

COVID-19 vaccines FAQs: 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, Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) recommended resuming use of this vaccine in the United States given that the benefits outweigh the risks. Read the Advisory Committee on Immunization Practices's (ACIP) updated recommendations.

What are the symptoms of TTS?

TTS is rare, occurring at a rate of about seven cases per 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 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 the Vaccine Adverse Event Reporting System (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.
- Patient's personal risk of contracting COVID-19.
- Increased risks of severe COVID-19 to the patient and potential risks to the fetus.
- Known and potential benefits of vaccination, efficacy of the vaccine, side effects of the vaccine.
- 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 ACIP COVID-19 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 dose 2 and typically within 4 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.