COVID-19 Vaccines Frequently Asked Questions

Summary of Recent Changes (Updated 2021.11.05)

- New section added under General Vaccine Questions for terminology used in this document
- New section added under General Vaccine Questions for CDC/ACIP recommendations for COVID-19 vaccination
- New section added under General Vaccine Questions for primary vaccine series administration
- Updated COVID-19 vaccine eligible age groups
- Updated FDA-authorized/approved uses of COVID-19 vaccine to include booster/third doses for Moderna and J&J/Janssen COVID-19 vaccines
- Updated CDC/ACIP recommendations for booster/third doses for Moderna and J&J/Janssen COVID-19 vaccines
- New section added under General Vaccine Questions which outlined the doses and dosing schedules for the additional and booster vaccine doses
- New section added under Special Populations Questions to include vaccination of individual with history of myopericarditis prior to COVID-19 vaccination
- Updated guidance on the vaccination of individuals who had developed myopericarditis due to a mRNA COVID-19 vaccine
- Updated guidance on vaccination of individuals who previously received antibody therapy
- Updated guidance on vaccination of immunocompromised individuals to recommend revaccination of individuals with HCT or CAR-T-cell therapy
- Updated guidance on vaccinating individuals who previously experienced severe adverse reactions of a prior COVID-19 vaccine dose
- Updated guidance on interchangeability of COVID-19 vaccine products
- Updated guidance on vaccine contraindications
- Updated guidance on management of post-vaccination syndrome
- New section added under Other Vaccine-Related Questions to address individuals who were vaccinated outside of the U.S. or with non-FDA-approved/authorized vaccines
- Updated Vaccine Administration Errors/Deviation information
- New section added under Vaccine-Related Adverse Reaction to include commonly reported adverse reactions in children
- New item added to Common COVID-19 Vaccine Myths
- Updated table of Ingredients included in COVID-19 vaccines
- Updated table of Triage of people with a history of allergies or allergic reactions

General Vaccine Questions	
Terminology used in this document (Reviewed/updated 2021.11.05)	• **Emergency Use Authorization (EUA)/FDA Authorized**: mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. Under an EUA, the U.S. Food and Drug Administration (FDA) can make a product available to the public based on the best available evidence, without waiting for all the evidence that would be needed for FDA approval. • **FDA-Approved**: FDA-approved vaccines have undergone the agency's standard process for reviewing the quality, safety and effectiveness of medical products included in a manufacturer's submission of a Biologics License Application (BLA)–a comprehensive document that addresses specific requirements. • **Primary (vaccine) series**: two-dose series of a mRNA COVID-19 vaccine or a single dose of Johnson & Johnson/Janssen COVID-19 vaccine. • **Additional dose (after an initial primary series)**: subsequent dose of vaccine administered to people who likely did not mount a protective immune response after primary vaccination to optimize vaccine-induced protection. An additional mRNA COVID-19 vaccine dose is recommended for moderately and severely immunocompromised people who received an mRNA vaccine primary series. • **Booster dose**: subsequent dose of vaccine administered to people in whom protection from primary vaccination is likely to have waned over time. • **Homologous booster dose**: a subsequent dose of vaccine that is the same product as the primary series. • **Heterologous booster dose (mix and match booster)**: a subsequent dose of vaccine that is a different product than the primary series. • **"Should"**: recommendations that are based on currently available evidence. • **"May"**: recommendations, mostly expert opinion, that can be considered after discussing with individuals on their risks and benefits of such action. • **mRNA vaccine**: refers to either Pfizer-BioNTech BNT162b2 or Moderna mRNA-1273 COVID-19 vaccine, or both. • **Pfizer-BioNTech (orange top)**: Pfizer-BioNTech COVID-19 Vaccine 5-11 years formulation; not interchangeable with Pfizer-BioNTech/Cominarty® (purple top) • **Pfizer-BioNTech/Cominarty® (purple top)**: Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation; not interchangeable with Pfizer-BioNTech (orange top)
What are the COVID-19 vaccines that are currently available in the U.S.? (Reviewed/updated on 2021.11.05)	• Pfizer-BioNTech (orange top): mRNA encoding prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein • Pfizer-BioNTech/Comirnaty® (purple top): mRNA encoding prefusion stabilized, membrane-anchored SARS-CoV-2 full-length spike protein

	• Moderna mRNA-1273: mRNA encoding prefusion stabilized SARS-CoV-2 spike protein with a transmembrane anchor and an intact S1-S2 cleavage site • Johnson & Johnson/Janssen Ad23.COV2.S/JNJ-78436735: replication-incompetent human adenovirus 23 encoding full-length prefusion stabilized SARS-CoV-2 spike protein
What are the FDA-authorized/approved uses for the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• Pfizer-BioNTech COVID-19 Vaccine (orange cap) is authorized for emergency use in all individuals who are aged 5 -11 years. • Pfizer-BioNTech/Comirnaty® COVID-19 Vaccine (purple cap) is o Approved for use in all individuals who are aged 16 years and older o Authorized for emergency use in all individuals who are aged 12-15 years o Authorized for emergency use for a third dose in individuals aged 12 years and older who are moderately-to-severely immunocompromised o Authorized for emergency use for a single booster dose in individuals aged 65 years and older o Authorized for emergency use for a single booster dose in individuals aged 18 through 64 years who are at high risk of severe COVID-19 o Authorized for emergency use for a single booster dose in individuals who are aged 18-64 years whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19 • Moderna COVID-19 Vaccine is o Authorized for emergency use in all individuals aged 18 years and older o Authorized for emergency use for a third dose in individuals aged 18 years and older who are moderately-to-severely immunocompromised • J&J/Janssen COVID-19 Vaccine is o Authorized for emergency use in all individuals aged 18 years and older o Authorized for emergency use for a single booster dose in individuals aged 18 years and older
What is the CDC/ACIP recommendation for the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• COVID-19 vaccination is recommended for all people aged 5 years and older in the United States for the prevention of COVID-19. However, the age groups FDA-approved under BLA or FDA-authorized under EUA to receive vaccination vary by vaccine product. CDC has issued recommendations for primary series, additional, and booster doses of COVID-19 vaccines. • Primary series o Pfizer-BioNTech (orange top): 2-dose series given in persons aged 5-11 years o Pfizer-BioNTech/Cominarty® (purple cap): 2-dose series given in persons aged ≥12 years o Moderna: 2-dose series given in persons aged ≥18 years

	○ Johnson & Johnson/Janssen: single dose in persons aged ≥18 years • Individuals are considered fully vaccinated if they meet either of the following criteria ○ mRNA vaccine: 14 days after the second dose ○ J&J/Janssen: 14 days after the single dose
How are the primary vaccine series administered? (Reviewed/updated on 2021.11.05)	• Pfizer-BioNTech BNT162b2 (orange cap) between ages 5 years and <12 years: 10 µg (0.2 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh); **21 days apart**. • Pfizer-BioNTech, Comirnaty® (purple cap), for ages 12 years and older: 30 µg (0.3 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh); **21 days apart**. • Moderna mRNA-1273: 100 µg (0.5 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh); **28 days apart**. • J&J/Janssen Ad26.COV2.S: 5×10^{10} viral particles (0.5 mL) intramuscularly (deltoid muscle, or alternatively, anterolateral thigh), **single dose**.
What dose of the Pfizer-BioNTech vaccine should be given to a child if he/she initially received the lower dose at age 11 years and then turned age 12 years by the time he/she is eligible to receive the second dose? (Reviewed/updated on 2021.11.05)	• Individuals should receive the vaccine dose appropriate for their age at the time of administration, not based on their size or weight. • If a child is 11 years old when receiving first dose of COVID-19 vaccine, he/she should receive the 10 µg dose and he/she turns 12 years old by the time the second dose is due, he/she should receive the 30 µg dose.
What are additional CDC/ACIP recommendations for the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• CDC/ACIP recommends that individuals ages ≥12 years who are moderately to severely immunocompromised **should** receive an **additional dose** of mRNA vaccine given at least 28 days after a second dose of Pfizer-BioNTech/Comirnaty® (purple top) or Moderna vaccine. These individuals include but not limited to the following ○ Active treatment for solid tumor and hematologic malignancies ○ Receipt of solid-organ transplant and taking immunosuppressive therapy ○ Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years so of transplantation or taking immunosuppression therapy) ○ Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome) ○ Advanced or untreated HIV infection ○ Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory. • CDC/ACIP recommends that the following groups **should** receive a **booster dose** of Pfizer-BioNTech/Comirnaty® (purple top) or Moderna vaccine at least 6 months after completing the primary series with their respective COVID-19 vaccine.

	○ Individuals aged 65 years and older ○ Residents of long-term care settings who are aged 18 years and older ○ Individuals aged 50-64 years with underlying medical conditions. They include ▪ Cancer/malignancy ▪ Chronic kidney disease ▪ Chronic lung diseases ▪ Dementia ▪ Diabetes mellitus (type 1 or type 2) ▪ Down syndrome ▪ Cardiac/cardiovascular conditions ▪ HIV infection ▪ Immunocompromised state (any degree) ▪ Liver disease ▪ Overweight & obesity ▪ Pregnancy ▪ Sickle cell disease or thalassemia ▪ Smoking, current or former ▪ Solid organ or blood stem cell transplant ▪ Stroke or cerebrovascular disease ▪ Substance use disorders • CDC/ACIP recommends that the following groups **may** receive a **booster dose** of Pfizer-BioNTech/Comirnaty® (purple top) or Moderna vaccine at least 6 months after completing the primary series with their respective COVID-19 vaccine ○ Individuals aged 18-49 with underlying medical conditions ○ Individuals aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting. They include ▪ First responders, e.g., HCW, firefighters, police, congregate care staff ▪ Education staff, e.g., teachers, support staff, daycare workers ▪ Food and agriculture workers ▪ Manufacturing workers ▪ Corrections workers ▪ U.S. Postal Service workers ▪ Public transit workers ▪ Grocery store workers ○ Individuals who are moderately to severely immunocompromised and had received an additional mRNA vaccine dose beyond the primary series. (These individuals potentially may receive up to 4 vaccine doses). • CDC recommends that all recipients of J&J/Janssen COVID-19 vaccine **should** receive a **booster dose** at least 2 months after the initial dose.

	• CDC has not recommended additional or booster doses in children ages <12 years.

How should the additional vaccine dose for moderately to severely immunocompromised individuals be given? (Reviewed/updated on 2021.11.05)	• Individuals ages ≥12 years who received the mRNA vaccine should continue to receive the same vaccine product used in the primary vaccine series. However, heterologous vaccine dose may be given.
	• The additional dose should be given at least 28 days after the second mRNA vaccine dose
	  ○ Pfizer-BioNTech/Cominarty® (purple top): 30 µg (0.3 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh)
	  ○ Moderna: 100 µg (0.5 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh)
	• There is no recommendation for individuals who received the J&J/Janssen vaccine to receive an additional dose. However, please review the section for booster doses for these individuals.
	• Children ages <12 years who are moderately to severely immunocompromised have not been recommended to receive the additional vaccine dose.

How is the booster dose for eligible individuals given? (Reviewed/updated on 2021.11.05)	• Please review the criteria under additional CDC/ACIP recommendations section to ensure your patient is eligible.
	• Although eligible fully vaccinated individuals should receive homologous booster dose, heterologous booster dosing is allowed.
	• The vaccine dose and time interval after the last vaccine dose of fully vaccinated individuals are eligible for a booster dose are as follows
	  ○ Pfizer-BioNTech/Cominarty® (purple top): 30 µg (0.3 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh), ≥6 months
	  ○ Moderna: **50 µg (0.25 mL)** intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh), ≥6 months
	  ○ Johnson & Johnson/Janssen: 5×10^{10} viral particles (0.5 mL) intramuscularly (deltoid muscle, or alternatively, anterolateral thigh), ≥2 months

What are the contraindications to receiving the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• Individuals with a history of the following should not receive any of the COVID-19 vaccines unless already evaluated and approved by an allergist:
	  ○ 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 allergy to a component of the vaccine. Please see Figure 1 for the list of components in the vaccines.
	• Additionally, known polysorbate allergy to is a contraindication to J&J/Janssen vaccine but a precaution to the mRNA vaccines. Please see Figure 2 for a list of medications containing polysorbates.

	• Individuals with a contraindication to one of the mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine and vice versa after they have been evaluated and approved by an allergist. • Allergic reactions not related to vaccines, injectable therapy, components of any of the COVID-19 vaccines, such as allergic reactions to food, pet, venom, environmental allergens, or oral medications, are not contraindications to vaccination. • Please review Figure 3 for the triage and management of people with known allergies or allergic reactions.
Are there any testing requirements, e.g., testing for COVID-19 or pregnancy, prior to vaccination? (Reviewed/updated on 2021.09.27)	• No prerequisite testing is recommended to determine vaccine eligibility. This includes SARS-CoV-2 RT-PCR or antigen-based testing and serologic antibody assays.
How and when the booster or third COVID-19 vaccine doses should be administered? (Reviewed/updated on 2021.11.05)	• All fully vaccinated individuals are allowed to receive any of the currently available COVID-19 vaccine as a heterologous booster dose, i.e., "mix and match" dose. • All moderately to severely immunocompromised individuals who completed a 2-dose mRNA COVID-19 vaccine series are allowed receive either mRNA COVID-19 vaccine as a third vaccine dose. • Pfizer-BioNTech/Comirnaty® (purple top) o Booster dose: 30 µg (0.3 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh) given at least 6 months after a second mRNA vaccine dose or 2 months after last viral vector vaccine dose. o Third dose (immunocompromised individuals only, ages 12 years and older): 30 µg (0.3 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh) given at least 28 days after the second mRNA COVID-19 vaccine dose. • Moderna mRNA-1273 o Booster dose: **50 µg (0.25 mL)** intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh) given at least 6 months after the second mRNA vaccine dose or 2 months after last viral vector vaccine dose. o Third dose (immunocompromised individuals only, ages 18 years and older): 100 µg (0.5 mL) intramuscularly (deltoid muscle preferably, or alternatively, anterolateral thigh) given at least 28 days after a second mRNA COVID-19 vaccine dose. • J&J/Janssen Ad26.COV2.S o Booster dose: 5×10^{10} viral particles (0.5 mL) intramuscularly (deltoid muscle, or alternatively, anterolateral thigh) given at least 6 months after the second mRNA vaccine dose or 2 months after last viral vector vaccine dose. o Third dose (immunocompromised individuals only): not applicable
What are the acceptable dosing intervals of the COVID-19 vaccines?	• The dose of any COVID-19 vaccines should be given as close to the recommended intervals as outlined by the manufacturers and CDC/ACIP.

(Reviewed/updated on 2021.11.05)	• A vaccine dose may be administered up to 4 days prior to the recommended interval and any time after the recommended dose interval.
Is there a preferred COVID-19 vaccine? (Reviewed/updated on 2021.11.05)	• Neither CDC nor UHC has a preferred COVID-19 vaccine or recommended one vaccine over another. • Eligible individuals should be encouraged to get whichever COVID-19 vaccine that is readily available to them.
Are there any considerations or precautions that vaccine recipients should be made aware regarding the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• For the mRNA vaccines (Pfizer-BioNTech (Comirnaty®) and Moderna), ○ All individuals should be counseled about expected local and systemic (non-allergic) symptoms, especially if receiving the second dose and/or history of SARS-CoV-2 infection. It is important to be aware that development of these symptoms following the first dose is not a contraindication to receiving the second dose. These individuals should be encouraged to complete the vaccination series to be optimally protected. ○ All individuals, especially males aged 12-29 years, should be aware of the **rare** possibility of myocarditis or pericarditis following the vaccination. It is important to note that the risk of developing myocarditis or pericarditis after receiving the mRNA vaccine is lower than risk of myocarditis or pericarditis associated with SARS-CoV-2 infection. Individuals who develop symptoms, such as chest pain, dyspnea, or palpitations, usually within a few days after the second dose, should be advised to seek medical care immediately. • For J&J/Janssen vaccine, ○ Women who are less than 50 years-old should be advised of the increased incidences of thrombosis with thrombocytopenia syndrome (TTS) and offering the choice of another COVID-19 vaccine, i.e., mRNA COVID-19 vaccine, if readily available. ○ Individuals with history of immune-mediated condition associated with thrombosis and thrombocytopenia should be offered one of the mRNA vaccines if they are within at least 90 days after resolution of their illness. • Individuals with contraindications to the mRNA vaccines have a precaution to the J&J/Janssen vaccine and vice versa. Consultation with an allergist is strongly advised to determine if the alternative vaccine is safe for administration. • Individuals with history of immediate allergic reactions to other vaccines or injectable therapy should be monitored for 30 minutes after receiving any of the COVID-19 vaccine.
Special Populations Questions	
What are the age groups that are eligible to receive the COVID-19 vaccine? (Reviewed/updated on 2021.11.05)	• The FDA has authorized the emergency use of the Pfizer-BioNTech vaccine for ages 5-15 years and approved for use for ages 16 years and older. • Moderna and J&J/Janssen vaccines are authorized for use in individuals ages 18 and older.

Should women who are pregnant, planning to be pregnant or breastfeeding receive the COVID-19 vaccine? What is the safety profile of the COVID-19 vaccines in this group? (Reviewed/updated on 2021.09.27)	• CDC and American College of Obstetrics and Gynecology recommend the vaccination of all eligible women who are pregnant, planning to be pregnant, or breastfeeding because of the high risk in developing severe illness from COVID-19. • Routine pregnancy testing before vaccination is not recommended.
Should individuals who are immunocompromised, including those with HIV, or receiving immunosuppressive therapy receive the COVID-19 vaccine? What is the safety profile of the vaccines in individuals in this population? (Reviewed/updated on 2021.09.27)	• All eligible immunocompromised individuals should be vaccinated against COVID-19. • Individuals in this population are considered to have higher risk for developing severe illness due to COVID-19. • Fully vaccinated individuals with a mRNA vaccine who meet the criteria of moderately-to-severely immunocompromised status should receive an additional mRNA vaccine dose, at least 28 days after the last dose. • Individuals who were vaccinated prior to receiving either hematopoietic cell transplantation (HCT) or chimeric antigen receptor (CAR)-T-cell therapy should be revaccinated at least 3 months after the procedure. The administration of an additional dose may be given if they continued to have moderate to severe immunocompromised state. • Serologic antibody testing to confirm immunity is not recommended.
Should individuals with autoimmune diseases receive the COVID-19 vaccine? What is the safety profile of the vaccines for individuals in this population? (Reviewed/updated on 2021.11.05)	• Individuals with autoimmune diseases should receive the COVID-19 vaccine. • The safety and efficacy profiles of the COVID-19 vaccines are similar to the general population.
Should the COVID-19 vaccine be administered to individuals with history of severe allergies or anaphylaxis? (Reviewed/updated on 2021.11.05)	• The COVID-19 vaccines should not be given to individuals with documented history of allergic reaction of any severity or anaphylaxis to a previous dose of the COVID-19 vaccines or to any components of the COVID-19 vaccines unless approved by an allergist. See Figure 1 for the components of the COVID-19 vaccines. • The J&J/Janssen vaccine should not be given to individuals with documented history of allergy to polysorbate unless they have been evaluated and approved by an allergist. See Figure 2 for a list of medications and vaccines containing PEG and polysorbates. • Known polysorbate allergy is not a contraindication, but a precaution, to receiving the mRNA vaccines. • Individuals who are allergic to the mRNA vaccines may be considered to receive the J&J/Janssen vaccine, and vice versa, after evaluation and approval by an allergist. Administration of the vaccine should be conducted under the supervision of HCP experienced in the management of severe allergic reactions. • The COVID-19 vaccines may be given to individuals regardless of history of allergic reactions of any severity to foods, medications, insects, latex, vaccine, or other injectable therapy except as noted above. However, individuals with allergic reactions to other vaccines or injectable therapies should be monitored for 30 minutes after receiving the COVID-19 vaccine.

Can individuals with history of Guillain-Barré syndrome (GBS) receive the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• Individuals with GBS may receive any of the FDA-authorized or FDA-approved COVID-19. • Because of a possible association of the J&J/Janssen vaccine with GBS, clinicians with such a patient may consider offering a mRNA vaccine instead.
Should individuals who had COVID-19 (asymptomatic or symptomatic) still receive the COVID-19 vaccines? (Reviewed/updated on 2021.11.05)	• In general, individuals who recovered from COVID-19 are encouraged to receive the vaccine once they have recovered from their illness and met the criteria for discontinuation of isolation. There is no established recommended minimal interval between infection and vaccination. • Individuals who received anti-SARS-CoV-2 monoclonal antibodies or developed certain complications due to COVID-19, e.g., myocarditis, MIS-C/MIS-A, may need to defer vaccination for a period. Please review questions listed below.
Should individuals with history of multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) due to COVID-19 receive the COVID-19 vaccine? (Reviewed/updated on 2021.11.05)	• Because of lack of data on the safety of COVID-19 vaccines in individuals who had either MIS-C or MIS-A, these individuals should hold discussions with their providers about vaccination. • Considerations for vaccination include: o Recovery from MIS-C or MIS-A o Personal risk of severe acute COVID-19 o Level of community COVID-19 transmission and risk of reinfection o Lack of safety data of COVID-19 vaccines following those illnesses o Timing of any immunomodulatory therapies • Individuals who choose to do so should delay vaccination until they have recovered from their illness and waited 90 days after the diagnosis of MIS-C or MIS-A.
Should individuals with history of myocarditis or pericarditis prior to COVID-19 vaccination receive the COVID-19 vaccine? (Reviewed/updated 2021.11.05)	• Individuals with history of myocarditis or pericarditis *prior* to receiving a mRNA COVID-19 vaccine may receive the COVID-19 vaccine. • These individuals should not be vaccinated until they had resolution of their symptoms and no evidence of ongoing cardiac inflammation or sequelae as determined by a cardiologist or their care team.
Should individuals with history of myocarditis or pericarditis after the first mRNA vaccine dose receive the second dose? (Reviewed/updated on 2021.11.05)	• It is not clear if there is further/increased risk of future episodes of myocarditis or pericarditis following a subsequent dose of mRNA vaccine. • In general, it is recommended to defer subsequent mRNA vaccine doses in those individuals who developed myocarditis or pericarditis following a dose of mRNA vaccine. • The administration of subsequent mRNA vaccine dose(s) may be considered after reviewing the following: o Personal risk of severe acute COVID-19 o Level of community transmission and risk of infection o Additional data on the risk of myocarditis or pericarditis following vaccination

	○ Additional data on the long-term outcomes of myocarditis or pericarditis following vaccination • Those individuals who choose to receive the second dose of an mRNA vaccine should wait at least until their episode of myocarditis or pericarditis has completely resolved. • Alternatively, the J&J/Janssen vaccine may be considered to complete the vaccination series if age eligible.
Should individuals with a history of dermal fillers receive the mRNA COVID-19 vaccine? (Reviewed/updated on 2021.09.27)	• Yes, if they have no contraindications to receiving the vaccine. No additional precautions are needed.
Other Vaccine-Related Questions	
When should a subsequent COVID-19 vaccine dose be given if an individual develops COVID-19 after the first vaccine dose? (Reviewed/updated on 2021.11.05)	• The second dose should be given once the individual has recovered from COVID-19 but still has met the minimum dose interval period recommended by the manufacturer.
When should individuals who received passive antibody products, e.g., convalescent, or anti-SARS-CoV-2 monoclonal antibody therapy, receive the COVID-19 vaccines before vaccination or in between doses? (Reviewed/updated on 2021.11.05)	• Individuals who received antibody therapy for post-exposure prophylaxis against COVID-19 should wait at least 30 days after receiving the treatment before receiving the COVID-19 vaccine. • Individuals who received antibody therapy for treatment of COVID-19 should wait at least 90 days after receiving the treatment before receiving the COVID-19 vaccine. • Individuals who received passive antibody therapy that is not specific to the treatment of COVID-19, e.g., IVIG, RhoGAM, may receive the COVID-19 vaccine without a wait period.
If a vaccine recipient experienced a severe adverse or allergic reaction after a COVID-19 vaccine, should they receive any subsequent doses of the same type of vaccine? (Reviewed on 2021.11.05)	• If the vaccine recipient develops a severe adverse reaction to one of mRNA vaccines that is determines to be a contraindication to future doses of a mRNA vaccine, the J&J/Janssen vaccine may be used instead to complete the vaccination series, if age eligible. • Alternatively, if the vaccine recipient develops a severe adverse reaction to the J&J/Janssen vaccine, any of the mRNA vaccines may be used as a booster dose instead.
Will antiviral therapy, whether for COVID-19 or other viral infections, affect COVD-19 vaccination? (Reviewed/updated on 2021.09.27)	• Individuals who have received antiviral therapy for any reason may receive any of the COVID-19 vaccines, including the J&J/Janssen vaccine, without restrictions.
Should individuals who are acutely ill, including fever alone, receive the COVID-19 vaccine? (Reviewed/updated on 2021.09.27)	• Individuals who are acutely ill should defer vaccination until they have recovered. • Individuals with fever but without other symptoms should defer vaccination until the fever has resolved. • Individuals with active tuberculosis or being evaluated for tuberculosis may receive the vaccine.

If a vaccine recipient did not receive the subsequent vaccine dose at around the recommended time interval, does vaccination series needs to be restarted? (Reviewed/updated on 2021.11.05)	• No. The vaccination series does not need to be restarted. • The subsequent dose should be given as soon as possible after missing the recommended time interval.
Are the COVID-19 vaccines interchangeable? (Reviewed/updated on 2021.11.05)	• In general, vaccine recipients should receive the same COVID-19 vaccine for additional and booster dose(s). • The use of heterologous, i.e., mix and match, booster doses is allowed • If the same COVID-19 vaccine product is not readily available for use for the second dose, it is acceptable to delay the second dose until the same vaccine product is available. • If another COVID-19 vaccine product was used as the second dose, the vaccination series does not need to be restarted and the vaccine recipient should be considered fully vaccinated 2 weeks after the second dose.
Are the Pfizer-BioNTech vaccine vials for children ages 5-11 years (orange top) and for individuals ≥12 years (purple top) interchangeable? (Reviewed/updated 2021.11.05)	• The two different vials of the Pfizer-BioNTech vaccine are not interchangeable. • The Pfizer-BioNTech 10 μg/dose formulation (orange cap) is authorized for use only in children aged 5-11 years for primary vaccination. • The Pfizer-BioNTech 30 μg/dose formulation (purple cap) is authorized for use only in individuals aged ≥12 years only.
Do the vaccines interact with other medications or therapy? (Reviewed/updated on 2021.09.27)	• There are no known medication or vaccine interactions with any of the COVID-19 vaccines.
Can the COVID-19 vaccines be co-administered or administered around the same time as other vaccines? (Reviewed/updated on 2021.09.27)	• The COVID-19 vaccines may be given around the same time or co-administered with other vaccines. • The vaccines, however, should be administered at different sites.
What concomitant medications or conditions may inhibit or prevent the COVID-19 vaccines from inducing immune response? (Reviewed/updated on 2021.09.27)	• The following populations may have reduced or lack of immune response to the COVID-19 vaccines as listed by CDC: o Immunodeficiencies involving adaptive immunity o Asplenia o B-cell directed therapy o T-cell directed therapy o Many chemotherapy regimens o Hematopoietic cell transplantation o Underlying aberrant immunity, e.g., graft-vs.-host disease, graft rejection, absent or incomplete immune reconstitution, neutropenia, lymphopenia o High-dose corticosteroids, ≥20 mg per dose or >2 mg/kg/d daily of prednisone or equivalent • Regardless, all eligible immunocompromised and immunosuppressed individuals should be vaccinated against COVID-19.

	• If possible, it is suggested that immunosuppressive therapies are deferred until at least 2 weeks after completing the vaccination series.
Will vaccinated individuals be able to travel by air internationally without the need to be tested for SARS-CoV-2 prior to departure? (Reviewed/updated on 2021.09.27)	• Before travel, make sure your patient reviews and understands all airline and destination requirements as they may differ from U.S. requirements. • Vaccination is currently not accepted as an alternative to a negative SARS-CoV-2 test result to meet the requirement to allow entry into the U.S. • Individuals who are traveling internationally will be required to have proof of a negative SARS-COV-2 test that is performed up to 3 days prior to their departure to the U.S. • Recovered individuals with previous diagnosis of COVID-19 within 90 days of departure and met the criteria to end isolation do not need to be tested but will require "documentation of recovery" from public health or a healthcare provider stating that that they have recovered with a copy of the test result attached.
Will the COVID-19 vaccines affect SARS-CoV-2 test results? (Reviewed/updated on 2021.09.27)	• Vaccination will not affect the results of molecular diagnostic tests, i.e., PCR- or antigen-based tests. • Serologic anti-SARS-CoV-2 antibody tests against the spike (S) protein, however, will be positive in vaccinated individuals.
Should serologic antibody tests be performed after completing the vaccination series to ensure immunity? (Reviewed/updated on 2021.09.27)	• Routine serologic testing for anti-SARS-CoV-2 antibodies to confirm vaccine-induced immunity is not recommended at this time.
How should vaccinated individual be evaluated for possible past infection with SARS-CoV-2? (Reviewed/updated on 2021.09.27)	• Fully vaccinated individuals may be assessed for past infection with SARS-CoV-2 by serologic tests that specifically detect anti-SARS-CoV-2 nucleocapsid (N) protein antibody. • The use of tests that detect anti-SARS-CoV-2 spike (S) glycoprotein antibody will not differentiate between immunity from natural infection and vaccine.
When should individuals who are receiving the COVID-19 vaccine undergo screening for tuberculosis? (Reviewed/updated on 2021.09.27)	• The use of either tuberculin skin test (TST) or interferon gamma releasing assay (IGRA) may be performed before, during, or after the same encounter as the COVID-19 vaccination.
Should individuals who received a COVID-19 vaccine outside of the U.S. need to restart their primary series or be revaccinated? (Reviewed/updated on 2021.11.05)	• All individuals who received all recommended doses of a currently FDA-approved, FDA-authorized, or WHO-EUL COVID-19 vaccine outside of the U.S. will be considered fully vaccinated and do not need to have their primary series repeated or receive subsequent primary series doses. • All individuals who started the primary series with an FDA-authorized or FDA-approved mRNA vaccine outside of the U.S. do not need to restart the vaccine series. They should receive the second vaccine dose in accordance with the recommended time interval and will be considered fully vaccinated upon completion of the primary series. • All individuals who completed the primary series outside of the U.S. with a mixed dose regimen will be considered fully vaccinated and do not need to repeat the primary series while in the U.S.

	• All individuals who are partially vaccinated with a COVID-19 vaccine that is not FDA-approved/authorized but is listed for emergency use by WHO may complete the primary series with any of a FDA-approved/authorized COVID-19 vaccine. The minimal interval between the receipt of the two vaccine doses is at least 28 days. • All individuals who are partially or fully vaccinated with a COVID-19 vaccine that is not FDA-approved/authorized or listed for emergency use by WHO may complete with or receive any of a FDA-approved/authorized COVID-19 vaccine to complete the primary series. The minimal interval between the receipt of the non-FDA approved/authorized vaccine and the initiation of the FDA-approved/authorized vaccine is at least 28 days.
Vaccine Administration Errors/Deviations Management	
The vaccine was administered in the incorrect site, i.e., site other than the deltoid or anterolateral thigh. (Reviewed/updated on 2021.09.27)	• Do not repeat dose. • Inform the vaccine recipient for the potential of local and systemic adverse events.
The vaccine was administered via the incorrect route, e.g., subcutaneous. (Reviewed/updated on 2021.09.27)	• Do not repeat dose. • Inform the vaccine recipient for the potential of local and systemic adverse events.

The vaccine was administered to someone who was not in the authorized age group.
(Reviewed/updated on 2021.11.05)
	• If the recipient is less than 5 years old, do not administer additional doses.
	• If the recipient is aged 5-11 years and received one of the following vaccines
	  ○ Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation}
	  ▪ Do not repeat dose.
	  ▪ If this is the first dose, administer Pfizer-BioNTech (orange top) {5-11 years formulation} 21 days later.
	  ○ Moderna COVID-19 Vaccine
	  ▪ Do not repeat dose.
	  ▪ If this is the first dose, administer Pfizer-BioNTech (orange top) {5-11 years formulation} 21 days later.
	  ○ J&J/Janssen COVID-19 Vaccine
	  ▪ Do not repeat dose.
	  ▪ The recipient can be considered to receive Pfizer-BioNTech (orange top) {5-11 years formulation} at least 2 months later.
	• If the recipient is between 12 to 17 years old and received a COVID-19 vaccine other than the Pfizer-BioNTech COVID-19/Comirnaty® (purple top) {≥12 years formulation} as the first dose
	  ○ Pfizer-BioNTech (orange top) {5-11 years formulation}
	  ▪ Do not repeat dose.
	  ▪ If this is the first dose, administer the Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation} 21 days later as the second dose.
	  ○ Moderna COVID-19 Vaccine,

	▪ Do not repeat dose. ▪ If this is the first dose, administer the Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation} at least 28 days after the last dose of Moderna COVID-19 Vaccine as the second dose. o J&J/Janssen COVID-19 Vaccine ▪ Do not repeat dose. ▪ The recipient can be considered to receive the Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation} at least 2 months later. • If the recipient is ≥18 years and received the Pfizer-BioNTech (orange top) {5-11 years formulation} o Repeat dose immediately with the Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation}. o If this is the first dose, administer the Pfizer-BioNTech/Comirnaty® (purple top) {≥12 years formulation} 21 days later as the second dose.
A vaccine recipient was administered the second mRNA COVID-19 vaccine dose for the primary vaccine series is earlier than the 4-day grace period from the recommended interval time, i.e., fewer than 17 days for Pfizer-BioNTech vaccine or fewer than 24 days for Moderna vaccine. (Reviewed/updated on 2021.11.05)	• Repeat dose. • The repeat dose should be spaced from the improperly administered dose by the recommended dose interval for the given vaccine product, i.e., 21 days for Pfizer-BioNTech vaccine or 28 days for Moderna vaccine.
The interval between a single dose of mRNA vaccine and a J&J/Janssen vaccine for the primary vaccine series is fewer than 24 days. (Reviewed/updated on 2021.11.05)	• Do not administer a second primary dose of mRNA vaccine. • The individual will be considered fully vaccinated 14 days after the J&J/Janssen vaccine dose.
The interval between the last dose of the primary vaccine series and additional dose (for moderately-to-severely immunocompromised individuals) is given fewer than 24 days. (Reviewed/updated on 2021.11.05)	• Repeat dose. • The repeat dose should be spaced from dose given in error for the recommended minimum interval.
The interview between the last dose of the primary vaccine series (or additional dose) and booster dose is given earlier than 4 days before recommended interval, e.g., 6 months for mRNA vaccines and 2 months for J&J/Janssen vaccine. (Reviewed/updated on 2021.11.05)	• Do not repeat dose.
A vaccine recipient received the second dose of mRNA COVID-19 vaccine past the recommended interval. (Reviewed/updated on 2021.11.05)	• Do not repeat dose. • The vaccination series does not need to be restarted. • This does not require VAERS reporting.

A vaccine recipient was inadvertently administered two different mRNA COVID1-9 vaccines during the vaccination series. (Reviewed/updated on 2021.11.05)	• Do not repeat dose. • The vaccination series does not need to be restarted. • This does not require VAERS reporting.
A vaccine recipient received higher-than-authorized vaccine dose or volume. (Reviewed/updated on 2021.11.05)	• Do not repeat dose. • Inform the vaccine recipient of potential for local and systemic adverse reactions.
A vaccine recipient received lower-than-authorized vaccine dose or volume, e.g., leaked out, syringe failure. (Reviewed/updated on 2021.11.05)	• Repeat dose immediately • If a half-volume formulation of vaccine is administered on the same clinic day to a patient recommended for the full volume formulation, another half-volume dose can be administered, and the two doses can count as one full dose.
A vaccine recipient was administered the vaccine dose without diluent. (Pfizer-BioNTech/Cominarty® only) (Reviewed/updated on 2021.11.05)	• Do not repeat dose. • Inform the vaccine recipient of potential for local systemic adverse reactions.
When should I contact the vaccine manufacturer for more information and instructions? (Reviewed/updated on 2021.11.05)	• When the vaccine administered was improperly stored and handled. • When the vaccine administered was past the expiration/beyond use date. • When the incorrect diluent type was used. If the manufacturer recommends repeating the vaccine dose, the repeat dose should be administered immediately in the opposite arm.
A vaccine recipient was administered a COVID-19 vaccine dose within 90 days of receiving antibody therapy, i.e., anti-SARS-CoV-2 monoclonal antibodies or convalescent antibodies, for the treatment of COVID-19. (Reviewed/updated on 2021.11.05)	• Do not repeat dose. • If the vaccine recipient is scheduled to receive a subsequent vaccine dose, defer 90 days after receiving the antibody therapy before administering the second dose. • This does not require VAERS reporting.
A vaccine recipient was administered a COVID-19 vaccine dose within 30 days of receiving anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis. (Review/updated 2021.11.05)	• Do not repeat dose. • If the vaccine recipient is scheduled to receive a subsequent vaccine dose, defer 30 days after receiving the antibody therapy before administering the second dose. • This does not require VAERS reporting.
Vaccination Benefits Questions	
When are vaccine recipients considered fully vaccinated? (Reviewed/updated on 2021.10.28)	• Vaccine recipients are considered fully vaccinated 2 weeks after completing the vaccination series of either mRNA COVID-19 vaccines or one dose of the Janssen COVID-19 vaccine. • Those did not complete the vaccination series for any reason are not considered fully vaccinated.
What are the medical benefits of vaccination? (Reviewed/updated on 2021.09.27)	• All three COVID-19 vaccines significantly reduce the risk of developing symptomatic COVID-19.

	• All three COVID-19 vaccines significantly reduce the risk of developing severe illness, hospitalization, and death due to COVID-19.
Can vaccinated individuals still develop COVID-19? (Reviewed/updated on 2021.09.27)	• It is still possible for fully vaccinated individuals to get infected by SARS-CoV-2 and develop COVID-19. • The risk, however, of developing symptomatic COVID-19 is significantly lower, even after the first dose. • Fully vaccinated individuals who test positive for SARS-CoV-2, either PCR or antigen, should have a specimen submitted to Montana Public Health Laboratory for whole genome sequencing to detect the presence of a SARS-CoV-2 variant of concern. Additionally, these cases should also be reported to VAERS.
Are the current COVID-19 vaccines effective against the reported variants of concern, i.e., Alpha (B.1.1.7), Beta (B.1.135), Delta (B.1.617.2), and Gamma (P.1)? (Reviewed/updated on 2021.09.27)	• The effectiveness of all FDA-authorized COVID-19 vaccines is preserved against all variants that are circulating in the U.S. • It is expected that cases of COVID-19 will occur in those who are fully vaccinated (breakthrough infections) are immunologic responses may be variable depending on underlying factors, e.g., immunocompromised status. The overall number of these cases, however, is small.
Will vaccination prevent asymptomatic COVID-19? (Reviewed/updated on 2021.09.27)	• Some studies suggest that vaccination reduces of incidence of asymptomatic infections. • It is still important, however, to emphasize that infection with SARS-CoV-2 can still occur after vaccination, especially with the Delta variant. Therefore, it is important to encourage the continued use of facemasks and physical distancing while in public of all fully vaccinated individuals.
Will vaccination prevent transmission of SARS-CoV-2? (Reviewed/updated on 2021.09.27)	• There are limited data to suggest that vaccination may reduce the transmission of SARS-CoV-2. • At present, it is still important that vaccinated persons continue to follow transmission-based mitigation and prevention practices.
What is the expected duration of immunity of fully vaccinated individuals? (Reviewed/updated on 2021.09.27)	• There are several factors that influences the durability of the immunity derived from vaccination, such as age, underlying medical conditions, and impaired immune response. • Studies suggest that antibody titers do appear to wane over time but remain effective against severe illness, hospitalizations, and death due to COVID-19. • Certain populations are recently recommended to receive a supplemental vaccine dose, i.e., additional or booster dose, after completing the primary mRNA vaccine series. Details are outlined under the "General Vaccine Questions" section.
Infection Prevention & Control	
Should the COVID-19 vaccine be given after an exposure to known SARS-CoV-2 infection or during an outbreak to prevent infection? (Reviewed/updated 2021.09.27)	• It is not recommended to administer the COVID-19 vaccine as post-exposure prophylaxis or management of an outbreak because the incubation period of SARS-CoV-2 infection is shorter than the immune response to the vaccine.

What can fully vaccinated individuals safely do? (Reviewed/updated on 2021.09.27)	• Because of the rapid spread of the Delta variant, all individuals regardless of their vaccination status should continue to wear facemasks while in indoor public settings in areas of substantial or high level of transmission of SARS-CoV-2. • In most outdoor settings, most fully vaccinated individuals do not need to wear facemasks. Facemasks should be worn, however, in large group settings. • Immunocompromised or immunosuppressed are also strongly encouraged to use facemasks and practice physical distancing while in public. • Facemask use is still required for who those individuals traveling via public transportation, regardless of vaccination status. • They are not required to be tested before or after travel, or self-quarantine after domestic travel. • They can refrain from testing before leaving the US. for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in the US. They are, however, still required to have a negative SARS-CoV-2 test performed no more than 3 days prior to boarding a departure flight to the US.
What should fully vaccinated individuals continue to do? (Reviewed/updated on 2021.09.27)	• They should get tested if experiencing COVID-19 symptoms. • They should follow CDC and state/local health department travel requirements and recommendations.
Are fully vaccinated individuals still required to be quarantined if they are exposed to suspected or known COVID-19 cases? (Reviewed/updated on 2021.09.27)	• CDC does not require any fully vaccinated individuals who are exposed to suspected or confirmed cases of COVID-19 to be quarantined if they remain asymptomatic. They should, however, be advised to monitor for symptoms for 14 days after the last exposure event. Additionally, they should be tested 3-5 days after exposure.
Are vaccinated individuals still required to be isolated if diagnosed with COVID-19? (Reviewed/updated on 2021.09.27)	• Yes. All individuals diagnosed with COVID-19 are required to be isolated for the recommended duration, regardless of their vaccination status.
If individuals who have positive results with either PCR- or antigen-based tests after vaccination, should the results be considered as false-positive? (Reviewed/updated on 2021.09.27)	• Vaccination does not affect the results of any PCR- or antigen-based tests. • Individuals who have received the any of the vaccines and have positive results from either test should be considered infected.
Vaccine-Related Adverse Reactions	
Should vaccine recipients who developed allergic reactions to a prior mRNA COVID-19 vaccine be given the second dose? (Reviewed/updated on 2021.09.27)	• Individuals who had immediate allergic reaction of any severity, including anaphylaxis, to a previous dose of a COVID-19 vaccine should not receive the second dose until they have been evaluated and approved to receive the vaccine by an allergist.
Should individuals who developed significant systemic (non-allergic) symptoms following the first of an mRNA COVID-19 vaccine receive the second dose? (Reviewed/updated on 2021.09.27)	• Unless the symptoms are related to anaphylaxis or an immediate allergic reaction, the development of these symptoms are not considered to be contraindication to receiving the second dose of mRNA COVID-19 vaccine.

	• Individuals who developed significant symptoms should be encouraged to receive the second dose of the mRNA COVID-19 vaccine to be fully protected.
If a vaccine recipient is unable to complete the vaccination series due to a contraindication, e.g., severe allergic reaction to a prior dose of either mRNA vaccines, is there another option to fully vaccinate against COVID-19? (Reviewed/updated on 2021.09.27)	• The J&J/Janssen COVID-19 vaccine may be used to complete the mRNA vaccination series. It should be administered 28 days after the first mRNA COVID-19 vaccine dose. • In these individuals, a single dose of the Janssen COVID-19 vaccine may be considered at a minimal interval of 28 days from the mRNA COVID-19 vaccine dose. • If this option is employed, these individuals will be considered to vaccinated based on receiving the Janssen COVID-19 vaccine instead of a mixed vaccination series.
What is the safety profile of the COVID-19 vaccines? (Reviewed/updated on 2021.09.27)	• Over 200 million doses of the COVID-19 vaccines have been given since the vaccinated efforts have been started. The incidence of severe adverse reactions, e.g., anaphylaxis, TTS, myocarditis/pericarditis, is rare. • No cases of myocarditis/pericarditis were reported in the clinical trial of children ages 5 to <12 years. • Most adverse reactions are related to vaccine reactogenicity.
What are the commonly reported adverse reactions to the COVID-19 mRNA vaccines? (Reviewed/updated on 2021.09.27)	• Reactogenicity commonly reported to v-safe include pain at the injection site, fatigue, headache, muscle ache, chills, fever, joint pain, and nausea. • Adverse events commonly reported to VAERS for the Pfizer-BioNTech COVID-19 vaccine include headache, fatigue, dizziness, nausea, chills, fever, pain, injection site pain, pain in extremity, and dyspnea. • Adverse events commonly reported to VAERS for the Moderna COVID-19 vaccine include headache, fever, chills, pain, dizziness, fatigue, nausea, injection site pain, pain in extremity, and dyspnea. • Vaccine recipients should also be advised that self-limiting lymphadenopathy following vaccination has been reported. • Most adverse reactions last about 1-2 days but usually not more than 3 days.
What are the commonly reported adverse reactions of Pfizer-BioNTech COVID-19 vaccine in children? (Reviewed/updated on 2021.11.05)	• Children may experience fewer adverse reactions than adolescents and young adults. • Expected adverse reactions include pain, swelling and/or erythema at the injection site, fever, fatigue, headache chills, myalgia, arthralgia, and lymphadenopathy
What are the commonly reported adverse reactions to the Janssen COVID-19 vaccine? (Reviewed/updated on 2021.09.27)	• Most adverse reactions with this vaccine are mild to moderate in severity. • Injection site pain is the most common injection site reaction, followed by erythema and swelling. All reactions resolve in 2-3 days • Common systemic adverse events include (in decreasing frequency) fatigue, headache, myalgia, nausea, and fever. Most vaccine recipients will experience at least one adverse event. All reactions resolve in 1-2 days.
How should most of the commonly reported adverse reactions be managed? (Reviewed/updated on 2021.09.27)	• The commonly reported adverse reactions can be managed as needed with either NSAIDs or acetaminophen. • Routine prophylactic use of NSAIDs or acetaminophen to prevent post-vaccination symptoms is not recommended.

	• Aspirin should not be used in the management of post-vaccination syndrome, especially in children and adolescent <18 years because of risk of Reye's syndrome. • Additionally, prophylactic use of antihistamine to prevent allergic reactions is not recommended as they may mask symptoms of hypersensitivity reactions.
What should be done if a vaccine recipient has persistent reaction symptoms? (Reviewed/updated on 2021.09.27)	• Since infection with SARS-CoV-2 may still occur, vaccine recipients with persistent fever, fatigue, headache, muscle ache, joint pain, or diarrhea should be evaluated and ruled out for COVID-19.
What should be done if vaccine recipients develop symptoms that are not listed on the commonly reported vaccine-related adverse reactions? (Reviewed/updated on 2021.09.27)	• Vaccine recipients who developed symptoms should be evaluated for other causes of their symptoms. If no obvious cause has been identified, the symptoms should be reported as a possible vaccine-related adverse reaction. • Individuals who report respiratory symptoms, anosmia and/or dysgeusia should be ruled out for infection with SARS-CoV-2.
Should vaccine recipients who developed delayed-onset local reaction after the first mRNA COVID-19 vaccine dose avoid receiving the second vaccine dose? (Reviewed/updated on 2021.09.27)	• Delayed-onset local reaction may include erythema, induration, pruritis, and pain that occur on the same arm where the vaccine was administered. It may present as early as few days and through the second week after the injection. This reaction seems to occur more commonly with Moderna mRNA COVID-19 vaccine. • Development of this reaction after the first dose of mRNA COVID-19 vaccine is not considered a precaution or contraindication to receiving the second vaccine dose, preferably given in the opposite arm. • The symptoms are usually self-limited and may be managed with analgesics.
Are the COVID-19 vaccines associated with increased incidence in Bell's palsy? (Reviewed/updated on 2021.09.27)	• Although cases of Bell's palsy have been reported during the clinical trials of the COVID-19 vaccines, CDC considers the incidence of Bell's palsy of vaccine recipients like that of the expected incidence in the general public. Thus, they do not feel that the reported cases are vaccine-related.
How should reactions to dermal fillers be managed? (Reviewed/updated on 2021.09.27)	• Vaccine-related reactions involving dermal fillers are temporary and may be managed oral corticosteroids and diphenhydramine (Benadryl).
Are there any reported cases of hypersensitivity or anaphylaxis to the vaccines? (Reviewed/updated on 2021.09.27)	• Yes, but analyses of VAERS data indicate that they are rare.
How should vaccine-related adverse reactions be reported? (Reviewed/updated on 2021.09.27)	• For individuals who received their vaccine at Billings Clinic, providers are asked to enter all adverse reactions into Safety Net. • For all others, all adverse reactions should be entered into the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/.
Can vaccine recipients self-report adverse reactions? (Reviewed/updated on 2021.09.27)	• Yes. All vaccine recipients are encouraged to register with v-safe at https://vsafe.cdc.gov/ to report adverse reactions.
Common COVID-19 Vaccine Myths	
COVID-19 vaccination will nullify or diminish immunity derived from previous SARS-CoV-2 infection.	• There is no evidence to suggest that COVID-19 vaccination will decrease existing immunity against SARS-CoV-2.

	• There is evidence, however, that COVID-19 vaccination will bolster protection against severe illness and hospitalized due to COVID-19 acquired from prior SARS-CoV-2 infection.
The COVID-19 vaccines cannot be trusted because their development was rushed.	• The pharmaceutical companies were able to develop the COVID-19 vaccines because of the worldwide effort. • All three COVID-19 vaccines were developed based on existing technology. Their effectiveness and safety profile have been established prior to the development of the COVID-19 vaccines.
The COVID-19 vaccines can make me sick with COVID-19.	• None of the available vaccines contain SARS-CoV-2. Therefore, the vaccine cannot cause COVID-19.
The COVID-19 vaccines can alter my DNA.	• The mRNA in the Pfizer-BioNTech and Moderna vaccines do not enter the cell nucleus. It is quickly degraded after entering the cells. • The DNA in the Janssen vaccine is not able to integrate into the host cell DNA.
The COVID-19 vaccines can affect fertility.	• There is no evidence during animal trials that the vaccines affect fertility. • Observational studies have not demonstrated that the vaccines affect fertility.
Since some observational studies have shown substantial immunity after the first dose of mRNA vaccines, a second dose is not necessary.	• We do not know the long-term efficacy of either mRNA vaccines as the clinical trials only evaluated two-dose regimens. • The efficacy of the Pfizer-BioNTech mRNA COVID-19 vaccine against the Delta variant is about 44% after one dose but increases to >90% after the second dose. • Therefore, everyone who are receiving a mRNA vaccine should get both doses. • To be deemed fully vaccinated, recipients of the mRNA vaccine must receive two doses.
Because the survival rate is so high, vaccination is not needed.	• Although the death rates from COVID-19 is still around 1.5%, the number of individuals hospitalized for moderate to severe COVID-19 can be high and overwhelm the capacity of many hospitals. • Vaccination can help to reduce the likelihood of hospitalization. • Vaccination can help the development of severe disease. • Vaccination can potentially help the spread of the disease to others who are likely to develop severe disease.
After vaccination, face coverings and physical distancing are not needed.	• Preventative measures are needed because the vaccine is not 100% effective against developing COVID-19. • Until the effectiveness of the vaccines against the variants of concern have been established, it is wise to continue all preventative measures.
If someone had COVID-19, the vaccine is not needed because they will already have immunity.	• If eligible and there are no contraindications, everyone should receive the COVID-19 regardless of prior history of COVID-19. • Re-infection, particularly with variants of concern, has been reported.
Immunity through natural infection is always better than through vaccination.	• Although for infections, this may be the case. For other infections, such as measles, a vaccine provides better protection.

	• Immunity through vaccination is much safer than through natural infection. • Vaccination also do not have the post-infection complications like some natural infections may have, e.g., chickenpox and shingles.
Since there is monoclonal antibody therapy available, there really isn't any need to vaccinate.	• Although monoclonal antibody therapy may help those
The side effects of the COVID-19 vaccines are severe and serious.	• Most reported vaccine-related symptoms are mild to moderate and well tolerated. • Although hypersensitivity reactions have been reported, they are rare. • Clinical trials demonstrated very few serious adverse events.
The COVID-19 vaccines contain controversial substances.	• The vaccines do not contain implants, microchips, tracking devices, or fetal tissue.
If a vaccine recipient had a "bad reaction" to the first mRNA vaccine, the second dose should not be given.	• Unless the recipient experienced a reaction that was deemed to be a contraindication for the second dose by an allergist, the second dose should be given.
Those with egg allergy should not receive the vaccine.	• None of the COVID-19 vaccines do contain egg or are developed from eggs.

Summary of Previous Changes

2021.09.27

- Addition of an item under the section "General Vaccine Questions" which outlined the three available COVID-19 vaccines and their differences.
- The item under the section "General Vaccine Questions" which discussed indications for the three available COVID-19 vaccines are updated.
- Addition of an item under the section "General Vaccine Questions" which outlined CDC and/or ACIP recommendations for the use of the COVID-19 vaccines, including additional/supplemental doses.
- The item under the section "General Vaccine Questions" which discussed testing prerequisites for COVID-19 vaccination has been further clarified.
- The item on additional vaccine doses has been removed as this is covered in the indications and CDC and/or ACIP recommendations item.
- The item under the section "General Vaccine Questions" which discussed mRNA vaccine dose administration interval recommendation is updated.
- The item which discussed differences in the mRNA and J&J/Janssen COVID-19 section has been removed as this is included in a previous section.
- The item under the section "Special Population Questions" which discussed the use of vaccine in age groups less than 18 years has been further clarified.
- The item under the section "Special Population Questions" which discussed autoimmune diseases have been simplified.
- The item under the section "Special Population Questions" which discussed vaccinating individuals with history of severe allergic reactions and anaphylaxis has been clarified.
- The item under the section "Special Population Questions" which discussed vaccinating individuals with history of GBS has been updated.
- The item under the section "Special Population Questions" which discussed vaccinating individuals with previous SARS-CoV-2 infection has been revised.
- The item under the section "Other Vaccine-Related Questions" which discussed vaccine interchangeability has been clarified.
- The item under the section "Other Vaccine-Related Questions" which discussed was clarified to offer an option to complete the vaccination series of vaccine recipients who developed severe adverse reaction to the first dose of mRNA vaccine.
- The item under the section "Other Vaccine-Related Questions" which discussed vaccinating individuals who received antibody therapy has been revised.

- The item under the section “Other Vaccine-Related Questions” which discussed tuberculosis testing around the time of COVID-19 vaccination has been updated.
- The item under the section “Other Vaccine-Related Questions” which discussed international travel of vaccinated individuals have been clarified.
- The item under the section “Vaccine Administration Error” which discussed administration of a non-COVID-19 vaccine and the COVID-19 vaccine within 14 days has been removed.

Figure 1. Ingredients included in COVID-19 vaccines.

Description	Pfizer-BioNTech (mRNA) For persons aged 5-11 years (10µg dose) formulation	Pfizer-BioNTech (mRNA) For persons aged ≥12 years (30µg dose) formulation	Moderna (mRNA) For persons aged ≥18 years	Janssen (viral vector) For persons aged ≥18 years
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG:1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102:heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Tromethamine	Sodium chloride	Tromethamine	Sodium chloride
	Tromethamine hydrochloride	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Sucrose	Potassium chloride	Acetic acid	
		Dibasic sodium phosphate dihydrate	Sodium acetate	
		Sucrose	Sucrose	

* None of the vaccines contain eggs, gelatin, latex, or preservatives. All COVID-19 vaccines are **free from metals** such as iron, nickel, cobalt, lithium, rare earth alloys or any manufactured products such as microelectronics, electrodes, carbon nanotubes, or nanowire semiconductors.
Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called “pegylation” to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. CDC’s vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as a resource.

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

Figure 2. List of medications and vaccines reported to contain polysorbate or PEG.

TABLE II. Polysorbate and PEG excipients in select vaccines[12]

Excipient	Vaccine type	Vaccine	Amount per dose
Polysorbate 20	Influenza	Flublok&Flublock quad	≤27.5 μg (Tween20)
Polysorbate 20	Hepatitis A	Havrix	0.05 mg/mL
Polysorbate 20	Hepatitis A&B	Twinrix	Unknown
Polysorbate 20*	SARS-CoV-2 (Sanofi)		
Polysorbate 80	Tdap	Boostrix	≤100 μg (Tween 80)
Polysorbate 80	Influenza	Fluad	1.175 mg
Polysorbate 80	Influenza	Fluarix quad	≤0.055 mg (Tween 80)
Polysorbate 80	Influenza	Flucelvax quad	≤1500 μg (Tween 80)
Polysorbate 80	Influenza	Flulaval Quad	≤887 μg
Polysorbate 80	HPV	Gardasil and Gardasil -9	50 μg
Polysorbate 80	Hepatitis B	Heplisav-B	0.1 mg/mL
Polysorbate 80	DTaP	Infanrix	≤100 μg (Tween 80)
Polysorbate 80	Japanese encephalitis	JE-Vax	<0.0007%
Polysorbate 80	DTaP + IPV	Kinrix	≤100 μg (Tween 80)
Polysorbate 80	DTaP + HepB + IPV	Pediarix	≤100 μg (Tween 80)
Polysorbate 80	Pneumococcal 13-valent	Prevnar 13	100 μg
Polysorbate 80	DTaP + IPV	Quadracel	10 ppm
Polysorbate 80	Rotavirus	RotaTeq	?
Polysorbate 80	Zoster	Shingrix	0.08 mg
Polysorbate 80	Meningococcal group B	Trumenba	0.018 mg
Polysorbate 80	DTaP + IPV + HepB + Hib	Vaxelis	<0.0056%
Polysorbate 80*	SARS-CoV-2 (AstraZeneca) SARS-CoV-2 (Johnson & Johnson)		
PEG2000	SARS-CoV-2 (Moderna) SARS-CoV-2 (Pfizer)		

TABLE III. Common injectable medications containing PEG[14]

Generic name (brand name)	Molecular weight	General description
Methylprednisolone acetate (Depo-Medrol)	PEG 3350	An anti-inflammatory glucocorticoid for intramuscular, intra-articular, soft tissue or intralesional injection
Methoxy polyethylene glycol-epoetin beta (Micera)	30-kD methoxy PEG butanoic acid	Used to treat anemia in adults with chronic kidney disease
Pegfilgrastim (Neulasta)	20-kD monomethoxy PEG	Used to help reduce the chance of infection due to a low white blood cell count, in people with certain types of cancer (nonmyeloid), who receive anticancer medicines (chemotherapy) that can cause fever and low white blood cell count
Medroxyprogesterone acetate (Depo-Provera)	PEG 3350	Contraceptive and adjunctive therapy and palliative treatment of inoperable, recurrent, and metastatic endometrial or renal carcinoma
Brilliant Blue G Ophthalmic Solution (TissueBlue)	PEG 3350	Disclosing agent indicated to selectively stain the internal limiting membrane
Sulfur hexafluoride (Lumason)	PEG 4000	Ultrasound contrast agent
Biomatoprost implant (Durysta)	PEG, unspecified	Reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension
Trastuzumab (Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant)	PEG 3350	Adjuvant treatment of HER2 overexpressing node-positive or node-negative breast cancer
Rilonacept (Arcalyst)	PEG 3350	IL-1 blocker for treatment of cryopyrin-associated periodic syndromes
Perflutren lipid microsphere (Definity)	PEG 5000	Contrast agent used to brighten and clarify images of the heart during echocardiograms

TABLE IV. Common injectable medications containing polysorbate

Drug class	Generic name (brand name)	Polysorbate
Antiarrhythmic	Amiodarone hydrochloride (generics only)	Polysorbate 80
Antidiabetic	Exenatide (Bydureon Bcise)	Polysorbate 20
	Insuline glargine (Lantus, Semglee)	Polysorbate 20
	Insuline glulisine (Apidra)	Polysorbate 20
	Dulaglutide (Trulicity)	Polysorbate 80
Antidote	Hyaluronidase (Hylenex Recombinant)	Polysorbate 80
Antifungal	Anidulafungin (Eraxis)	Polysorbate 80
Anti-inflammatory	Interferon beta 1a (Avonex, Plegridy)	Polysorbate 20
	Omalizumab (Xolair)	Polysorbate 20
Antineoplastic	Ofatumumab (Kesimpta)	Polysorbate 80
	Siltuximab (Sylvant)	Polysorbate 80
Antipsychotic	Paliperidone palmitate (Invega Trinza, Invega Sustenna)	Polysorbate 20
	Aripiprazole lauroxil (Aristada)	Polysorbate 20
Antiretroviral	Ibalizumab (Trogarzo)	Polysorbate 80
Antipsoriatic	Adalimumab (Humira, Imraldi)	Polysorbate 20 (Imraldi)/ Polysorbate 80 (Humira)
	Golimumab (Simponi)	Polysorbate 80
	Guselkumab (Tremfya)	Polysorbate 80
	Infliximab - dyyb (Inflectra, Remicade, Renflexis)	Polysorbate 80
	Ustekinumab (Stelara)	Polysorbate 80
Antiviral	Interferon alfa-2b (Intron A)	Polysorbate 80
Biological response modifier	Interferon gamma-1b (Actimmune)	Polysorbate 20
Cancer treatment	Ado-trastuzumab emtansine (Kadcyla)	Polysorbate 20
	Atezolizumab (Tecentriq)	Polysorbate 20
	Avelumab (Bavencio)	Polysorbate 20
	Bevacizumab (Avastin, Zirabev)	Polysorbate 20
	Daratumumab/hyaluronidase (Darzalex Faspro)	Polysorbate 20
	Denosumab (Prolia, Xgeva)	Polysorbate 20
	Dinutuximab (Unituxin)	Polysorbate 20
	Enfortumab (Padcev)	Polysorbate 20
	Olaratumab (Lartruvo)	Polysorbate 20
	Palifermin (Kepivance)	Polysorbate 20
	Pertuzumab/trastuzumab/hyaluronidase (Phesgo)	Polysorbate 20
	Polatuzumab vedotin (Polivy)	Polysorbate 20
	Tafasitamab (Monjuvi)	Polysorbate 20
	Trastuzumab (Herceptin, Herceptin Hylecta, Herzuma, Kanjinti, Ontruzant, Trazimera)	Polysorbate 20
	Belantamab (Blenrep)	Polysorbate 80
	Brentuximab vedotin (Adcetris)	Polysorbate 80
	Cemiplimab (Libtayo)	Polysorbate 80
	Docetaxel (Taxotere)	Polysorbate 80
	Durvalumab (Imfinzi)	Polysorbate 80
	Elotuzumab (Empliciti)	Polysorbate 80
	Etoposide (Toposar, VePesid)	Polysorbate 80
	Fam-trastuzumab deruxtecan (Enhertu)	Polysorbate 80
	Fosaprepitant dimeglumine (EMEND, Fosaprepitant)	Polysorbate 80
	Inotuzumab ozogamicin (Besponsa)	Polysorbate 80
	Ipilimumab (Yervoy)	Polysorbate 80
	Isatuximab (Sarclisa)	Polysorbate 80
	Mogamulizumab (Poteligeo)	Polysorbate 80
	Moxetumomab pasudotox (Lumoxiti)	Polysorbate 80
	Nivolumab (Opdivo)	Polysorbate 80
	Ofatumumab (Arzerra)	Polysorbate 80
	Pembrolizumab (Keytruda)	Polysorbate 80

TABLE IV. *(Continued)*

Drug class	Generic name (brand name)	Polysorbate
	Ramucirumab (Cyramza)	Polysorbate 80
	Rituximab (Truxima, Rituxan, Ruxience)	Polysorbate 80
	Rituximab and hyaluronidase (Rituxan Hycela)	Polysorbate 80
	Temsirolimus (Torisel)	Polysorbate 80
	Temozolomide (Temodar)	Polysorbate 80
Contraceptive	Medroxyprogesterone acetate (Depo-Provera, Depo-Provera CI, Depo-subQ provera 104)	Polysorbate 80
Corticosteroid	Methylprednisolone acetate (Depo-Medrol)	Polysorbate 80
	Triamcinolone acetonide (Aristocort Forte, Aristospan, Kenalog-40, Kenalog-10, Protherix, Triesence, Triloan Suik, Triloan II Suik, Zilretta)	Polysorbate 80
Diagnostic	Sincalide (Kinevac)	Polysorbate 20
	Tuberculin purified protein derivative (Aplisol, Tubersol)	Polysorbate 80
Disease-modifying antirheumatic drug	Anakinra (Kineret)	Polysorbate 80
	Tocilizumab (Actemra)	Polysorbate 80
Enzyme	Velaglucerase alfa (Vpriv)	Polysorbate 20
	Imiglucerase (Cerezyme)	Polysorbate 80
	Taliglucerase alfa (Elelyso)	Polysorbate 80
Erythoid maturation agent	Luspatercept (Reblozyl)	Polysorbate 80
Factor Xa inhibitor antidote	Coagulation factor Xa (recombinant), inactivated-zhzo (Andexxa)	Polysorbate 80
Gonadotropin	Follitropin (Menopur, Follistim)	Polysorbate 20
Growth hormone analog	Somatropin (Nutropin AQ Nuspin 5)	Polysorbate 20
Hematopoietic growth factor	Erythropoietin (Retacrit)	Polysorbate 20
	Pegfilgrastim (Fulphila, Neulasta, Nyvepria, Udenyca)	Polysorbate 20
	Romiplostim (Nplate)	Polysorbate 20
	Darbepoetin alfa (Aranesp)	Polysorbate 80
	Filgrastim (Neupogen, Nivestym, Granix, Zarxio)	Polysorbate 80
Hepatitis B/Hepatitis C agent	Peginterferon (Pegasys Pegintron)	Polysorbate 80
Hemostatic	Vitamin K (Phytonadione)	Polysorbate 80
Immune globulin	Hepatitis B immune globulin (HepaGam B, Nabi-HB)	Polysorbate 80
	Rho (d) immune globulin (WinRho)	Polysorbate 80
Immunomodulator	Interferon beta-1a (Avonex, Avonex Pen)	Polysorbate 20
	Emapalumab (Gamifant)	Polysorbate 80
Immunosuppressant	Mycophenolate mofetil (Cellcept IV)	Polysorbate 80
Inflammatory bowel disease agent	Vedolizumab (Entyvio)	Polysorbate 80
Interleukin inhibitor	Sarilumab (Kevzara)	Polysorbate 20
	Dupilumab (Dupixent)	Polysorbate 80
	Mepolizumab (Nucala)	Polysorbate 80
	Secukinumab (Cosentyx)	Polysorbate 80
	Tildrakizumab -asmn (Ilumya)	Polysorbate 80
Kallikrein inhibitor	Lanadelumab (Takhzyro)	Polysorbate 80
Leptin analog	Metreleptin (Myalept)	Polysorbate 20
Macular degeneration agent	Aflibercept (Eylea)	Polysorbate 20
	Ranibizumab (Lucentis)	Polysorbate 20
	Brolucizumab (Beovu)	Polysorbate 80
mAb treatment	Ocrelizumab (Ocrevus)	Polysorbate 20
	Remdesivir (Veklury)	Polysorbate 20
	Romosozumab (Evenity)	Polysorbate 20
	Teprotumumab (Tepezza)	Polysorbate 20
	Atoltivimab/maftivimab/odesivimab-ebgn (Inmazeb)	Polysorbate 80
	Bamlanivimab	Polysorbate 80
	Burosumab (Crysvita)	Polysorbate 80
	Canakinumab (Ilaris)	Polysorbate 80

TABLE IV. *(Continued)*

Drug class	Generic name (brand name)	Polysorbate
	Casirivimab/Imdevimab	Polysorbate 80
	Eptinezumab (Vyepti)	Polysorbate 80
	Fremanezumab (Ajovy)	Polysorbate 80
	Inebilizumab (Uplizna)	Polysorbate 80
	Raxibacumab	Polysorbate 80
Multiple sclerosis treatment	Natalizumab (Tysabri)	Polysorbate 80
Muscle relaxant	Dantrolene sodium (Dantrium, Ryanodex)	Polysorbate 80
P-selectin inhibitor	Crizanlizumab (Adakveo)	Polysorbate 80
Proprotein convertase subtilisin kexin type 9 inhibitor	Alirocumab (Praluent)	Polysorbate 20
	Evolocumab (Repatha)	Polysorbate 80
Rheumatologic	Belimumab (Benlysta)	Polysorbate 80
Thrombolytic	Tenecteplase (Tnkase)	Polysorbate 20
	Alteplase (Cathflo Activase)	Polysorbate 80
	Reteplase (Retavase)	Polysorbate 80
Vitamin infusion	Calcitriol (Calcijex, Rocaltrol)	Polysorbate 20
	Doxercalciferol (Hectorol)	Polysorbate 20
	Vitamins A, B1, B2, B6, C, D3, E, K (Infuvite)	Polysorbate 80

Adapted from Banerji A et al. mRNA Vaccine to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach. J Allergy Clin Immunol Pract 2020; Dec 31:S2213-2198(20)31411-2

Figure 3. Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine[1,2] • Known (diagnosed) allergy to a component of a COVID-19 vaccine[1]	**Among people without a contraindication, a history of:** • Any immediate allergic reaction[3] to other vaccines (non-COVID-19) or injectable therapies[4] • Non-severe, immediate (onset <4 hours) allergic reaction[2] after a previous dose of COVID-19 vaccine[6] Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa[5]	**Among people without a contraindication or precaution, a history of:** • Allergy (including anaphylaxis) to oral medications (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: • Do not vaccinate • Consider referral to allergist-immunologist • Consider other vaccine alternative if age appropriate[1,5]	**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

[1] 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). However, some of these individuals may be able to receive Janssen COVID-19 Vaccine after a detailed risk assessment and possibly allergy testing (see footnote 5 below).

[2]Severe allergic reactions include

- Possible anaphylaxis, a progressive life-threatening reaction that typically includes urticaria but also with other symptoms such as wheezing, difficulty breathing, or low blood pressure (see Appendix D)
- Any angioedema affecting the airway (i.e., tongue, uvula or larynx)
- Diffuse rash which also involves mucosal surfaces (e.g., Stevens-Johnson Syndrome)

Non-severe allergic reactions may include

- Urticaria (hives) beyond the injection site
- Angioedema (visible swelling) involving lips, skin of face or skin in other locations. NOTE: Any angioedema affecting the airway (i.e., tongue, uvula, or larynx) would NOT be in this category and is considered a severe allergic reaction

[3] Immediate allergic reaction to a vaccine or injectable therapy 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.

[4] People with a history of an immediate allergic 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. These individuals may benefit from consultation with an allergist-immunologist who can perform a more detailed risk assessment for COVID-19 vaccine receipt and possibly allergy testing.

[5] 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 a first 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. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare professionals 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 healthcare professional experienced in the management of severe allergic reactions.

[6] For people with a history of an immediate, non-severe allergic reaction after an mRNA COVID-19 vaccine, vaccination with a subsequent dose of either of the mRNA COVID-19 vaccines should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Similarly, for people with a history of an immediate, non-severe allergic reaction after Janssen COVID-19 Vaccine, vaccination with a subsequent dose of Janssen vaccine should only be undertaken under the supervision of a health care provider experienced in the management of severe allergic reactions. Administering the other vaccine type is another option; this can be done with a 30-minute observation period in a usual COVID-19 vaccination setting.