have found pregnant women are at increased risk of severe COVID-19 disease and adverse pregnancy outcomes, though overall risk is low. Pregnant women were excluded from clinical trials, so there are no safety data currently for this group.

The CDC recommends pregnant women discuss the risks and benefits of being vaccinated with their health care provider.

"Pregnant women and health care providers should consider the level of COVID-19 community transmission, her personal risk of contracting COVID-19, the risks of COVID-19 to her and potential risk to the fetus, the efficacy of vaccine, side effects of the vaccine, and the lack of data about vaccine use during pregnancy," said Sarah Mbaeyi, M.D., M.P.H., a medical officer with the CDC's National Center for Immunization and Respiratory Diseases.

Pregnant women who experience fever after vaccination should take acetaminophen, as fever has been associated with adverse pregnancy outcomes.

Data also are lacking regarding COVID-19 vaccines and breastfeeding.

"mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant," Dr. Mbaeyi said.

Additional CDC recommendations include:

- Give two doses of the vaccine 21 days apart with a four-day grace period. Doses do not need to be repeated if the period is longer.
- People who start the series with the Pfizer-BioNTech vaccine should complete the series with the same product. It is not interchangeable with other vaccines currently under review.
- Do not give the vaccine within 14 days of another vaccine.
- Offer the vaccine to people regardless of prior COVID-19 infection. If the person is currently infected, wait until recovery from acute illness and criteria have been met to discontinue isolation.
- Defer vaccination for 90 days for people who have received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
- Administer the vaccine to people with underlying conditions if they have no contraindications.
- Administer the vaccine to immunocompromised people without contraindications but counsel them about unknown safety and efficacy in this group and the potential for reduced immune responses to the vaccine.
- Counsel vaccine recipients about possible reactions and encourage them to complete both doses and to continue taking precautions, including wearing a face mask, keeping distance from others and washing their hands frequently.

The CDC has more details on this clinical guidance on its website at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html#contraindications-precautions and is holding a webinar about COVID-19 vaccine safety at 1 p.m. EST on Dec. 14. The webinars can be viewed at https://emergency.cdc.gov/coca/index.asp.

Contraindications and precautions

The CDC recommends individuals do not take the vaccine if they have had a severe allergic reaction to any component of the vaccine. For people with a history of severe allergic reaction to another vaccine or to an injectable medication, conduct a risk assessment when deciding whether to vaccinate. Appropriate medical treatment to manage an anaphylactic reaction must be available immediately for all patients. Vaccine providers should observe patients for 30 minutes if they have a history of anaphylaxis and 15 minutes if they do not. The CDC said it will continue to refine the language of this recommendation in the coming days to provide additional clarity and specificity.

Distribution

Every state and several major cities have created their own playbook for implementing a vaccination program.

The announcement late Friday granting the EUA for Pfizer's vaccine set into motion extensive coordination to ensure the first shipments arrive Monday at 145 predetermined sites, according to U.S. Army Gen. Gustav F. Perna, chief operating officer for Operation Warp Speed. Another 425 sites will receive their shipments Tuesday, followed by 66 sites Wednesday.

Once delivered to these sites, the vaccines will be paired with ancillary kits containing supplies to administer the vaccines, including needles, syringes and diluent.

"As I speak to you now, vaccines are being packaged with a lot of emphasis on quality assurance. To that end, tomorrow morning vaccines will start rolling from manufacturing to distribution hubs and then by Monday vaccines will be received," Gen. Perna said.

Calling the week ahead "monumental" in getting the first wave of doses delivered safely, Gen. Perna assured that a "steady cadence of delivery" can be expected in the following weeks.

He announced that distribution plans also are in development should Moderna's COVID-19 vaccine receive an EUA, a decision that could come within a week.

ACIP has recommended that health care workers and residents of long-term care facilities are vaccinated first while supplies are limited.

U.S. Department of Health and Human Services Secretary Alex M. Azar II, J.D., has said he expects about 20 million people could be vaccinated by the end of the year, which could grow to 100 million by the end of the first quarter of 2021. By the end of the second quarter, he expects enough vaccine will be available for anyone who wants it.

Resources

- Pfizer-BioNTech COVID-19 vaccine fact sheet for health care providers
- CDC guidance on COVID-19 vaccines for health care providers
- CDC toolkit for communicating with patients about COVID-19 vaccination
- AAP FAQ on COVID-19 vaccines
- AAP interim guidance on COVID-19