Influenza Vaccine Recommendation
Covid-19 Vaccine Updates

Andrew Kroger M.D., M.P.H.

Medical Officer

Immunization Services Division

Adult Immunization Coalition

Commonwealth of Massachusetts

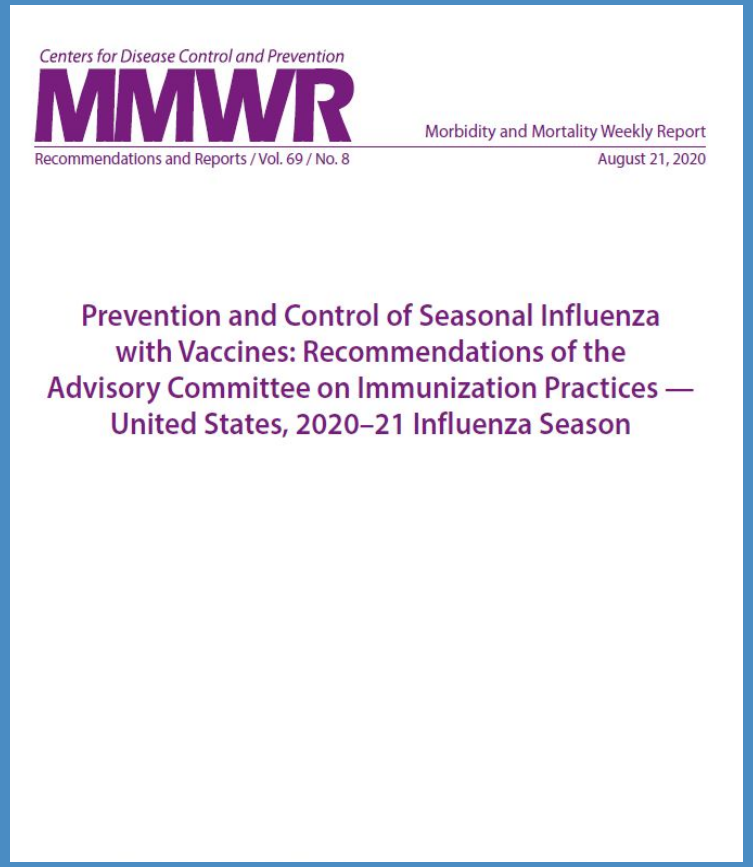
September 28, 2021

Speaker Disclosures

- The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Overview

- Influenza vaccination recommendations
- Covid-19 vaccination updates



Influenza Vaccination Recommendations

Revisions to the ACIP Influenza Vaccine Recommendations 2021-2022

- 2021-2022 strains
- Formulation information
- Timing of vaccination
- Contraindications and precautions - allergy

2021-2022 Strains

Egg-based Vaccine

- A/Cambodia/e0826360/2020 (H3N2-like)
- A/Victoria/2570/2019 (H1N1-like)
- B/Washington/2/2019 (Victoria)
- B/Phuket/3073/2013 (Yamagata)

Cell-culture and Recombinant Vaccine

- A/Cambodia/e0826360/2020 (H3N2-like)
- A/Wisconsin/588/2019 (H1N1-like)
- B/Washington/2/2019 (Victoria)
- B/Phuket/3073/2013 (Yamagata)

ACIP Influenza Vaccine Recommendations | CDC

Formulation Updates

- Flucelvax (ccIIV4) the cell culture inactivated vaccine

  - previously approved for persons 4 years old and older
  - now approved for persons 2 years old and older

ACIP Influenza Vaccine Recommendations | CDC

Timing of Influenza Vaccination

- Influenza vaccine usually becomes available in July.
- Optimal vaccination – vaccinated by the end of October
- Certain persons should be vaccinated earlier rather than later.
  - children, especially those requiring two doses of influenza vaccine in their first season of vaccination
  - persons who are in the third trimester of pregnancy
- Continue vaccinating throughout influenza season.

ACIP Influenza Vaccine Recommendations | CDC

Contraindications to Egg-based Influenza Vaccines

- History of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine (any valency) or to a previous (or prior) dose of any influenza vaccine (IIV, ccIIV, RIV, LAIV) (any valency).

ACIP Influenza Vaccine Recommendations | CDC

Contraindications to Cell-culture Influenza Vaccine

- History of severe allergic reaction (e.g. anaphylaxis) to a previous (or prior) dose of any cell-culture vaccine (any valency) or any component of **cell-culture vaccine** (any valency).

ACIP Influenza Vaccine Recommendations | CDC

Contraindications to Recombinant Influenza Vaccine

- History of severe allergic reaction (e.g. anaphylaxis) to a previous (or prior) dose of any recombinant influenza vaccine (any valency) or any component of **recombinant influenza vaccine** (any valency).

ACIP Influenza Vaccine Recommendations | CDC

Contraindications to Live-attenuated Influenza Vaccine

- History of severe allergic reactions (e.g. anaphylaxis) to any component of the vaccine (any valency) or to a previous (or prior) dose of any influenza vaccine (any valency)
- Concomitant aspirin or salicylate-containing therapy in children and adolescents
- Being a child age 2-4 years and have received a diagnosis of asthma or whose parents or caregivers report that a health care provider has told them during the preceding 12 months that their child had wheezing or asthma or whose medical record indicates a wheezing episode has occurred during the preceding 12 months
- Altered immunocompetence
- Anatomic and functional asplenia (e.g. sickle cell disease)
- Close contacts and caregivers of persons requiring care in a protected environment
- Pregnancy
- CSF leak
- Receipt of influenza antiviral medications within the previous 48 hours (oseltamivir/zanamivir), 5 days (peramivir), 17 days (baloxavir)

ACIP Influenza Vaccine Recommendations | CDC

Precautions to Egg-based Influenza Vaccines

- Moderate or severe acute illness with or without fever
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine

ACIP Influenza Vaccine Recommendations | CDC

Precautions to Cell-culture Influenza Vaccine

- Moderate or severe acute illness with or without fever
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
- **History of severe allergic reaction to a previous (a prior) dose of any other influenza vaccine (IIV, RIV, or LAIV) (any valency)**

ACIP Influenza Vaccine Recommendations | CDC

Precautions to Recombinant Influenza Vaccine

- Moderate or severe acute illness with or without fever
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
- **History of severe allergic reaction to a previous (a prior) dose of any other influenza vaccine (IIV, ccIIV, or LAIV) (any valency)**

ACIP Influenza Vaccine Recommendations | CDC

Precautions to Live-attenuated Influenza Vaccine

- Moderate or severe acute illness with or without fever
- History of Guillain-Barré syndrome within 6 weeks of receipt of influenza vaccine
- **Asthma in persons 5 years old and older**
- **Other underlying medical conditions that might predispose to complications after wild-type influenza infection (e.g. chronic pulmonary, cardiovascular [except isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])**

ACIP Influenza Vaccine Recommendations | CDC

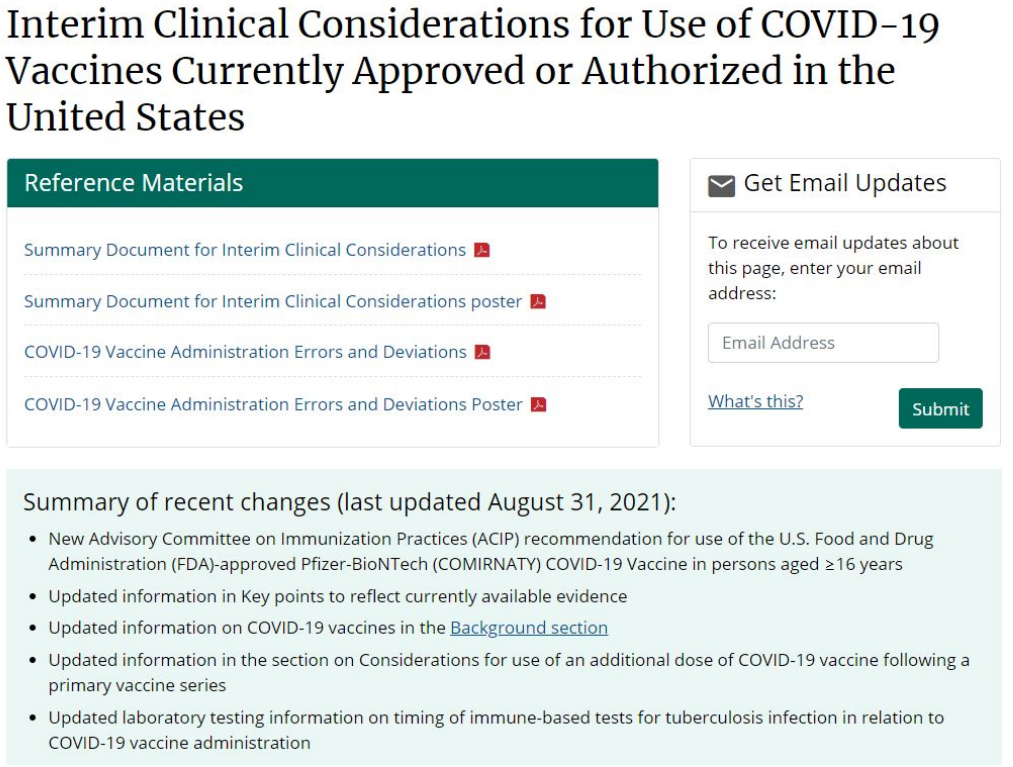
Covid-19 Vaccine Updates

Key Points: Interim Clinical Considerations for COVID-19 Vaccines

- COVID-19 vaccination is recommended for all people 12 years old and older
- Recommendations apply to the use of

  - Food and Drug Administration (FDA)-approved Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine in persons aged ≥16 years

  - Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines under the FDA's Emergency Use Authorization (EUA)
- Guidance may change as further information becomes available


Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States

Reference Materials

Summary Document for Interim Clinical Considerations

Summary Document for Interim Clinical Considerations poster

COVID-19 Vaccine Administration Errors and Deviations

COVID-19 Vaccine Administration Errors and Deviations Poster

Get Email Updates

To receive email updates about this page, enter your email address:

Email Address

What's this?

Submit

Summary of recent changes (last updated August 31, 2021):

- New Advisory Committee on Immunization Practices (ACIP) recommendation for use of the U.S. Food and Drug Administration (FDA)-approved Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine in persons aged ≥16 years
- Updated information in Key points to reflect currently available evidence
- Updated information on COVID-19 vaccines in the Background section
- Updated information in the section on Considerations for use of an additional dose of COVID-19 vaccine following a primary vaccine series
- Updated laboratory testing information on timing of immune-based tests for tuberculosis infection in relation to COVID-19 vaccine administration

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Key Messages

- COVID-19 vaccination is recommended for everyone 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States.
- COVID-19 vaccines currently approved or authorized by FDA **are highly effective in preventing serious outcomes of COVID-19, including hospitalization and death.**
- Available evidence indicates that these vaccines offer protection against known variants, including the Delta variant (B.1.617.2), particularly against hospitalization and death. The Delta variant, currently the predominant SARS-CoV-2 variant in the United States, is associated with increased transmissibility.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.

Dosing and Administration

	Pfizer-BioNTech	Moderna	Janssen
FDA-approved age groups	≥ 16 years		
FDA-authorized age groups	≥ 12-15 years	≥ 18 years	≥ 18 years
Number of doses in series	2 doses	2 doses	1 dose
Interval between 1st and 2nd doses*	3 weeks	1 month	NA
Dose volume	0.3 ml	0.5 ml	0.5 ml
Route	Intramuscular	Intramuscular	Intramuscular

*The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, individuals who receive the second dose up to 4 days before or at any time after the recommended date can be considered fully vaccinated.

Considerations for Use of an Additional mRNA COVID-19 Vaccine Dose After an Initial 2-dose COVID-19 mRNA Vaccine Series for Immunocompromised People

- People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 illness.
- For people with moderate to severe immune compromise due to a medical condition or immunosuppressive treatment, the potential to increase immune response coupled with an acceptable safety profile supports use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in this population.

Fully Vaccinated People

- People are considered fully vaccinated against COVID-19
  - ≥2 weeks after receipt of the 2nd dose in a 2-dose series (Pfizer-BioNTech, Moderna)
  - ≥2 weeks after receipt of the single dose of the Janssen vaccine
- People who have a contraindication to vaccination or who otherwise do not complete a vaccination series are **not** considered fully vaccinated.
- CDC has developed public health recommendations for fully vaccinated people.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html#_ednref1

Coadministration with Other Vaccines

- COVID-19 vaccines and other vaccines **may be administered without regard to timing***
  - includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, or at any interval.
  - it is not known if the reactogenicity of COVID-19 vaccines is increased with coadministration, including with vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines.

- Coadministration considerations
  - patient is behind or at risk of becoming behind on recommended vaccines
  - patient's risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposure)
  - reactogenicity profile of the vaccines

- Extensive experience with non-COVID-19 vaccines indicates immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone

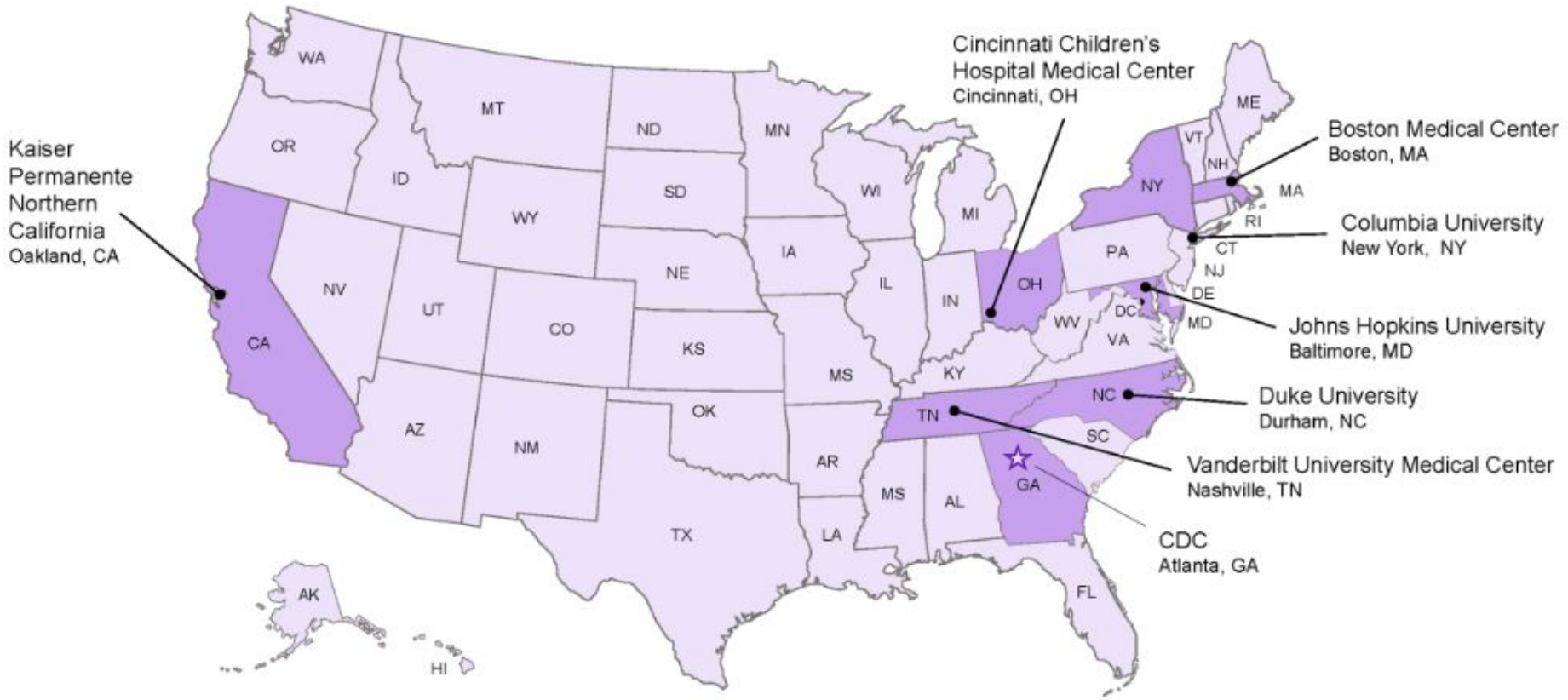
*Best practices for multiple injections can be found at: https://www.cdc.gov/vaccines/hcp/admin/administer-vaccines.html

Best Practices for Coadministration of Vaccines

- **If multiple vaccines are administered at a single visit, administer each injection in a different injection site.** For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection administered at different sites in the muscle.
- Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
- Separate injection sites by 1 inch or more, if possible.
- **Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing, HD-influenza vaccine, and adjuvanted vaccines) in different limbs, if possible.**

CISA

Clinical Immunization Safety Assessment (CISA) Project



- clinical consult services†
- enhanced surveillance
- clinical research

7 participating medical research centers with vaccine safety experts

†More information about clinical consults available at http://www.cdc.gov/vaccinesafety/Activities/CISA.html

CISA Research Study on Safety of Simultaneous COVID-19 and Influenza Vaccination

- Randomized clinical trial (goal to enroll 450 participants)
- Designed to assess simultaneous vs sequential receipt of mRNA COVID-19 vaccine and quadrivalent inactivated influenza vaccine (IIV4)
- Sites:
  - Duke University (Lead)
  - Johns Hopkins University
  - Cincinnati Children's Hospital Medical Center
- Study funded, currently protocol under IRB review
- Study will be registered on ClinicalTrials.gov

Myocarditis and Pericarditis after Vaccination with mRNA COVID-19 Vaccines

- Myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart) have occurred in some people following receipt of mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna).
  - cases have occurred predominantly in males aged <30 years
  - symptoms typically developed within a few days after receipt of the 2nd dose of vaccine

- Mechanisms that cause myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine are not well understood.

- Clinicians should consult the current clinical guidance for information on the evaluation and management of myocarditis or pericarditis and report all cases of myocarditis or pericarditis after COVID-19 vaccination to VAERS.

Considerations for Use of mRNA COVID-19 Vaccines in People with a History of Myocarditis or Pericarditis (1)

*People who develop myocarditis or pericarditis **after** receipt of the first dose of an mRNA COVID-19 vaccine but **before** administration of the second dose*

- Unclear if there is increased risk of further adverse cardiac effects following a second dose
- Until additional safety data are available, defer receiving the second dose.
- Can consider administration of a second dose in certain circumstances
  - personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - level of COVID-19 community transmission and personal risk of infection
  - availability of additional data on
    - risk of myocarditis or pericarditis following an occurrence of either condition after a first dose
    - long-term outcomes of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine
  - timing of any immunomodulatory therapies[1]

[1]ACIP's general best practice guidelines for immunization can be consulted for more information.

Considerations for Use of mRNA COVID-19 Vaccines in People with a History of Myocarditis or Pericarditis (2)

People who choose to receive a second dose of an mRNA COVID-19 vaccine following an occurrence of myocarditis or pericarditis after receipt of the first dose should

- Wait at least until episode of myocarditis or pericarditis has completely resolved:
  - resolution of symptoms attributed to myocarditis or pericarditis
  - no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to completely assess cardiac recovery
- Decisions about proceeding with vaccination should include a conversation between the patient, their parent, guardian, or caregiver (as relevant), and their clinical team
- Clinicians should consult current clinical guidance for information on the evaluation and management of myocarditis

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

Considerations for Use of mRNA COVID-19 Vaccines in People with a History of Myocarditis or Pericarditis (3)

*People with a history of myocarditis or pericarditis **prior to** COVID-19 vaccination*

- May receive any FDA-approved or FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - resolution of symptoms attributed to myocarditis or pericarditis
  - no evidence of ongoing heart inflammation or sequelae as determined by the person's clinical team, which may include a cardiologist, and special testing to completely assess cardiac recovery

Guillain-Barré Syndrome after Vaccination with Janssen COVID-19 Vaccine

- Guillain-Barré syndrome (GBS) is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis.
- Reports of adverse events following use of Janssen COVID-19 vaccine under EUA suggest an increased risk of GBS during the 42 days following vaccination.
- No increased risk of GBS identified with mRNA vaccines during use under EUA.
- ACIP's general best practices for immunization do not include a history of GBS as a contraindication to vaccination; it is a precaution for influenza vaccines and tetanus-toxoid containing vaccines in limited situations[1]

[1]In a post-marketing observational study of people vaccinated with Shingrix (for prevention of herpes zoster [shingles]), ~3-6 excess GBS cases per 1 million doses administered to persons ≥65 years in the 6 weeks after vaccination were observed. Although a causal relationship has not been established, FDA added a new warning about GBS in the Prescribing Information for Shingrix on March 24, 2021.

Thrombosis with Thrombocytopenia Syndrome (TTS) after Vaccination with Janssen COVID-19 Vaccine

- TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin
  - Most people with TTS after Janssen COVID-19 vaccination had clots in cerebral venous sinuses
  - Clots occurred in other unusual locations (e.g., portal vein, splenic vein) as well as a combination of venous and arterial thromboses
- Highest rates of TTS per vaccine doses administered are in women <50 years of age
- Clinicians can consult the Health Alert Network (HAN) notification published on April 13, 2021, and guidance from the American Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS.

https://emergency.cdc.gov/han/2021/han00442.asp
https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

Considerations for Use of Janssen COVID-19 Vaccine in Certain Populations

- Woman aged <50 years
  - can receive any FDA-approved or FDA-authorized COVID-19 vaccine.
  - should be made aware of the rare risk of TTS after the Janssen vaccine[1] and availability of other COVID-19 vaccines (i.e., mRNA vaccines).

- People with prior episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as heparin-induced thrombocytopenia (HIT)[2]
  - should be offered another FDA-approved or FDA-authorized COVID-19 vaccine (i.e., mRNA vaccine) if it has been ≤90 days since their illness resolved; after 90 days, patients may be vaccinated with any FDA-approved or FDA-authorized COVID-19 vaccine.

[1]The highest rates of TTS per vaccine doses administered were identified in women <50 years of age

[2]Although the etiology of TTS associated with the Janssen COVID-19 vaccine is unclear, it appears to be similar to HIT.

Considerations for Use of Janssen COVID-19 Vaccine in Certain Populations (Continued)

- People with risk factors for venous thromboembolism (VTE)[1]
  - unlikely to be at increased risk for TTS because the biologic mechanisms for VTE (as well as arterial thrombi) differ from the immune-mediated mechanism for HIT
  - can receive any FDA-approved or authorized vaccine, including Janssen COVID-19 vaccine.

- People who are pregnant, in the postpartum period, or take certain hormonal contraceptives
  - have an increased risk for VTE; experts believe these factors do not make people more susceptible to TTS after receipt of Janssen COVID-19 vaccine.
  - can receive any FDA-approved or authorized vaccine, including Janssen COVID-19 vaccine.

- Use of aspirin or anticoagulants
  - people should not take aspirin or an anticoagulant before vaccination with Janssen COVID-19 vaccine (or any other FDA-approved or FDA-authorized COVID-19 vaccine) unless these drugs are part of their routine medications..

[1]Risk factors for VTE include inherited or acquired thrombophilia or a prior history of other types of thromboses (including cerebral venous sinus thrombosis not associated with thrombocytopenia)

Contraindications to COVID-19 Vaccination

- Contraindications to vaccination with COVID-19 vaccines
  - severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
  - immediate allergic reaction* of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

- People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).
  - people with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa.
  - known polysorbate allergy is no longer a contraindication to mRNA vaccination but is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

*Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

Precautions to COVID-19 Vaccines

- Precaution to vaccination with COVID-19 vaccines
  - a history of an immediate allergic reaction to any other vaccine or injectable therapy*
- Most people deemed to have a precaution to a COVID-19 vaccine at the time of their vaccination appointment can and should be administered vaccine.
- People with a contraindication to one type of currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector)
  - consultation with an allergist-immunologist or the Clinical Immunization Safety Assessment COVIDvax should be considered because of potential cross-reactive hypersensitivity between COVID-19 vaccines.
  - vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

*People with a history of an immediate reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine even if it is unknown which component elicited the allergic reaction.

Potential Cross-reactive Hypersensitivity Between COVID-19 Vaccines: Polyethylene Glycol and Polysorbate

- Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines
- Polysorbate 80 is an ingredient in Janssen COVID-19 vaccine
- PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

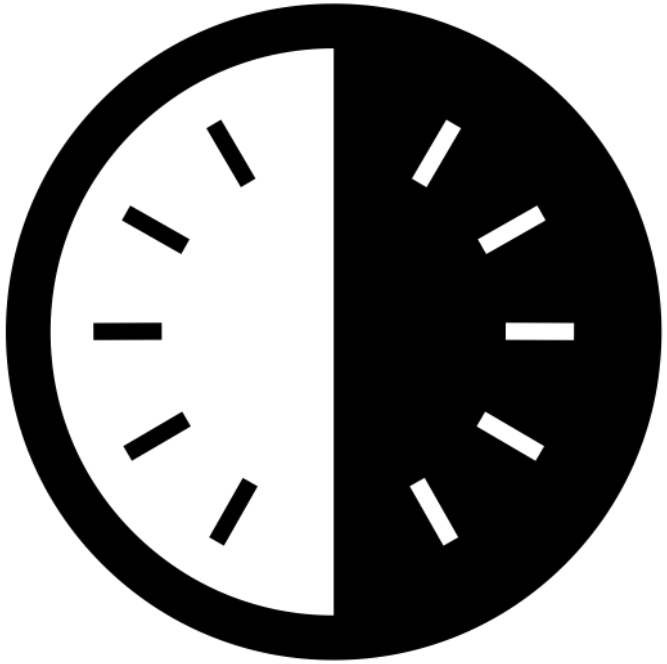
Post-vaccination Symptoms

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms.
- Although symptoms vary by vaccine product, age group, and dose, in general:
  - **local** (e.g., pain or swelling at injection site; swollen lymph nodes on same side as vaccinated arm) or **systemic** reactions (e.g., fever, fatigue, muscle aches, headache, chills) are frequent during the 7 days after vaccination.
  - most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-3 days of onset.
  - more frequent and severe following the second dose and among younger age groups.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html
https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html
https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/reactogenicity.html

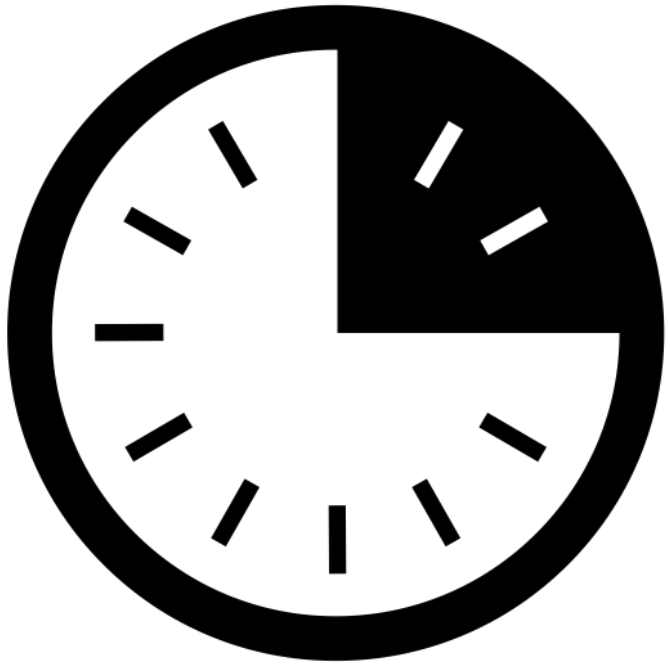
Observation Period Following Vaccination

- History of immediate allergic reaction to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis due to any cause



30 minutes

All other people



15 minutes

Triage of People Presenting for COVID-19 Vaccination

CONTRAINDICATION TO VACCINATION

History of the following:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine†
- Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†

Actions

- Do not vaccinate.
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative.†

PRECAUTION TO VACCINATION

Among people without a contraindication, a history of:

- Any immediate allergic reaction* to other vaccines or injectable therapies‡

Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#

Actions

- Risk assessment
- Consider referral to allergist-immunologist
- 30-minute observation period if vaccinated

Severe or moderate acute illness

MAY PROCEED WITH VACCINATION

Among people without a contraindication or precaution, a history of:

- Allergy to oral medications (including the oral equivalent of an injectable medication)
- History of food, pet, insect, venom, environmental, latex, etc., allergies
- Family history of allergies

Actions

- 30-minute observation period: People with a history of anaphylaxis (due to any cause)
- 15-minute observation period: All other people

† See Appendix C for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

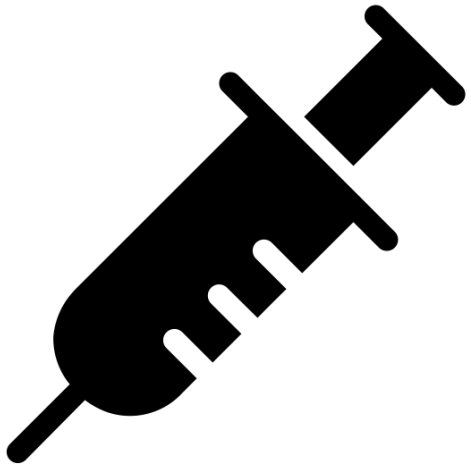
‡People with a history of an immediate reaction to a vaccine or injectable therapy that contains multiple components, one or more of which is a component of a COVID-19 vaccine, have a precaution to vaccination with that COVID-19 vaccine even if it is unknown which component elicited the allergic reaction.

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in 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 (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Early recognition of anaphylaxis symptoms

Prompt treatment with epinephrine



Activation of emergency medical services

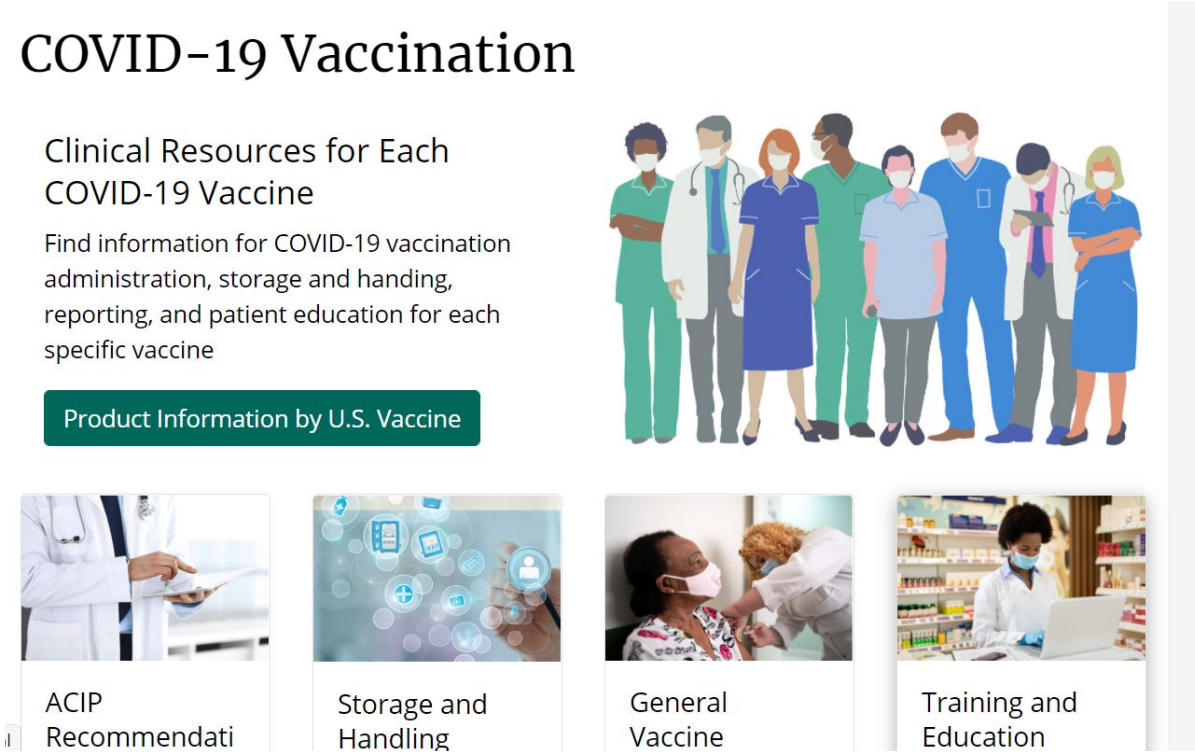
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

Additional Resources

CDC Resources

Learn more with **CDC's COVID-19 vaccine tools and resources.** Find information for COVID-19 vaccination administration, storage, reporting, patient education, and more.

- COVID-19 vaccination: [COVID-19 Vaccination Clinical and Professional Resources | CDC]



CDC COVID-19 Vaccine Clinical Trainings and Materials

Training and Education

Importance of trained healthcare professionals

A large number of healthcare professionals are needed to support COVID-19 vaccination efforts nationwide. These healthcare professionals are essential to ensuring the American population is vaccinated safely as soon as possible. They play critical roles in proper vaccine storage, handling, preparation, and administration, and they must be prepared to respond to vaccine recipients' questions and concerns. It is important these healthcare professionals receive the training needed to effectively meet the demands of their roles. Training must be ongoing as new COVID-19 vaccines become available and as vaccine recommendations evolve when we learn more about the vaccines and how to improve the vaccination process.

- Who needs to be trained +
- Training recommendations +

Training Required by Professional Qualification

Find the training and core competencies you will need by clicking on your professional qualification below:

- Healthcare professionals who have administered vaccine in the last 12 months
- Healthcare professionals or retired (past 5 years) physicians, nurses, or practical nurses who are licensed/previously licensed to administer COVID-19 vaccine but have not done so in the last 12 months

Pfizer-BioNTech COVID-19 Vaccine

Español

Summary of Recent Changes and Updates

Webpage content and individual PDFs are updated when there's new guidance concerning the Pfizer-BioNTech COVID-19 Vaccine. Expand each section below to see a summary of new and updated items.

- General Information Updates +
- Preparation and Administration Information Updates +
- Storage and Handling Information Updates +

Training and Education for COVID-19 Vaccination | CDC
Administration Overview for Pfizer-BioNTech COVID-19 Vaccine | CDC
Administration Overview for Moderna COVID-19 Vaccine | CDC
Administration Overview for Johnson & Johnson's Janssen COVID-19 Vaccine | CDC

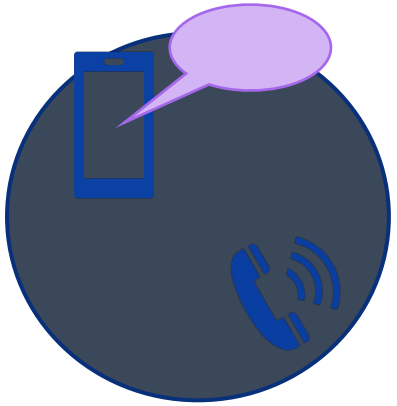
Reporting of Vaccine Adverse Events

- Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS* .
- FDA requires vaccination providers to report the following that occur after COVID-19 vaccination under EUA
  - vaccine administration errors
  - serious adverse events
  - cases of Multisystem Inflammatory Syndrome
  - cases of COVID-19 that result in hospitalization or death
- Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event.

*Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal or by calling 1-800-822-7967

Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety.
  - uses text messaging and web surveys to check in with vaccine recipients after vaccination
  - participants can report any side effects or health problems after COVID-19 vaccination.
  - parents/guardians can enroll adolescents (ages ≥12 years) in v-safe and complete health check-ins on their behalf
  - includes active telephone follow-up by CDC for reports of significant health impact

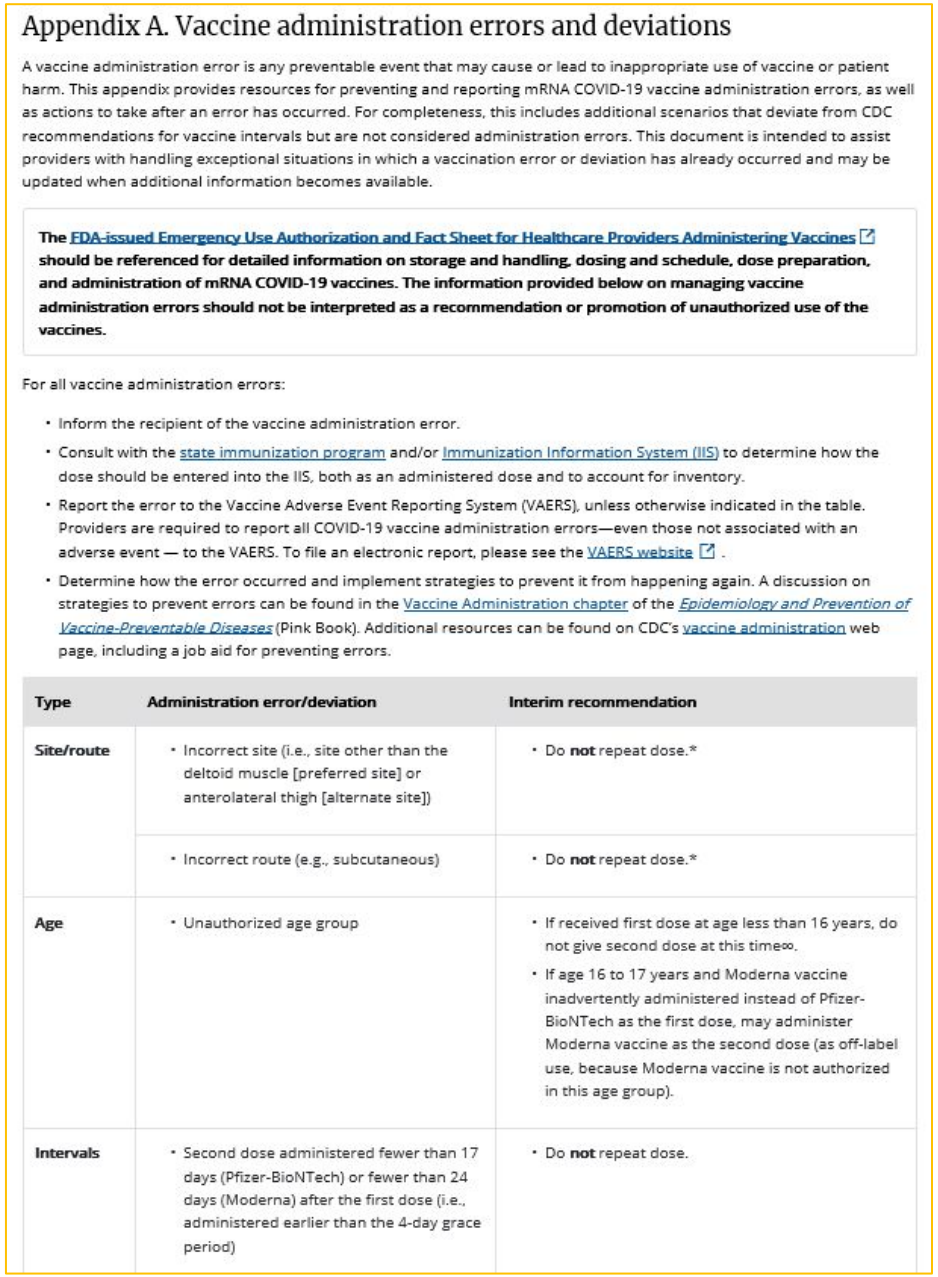


- **V-safe COVID-19 Vaccine Pregnancy Registry** collects additional health information from v-safe participants who report being pregnant at the time of vaccination or a positive pregnancy test after vaccination.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Appendix A:

How to manage vaccine administration errors and deviations



Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This appendix provides resources for preventing and reporting mRNA COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, this includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors. This document is intended to assist providers with handling exceptional situations in which a vaccination error or deviation has already occurred and may be updated when additional information becomes available.

The FDA-issued Emergency Use Authorization and Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of mRNA COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or Immunization Information System (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event — to the VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the Vaccine Administration chapter of the *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.*
	• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose.*
Age	• Unauthorized age group	• If received first dose at age less than 16 years, do not give second dose at this time∞. • If age 16 to 17 years and Moderna vaccine inadvertently administered instead of Pfizer-BioNTech as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group).
Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A

Thank You

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.