

Vaccine approval

What processes are in place to ensure vaccine safety and effectiveness?

Any vaccine candidate that is made available to the general public will first undergo safety and efficacy reviews by the Food and Drug Administration (FDA). The FDA, the agency responsible for regulation of medical products in the United States, will conduct a rigorous review of the safety and efficacy data collected by vaccine manufacturers throughout clinical trials conducted this year. Additionally, there are two primary committees that will review vaccine safety and efficacy:

The Food and Drug Administration's [Vaccines and Related Biological Products Advisory Committee](#) (VRBPAC), which provides advice to the Commissioner of the FDA and evaluates data concerning safety, effectiveness and appropriate use of vaccines, for which the FDA has regulatory responsibility.

The Centers for Disease Control and Prevention's [Advisory Committee on Immunization Practices](#) (ACIP), which provides advice and guidance to the Director of the CDC. ACIP provides recommendations on use of vaccines in the U.S. civilian population based on disease epidemiology, vaccine safety, vaccine efficacy and effectiveness, quality of evidence reviewed, economic analyses, and implementation issues.

The American Medical Association partnered with FDA for [two webinars](#) further outlining the vaccine development and FDA review process.

What information does FDA require of manufacturers to issue an “Emergency Use Authorization”?

Data and information needed to support the issuance of an Emergency Use Authorization (EUA) by FDA were outlined in guidance from FDA entitled “[Emergency Use Authorization for Vaccines to Prevent COVID-19 \(October 2020\)](#)”. The guidance discusses FDA’s current thinking regarding the circumstances under which the issuance of an EUA would be appropriate including the safety and efficacy data to support an EUA. Data to support an EUA request for an investigational COVID-19 vaccine that must be submitted to FDA include the following:

- Chemistry, manufacturing, and controls information
- Nonclinical data and information
- Clinical data and information
- Administrative and regulatory information

Are mRNA vaccines safe?

mRNA vaccines are being held to the same safety and effectiveness standards as all other types of vaccines in the United States. mRNA vaccines do not use the live virus that causes COVID-19 and they cannot give someone COVID-19. mRNA never enters the nucleus of the cell, which is where our genetic material (DNA) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions. The mRNA vaccines do not affect or interact with our DNA in any way.

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying mRNA vaccines for flu, Zika, rabies, and cytomegalovirus (CMV). As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine. Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells.

More [information on mRNA vaccines](#) is available from the CDC.

Vaccine allocation and distribution

Which populations will be prioritized to receive initial vaccine?

Final decisions are still being made about the allocation of initially available supplies of COVID-19 vaccines. These decisions will be partially informed by the proven efficacy of the vaccines coming out of Phase 3 trials. The CDC's Advisory Committee on Immunization Practices has [recommended](#) that health care personnel and long-term care facility residents be prioritized to receive vaccines in Phase 1a. Additional populations expected to be vaccinated later in Phase 1 include:

- Non-health care essential workers (i.e., food and agriculture, transportation, education, energy, police, firefighters, manufacturing, IT and communication, water and wastewater)
- Adults with underlying medical conditions that are risk factors for severe COVID-19 illness
- People 65 years of age or older

How will vaccine be allocated to jurisdictions and other entities (i.e., federal entities or tribal nations)?

Initial vaccine allocation to jurisdictions will happen on a pro rata basis according to the jurisdiction's population. Jurisdictions have provided the locations where initial vaccine doses will be shipped. After initial distribution, jurisdictions will order their weekly allocations. Jurisdictions will place orders on behalf of providers.

The following entities will receive a direct allocation of COVID-19 vaccine, outside of the jurisdiction's allocation:

- Federal Bureau of Prisons
- Department of Defense
- Department of State
- Veterans Health Administration
- Indian Health Service

Tribal Nations can opt to receive vaccine through their jurisdiction or through the Indian Health Service.

How can I determine my states plan for vaccine operations and distribution?

The Association of State and Territorial Health Officials has created a [compendium of state plans](#). The CDC has also posted the [executive summaries](#) of each jurisdiction's plan, to provide a general understanding of their strategy. Jurisdictions have provided the locations where initial vaccine doses will be shipped.

Vaccine administration

What do physicians need to do to be eligible to administer COVID-19 vaccines?

To receive and administer COVID-19 vaccine and ancillary supplies, vaccination providers must enroll in the federal government COVID-19 Vaccination Program, coordinated through their jurisdiction's immunization program, by signing and agreeing to conditions outlined in the CDC COVID-19 Vaccination Program Provider Agreement. CDC will make this agreement available to each jurisdiction's immunization program for use in conducting outreach and enrolling vaccination providers. Physicians should reach out to their state health department to enroll.

What vaccine storage and handling requirements do physicians need to be aware of?

COVID-19 vaccination providers should refer to the “EUA Fact Sheet for Healthcare Providers” and manufacturer information for detailed storage and handling information for each vaccine. Most vaccine products will be provided in a two-dose series, and some vaccine products will require special storage and handling (e.g., ultra-cold storage).

COVID-19 vaccine providers are required to:

- Store and handle COVID-19 vaccines under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with an EUA or vaccine package insert, manufacturer guidance, and CDC guidance.
- Monitor storage unit temperatures at all times, using equipment and practices that comply with guidance in the [CDC vaccine storage and handling toolkit](#).
- Comply with immunization program guidance for handling temperature excursions.
- Monitor and comply with COVID-19 vaccine expiration dates.
- Preserve all records related to COVID-19 vaccine management for a minimum of three years.
- Comply with federal instructions and timelines for disposing of COVID-19 vaccine and diluent, including unused doses.

What will be included in the vaccine ancillary supply kits?

Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators. Each kit that is centrally distributed by the CDC will include supplies needed to administer 100 doses of vaccine.

- Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider)
 - » 25-gauge, 1" (if vaccination indicated for pediatric population)
 - » 22–25-gauge, 1-1.5" (adult)
- Syringes, 105 per kit (ranging from 1–3 mL)
- Alcohol prep pads, 210 per kit
- Four surgical masks and two face shields for vaccinators per kit
- COVID-19 vaccination record cards for vaccine recipients, 100 per kit
- Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults)

If a COVID-19 vaccine that requires mixing with diluent is ordered and shipped from CDC’s centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment may be needed depending on vaccination provider site needs.

Note that early in the response, ultra-cold (–60°C to –80°C) vaccine (if authorized for use or approved) may be shipped directly from the manufacturer in 975-dose increment. For vaccines that are shipped directly from the manufacturer, a combined kit will be included. This combined kit will include administration supplies, mixing supplies, and vials of diluent to prepare the vaccine for use.

Is there training available for health care professionals on COVID-19 vaccine administration?

CDC is developing educational and [training](#) materials for health care professionals related to COVID-19 vaccine storage, handling and administration based on ACIP recommendations, the ACIP General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies.

Data reporting

What are the reporting requirements that physicians will need to comply with?

COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration, and use their best efforts to report administration data to the relevant system for the jurisdiction, i.e., Immunization Information System (IIS) as soon as practicable and no later than 72 hours after administration.

All COVID-19 vaccination providers must report COVID-19 vaccine inventory daily into VaccineFinder. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into VaccineFinder. If you have questions about the process for your jurisdiction, please contact your jurisdiction's immunization program.

For more information, see the CDC [COVID-19 Vaccination Provider Support page](#) for Data and Reporting.

Vaccine safety

What additional steps are being taken to ensure vaccine safety post-authorization?

After a vaccine is authorized or approved for use, numerous vaccine safety monitoring systems watch for adverse events. If an unexpected adverse event is identified, experts quickly study it further to assess whether it is a true safety concern. FDA, CDC and other federal partners will use established and new systems to monitor COVID-19 vaccines safety.

[VAERS](#) is a national early warning system to detect possible safety problems with vaccines. VAERS can identify "signals" that might indicate possible safety problems requiring additional investigation. COVID-19 vaccination providers are required to report the following to VAERS:

- Vaccine administration errors (whether associated with an adverse event or not)
- Serious adverse events (even if they are not sure if the vaccination caused the event)
- Multisystem inflammatory syndrome (MIS) in children or adults
- Cases of COVID-19 that result in hospitalization or death to VAERS

Physicians should encourage patients to participate in [V-SAFE](#). V-SAFE is a new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys to check in with vaccine recipients and will also provide telephone follow up to anyone who reports medically important adverse events.

If a link is found between a side effect and a COVID-19 vaccine, public health officials will take appropriate action by weighing the benefits of the vaccine against its risks to determine if recommendations for using the vaccine should change and continuously monitor and evaluate safety thereafter.

Building vaccine confidence

How can I best prepare to address patient questions about COVID-19 vaccines?

COVID-19 vaccines are new and questions from patients should be expected. Physicians are one of the most trusted sources of information for their patients on vaccines. Providing a strong recommendation is critical for vaccine acceptance. Physicians can share the importance of vaccines in protecting individual patient health as well as the health of loved ones or even discuss your personal plans as a health care professional to get vaccinated.

Examples:

- "I strongly recommend you get a COVID-19 vaccine once it is widely available..."
- "This vaccine is especially important for you because of your [job/underlying health condition]."
- "I believe in this vaccine so strongly that I plan to get it as soon as it is available."

The CDC has outlined [answers to common patient questions](#), and the AMA also offers a helpful patient-facing FAQ handout.