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Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine Updated: October 23, 2021

Note: For summary information on contraindications and precautions to vaccines, go to the ACIP's General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

1. Are you feeling sick today?

If yes, refer to the vaccination site healthcare provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the patient to return when symptoms improve.

- 2. In the last 10 days, have you had a COVID-19 test because you had symptoms and are still awaiting your test results or been told by a healthcare provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?
 - If yes, advise patient to return to isolation or quarantine and reschedule for after isolation/quarantine ends.
 - If the patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 72 hours or more, patient may be vaccinated.
 - If the patient has had a test in the last 10 days, ask for the result. If positive, send them home. If negative, they can proceed to vaccination. If the result is unsure or unknown, advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.
 - Persons with a history of multisystem inflammatory syndrome in children (MIS-C) or in adults (MIS-A) should consider delaying vaccination until they have recovered from their illness and for 90 days after the diagnosis of MIS-C or MIS-A. However, patients can choose to be vaccinated. For further information on counseling a patient with a history of MIS-C or MIS-A regarding COVID-19 vaccines, please see the Centers for Disease Control and Prevention's (CDC) section on MIS-C and MIS-A in their "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States" available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.
- 3. Have you been treated with antibody therapy or convalescent plasma for COVID-19 in the past 90 days (3 months)? If yes, when did you receive the last dose?
 - If yes, reschedule at least 90 days after last dose of antibody therapy.
- 4. Have you ever had an immediate allergic reaction, such as hives, facial swelling, difficulty breathing, anaphylaxis to any vaccine, injection, or shot or to any component of the COVID-19 vaccine, or a severe allergic reaction (anaphylaxis) to anything?

If yes, then refer to the vaccination site healthcare provider for assessment of allergic reaction. Review the ingredient lists at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC AA refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Appendix-C.

Contraindications to COVID-19 vaccine:

- Severe allergic reaction (e.g., anaphylaxis) or immediate allergic reaction of any severity after a previous dose or to a component of the COVID-19 vaccine.
- People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA COVID-19 vaccines (Pfizer or Moderna).

<u>Precautions to COVID-19 vaccine</u>: (Refer to your organization's protocol to see whether individuals with a precaution to vaccination warrant further evaluation.)

- Immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies excluding subcutaneous immunotherapy for allergies).
- Individuals with a contraindication to one type of COVID-19 vaccine (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector).
 - Consultation with an allergist-immunologist should be considered to help determine
 if the patient can safely receive vaccination, and vaccination of these individuals
 should only be undertaken in an appropriate clinical setting under the supervision of
 a healthcare provider experienced in the management of severe allergic reactions.
 - Note: These individuals should not be administered COVID-19 vaccine at Stateoperated vaccination sites.

For patients who are determined eligible for COVID-19 vaccination after assessment of allergy history, a 30-minute post-vaccination observation period is needed for the following:

- Patients with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy
- Patients with a contraindication to a different type of COVID-19 vaccine (e.g., mRNA vs. Janssen viral vector)
- Patients with a history of anaphylaxis due to any cause

5. Are you pregnant or considering becoming pregnant?

If yes, ask the patient if they would like to have a discussion with a healthcare provider at site for counseling on the risks and benefits of COVID-19 vaccine during pregnancy. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose.

6. Do you have cancer, leukemia, HIV/AIDS, or any other condition that weakens the immune system?

If yes, ask the patient if they would like to have a discussion with the vaccination site healthcare provider about what is known and not yet known about COVID-19 vaccine for immunocompromised people. You can tell the patient that they may have a less strong immune response to the vaccine but may still get vaccinated. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose not to.

7. Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?

If yes, ask the patient if they would like to have a discussion with the vaccination site healthcare provider about what is known and not yet known about COVID-19 vaccine for immunosuppressed people. You can tell the patient that they may have a less strong immune response to the vaccine but

may still get vaccinated. Patient may be vaccinated if they choose and does not need to go to medical evaluation if they choose not to.

8. Do you have a bleeding disorder, a history of blood clots or are you taking a blood thinner? If yes, refer to healthcare provider to assess the patient's bleeding risk and thrombosis history. Persons with a history of immune-mediated thrombosis and thrombocytopenia, such as Heparin-Induced Thrombocytopenia (HIT) within the past 90 days should be offered an mRNA COVID-19 vaccine (i.e., Pfizer or Moderna vaccine) instead of Janssen (Johnson & Johnson) vaccine. If a person with a bleeding disorder or taking a blood thinner is cleared for vaccination, then administer vaccine using a 23-gauge or smaller caliber needle and apply firm pressure on the site of vaccination, without rubbing, for at least 2 minutes after vaccination.

9. Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)? If yes:

- Evaluate if this history was in relation to a dose of mRNA vaccine. If it was not, then the patient can receive any U.S. Food and Drug Administration (FDA) authorized COVID-19 vaccine after complete resolution of a myocarditis or pericarditis episode.
- If the patient developed myocarditis or pericarditis after the first dose of an mRNA vaccine, experts recommend deferral of the second dose until additional safety data are available. However, the second dose can be considered after complete resolution of a myocarditis or pericarditis episode. Decisions to proceed with vaccination should include conversations with the patient, parent/legal representative, and the clinical team, including a cardiologist. Considerations for vaccination may include:
 - Personal risk of severe acute COVID-19 disease (e.g., age, underlying conditions).
 - Level of COVID-19 community transmission and personal risk of infection.
 - Additional data on the risk of myocarditis or pericarditis following an occurrence of either condition after the first dose of an mRNA COVID-19 vaccine.
 - Additional data on the long-term outcomes of myocarditis or pericarditis that occurred after receipt of an mRNA COVID-19 vaccine.
 - o Timing of immunomodulatory therapeutics; ACIP's <u>general best practice guidelines</u> for immunization can be consulted for more information.
- For the full CDC interim clinical considerations regarding a history of myocarditisand/or pericarditis, please see the CDC's <u>COVID-19 Vaccines Currently Authorized in the United States</u> and <u>Clinical Considerations</u>: <u>Myocarditis and Pericarditis after Receipt of mRNA</u> COVID-19 Vaccines Among Adolescents and Young Adults.

10. Are you 65 years of age or older?

If yes, they qualify for a booster dose of the Pfizer or Moderna COVID-19 vaccine if they completed the 2-dose series at least 6 months ago. If not, verify if they qualify for a Pfizer or Moderna booster under questions 11-16 below, or a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

11. Are you 18 years old or older AND a resident of a long-term care facility?

If yes, they qualify for a booster dose of the Pfizer or Moderna COVID-19 vaccine if they completed the 2-dose series at least 6 months ago. If not, verify if they qualify for a Pfizer or Moderna booster under questions 10, or 12-16 below, or a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance. Long-term care facilities include settings such as:

- Nursing homes
- Assisted living facilities
- Residential care communities
- Group homes
- Senior housing
- 12. Are you 50 through 64 years old AND have one or more of the following conditions due to increased risk of moderate or severe illness or death from the virus that causes COVID-19 AND you completed the Pfizer or Moderna 2-dose series at least 6 months ago?
 - Cancer (current or in remission, including 9/11-related cancers)
 - Chronic kidney disease*
 - Pulmonary disease, limited to chronic obstructive pulmonary disease (COPD), asthma (moderate to severe), pulmonary fibrosis, cystic fibrosis, tuberculosis, and 9/11 related pulmonary diseases
 - Intellectual and developmental disabilities including Down Syndrome
 - Heart conditions, including but not limited to heart failure, coronary artery disease, cardiomyopathies, or hypertension (high blood pressure)
 - Immunocompromised state (weakened immune system) including but not limited to solid organ transplant or from blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, use of other immune weakening medicines, or other causes
 - Severe obesity: body mass index ((BMI) 40 kg/m2 or higher)*, obesity: (BMI of 30 kg/m2 or higher but < 40 kg/m2)*, overweight (BMI of 25 kg/m2 or higher but < 30kg/m2)
 - Pregnant or recently pregnant
 - Sickle cell disease or thalassemia
 - Type 1 or 2 diabetes mellitus*
 - Cerebrovascular disease (affects blood vessels and blood supply to the brain)
 - Neurologic conditions including but not limited to Alzheimer's disease or dementia
 - Liver disease limited to cirrhosis, non-alcoholic fatty liver disease, alcoholic liver disease, or autoimmune hepatitis.
 - Current or former smoker
 - Substance use disorder
 - Mental health disorders limited to mood disorders including depression, schizophrenia spectrum disorders.

If yes, they qualify for a booster dose of the Pfizer or Moderna COVID-19 vaccine if they completed the 2-dose series at least 6 months ago. If not, verify if they qualify for a Pfizer or Moderna booster under questions 10, 11, 13-16 below, or a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary

^{*} indicates underlying conditions with evidence for pregnant and non-pregnant people

series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

13. Are you 18 through 49 years old AND have one or more of the underlying medical conditions listed above AND are seeking a booster because the benefits outweigh the risks?

If yes, they qualify for a booster dose of the Pfizer or Moderna COVID-19 vaccine if they completed the 2-dose series at least 6 months ago. Consider having a conversation with the patient about the known and unknown benefits and risks of receiving a booster dose of the Pfizer or Moderna COVID-19 vaccine based on their medical history and risk of exposure to SARS-CoV-2. The patient's clinical team is best situated to determine the appropriateness of a booster dose. If not, verify if they qualify for a Pfizer or Moderna booster under questions 10-12, or 14-16 below, or a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

14. Are you 18 through 64 years old AND are at increased risk for COVID-19 exposure and transmission because of working or living in a high-risk setting?

Occupational high-risk settings that apply include:

- Essential workers (frontline and nonfrontline) https://www.cisa.gov/publication/guidance-essential-critical-infrastructure-workforce
- Unpaid caregiver of a frail or immunocompromised person
- Paid and unpaid workers who interact within <6ft of others
- Live in a congregate setting (e.g. homeless shelter, correctional facility)

If yes, they qualify for a booster dose of the Pfizer or Moderna COVID-19 vaccine if they completed the 2-dose series at least 6 months ago. Consider having a conversation with the patient about the known and unknown benefits and risks of receiving a booster dose of the Pfizer or Moderna COVID-19 vaccine based on their medical history and risk of exposure to SARS-CoV-2. The patient's clinical team is best situated to determine the appropriateness of a booster dose. If not, verify if they qualify for an mRNA booster under questions 10-13 or 15-16, or a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

15. Have you received 2 doses of the Pfizer vaccine, the second dose being at least 6 months ago?

If no, verify if this is a second dose vaccine appointment. If this is a second dose of mRNA COVID-19 vaccine, be sure it is from the same manufacturer as the previous dose and that the second dose is being administered within the correct timeframe (21 days from first dose for Pfizer). If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received. The second dose of an mRNA COVID-19 vaccine should be administered as close to the recommended interval as possible.

If this is a third dose, verify if this is a booster dose of the Pfizer COVID-19 vaccine, or an additional third dose for a person who is moderately to severely immunocompromised.

- If this is a booster dose, verify that the person received Pfizer COVID-19 vaccine for their primary series, that it has been at least 6 months since the second dose and that they have a qualifying condition. Qualifying conditions for an mRNAbooster dose are listed in questions 10-16, and a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.
- If this dose is an additional third dose of the Pfizer COVID-19 vaccine) for a person who is moderately to severely immunocompromised, there is a separate screening and consent form and a separate instruction document available for providers and these patients. These forms are available here:
 - <u>COVID-19 Immunization Screening and Consent Form: Additional Dose for Moderately to Severely Immunocompromised</u>
 - Information for Health Care Professionals about the Screening Checklist for the COVID-19 Vaccine: Additional Dose for Moderately to Severely Immunocompromised.
- 16. Have you received 2 doses of the Moderna vaccine, the second dose being at least 6 months ago? If no, verify if this is a second dose vaccine appointment. If this is a second dose of mRNA COVID-19 vaccine, be sure it is from the same manufacturer as the previous dose and that the second dose is being administered within the correct timeframe (28 days from first dose for Moderna). If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received. The second dose of an mRNA COVID-19 vaccine should be administered as close to the recommended interval as possible.

If this is a third dose, verify if this is a booster dose of the Moderna COVID-19 vaccine or an additional third dose for a person who is moderately to severely immunocompromised.

If this is a booster dose, verify that the person received Moderna COVID-19 vaccine for their primary series, that it has been at least 6 months since the second dose, and that they have a qualifying condition. Qualifying conditions for an mRNA booster dose are listed in questions 10-16, and a Janssen booster under question 17. The booster dose should be given using the same vaccine manufacturer that the person received for the primary series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA-approved or authorized COVID-19 vaccine can be used for the booster dose, according to FDA and CDC guidance.

- If this dose is an additional third dose of the Moderna COVID-19 vaccine for a person who is moderately to severely immunocompromised, there is a separate screening and consent form and a separate instruction document available for providers and these patients. These forms are available here:
 - COVID-19 Immunization Screening and Consent Form: Additional Dose for Moderately to Severely Immunocompromised

 Information for Health Care Professionals about the Screening Checklist for the <u>COVID-19 Vaccine: Additional Dose for Moderately to Severely</u> Immunocompromised.

17. Have you received a previous dose of the Janssen vaccine, at least 2 months ago?

If yes, verify if this is a booster dose. If this is a booster dose of Janssen COVID-19 vaccine, be sure that the dose is being administered at least 2 months from the first Janssen vaccine dose. If patient does not recall previous COVID-19 vaccine received, check medical records, NYSIIS, CIR, or CDC vaccination cards to help determine the initial product received.

The booster dose should be given using the same vaccine manufacturer that the person received for the primary vaccine series. If the same product used for the primary series is no longer available, or a different COVID-19 vaccine is desired, any FDA approved, or authorized COVID-19 vaccine can be used for the booster dose according to FDA and CDC guidance.

18. If you had a previous dose of Janssen, did you develop thrombosis with thrombocytopenia syndrome (TTS)?

If yes, do not administer a Janssen booster dose. TTS is a rare condition diagnosed by a health care provider in which people have blood clots and low platelet counts. Persons with a history of TTS following the Janssen vaccine should be offered an mRNA COVID-19 booster dose instead of an additional Janssen vaccine.

19. Have you received a previous dose of a COVID-19 vaccine authorized by the WHO but not by the FDA (AstraZeneca – VAXZEVRIA, Sinovac – CORONAVAC, Serum Institute of India – COVISHIELD, Sinopharm/BIBP)?

- If yes, identify if the patient has received a complete or partial series of the vaccine. If the patient received a complete series (e.g., 2 doses), CDC considers them to be fully vaccinated and no additional doses are needed.
- If a patient received a partial series of a WHO authorized COVID-19 vaccine that is not currently authorized for use in the U.S. by the FDA, the CDC does NOT consider these persons to be fully vaccinated. If at least 28 days has passed since the vaccine dose was administered, a complete series of an FDA authorized COVID-19 vaccine can be offered to the patient.
- If the patient received either a partial series or complete series of a COVID-19 vaccine that is
 not authorized for use by either the WHO or the FDA, the CDC does NOT consider these
 persons to be fully vaccinated. If at least 28 days has passed since the last vaccine dose was
 administered, a complete series of an FDA authorized COVID-19 vaccine can be offered to
 the patient.

At State-operated vaccination sites: If a person presents for a Janssen COVID-19 vaccine after previously having received one dose of the Pfizer or Moderna COVID-19 primary vaccine series due to allergic reaction or other adverse event, they should not be administered the Janssen COVID-19 vaccine at a state-operated site and should consult with their healthcare provider.

Due to insufficient data at this time, the EUA amendments authorizing additional doses of mRNA vaccines for moderately to severely immunocompromised individuals, as well as the EUA amendment authorizing booster doses of the Pfizer COVID-19 vaccine, do not apply to the vaccines authorized by the

WHO but not the FDA. They do not support the use of additional/third or booster doses of vaccine after receipt of these WHO-authorized vaccines at this time.

* Anyone answering "Unknown" to any screening question should be referred to the medical director or responsible healthcare provider at the POD or clinic to further assess their answer to that question (e.g., the person might not have understood the question and the healthcare provider could explain it further).