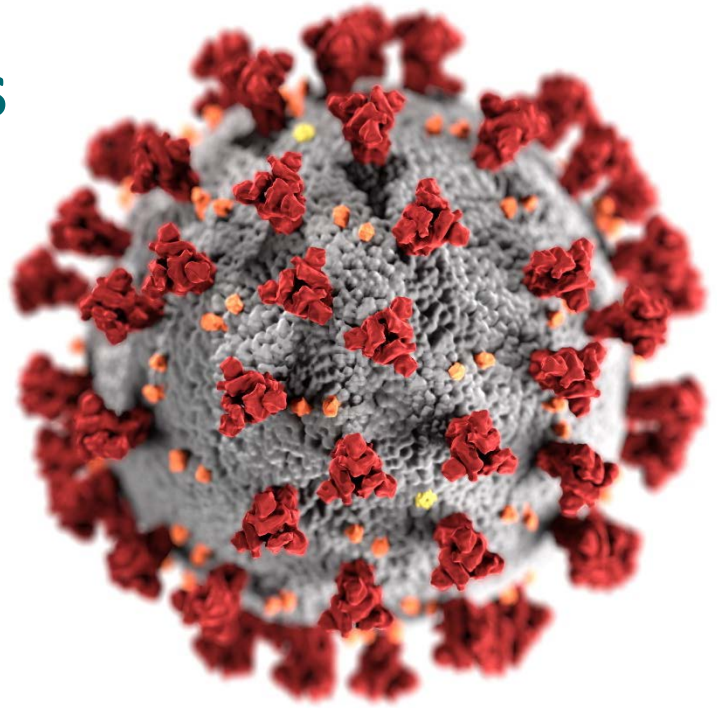
Interim Clinical Considerations for COVID-19 Vaccine in Children Ages 5–11 Years



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cdc.gov/coronavirus

Outline of Presentation

- The Pfizer-BioNTech COVID-19 Vaccine for children ages 5–11 years
  - Formulation and dosing
- Vaccine recipients
  - Underlying medical conditions
  - Prior SARS-CoV-2 infection
  - Children with a history of MIS-C
- Patient and parent/guardian counseling
- Vaccine administration
  - Coadministration
  - Administration errors

Pfizer-BioNTech COVID-19 Vaccine Formulation and Dosing in Children Ages 5–11 years

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Age group	12 years and older	5-11 years
Vial cap color		
Dose (mRNA concentration)	30 ug	10 ug
Injection volume	0.3 mL	0.2 mL
Fill Volume (before dilution)	0.45 mL	1.3 mL
Amount of Diluent* Needed per vial	1.8 mL	1.3 mL
Doses per Vial	6 (after dilution)	10 (after dilution)

*Diluent: 0.9% sterile Sodium Chloride Injection, USP (non-bacteriostatic; DO NOT USE OTHER DILUENTS)
Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Storage conditions		
Ultralow temperature freezer (-90°C to -60°C)	9 months	6 months
Freezer (-25°C to -15°C)	2 weeks	N/A
Refrigerator (2°C to 8°C)	1 month	10 weeks

Modified from https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf

Formulation and Dosing for Pfizer-BioNTech COVID-19 Vaccines

	Formulation for ≥12-year-olds (purple cap)	Formulation for 5–11-year-olds (orange cap)
Number of doses	2	2
Interval	3 weeks (21 days)	3 weeks (21 days)
Additional primary dose	Moderate and severe immunocompromise	Not recommended
Booster dose	Not recommended 12–17 years	Not recommended
	Recommended for certain groups ≥18 years*	

*Individuals 65 years and older or individuals ages 18 years and older who live in long-term care settings, have underying medical conditions, or who work or live in high-risk settings. Mbaeyi S, Oliver SE, Collins JP, et al. The Advisory Committee on Immunization Practices' Interim Recommendations for Additional Primary and Booster Doses of COVID-19 Vaccines — United States, 2021. MMWR Morb Mortal Wkly Rep. ePub: 29 October 2021

Vaccine Dosage

- **Children should receive the age-appropriate vaccine formulation regardless of their size or weight**.
  - As opposed to many medications, vaccine dosages are based on age and not size or weight.

- The dosage should be based on the child's age on the day of vaccination.
  - If a child turns from 11 to 12 years of age in between their first and second dose and receives 5–11 years 10 µg (orange cap) for their second dose, they do not need to repeat the dose and this is not considered an error per the EUA.

Vaccine Recipients

Underlying Medical Conditions

- Children with underlying medical conditions may be at increased risk for severe illness from COVID-19[1], however, severe COVID-19 can occur in children with and without underlying medical conditions.

- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, **regardless of underlying medical conditions**.

[1]https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html#ChildrenAndTeens
[2]https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Current or Prior SARS-CoV-2 Infection

- People with known current SARS-CoV-2 infection should defer vaccination at least until the person has recovered from the acute illness (if the person had symptoms) AND they have met criteria to discontinue isolation[1].
  - Isolation and precautions can typically be discontinued 10 days after positive test if asymptomatic or 10 days after symptom onset and after resolution of fever for at least 24 hours)

- Serologic testing to assess for prior infection is **not** recommended for the purpose of vaccine decision-making[2].

[1] https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html
[2]https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Prior SARS-CoV-2 Infection

- COVID-19 primary vaccination would be recommended for everyone ages 5 years and older, **regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection or seropositivity**.

- **>7 million** adolescents ages 12–15 years have been fully vaccinated with Pfizer-BioNTech COVID-19 Vaccine in the United States[1] and in the general population there has been no safety concerns associated with vaccination of those who had prior infection.

[1]https://covid.cdc.gov/covid-data-tracker/#vaccination-demographic

Prior SARS-CoV-2 Infection

Data from clinical trials in children ages 5–11 years indicate that the Pfizer-BioNTech COVID-19 Vaccine **can be given safely** to those with evidence of a prior SARS-CoV-2 infection.

Current evidence suggests that protection from reinfection is high after initial infection but decreases with time due to **waning immunity**.

Substantial **heterogeneity** exists in individual immune response to infection, and in adults, asymptomatic infection leads to **lower antibody levels**.

Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection **increases protection** from subsequent infection, including in the setting of more infectious variants.

Dan 2021, Science: https://doi.org/10.1126/science.abf4063; Cavanaugh 2021, MMWR; 70(32):1081-3. Lumley 2021; Clin Infect Dis; doi: 10.1093/cid/ciab608. Gazit 2021, medRxiv; https://doi.org/10.1101/2021.08.24.21262415. Shenai 2021, medRxiv; https://doi.org/10.1101/2021.09.12.21263461.

Limitations of Antibody Testing

- Antibody tests cannot determine when a person was infected.
- Antibody tests greatly vary in their sensitivity, particularly >3 months after infection.
- People can test positive on commercial antibody tests even after other markers of immunological response, such as neutralizing antibodies, have waned.
- At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.

Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- The benefits of COVID-19 vaccination for children and adolescents with a history of MIS-C are likely to outweigh a theoretical risk of an MIS-like illness or the known risks of COVID-19 vaccination for people who meet all of the following criteria:

  1) Clinical recovery has been achieved, including return to normal cardiac function;

  2) It has been ≥90 days since their diagnosis of MIS-C;

  3) They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission;

  4) Onset of MIS-C occurred before any COVID-19 vaccination.

Vaccination of Children with a History of Multisystem Inflammatory Syndrome in Children (MIS-C)

- COVID-19 vaccination may also be considered for children with a history of MIS-C who do not meet all the prior criteria.
- Experts view clinical recovery, including return to normal cardiac function, an important factor when considering COVID-19 vaccination.
- Additional factors when considering individual benefits and risks may include:

    1) An increased personal risk of severe COVID-19 (e.g., age, underlying conditions)

    2) Timing of immunomodulatory therapies

Children Diagnosed with MIS-C after COVID-19 Vaccination

- In the rare instance a person develops MIS-C or a similar clinical illness after receipt of a COVID-19 vaccine, referral to a specialist should be considered.
- Because MIS-C is a condition known to occur with SARS-CoV-2 infection, these individuals should be assessed for laboratory evidence of current or prior SARS-CoV-2 infection.

Any cases should be reported to Vaccine Adverse Event Reporting System (VAERS)

https://vaers.hhs.gov/reportevent.html

Consultation from Clinical Immunization Safety Assessment Project is available

http://www.cdc.gov/vaccinesafety/Activities/CISA.html

Counseling


DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Counseling: Expected Side Effects from Pfizer-BioNTech COVID-19 Vaccine

- Children may experience **fewer side effects** than adolescents or young adults[1].
- Children with evidence of prior infection may have fewer side effects than those without evidence of prior infection[1].

- Expected side effects include
  - Local: pain, swelling, erythema at the injection site
  - Systemic: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy

- Routine antipyretic or analgesic medications can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate.
  - In general, Aspirin is **not** recommended for use in children and adolescents ≤18 years due to risk of Reye's syndrome.

[1]https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Counseling: Possible Risk of Myocarditis

- Myocarditis and/or pericarditis have occurred rarely in some people following receipt of mRNA COVID-19 vaccines, typically within a few days following receipt of the second dose.
- The observed risk is highest in males 12–29 years of age[1].
- The risk of myocarditis or pericarditis after receipt of an mRNA COVID-19 vaccine is **lower** than the risk of myocarditis associated with SARS-CoV-2 infection in adolescents and adults[2].

[1]Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep 2021;70:977–982. DOI: http://dx.doi.org/10.15585/mmwr.mm7027e2

[2]Boehmer TK, Kompaniyets L, Lavery AM, et al. Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data — United States, March 2020–January 2021. MMWR Morb Mortal Wkly Rep 2021;70:1228–1232. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e5

Counseling: Possible Risk of Myocarditis

- No cases of myocarditis or pericarditis were reported in clinical trial for children ages 5–11 years (n=3,082), although the study was not powered to assess the risk of myocarditis[1].

- The baseline risk of myocarditis is much higher in adolescents ages 12–17 years compared to children ages 5–11 years.

[1]https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Counseling: Possible Risk of Myocarditis

- FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine in children ages 5–11 years based on the determination that **the benefits of COVID-19 vaccination outweigh risks in this population**.
- People receiving mRNA COVID-19 vaccines, especially males ages <30 years, should be made aware of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines.
  - Seek care for symptoms of
    - Chest pain
    - Shortness of breath
    - Feelings of having a fast-beating, fluttering, or pounding heart

Any cases should be reported to VAERS
https://vaers.hhs.gov/reportevent.html

Administration

Coadministration

- COVID-19 vaccines **may be administered without regard to timing of other vaccines**. This includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day.
- If multiple vaccines are administered at a single visit, administer each injection in a different injection site, according to recommendations by age[1].
  - Separate injection sites by 1 inch or more.
  - For older children (≥11 years), the deltoid muscle can be used.
  - For younger children (5–10 years), if more than 2 vaccines are injected in a single limb, the vastus lateralis muscle of the anterolateral thigh is the preferred site because of greater muscle mass.

[1]https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Administration Errors

- Formulations of the Pfizer-BioNTech COVID-19 Vaccines are **NOT** interchangeable.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their first dose, they should receive a single age-appropriate 10 µg dose for their second dose 21 days later and should be considered as having a completed primary series.
  - If a child ages 5–11 years inadvertently receives a 30 µg dose for their second dose, they should be considered has having a completed primary series.

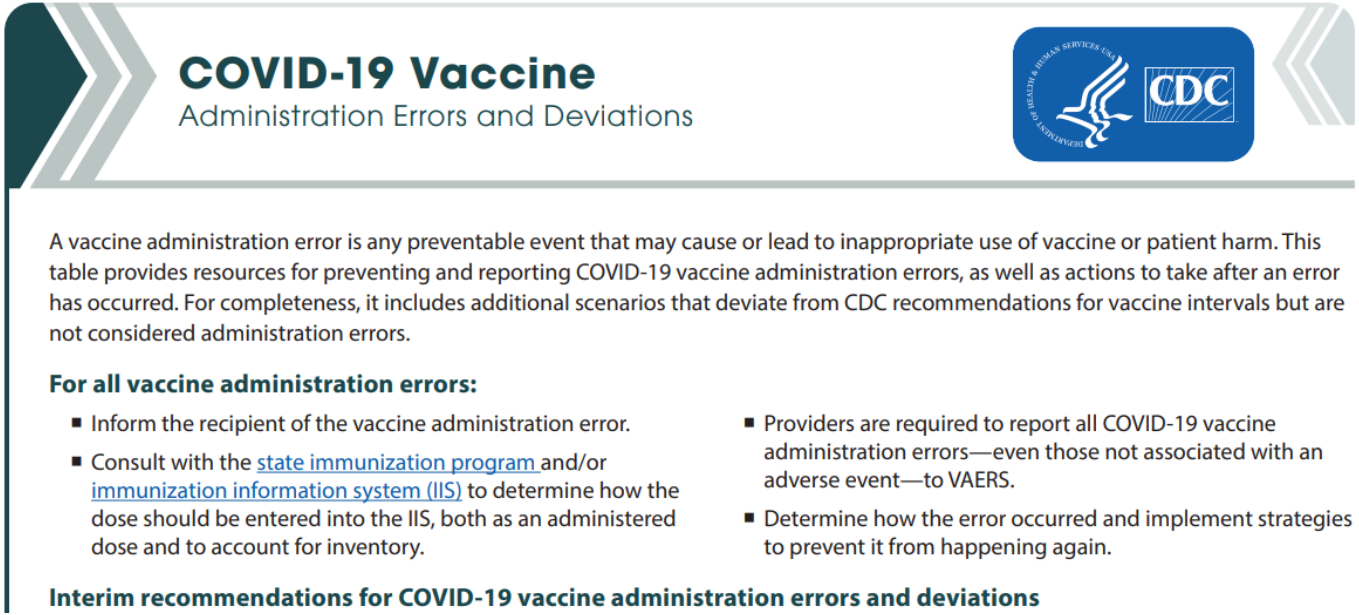
Administration Errors

- If an individual aged ≥12 years inadvertently receives a 10 µg dose, the dose should be repeated with the age appropriate 30 µg dose immediately.
  - Exception for children who turned from 11 to 12 years in between their first and second dose and receive a second 10 µg dose to complete their series.

- Due to the rare risk of myocarditis, males aged <30 years may consider waiting 21 days (the recommended interval) after the erroneous dose to repeat the dose.

Administration Errors

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



COVID-19 Vaccine

Administration Errors and Deviations

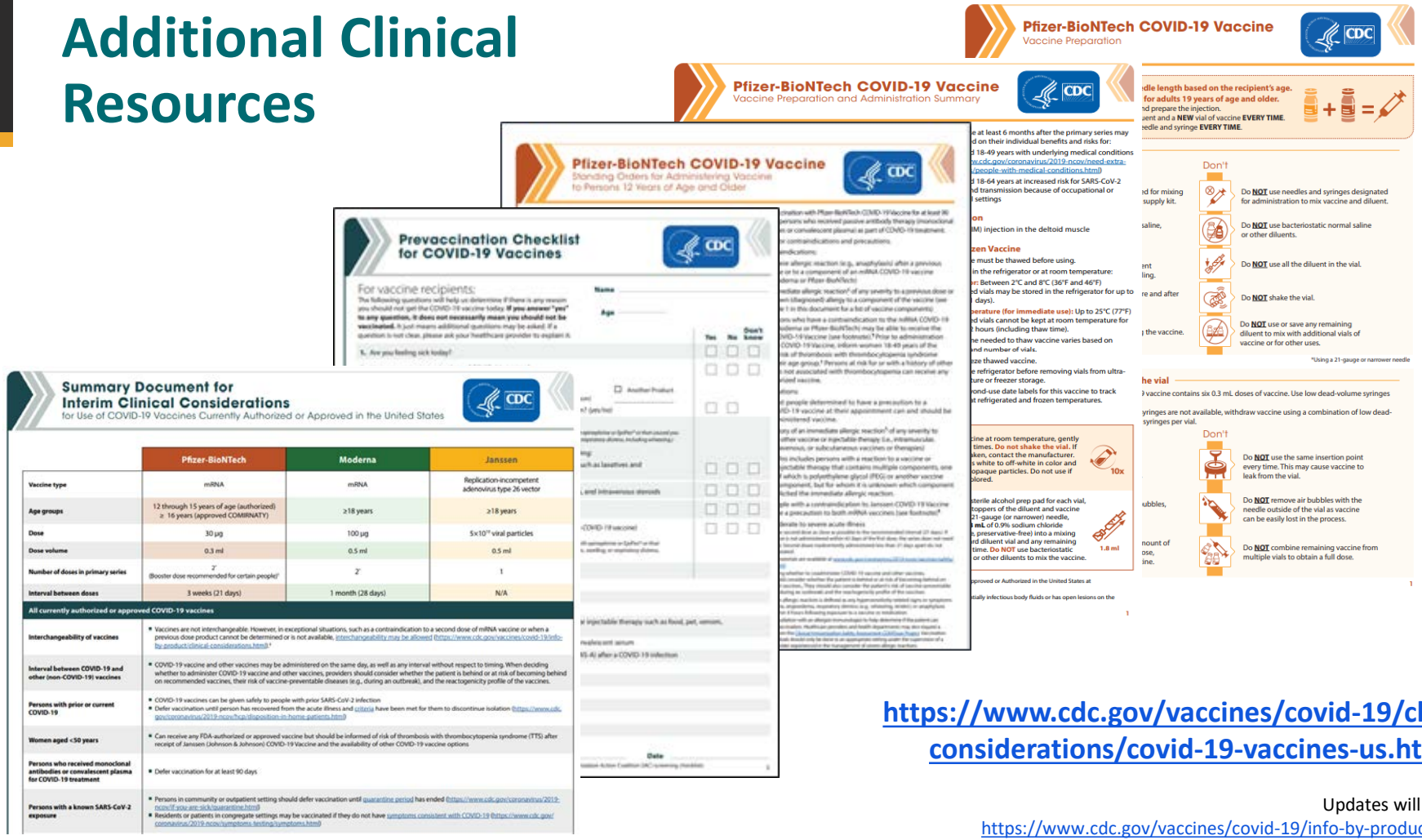
A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This table provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, it includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors.

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.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.

Interim recommendations for COVID-19 vaccine administration errors and deviations

Additional Clinical Resources



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

Updates will be posted at:
https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

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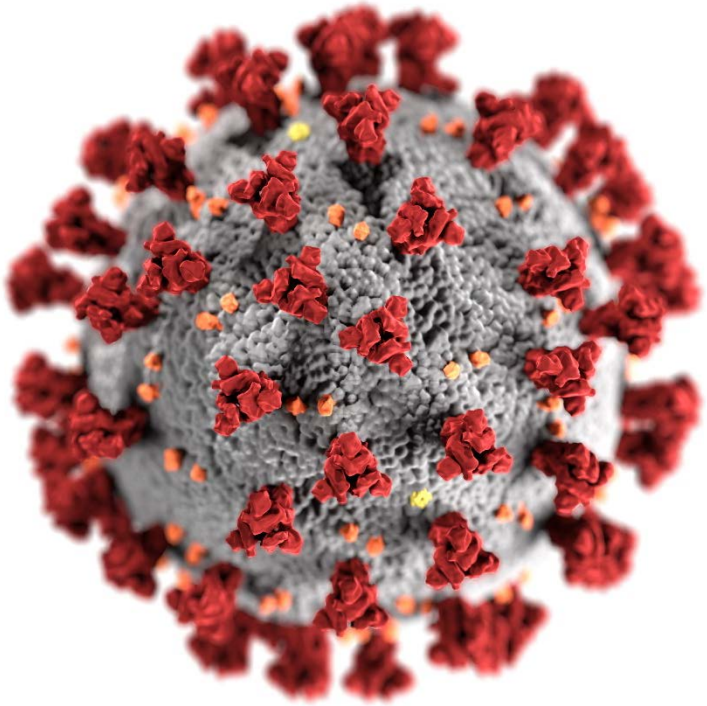

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

Back up slides

Administration Sites

Age	Needle length	Injection site
3-10 years	⅝–1“[1]	Deltoid muscle of arm (preferred)
	1–1¼"	Vastus lateralis muscle of anterolateral thigh (alternative)
11-18 years	⅝–1“[1]	Deltoid muscle of arm (preferred)
	1–1½"	Vastus lateralis muscle of anterolateral thigh (alternative)

[1] A 5/8"needle may be used in newborns, preterm infants, and patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin. https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

Triage of persons Presenting for COVID-19 Vaccination

CONTRAINDICATION TO VACCINATION

ALLERGIES

History of the following:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine
- Known (diagnosed) allergy to a component of the vaccine

ACTIONS

- Do not vaccinate.
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative if age appropriate.

PRECAUTION TO VACCINATION

ALLERGIES

Among people without a contraindication, a history of:

- Any immediate allergic reaction to other vaccines (non-COVID-19) or injectable therapies
- Non-severe, immediate (onset <4 hours) allergic reaction after a previous dose of a COVID-19 vaccine

Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa.

ACTIONS

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

MAY PROCEED WITH VACCINATION

ALLERGIES

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

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

ACTIONS

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

* For additional information please see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Triage of persons Presenting for COVID-19 Vaccination

Appendix B: Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH 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	• **Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines (non-COVID-19) or injectable therapies • Non-severe, immediate (onset <4 hours) allergic reaction after a previous dose of of COVID-19 vaccine Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa.	• **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:** • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.	• **Actions:** • Risk assessment • 30-minute observation period if vaccinated • Consider referral to allergist-immunologist	• **Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people