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#### I. Providing COVID-19 Vaccines Outside of a COVID-19 Vaccine Clinic

- 1. As the primary—and often only—health-care access point for many Americans, hospitals, emergency departments (EDs), and urgent care centers (UCCs) should consider **administering the COVID-19 vaccine before discharging patients** to increase vaccine access.
- 2. Order COVID-19 vaccine in quantities as low as a single vial for your ED, UCC, private practice, small clinic, or any site that needs a lower volume of vaccine through <u>VDH's Small Shipment Redistribution Program</u>.



#### II. Clinic Management & Operations

#### 1. Clinic Setup

- a. Consider federal, state, and local guidance when establishing measures (such as inventory management, appropriate personal protective equipment [PPE], hand hygiene, physical distancing, safety, etc.) to protect clinic staff and patients. Overall guidance for vaccination clinic location and layout from the CDC can be found <a href="https://example.com/here">here</a>.
- Refer to the Cybersecurity and Infrastructure Security Agency (CISA) <u>COVID-19 Vaccine</u>
   <u>Distribution Physical Security Measures Infographic</u> for a non-comprehensive list of proactive
   measures to enhance physical security.
- c. It is always preferable to have vaccine(s) shipped directly to the clinic site instead of transporting them from another facility. Therefore, if possible, select a location with on-site equipment that can secure and store vaccines at appropriate temperatures. Plans must be in place to ensure staff can check the shipment immediately upon arrival to ensure there has been no temperature excursion, place the vaccines in storage unit(s), and regularly monitor vaccine temperatures.
- d. Regardless of whether vaccines are delivered to the site or transported there, plans must include regular monitoring of vaccine temperature before, during, and after the clinic.
- e. When temperatures rise during the summer, it is critical to follow all guidance for maintaining COVID19 vaccines at the proper temperatures at all times (this includes storage, transport, and pre-drawn syringes or bottles prior to vaccine administration). If you are hosting a mobile, pop-up, or outdoor vaccine clinic, plan accordingly so vaccines never reach a temperature over 77 degrees Fahrenheit. VDH encourages drawing up vaccine doses as needed versus pre-drawing multiple doses.
- f. If you do not anticipate a large volume of patients, order COVID-19 vaccine in quantities as low as one vial through <u>VDH's Small Shipment Redistribution Program</u>.



#### 2. Clinic Operations

- a. Have EUA fact sheets and consent forms (if applicable) ready in a convenient location to provide to patients before vaccine administration.
- b. COVID-19 vaccines (regardless of manufacturer) and other vaccines no longer have to be given more than 14 days before or after giving other vaccines. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days. However, administering vaccines (including live attenuated vaccines) and TB testing should still follow all guidelines as recommended in <u>ACIP's General Practice Guidelines for Immunization</u>.
  - i. It is unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines.
  - ii. When deciding whether to co-administer with COVID-19 vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines and the reactogenicity profile of the vaccines.
  - iii. For more details, refer to <u>CDC's Interim Clinical Considerations for Use of COVID-19</u>
    Vaccines Currently Authorized in the United States.
- c. Request that patients coming in bring their vaccination card and confirm with the patient which vaccine they received for previous doses and when.
- d. Ensure all patients and accompanying attendants wear a mask or cloth face covering that covers the nose and mouth. If a patient or attendant is not wearing a mask or cloth face covering, they must be provided one. Note: Masks or cloth face covering should not be placed on a child under 2 years of age, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask or cloth face covering without assistance.
- e. Ensure all staff are wearing appropriate PPE.
- f. Ensure supplies such as tissues, hand sanitizer, and wastebaskets are readily accessible throughout the clinic.
- g. Hand hygiene must be performed between patients. If gloves are worn by those administering the vaccine, they should be changed, and hand hygiene should be performed between patients.
- h. Provide extra cleaning and sanitizing support. Frequently clean and disinfect all patient service counters and patient contact areas, including frequently touched objects and surfaces, such as workstations, keyboards, telephones, and doorknobs. If the observation area includes chairs, clean and disinfect these between every patient.
- i. Ensure staff is wearing identification cards or other identification (vests, shirts, etc.), as appropriate.



#### 3. Staffing

- a. Ensure staff is properly trained to administer the COVID-19 vaccine. VDH resources can be found <a href="here">here</a>. CDC COVID-19 Vaccine Training Modules can be found <a href="here">here</a>.
- b. Visit VDH's <u>Lightning Learning</u>: <u>Best Practices for Busy Providers</u> for quick bites of learning on COVID19 vaccination topics, including post-vaccination observation, avoiding needlesticks, handling vaccines safely, vasovagal syncope, administration of intramuscular vaccines, vaccinating adolescents, and proper use of PPE.
- C. Provide relevant staff with handouts and information regarding proper storage and handling of COVID-19 vaccines (see "Supplies & Materials" section for more details).
- d. Ensure staff assigned to post-vaccination observation are educated on adverse reactions to vaccines as well as anxiety or other types of reactions. Provide guidance on how to identify and respond to any potential adverse reaction. Consider partnering with local EMS to have their trained personnel monitor individuals in the observation area.



#### 4. Supplies & Materials

- Ensure the clinic is stocked with an adequate number of vaccination cards, <u>EUA Fact Sheets for Vaccine Recipients and Caregivers</u>, consent forms, and educational materials. Provide staff with detailed lists of supplies and equipment needed daily for staff.
- b. If using paper, compile patient packets with educational material and required documents before the clinic opening.
- c. During the COVID-19 pandemic, protection must be available for staff and patients. <u>Supplies</u> required during the COVID-19 pandemic include:
  - i. Alcohol-based hand sanitizer with at least 60% alcohol and hand soap.
  - ii. Cleaning supplies for more frequent cleanings, using <u>EPA's Registered Antimicrobial</u> Products for Use Against Novel Coronavirus SARS-CoV-2.
  - iii. Masks for patients who arrive without one.
  - iv. <u>PPE</u> for staff, including face masks, gloves, and eye protection, based on <u>current</u> guidance for the safe delivery of vaccination services.
  - v. Thermometers for checking patients' temperatures before they <u>enter the clinic</u>, if required.
  - vi. Tissues.
- d. Ancillary kits will contain supplies necessary for vaccine administration; kit contents: needles, syringes, alcohol pads, vaccination record cards, needle gauge and length chart, and diluent vials (if applicable). Providers are also able to request Pfizer-BioNTech ancillary kits to support primarily adult or adolescent vaccinations through VaxMaX. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment may be needed depending on vaccination provider site needs.
- e. Use 3mL syringes for optimal performance when mixing Pfizer-BioNTech vaccine.
- f. Anaphylaxis after vaccination is rare but can occur. It is mandatory that all vaccination providers have supplies immediately available to address acute anaphylactic reactions.
  - i. To appropriately monitor and attend to any allergic reaction to the vaccine, all vaccine providers should have the following supplies available to assess and treat anaphylaxis: epinephrine (first drug of choice), H1 antihistamine (may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis), blood pressure cuff, stethoscope, and a timing device to assess pulse.
  - ii. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found <a href="here">here</a>.



- iii. Each health district should have a well-developed plan for addressing anaphylaxis. Yearly emergency procedures drills are mandatory for all staff.
- iv. A minimum of three doses of epinephrine must be available at each clinical site.
- v. Consider requesting EMS personnel to assist with monitoring for post-vaccination anaphylaxis.
- g. Have a means of measuring blood pressure and, if available and staff are trained, a pulse-ox machine in the post-vaccination observation area.
- h. Make every effort to vaccinate each eligible person.
  - i. It is acceptable to open a multi-use vial without a guarantee of using all doses contained within it if it means vaccinating one or more eligible individuals.
  - ii. Follow <u>clinical best practice for vaccination as well as best practices when managing inventory</u> to maximize vaccination and minimize dose wastage.
  - iii. It no longer is imperative to use every dose the week it is received; rather it is acceptable to have multiple weeks of inventory on hand as long as all manufacturer specifications for storage and handling are followed.
- i. For those holding open clinics, please be flexible in accommodating sequential-dose needs. Try to schedule subsequent clinics to accommodate additional doses needed. If that is not possible, make sure they understand that they can receive sequential doses anywhere that offers that vaccine. They can request assistance finding a vaccine appointment by visiting vaccinate.virginia.gov or by calling 877-VAX-IN-VA (877-829-4682).
- j. Take the following actions to avoid wasting doses.
  - i. Count how many appointments are scheduled each day in order to estimate how many vials will need to be thawed and removed from storage throughout the day. Do not take them out and thaw them all at once. During the clinic, continuously communicate how many patients have arrived and how many are still expected to show up so doses can be prepared accordingly based on the actual number of patients.
  - ii. Create standby lists of prioritized persons to receive any unused doses and call individuals on the list if there are extra doses.
  - iii. Monitor vaccine to ensure it is consistently stored at the temperatures indicated by the manufacturer. Label vials with the "thawed on" and "discard by" dates and times. Ensure relevant staff are provided with the following information. It is critical to monitor vaccine storage temperatures hourly when on site or to use a data logger to ensure vaccine stability and viability.



- During shipping of the vaccines, the temperature-monitoring device continuously tracks the temperature to ensure the frozen vaccine product has been maintained at the required temperature during transport to vaccination centers.
- 2. While digital data loggers (DDLs) are the preferred method for monitoring temperature of all COVID-19 vaccines, they may not always be available. Below is a list that provides a variety of options that can be used when monitoring temperatures.
  - a. First choice: DDL: Check and record minimum and maximum temperatures (min/max) on each day of the clinic before it opens.
  - b. Second choice: Recently expired DDL (≤ 2 years): Check and record min/max temperatures on each day of the clinic before it opens.
  - c. Third choice: Min/Max thermometer: Check and record min/max temperatures before and at the end of the clinic day.
  - d. Fourth choice: Digital thermometer: Check and record the point-in-time temperature before and at the end of the clinic day.
- k. CDC's COVID-19 vaccine refrigerator temperature monitoring log can be found here.
- I. Vaccine-specific requirements for storage and handling are summarized below:
  - i. Pfizer-BioNTech COVID-19 Vaccine:

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use
Ultra-Low-Temperature (ULT) Freezer [-90°C to -60°C (-130°F to -76°F)]	12 months <sup>†</sup>	12 months <sup>‡</sup>	12 months <sup>‡</sup>
Freezer [-25°C to -15°C (-13°F to 5°F)]	2 weeks	DO NOT STORE	DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks
Room Temperature [8°C to 25°C (46°F to 77°F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2°C to 25°C (35°F to 77°F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours

- 1. More information about Pfizer-BioNTech storage can be found <a href="here">here</a>.
- 2. Labels for Pfizer-BioNTech are available here.



- ii. Moderna/Spikevax COVID-19 Vaccine
  - 1. Unopened frozen vials may be stored in the freezer [-50°C to -15°C (-58°F to 5°F)] until the expiration date. Unopened thawed vials may be stored in the refrigerator [2° to 8°C (36° to 46°F)] for up to 30 days. Once a vial is punctured or at room temperature, the vaccine must be used within 12 hours. After a vial is punctured 20 times it should be discarded even if the 12 hour time limit has not been met.
  - 2. More information about Moderna/Spikevax storage can be found here.
  - 3. Labels for Moderna vaccine storage and handling are available <a href="here">here</a>. Guidance and labels for transport can be found <a href="here">here</a>.
- iii. Janssen (J&J) COVID-19 Vaccine
  - Vials will arrive refrigerated and may be stored in the refrigerator [2°C and 8°C (36°F and 46°F)] until its expiration date, so long as the vial has not been punctured.
  - 2. Punctured vials can be stored for up to 6 hours (refrigerated) or 2 hours (at room temperature).
  - 3. Do not freeze this vaccine
  - 4. More information about J&J storage can be found <a href="here">here</a>.
  - 5. Labels for Janssen (J&J) vaccine storage and handling are available <a href="here">here</a>. Guidance for transport can be found <a href="here">here</a>.
- m. Consider using a portable refrigerator to store vaccine in points of dispensing (PODs).
- n. Use the recommended syringe type by the vaccine manufacturer. Some sites have reported VanishPoint® Syringes losing doses.
- o. Report wasted doses using the Vaccine Wastage Reporting Tool.
- p. Report all doses that are excess or are at-risk of expiring in the <u>At-Risk Doses Survey</u> so that the VDH allocation team can look for potential redistribution opportunities to avoid all potential spoilage. Ideally, providers will give VDH 30-days notice prior to the expiration of the doses, but providers should always report the doses as soon as the issue is identified.
- q. As of February 16, in support of the <a href="Pfizer-BioNTech EUA">Pfizer-BioNTech COVID-19</a> vaccine vials as containing six doses, versus the original five. If a 6th dose cannot be obtained or used, it should be reported as wastage in the <a href="Vaccine Wastage">Vaccine Wastage</a> <a href="Reporting Tool">Reporting Tool</a>.



#### III. Pre-Vaccination Patient Intake and Education

- 1. Follow these tips to encourage vaccination among children and adolescents, as discussed during the <u>Parents Trusted Messenger Roundtable with Surgeon General Vivek Murthy:</u>
  - a. Use viral videos to share important messages.
  - b. Engage parents of adolescents, who are the messengers and ultimate decision makers.
  - c. Leverage social media to share positive vaccination experiences.
  - d. Don't assume messages that work with adults also work with children or adolescents.
  - e. Provide cool stickers to vaccinated patients.
  - f. Partner with local influencers and artists to create content and artwork encouraging vaccination.
  - g. Use pediatricians as trusted messengers of COVID-19 vaccine information.
  - h. Send a message or video to patients of private practices to encourage vaccination.
  - i. Tell stories founded in facts about what children and adolescents can do again once they are vaccinated.
  - j. Use mobile vaccination units to make getting vaccinated as convenient as possible.
  - k. Share the following information for parents and adolescents with your patients and communities:
    - i. <u>COVID-19 Vaccines for Children and Teens</u> provides information about the benefits of COVID19 vaccines for adolescents aged 12 years or older, how to find a vaccine provider for adolescents, and what to expect during and after vaccination.
    - ii. Menstrual cycles cannot be affected by being near someone who received a COVID-19 vaccine. This <u>question and answer</u> explains why.
    - iii. It is safe for people who would like to have a baby one day to get a COVID-19 vaccine. This <u>question and answer</u> explains why.
    - iv. The web pages <u>Key Things to Know about COVID-19 Vaccines</u> and <u>About COVID-19 Vaccines</u> have been updated to include the recommendation that adolescents aged 12 years or older get vaccinated.
    - v. The web page <u>COVID-19 Vaccine Information for Specific Groups</u> has been updated to help the public find information about vaccination for adolescents.
    - vi. Visit VDH's <u>Lightning Learnings</u> and/or <u>watch the recorded VDH webinar</u> focusing on COVID-19 Vaccines for Pediatrics and the corresponding <u>slides</u> for additional resources and tips for vaccinating adolescents.
    - vii. Package the <u>EUA Fact Sheet for Recipients and Caregivers</u>, <u>VaxText</u>, <u>v-safe</u>, and other education or consent forms (if applicable) and give to patients before their appointment. For example, email the package to patients after online registration, put it in their patient portal, or send it with the appointment reminder.





- viii. Ensure staff is prepared to properly address common patient questions and hesitations and clarify misinformation respectfully. Spend time educating staff about the vaccine. Guidance on patient counseling can be found in the CDC Clinical Considerations.
- ix. Visit <u>VDH's Vaccinate with Confidence webpage</u> for many levels of support and resources for providers to inspire vaccine confidence in their communities. These include webinar recordings, a toolkit with tele-town hall slides for primary care physicians and pediatricians to use and adapt for their patients, and an option to request technical platform and/or VDH expert support.
- x. Talking with Patients about COVID-19 Vaccination: An Introduction to Motivational Interviewing for Healthcare Professionals can be found <a href="https://example.com/here/">https://example.com/here/</a>.
- xi. Address patient's questions and gather patient information, such as contraindications, before the visit to expedite the screening process.
- xii. If patients are concerned about the reports of myocarditis and pericarditis post mRNA COVID-19 vaccination, share these resources for the public from CDC to address their concerns.
- xiii. Some people receiving a vaccination may experience a vasovagal reaction; meaning they may get light-headed, sweaty or they may briefly faint or lose consciousness (vasovagal syncope).
  - 1. Vasovagal reactions, also called neurocardiogenic syncope or reflex syncope, are the most common cause of fainting and are generally not harmful nor a sign of a more serious problem.
  - 2. Those under 30 years of age, including adolescents, are more likely to faint after vaccination. For this reason, it will be especially critical to screen patients for and be prepared for syncope when vaccinating adolescent and young adult populations.
  - 3. Fainting itself is generally not serious, but harm from related falls or other accidents can cause injury. The main concern is head injury.
  - 4. Ensure vaccinators are aware of the potential for syncope after vaccination and the related risk of injury caused by falls. Appropriate measures should be taken to prevent injuries from fainting, including:

#### a. Preparing clinic staff:

- i. Be aware of symptoms that are associated with fainting (e.g., pallor, sweating, weakness, dizziness, nervousness, vomiting).
- ii. Consider keeping a few cots on site for those who become pre-syncopal or who have a history of fainting.

#### b. **Before vaccination:**

- Ask patients if they have ever fainted while getting a vaccine or giving blood.
- ii. Give patients a beverage and a snack.



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- iii. Reassure patients about vaccination.
- iv. Have patients seated or lying down for vaccination.

#### c. After vaccination:

- i. Ensure patients are sitting or lying down.
- ii. If patients exhibit any of the above symptoms after vaccination:
  - 1. Ask them to sit and put their head between their knees.
  - 2. Consider escorting them to a cot to lie down.
  - 3. Instruct them to remain seated or lying down until they feel better, even if it's longer than their 15-30 minute post-vaccination observation period.
- iii. If a patient faints after vaccination:
  - 1. Rapidly assist the person to a supine or seated position and help protect them from injury and falls.
  - 2. Medical personnel should observe the patient until they are fully alert so that further treatment needs can be determined.
  - 3. VDH does not recommend using ammonia capsules or smelling salts to revive patients, nor providing them with juice as soon as they wake up as these practices can cause adverse events.

#### 5. Before administering the vaccine:

- a. Screen patients for acute SARS-CoV-2 infection and defer those with current infection from vaccination until they have recovered and have <u>met the criteria to</u> discontinue isolation.
- b. Screen patients for a history of fainting with vaccines or blood draws. If the answer is affirmative, take the aforementioned actions to prevent injury if the patient does faint.
- c. Explain to patients what subsequent doses they may need and when to get them
- d. Provide the <u>EUA Fact Sheet for Recipients and Caregivers</u> to every patient and/or caregiver. Verify the patient/parent/caregiver receives the fact sheet, has time to read information and ask questions, and has an opportunity to discuss side effects.
- e. Screen all recipients for contraindications and precautions. Review for appropriate vaccination or deferral. Those with a <u>contraindication</u> should not be vaccinated. A <u>COVID-19</u> <u>pre vaccination questionnaire</u> is available to assist with screening. Refer to Appendix A for the triage form from CDC.
- f. CDC currently recommends the following observation periods after vaccination\*:



- i. 30 minutes for:
  - 1. People with a history of anaphylaxis due to any cause.
  - 2. People with a history of an immediate allergic reaction of any severity to another vaccine or injectable therapy.
  - 3. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen (J&J) viral vector vaccine should be observed for 30 minutes following Janssen (J&J) vaccination). For people with these precautions, referral to an allergist-immunologist should be considered.
- ii. 15 minutes for:
  - 1. All other persons. Some examples are below:
    - An immunocompromised person without any contraindications or history of immediate allergic reactions.
    - A person with other allergies such as to peanuts or oral medications (without any history of anaphylaxis or other precautions or contraindications)
- \* Note: People may be observed longer based on clinical concern. For example, if a person develops itching and swelling confined to the injection site during their post vaccination observation period, this period may be extended to assess for development of any hypersensitivity signs or symptoms consistent with anaphylaxis (described below).
- 6. Persons who have had a severe allergic reaction to a first dose of a COVID-19 vaccine should not receive the second dose.
  - a. Refer to the <u>CDC Interim Clinical Considerations</u> for guidance for vaccinating patients who are pregnant or have underlying medical conditions.
  - b. Capture date of birth.
  - c. Ensure patients are receiving the age-appropriate COVID vaccine.
  - d. Make sure patient education is accessible to all.





- i. If working in English as a second language (ESL) communities, prepare to accommodate their needs. Ensure there is a translator for patient questions. When possible, provide patients with required documents and handouts in their own language. Translations for EUA Fact Sheets can be found <a href="https://example.com/here-for-Moderna">here-for Moderna</a>, and <a href="here-for-here-for-Moderna">here-for Moderna</a>, and <a href="here-for-
- ii. Ensure that a language line is available to assist patients for whom an interpreter is not available on site.
- iii. Obtain handouts in larger fonts to make information more accessible to elderly and visually impaired populations.
- iv. Modify <u>VaxText</u> and <u>v-safe</u> handouts to suit the anticipated language and accessibility needs of your patient population.
- 7. Use software to send fact sheets and other educational materials to maximize distribution and expedite on-site processes. Utilize QR codes located at the bottom of the <u>EUA Fact Sheet for Recipients and Caregivers</u> to connect patients with key information, to reduce printing time, and to eliminate paper waste.
  - a. Establish a strong communication line between the clinic and patients to provide appointment updates, ensure patients arrive no more than 5 minutes before allotted time, and reduce missed appointments.
  - b. Ensure patients know they need to come back for a second dose and ensure they are sent a reminder when the time comes. Consider setting this up through an automatic electronic system, or by utilizing <a href="VaxText">VaxText</a>.



#### IV. Vaccine Storage & Handling

- Refer to CDC's <u>Vaccine Storage and Handling Toolkit</u> and VDH's <u>COVID-19 Vaccine Storage and Handling One Stop Shop</u> for guidance on safe and effective COVID-19 vaccine management practices for all healthcare providers.
- 2. Ensure plans are in place for maintaining vaccines at appropriate temperatures while stored and throughout the clinic day based on <u>vaccine storage and handling guidance</u>. Monitor and document vaccine temperatures as required throughout the day.
- 3. Regularly checking dates on stored vials will help reduce waste. Follow a "first-in/first-out" practice for vaccine administration and store your vaccine inventory to ensure the older vials are used first.
  - a. If nearing expiration, check posted manufacturer information, use the <u>CDC's Vaccine Lot Number and Expiration Date webpage</u>, or <u>request access to</u> a new COVID-19 Vaccine Lot Number report via CDC's Vaccine Code Set Management Service (VCSMS). This report is updated daily and includes COVID-19 vaccine lot numbers and expiration dates provided to the CDC by the vaccine manufacturers.
  - b. When the expiration date has only a month and year, the product may be used up to and including the last day of that month unless the vaccine was contaminated or compromised in some way.
  - c. If a day is included with the month and year, the product may only be used through the end of that day unless the vaccine was contaminated or compromised in some way, necessitating an earlier date.
  - d. To minimize waste and ensure the opportunity to redeploy vaccine at risk of expiring to an area in need of additional supply, complete this VDH survey.
  - e. If doses are expired or wasted:
    - i. Remove any expired vaccine from the storage unit immediately. Do not administer expired vaccine.
    - ii. If expired vaccine is inadvertently administered, this is considered a vaccine administration error and requires remediation, including submitting a VAERS report, contacting the recipient to inform them of the error, and it may or may not require revaccination based on the manufacturer's guidance. Guidance on vaccine administration errors can be found in Appendix C of CDC's Interim Clinical
      - Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.
    - iii. Dispose of expired vaccine vials (with any remaining vaccine) and packaging as medical waste according to your local and state regulations. Do not return vaccine in the thermal shipping container.



- iv. Promptly report any expired vaccine using the <u>COVID-19 Wastage Report Form</u>. There are no negative consequences for reporting waste, and it will not negatively impact future allocations.
- v. Refer to the following resources for additional guidance:
  - Commonwealth of Virginia COVID-19 Accountability Transport, Redistribution, Transfer & Waste
  - 2. VDH Guidance on Additional, Extra, Expiring COVID-19 Vaccine for Providers
  - 3. Participating in the Commonwealth of Virginia COVID-19 Vaccination Program
  - 4. CDC: Identification, Disposal, and Reporting of COVID-19 Vaccine Wastage
- f. The U.S. Pharmacopeia (USP) COVID-19 Vaccine Storage and Handling Toolkit includes guidance for labeling individual syringes that are being transported off-site such as for use in homebound vaccinations.
- g. A contingency plan should also be in place, in case vaccines are delayed or compromised and need to be replaced.

#### V. Vaccine Preparation & Administration

#### 1. Vaccine Preparation

- a. The expiration date should be checked before preparing and administering the vaccine.
  - i. Pfizer-BioNTech expiration dates are written on the vial.
  - ii. Moderna expiration dates can be checked by scanning a QR code on the vial (open the camera app on your smartphone and direct it at the QR code)
  - iii. Janssen (J&J) expiration dates can be checked by scanning the QR code on the outer carton, calling 1-800-565-4008, or going to <a href="https://www.vaxcheck.inj">www.vaxcheck.inj</a>
- b. See the Pfizer-BioNTech 12+ (purple cap) instructions
- c. See the Pfizer-BioNTech 12+ (gray cap) instructions
- d. See the Pfizer-BioNTech 5-11 (orange cap) instructions



- e. See the Moderna instructions
- f. See the Janssen (J&J) instructions
- g. Do not refreeze thawed vials
- h. See <u>CDC Clinical Considerations</u> for more information.

#### 2. Vaccine Administration

- a. Needles can separate from syringes before or during vaccination because they are not tightly attached. Before injecting, vaccinators should always check to be sure that the needle hub is tightly secured.
- b. Vaccine must be administered Intramuscularly (IM) in the deltoid muscle. Take care to avoid shoulder injury. Pinching the skin, which is recommended for subcutaneous injections, should not be performed for IM injections.
- c. Follow the "seven rights" of vaccine administration: right patient, right vaccine/diluent, right time, right dose, right route, right site, and right documentation.
- d. The effort to administer COVID-19 vaccines to a large number of people in a variety of settings may increase the risk for needlestick injuries among vaccinators and other vaccination site workers.
- e. Needlestick injuries (NSIs) can transmit bloodborne pathogens, including hepatitis B, hepatitis C, and HIV. Mass vaccination clinics may pose greater risks for NSIs to vaccinators, especially when performed in non-traditional settings and in high volumes. NSIs might be more common among inexperienced vaccinators. To prevent NSIs at your clinic, employ the following safety and health measures:
  - i. Vaccinators must be trained on the vaccination process, including dilution and administration of the vaccine. Training should include device review and hands-on practice with devices (syringes and needles) that will be used in the clinic. All training should occur in advance of performing vaccinations.
  - ii. Devices with engineered sharps injury protection features can significantly reduce the risk of a NSI and are critical to a successful vaccine clinic program. All vaccinators should be trained in the proper activation of the sharps injury prevention feature before use. iii. Generally, if vaccinators use two hands to engage the safety device, they have a higher risk of NSI. Ensure vaccinators are comfortable operating the device with a single hand. iv. Puncture-resistant sharps containers must be located as close to the point of use as possible to discard all used syringe and needle devices. The container should be labeled, color-coded, secured to prevent tipping over, and closed and replaced when three quarters full.



- iii. Ensure vaccinators understand the need to contact a supervisor immediately if a needlestick occurs.
- f. Additional information and safety measures to avoid NSIs can be found at the following links.
  - NIH: Injection Safety for COVID-19 Vaccinators & Vaccine Administrators Preventing
     Needlesticks and Blood Exposures
  - ii. <u>CDC NIOSH Science Blog: Preventing Needlestick Injuries at COVID–19 Vaccination Sites</u>
- g. Follow best practices from the <u>CDC Pink Book</u> and <u>healthychildren.org</u> when providing COVID-19 vaccines to children (in accordance with an EUA for the respective age group) to minimize stress and pain.
- h. For school-aged children, a combination of distraction techniques (e.g. playing games), numbing creams, and/or sprays can be very effective.
- i. Numbing agents include:
  - i. A cooling spray that can be applied just before shots are given so there is no poking sensation.
  - ii. A plastic plate covered with small points and a buzzing sensation that blocks pain signals.
  - iii. Topical anesthetic creams that can be applied ahead of time to make the skin numb when the shot is given. As per the CDC Pink Book, these products should be used only for the ages recommended and as directed by the manufacturer. Because using topical anesthetics may require additional time, consider applying them during the usual clinic waiting times, or before the patient arrives at the clinic provided parents and patients have been shown how to use them appropriately.
  - iv. Consider applying moderate tactile stimulation (rubbing or stroking the skin) near the injection site before and during the injection process, which may decrease pain in patients aged 4 years and older.



#### VI. Post Vaccination

- 1. Inform patients that COVID-19 vaccines (regardless of manufacturer) and other vaccines no longer have to be given more than 14 days before or after giving other vaccines. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days.
  - a. Before getting any other vaccines, they should still inform their provider, as administering vaccines (including live attenuated vaccines) and TB testing should still follow all guidelines as recommended in <u>ACIP's General Practice Guidelines for Immunization</u>.
- 2. Have patient education handouts available in case patients would like to read them during their observation period.
- 3. If patients indicate an immunocompromised state, inform them that they may not be fully protected even if they are fully vaccinated and may need to continue <u>precautions</u> after being vaccinated. Encourage them to discuss their status with their healthcare provider.
- 4. Inform your patients and communities that they can view their COVID vaccine history here.
- 5. Place nervous patients or those with concerns for adverse reactions closer to a clinical observer.
- 6. Provide all patients with:
  - a. Details on how to sign up for v-safe. V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccine and allows CDC to monitor vaccine safety. Handouts in multiple languages can be found here.
  - b. Providers vaccinating adolescents should inform parents and guardians that they can now enroll their adolescents (aged 12 years or older) in v-safe and complete registration and health check-ins on behalf of each adolescent by using their own smartphone. All v-safe communications will be sent to the parent or guardian's smartphone. Parents and guardians can use the same phone number to register both themselves and any adolescents.
  - c. Details for signing up for VaxText, a free text messaging platform that sends text message reminders to patients to get their second dose of COVID-19 vaccine. Consider using this <a href="handout.">handout.</a>





- d. A COVID-19 Vaccination Record Card, including a scheduled date for their follow up appointment. Persons should not be scheduled to receive subsequent doses earlier than recommended. However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period do not need to be repeated. There is no maximum interval between doses therefore, if a dose is administered at any point beyond the recommended time frame, there is no need to restart the series. Vaccine administration errors should be reported to the <u>Vaccine Adverse Event Reporting System (VAERS)</u>, a national early warning system to detect possible safety problems in US-licensed vaccines.
- e. People who have been vaccinated and are in their observation period must be wearing masks or cloth face coverings and distanced at a minimum of 6 feet apart in a well-ventilated indoor or outdoor space in the direct sight line of an observer. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. Others should be observed for 15 minutes. Staff should be prepared to respond to any immediate reactions that occur during the observation period. For guidance on triaging vaccination patients, refer to Appendix A.
- 7. You are required to report the following to VAERS:
  - a. Vaccine administration errors (whether associated with an adverse event [AE] or not)
  - b. <u>Serious AEs</u> (irrespective of attribution to vaccination)
  - c. Multisystem inflammatory syndrome (MIS)
  - d. Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- 8. You are encouraged to report any clinically significant AEs that occur after vaccine administration.
- 9. Adverse events should be reported even if the cause of the AE is uncertain.
- 10. Immediately treat suspected cases of anaphylaxis with an intramuscular injection of epinephrine. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found <a href="here">here</a>.



#### VII. Record Keeping

- 1. Enter doses in the Virginia Immunization Information System (VIIS) within 24 hours
  - a. The goal of VIIS is to support individuals, families and clinicians in making the best health decisions by providing a statewide, readily accessible and reliable Immunization Information System. VIIS is a free statewide registry system that combines immunization histories for persons of all ages from both the public and the private sector.
  - b. Because real-time data are critical to rapid decision-making and reallocation of vaccines, COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration. To expedite the process, consider using an electronic medical record system that automatically uploads to VIIS, such as PrepMod. To learn more about VIIS, visit the <u>VDH VIIS Website</u>.
  - c. Obtain and enter all key patient information into VIIS, including race and ethnicity. This allows VDH to identify gaps in coverage, especially in regard to vaccine equity, which can inform outreach efforts.
  - d. Reliable data entry into VIIS is critical to vaccine allocation and second dose distribution across the state. Second dose allocations are dependent on accurate entries of first dose administration records into VIIS. One of the factors VDH uses to prioritize vaccine allocations is a provider's ability to accurately report doses to VIIS in a timely manner.
  - e. Reporting redistribution information is also critical because this may impact future allocation of vaccine. Facilities or systems that intend to redistribute or transfer COVID-19 vaccine to other providers should ensure they understand and follow the <a href="COVID-19 Vaccine Redistribution">COVID-19 Vaccine Redistribution</a>
    Process.
- 2. Fully document vaccine in the patient chart: date, lot number, expiration, manufacturer, injection site, vaccinator, EUA vaccine fact sheet date.
- 3. It is essential to track the lot numbers of the vaccines in case of adverse reactions.
- 4. Attend updated trainings to understand systems used for record keeping, such as PrepMod and VIIS.
- 5. Ensure you have maintained required documentation from the Board of Pharmacy.
- 6. If you are using PrepMod, refer to <u>this VDH webpage</u> to review resources (e.g., quick reference guides) that walk through using PrepMod at a VDH-sponsored clinic.



#### VIII. Mobile, Community, and School-Based Large-Scale Vaccine Clinics

#### 1. Clinic Setup

- a. Consider federal, state, and local guidance when establishing measures (such as inventory management, appropriate personal protective equipment [PPE], hand hygiene, physical distancing, safety, etc.) to protect clinic staff and patients. Overall guidance for vaccination clinic location and layout from the CDC can be found <a href="here">here</a>.
- b. Set up your clinic in a well-ventilated facility (e.g., large gymnasium) or space that can hold the maximum number of individuals expected at a time and follow the recommended current phase guidelines issued by the Governor (physically distanced at least 6 feet apart with masks or cloth face coverings for those who will be vaccinated and appropriate PPE for vaccinators).
- c. Dedicate a large space for patient observation post-vaccination. Patient observation is the primary bottleneck during the vaccination process, particularly because of space constraints. Consider partnering with community centers or utilize patient vehicles to expand observation areas and increase capacity.
- d. Clinic locations and processes that were successful in previous years might not be appropriate during the COVID-19 pandemic because of the need for enhanced safety precautions. Even if the same space is used, it will likely need to be set up and function differently because of COVID-19 social distancing requirements.
- e. Identify clinic capacity to optimize patient scheduling and adjust for walk-ins.
  - i. Consider separating patients by wait time (e.g., 15-and 30-minute sections) to optimize flow.
  - ii. To maximize space, set up observation areas in the center of a room to increase space for chairs and uphold the physical distancing protocol.
  - iii. Monitor observation times for patients to prevent delays. Use a nonclinical staff member to act as timekeeper where patients have name tags with the time they can leave or provide patients with properly cleaned timers.
- f. Consider conducting appointment-only temporary clinics held in schools, churches, and pharmacies. Consider using large venues with multiple vaccination and waiting areas.



- g. Regardless of the site type (e.g., walk-through, curbside, drive-through, or mobile clinic), temporary locations must have sufficient capability to accommodate physical distancing, inventory management, and appropriate PPE for staff and masks for patients.
- h. Slips, trips, and falls (STFs) can lead to broken bones, concussions, or even life-threatening conditions and death in serious cases. COVID-19 vaccination sites should implement mitigation strategies to prevent STFs of both their patients and clinic staff. To prevent slips, trips and falls in vaccination sites, it is important to evaluate key exposure risks that may be present and implement controls that may result in a reduction in injury frequency and severity. Zurich, an insurance company, has developed the following <u>recommendations</u> to mitigate STFs when identifying and preparing COVID-19 vaccination sites:
  - When possible, choose an area with surfaces with higher slip resistance, such as non-slippery natural stone, broom-finished concrete and carpet versus hard, smooth surfaces.
  - ii. Review surface conditions as you consider areas to be used for vaccination sites. For example, raised or recessed sidewalk edges or curbing, potholes in parking lots, painted surfaces, loose carpeting, loose or broken tiles, holes or pits on the surface, or unusual wear could lead to STFs.
  - iii. Ice, water, liquids, powders, grease or any substances that could be tracked into the building or spilled in the vaccination area could cause STFs. Consider the use of walk-off mats at building entrances to minimize the tracking of water or other substances that increase the risk of STFs. Review surfaces periodically to identify potential spills that could cause a slip/fall incident. Also, control the types of and quantities of liquids in the vaccination sites to minimize potential spills. Soft drinks, water and vaccines may spill if mishandled and create a slip hazard.
  - iv. Review the room/spaces to be used along with the paths of travel to/from the rooms to assure that level changes can be navigated by all persons expected to utilize the spaces.



- Obstructions, such as extension cords, hoses, portable freezer storage, concrete posts, and temporary storage/holding areas can contribute to the likelihood of an STF.
   Consider using cord guards or adhesive tape to secure obstructions and minimize the potential trip hazard.
- i. <u>Curbside and drive-through clinics</u> may provide the best option for staff and patient safety during the COVID-19 pandemic for sites with limited indoor space. Consider implementing the following best practices when setting up a drive-through clinic.
  - i. If vaccinating patients while they are in their vehicles, ensure patients put their vehicle in park for the entire time (or ask them to turn the vehicle off) and bring stools for vaccinators to ensure they can vaccinate patients in taller trucks or vans.
  - ii. Consider having patients wait their 15-30-minute observation period after vaccination in their cars in a separate parking lot that is monitored by EMS. Instruct any patient waiting in a car to activate their car's panic alarm or horn if they need emergency assistance.
  - iii. In all situations when patients will be waiting in cars, staff should be continuously walking through the parking lot to monitor the individuals in their cars. For example, consider having EMS continually traverse the lines of cars in golf carts to identify those that may be compromised and unable to hit the panic button or sound their horn, and to assist those who sound their alarm and need immediate assistance.
  - iv. Cones with white boards in front of the cars may be used to indicate the time the vaccine was administered and estimated time the individual may be released.



- v. Patients requiring a 30-minute observation period should wait within continuous direct sight of the observing staff inside in the monitored medical observation waiting area. If sent to their car for observation, ensure they are differentiated in some way from those waiting only 15 minutes. For example, provide recipients with colored wristbands based on how long they need to wait. Then, instruct those with 30-minute wristbands park their cars in a separate area than those with 15-minute wristbands. To determine if a patient needs to be observed for 15 minutes or 30 minutes, refer to Appendix A.
- vi. For more guidance, watch the short post-vaccination period <u>Lightning Learning</u> on the VDH website in the <u>resources for vaccine clinics site</u>.
- j. For walk-through clinics, it's important to establish line queues that maintain separation between individuals or to ask individuals to wait in their vehicles or another location until called. Consider the use of a text message alert when it is the individual's time to come into the clinic. Clinic flow should be one-way. Individual sites will have benefits and limitations, and site assessments will be required before use.
  - i. Clearly mark walls and rooms to create clear visual and physical clinic flow:
     Registration > Education > Vaccination > Observation > Check Out. To promote operational efficiency, it is recommended to:
  - ii. Separate areas for registration, education, vaccination, observation, and check out.
  - iii. Dedicate the largest spaces to immunization and observation.
  - iv. Establish one-directional travel routes with proper physical distancing and accessibility.
  - v. Combine patient observation with second dose sign up to expedite the check-out process.



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k. It is important that everyone is able to receive a vaccination when it is available. This means making sure nothing gets in the way of access. Vaccination sites should be <u>evaluated for accessibility</u>. Access and functional needs (AFN) can include but are not limited to: limited mobility (e.g., use of a wheelchair, walker, or cane); blindness or low vision; difficulty hearing, communicating or understanding information; sensory sensitivities and limited English proficiency.

#### I. It is important to:

- i. Recognize that people with disabilities are diverse. Many disabilities are not visible or immediately clear.
- ii. Know that people with disabilities and health conditions may need assistance making an appointment and getting to the vaccination site. They may also need support during the onsite vaccination process.
- iii. Ask the person with a disability what they need, and work with them to find a reasonable accommodation. They will be most knowledgeable about accommodations that will provide them with effective access to information and services. Over 20% of individuals report a disability, which can lead to health inequities and poor health care access. Many of these barriers can be addressed through simple steps. Providing an avenue for patients to communicate accessibility challenges and request accommodations before their appointment will help these individuals obtain their COVID-19 vaccines equitably upon arrival. CDC and Georgia Tech have partnered to develop COVID-19 vaccine resources in alternative formats for individuals with disabilities. These resources can be found <a href="here">here</a>.
- m. Visit the <u>VDH Vaccination Site Access and Functional Needs Guidance</u> for a comprehensive guide to making your clinic accessible, understanding how to communicate effectively with patients with a disability, and more. For additional guidance on how to accommodate patients with disabilities, view guidelines from <u>Michigan Medicine</u> and the <u>Minnesota Department of Health</u>.



- n. If you are hosting a mobile, pop-up, or outdoor vaccine clinic, plan accordingly so vaccines never reach a temperature over 77 degrees Fahrenheit.
- o. During the COVID-19 pandemic, physical distancing practices must be integrated into clinic flow and setup, including:
  - i. A screening station at the entrance for temperature checks (if required) and any screening questions for COVID-19.
  - ii. Vaccination stations should be at least 6 feet apart, and clinic flow should be one-way and allow maintenance of at least 6 feet between individuals, including in all waiting areas.
  - iii. Signage, banners, and floor markers to instruct patients to wear masks, to remain 6 feet apart from other patients and clinic staff, and to move clinic flow in one direction.
  - iv. Hard plastic barriers at patient contact areas, as appropriate, to provide barrier protection. Consider desks and counters at registration and screening areas to minimize contact.
  - v. Visual alerts such as signs and posters at entrances and in strategic places to provide instructions on hand hygiene, respiratory hygiene, and cough etiquette.
- p. Signage or staff asking patients waiting to remain outside (e.g., stay in their vehicles, if applicable) until called in for their appointments, or set up triage booths to safely screen patients and reduce crowding in waiting areas. Provide adequate covered space, taking weather into consideration, for those asked to wait outside.
- q. People who have been vaccinated and are in their observation period must be wearing masks or cloth face coverings and distanced at a minimum of 6 feet apart in a well-ventilated indoor or outdoor space in the direct sight line of an observer. Consider implementing the following:
  - Ensure all patients are wearing a mask or cloth face covering throughout the entire observation period.
  - ii. Choose an area with no foot or vehicle traffic.
  - iii. Adhere to 6 feet physical distancing.
  - iv. Ensure people feel safe and comfortable.



v. Consider giving each recipient a timer to track their 15 minutes (some will need 30 minutes of observation), then clean the timers and reuse them.

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- r. Provide ample time for clinic setup. Planning is critical. Consider facilitating a dry run or mock clinic before the actual clinic day and/or meeting the day before to ensure room layout is appropriate and all key players understand their roles. If possible, get permission to watch a successful vaccination clinic in action.
- s. At drive-through venues, adequate parking must be available so those receiving vaccines have a place to wait post-vaccination where they can be safely monitored.
- t. Prepare to adapt to a constantly changing environment, such as changing clinic operations or setup on the fly. Plan to meet at the beginning or end of each clinic day to review and implement needed changes for the next day in clinic.
- u. Consider using online or phone options for scheduling appointments and completing paperwork, when possible. Such processes should include:
  - i. Registration.
  - ii. Obtaining insurance information (if applicable).
  - iii. Screening for contraindications and precautions.
  - iv. Texting or emailing vaccine immunization information statements (VIISs) or emergency use authorization (EUA) forms.
  - v. Remind patients not to come more than 5 minutes early to avoid overcrowding at the clinic, to wear a mask or cloth face covering, and ensure they know about the post-vaccination observation time.

#### 2. Clinic Operations

- a. Cleanse and disinfect vaccination stations at a minimum every hour, between shifts and if station areas become visibly soiled. Incorporate other <u>CDC/EPA guidance</u> as appropriate for your clinic circumstances.
- b. Communicate clinic updates and wait times.



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c. Have a plan in place for using ALL doses available in open vials, even if all appointments are completed for the day. Vaccine doses should not be wasted. Consider having a standby list of individuals who were not able to make an appointment and call them if additional doses are available.

#### 3. Record Keeping

- a. The record keeping process is critical, and time-sensitive but will likely also be time-consuming. Ensure adequate staff, time, and resources are allotted.
- b. Have a designated check out area to make sure all forms are filled out and vaccination is recorded.
- c. Enter data at the clinic site and document in real time.
  - i. If using paper, dedicate a support staff member to enter data.
  - ii. Assign 1-2 staff to data entry for real-time record keeping.
- d. Have a copier nearby in case you need to duplicate cards, paperwork, etc.
- e. Identify an IT point of contact or specialist to help troubleshoot if systems issues arise.

#### 4. Staffing

- a. Establish a staffing plan and identify functional roles and responsibilities for each clinic. More guidelines on administrative and clinical staffing from the CDC can be found <u>here</u>. Employ a variety of staff and define roles and responsibilities clearly. Consider implementing the following:
  - Appoint a clinic lead to facilitate overall operations and communications who can also troubleshoot as needed.
  - ii. Assign 1-2 support staff to focus on paperwork and data input.
  - iii. Utilize local government and volunteer organizations for additional support or administrative tasks.
  - iv. Assign a staff member to ensure the vaccine is subject to acceptable storage and handling to prevent wastage.
- b. Create physical vaccine clinic calendars in addition to regular emails to align staff and disseminate key information to employees.





- c. Additional staff may be needed to:
  - i. Help enforce physical distancing measures.
  - ii. Clean the facility frequently.
  - iii. Provide IT support for online processes, including registration, scheduling, screening for eligibility, contraindications, and precautions, obtaining insurance information, providing vaccine information statements or emergency use authorization (EUA) forms, etc.
- d. Share this <u>Satellite</u>, <u>Temporary</u>, and <u>Off-Site Vaccination Clinic Supply Checklist</u> with clinic staff.



#### Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination

# CONTRAINDICATION TO VACCINATION

#### History of the following:

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

#### **Actions:**

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

#### PRECAUTION TO VACCINATION

Among people without a contraindication, a history of:

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

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

#### **Actions:**

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

# MAY PROCEED WITH VACCINATION

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

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

#### **Actions:**

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

Source: CDC COVID-19 Clinical Considerations, updated April 21, 2022

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

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

‡People with a history of an immediate 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.





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



#### **Appendix B: Resources & References**

- 1. CDC Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations: <a href="https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html">https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html</a>
- 2. VDH Recognition and Treatment of Anaphylaxis in Public Places: <a href="https://www.vdh.virginia.gov/content/uploads/sites/20/2021/11/Anaphylaxis-Guidelines-public-places-.pdf">https://www.vdh.virginia.gov/content/uploads/sites/20/2021/11/Anaphylaxis-Guidelines-public-places-.pdf</a>
- 3. VDH COVID-19 Vaccination Response Resources for Healthcare Professionals: https://www.vdh.virginia.gov/covid-19-vaccine/healthcare-professionals/
- CDC Clinical Considerations for COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid19/clinical-considerations/index.html
- 5. U.S Pharmacopeia (USP) COVID-19 Vaccine Storage and Handling Toolkit: https://www.usp.org/covid-19/vaccine-handling-toolkit
- 6. CDC | Fainting (Syncope) after Vaccination: https://www.cdc.gov/vaccinesafety/concerns/fainting.html
- 7. CDC | Pink Book: Syncope Section: https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
- 8. CDC | COVID-19 Vaccine Webinar Series: https://www.cdc.gov/vaccines/covid-19/trainingeducation/webinars.html
- COVID-19 Vaccine Storage & Handling Compliance Resources One Stop Shop:
   https://www.vdh.virginia.gov/content/uploads/sites/191/2021/06/COVID-19-Vaccine-StorageHandling-Complian ce-One-Stop-Shop.pdf
- 10. CDC Training for Healthcare Professionals: https://www.cdc.gov/coronavirus/2019ncov/hcp/training.html





- 11. COVID-19 Workplace and Business Resources (includes post vaccination considerations):

  https://www.cdc.gov/coronavirus/2019-ncov/community/workplacesbusinesses/?CDC\_AA\_refVal=https%3A%2F
  %2Fwww.cdc.gov%2Fcoronavirus%2F2019ncov%2Fhcp%2Fpost-vaccine-considerations-healthcare-personnel.ht
  ml
- 12. CDC Immunization Courses: Webcasts and Self Study: https://www.cdc.gov/vaccines/ed/courses.html
- 13. CDC Clinical Resources for Each COVID-19 Vaccine: <a href="https://www.cdc.gov/vaccines/covid19/index.html">https://www.cdc.gov/vaccines/covid19/index.html</a>
- 14. Vaccine Finder: <a href="https://www.vaccines.gov/">https://www.vaccines.gov/</a>

