

## Vaccine authorization

---

### 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 Centers for Disease Control and Prevention (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 and CDC for [a series of webinars](#) further outlining the vaccine development and 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

### How does a vaccine go from “Authorized for emergency use” to “Licensed” (i.e., approved), and how long will that take?

The FDA has indicated that following submission of an EUA request and the issuance of an EUA, they expect vaccine manufacturers to continue to collect placebo-controlled data in any ongoing trials for as long as feasible to obtain additional safety and effectiveness information and work towards submission of a Biologics License Application (BLA) as soon as possible. Both Pfizer and Moderna have announced they plan to submit a BLA.

## 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

---

### 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.

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

### How can I determine my state's 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.

### When will vaccine be distributed to physician offices?

In April of 2021, the Biden administration issued guidance to states on [Expanding COVID-19 Vaccine Distribution to Primary Care Providers to Address Disparities in Immunization](#). The guidance encourages states to significantly increase allocation of vaccines to primary care providers. The guidance recommends that at least 60% of doses distributed to medical offices be allocated to those located in the most socially vulnerable communities in each jurisdiction. The AMA has been urging the administration to increase the vaccine distribution to physician offices and this is a good first step.

## 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 ( $-60^{\circ}\text{C}$  to  $-80^{\circ}\text{C}$ ) 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 Vaccines.gov. In some jurisdictions, providers may report vaccine inventory to the jurisdiction's IIS for the jurisdiction to upload into Vaccines.gov. 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

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.

## Clinical considerations

---

### What are the current clinical considerations for use of the J&J/Janssen vaccine given the risk of thrombosis with thrombocytopenia syndrome (TTS)?

There is a plausible causal relationship between J&J/Janssen COVID-19 vaccine and a rare and serious adverse event—blood clots with low platelets (thrombosis with thrombocytopenia syndrome, or TTS). However, after reviewing all available safety data, the CDC and FDA recommended resuming use of this vaccine in the United States given that the benefits outweigh the risks. See the updated [recommendations](#) from the ACIP.

### What are the symptoms of TTS?

TTS is rare, occurring at a rate of about 7 per 1 million vaccinated women between 18 and 49 years old. For women 50 years and older and men of all ages, this adverse event is even more rare. For three weeks after

receiving the vaccine, physicians and patients should be on the lookout for possible symptoms of a blood clot with low platelets. These include severe or persistent headaches or blurred vision, shortness of breath, chest pain, leg swelling, persistent abdominal pain or petechiae.

### **What is the appropriate clinical course of action if TTS is suspected in a patient following the J&J/Janssen COVID-19 vaccine?**

If TTS is suspected physicians should obtain platelet counts and screen for evidence of immune thrombotic thrombocytopenia. In patients with a thrombotic event and thrombocytopenia after the J&J/Janssen COVID-19 vaccine, evaluate initially with a screening PF4 enzyme-linked immunosorbent (ELISA) assay as would be performed for autoimmune heparin-induced thrombocytopenia (HIT). Consultation with a hematologist is strongly recommended. Patients with TTS following receipt of J&J/Janssen COVID-19 vaccine should not be treated with heparin, unless HIT testing is negative. If HIT testing is positive or unable to be performed, non-heparin anticoagulants and high-dose intravenous immune globulin should be strongly considered. Report adverse events to VAERS.

For more information see the CDC [Health Alert](#) and [guidance](#) from the American Society of Hematology.

### **What allergic reactions are a contraindication to vaccination for COVID-19?**

Contraindications to COVID-19 vaccines include severe allergic reaction after a previous dose or to a component of the COVID-19 vaccine or immediate allergic reaction of any severity to a previous dose or a known allergy to a component of the vaccine.

Polyethylene glycol (PEG) is an ingredient in mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in J&J/Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines have a precaution to J&J/Janssen COVID-19 vaccine, and vice versa. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with J&J/Janssen COVID-19 vaccine at least 28 days after the mRNA COVID-19 dose.

For people with these contraindications or precautions, referral to an allergist-immunologist should be considered. For more information see the CDC's [Interim Clinical Considerations](#) for COVID-19 vaccines.

### **What is the ACIP's position on the vaccination of pregnant or lactating people?**

Pregnant persons are eligible for and can receive a COVID-19 vaccine. A conversation between the patient and their clinical team, while not required, may assist with decisions about the use of a COVID-19 vaccine. Data on the safety of COVID-19 vaccines in pregnant people are limited. Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus. When making a decision, pregnant people and their physician should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the increased risks of severe COVID-19 to the patient and potential risks to the fetus, the known and potential benefits of vaccination, efficacy of the vaccine, side effects of the vaccine, and the limited but growing data about the safety of the vaccine during pregnancy.

Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are underway or planned. Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant. Early data from vaccine safety surveillance systems have not identified safety concerns for pregnant people who were vaccinated or for their babies. Most of the pregnancies in these systems are ongoing; additional follow-up is needed, particularly among those vaccinated in the first and second trimesters of pregnancy.

For more information, see the American College of Obstetricians and Gynecologists' [Practice Advisory](#) for vaccinating pregnant and lactating patients against COVID-19.

### **What is known about the risk of myocarditis in kids following mRNA vaccines?**

The Advisory Committee on Immunization Practices COVID-19 Vaccine Safety Technical (VaST) Work Group concluded that there are relatively few reports of myocarditis to date and the cases are occurring predominately

in adolescents and young adults; more often in males than females, more often following an individual's second dose, and typically within four days after vaccination. Most cases appear to be mild. Within CDC safety monitoring systems, rates of myocarditis reports in the window following COVID-19 vaccination have not differed from expected baseline rates. However, information is being collected and reviewed on potential myocarditis cases that were reported into VAERS.

For more information, see the CDC's [Clinical Considerations](#) for Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults.

## **What is the safety and efficacy of COVID-19 vaccines in immunocompromised patients?**

Immunocompromised people can receive COVID-19 vaccination. People with immunocompromising conditions or who take immunosuppressive medications [might be at increased risk for severe COVID-19](#). While no data are available to establish COVID-19 vaccine safety and efficacy in these groups, currently authorized COVID-19 vaccines are not live vaccines and therefore can be [safely administered to immunocompromised people](#).

Based on [general best practices for vaccination of immunocompromised people](#), ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccination series (i.e., two doses of an mRNA vaccine or a single dose of J&J/Janssen COVID-19 vaccine) in advance, people on immunosuppressive therapy can still receive COVID-19 vaccination.

People should be counseled about the potential for reduced immune responses and the need to continue to follow [current guidance](#) to protect themselves against COVID-19.

## **Can COVID-19 vaccines be co-administered with other vaccines?**

Data are not currently available for COVID-19 vaccines administered simultaneously with other vaccines. However, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone. As a result, the CDC has indicated that COVID-19 vaccines may be administered along with other vaccines without regard to timing. If multiple vaccines are administered in a single visit, each vaccine should be administered in a different injection site. The deltoid muscle can be used for more than one intramuscular injection.

## **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](#).