



COVID-19 Vaccination Clinic Best Practices

Last Updated: March 24, 2021

Summary of recent changes, indicated in green text (last updated March 24, 2021)

- *Added information about Janssen (Johnson & Johnson) Vaccine*
- *Updated Pfizer storage requirements which now allow for storage for up to two weeks in a freezer between -25°C and -15°C (-13°F to 5°F).*
- *Updated best practices for post-vaccination observation periods at curbside clinics*
- *Added best practices to avoid needlestick injury*
- *Added best practices for reporting in the Virginia Immunization Information System (VIIS)*
- *Shared the U.S Pharmacopeia (USP) COVID-19 Vaccine Storage and Handling Toolkit*
- *Updated Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination*

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I. Clinic Management & Operations

a. Clinic Set Up

Consider federal, state, and local guidance when establishing measures (such as inventory management, appropriate personal protective equipment [PPE], hand hygiene, physical distancing, etc.) to protect clinic staff and patients. Overall guidance for vaccination clinic location and layout from the CDC can be found [here](#) and [here](#).

1. 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).
2. 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.
3. 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.
4. 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.
5. Identify clinic capacity to optimize patient scheduling and adjust for walk-ins.
 - a. Consider separating patients by wait time (e.g., 15- and 30-minute sections) to optimize flow.
 - b. To maximize space, set up observation areas in the center of a room to increase space for chairs and uphold the physical distancing protocol.



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- c. 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.
6. Consider conducting appointment-only temporary clinics held in schools, churches, and pharmacies. Consider using large venues with multiple vaccination and waiting areas. Mark areas with 6 feet of spacing using circles or blocks. Seat household groups together.
7. [Curbside and drive-through clinics](#) 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.
 - a. 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.
 - b. 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.
 - c. 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.
 - d. 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.
 - e. 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](#).
 - f. For more guidance, watch the short post-vaccination period [micro learning](#) on the VDH website in the [resources for vaccine clinics site](#).



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8. 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 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.
9. 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:
 - a. Separate areas for registration, education, vaccination, observation, and check out.
 - b. Dedicate largest spaces to immunization and observation.
 - c. Establish one-directional travel routes with proper physical distancing and accessibility.
 - d. Combine patient observation with second dose sign up to expedite the check-out process.
10. Ensure your clinic is accessible to patients with disabilities.
 - a. Factors that can make it hard for some people to get vaccinated include: limited mobility; blindness; low vision; difficulty hearing, communicating or understanding information; and in some cases, sensory challenges.
 - b. Over 20% of individuals report a disability, which can lead to health inequities and poor health care access. Many of these barriers are addressable 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.
 - c. For guidance on how to accommodate patients with disabilities, view guidelines from [Michigan Medicine](#) and the [Minnesota Department of Health](#).
11. Refer to the Cybersecurity and Infrastructure Security Agency (CISA) [COVID-19 Vaccine Distribution Physical Security Measures Infographic](#) for a non-comprehensive list of proactive measures to enhance physical security.
12. 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



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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.

13. 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.
14. During the COVID-19 pandemic, physical distancing practices must be integrated into clinic flow and setup, including:
 - a. A screening station at the entrance for temperature checks (if required) and any screening questions for COVID-19.
 - b. 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.
 - c. 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.
 - d. 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.
 - e. Visual alerts such as signs and posters at entrances and in strategic places to provide instructions on hand hygiene, respiratory hygiene, and cough etiquette.
 - f. 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.
15. 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.

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16. 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.

17. Examples of optimal clinic set up below:



Gymnasium in Richmond



Salem Civic Center, Salem



Drive-in pod in Virginia Beach



Bus loop vaccination at a middle school in
Charlottesville

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Patient registration in Pittsylvania/Danville



Three Rivers post vaccination parking area
with timing for post-vaccination observation

b. Clinic Operations

1. 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.
2. Consider using online or phone options for scheduling appointments and completing paperwork, when possible. Such processes should include:
 - a. Registration.
 - b. Obtaining insurance information (if needed).
 - c. Screening for contraindications and precautions.
 - d. Texting or emailing vaccine immunization information statements (VIISs) or emergency use authorization (EUA) forms.
3. Have EUA fact sheets and consent forms (if applicable) ready in a convenient location to provide to patients before vaccine administration.



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4. Confirm patients have not received any other vaccines in the past two weeks. CDC has recommended that no other vaccines be given two weeks before or after a COVID-19 vaccine.
5. Request patients coming in for the second dose to bring their vaccination card and confirm with the patient which vaccine they received for their first dose and when.
6. 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.
7. Cleanse and disinfect vaccination stations at a minimum every hour, between shifts and if station areas become visibly soiled. Incorporate other [CDC/EPA guidance](#) as appropriate for your clinic circumstances.
8. Ensure staff is wearing appropriate [PPE](#).
9. Ensure supplies such as tissues, hand sanitizer, and wastebaskets are readily accessible throughout the clinic.
10. Hand hygiene must be performed between patients. If gloves are worn by those administering vaccine, they should be changed, and hand hygiene should be performed between patients.
11. Make sure there are signs, barriers, and floor markers throughout the clinic to instruct patients to maintain a 6-foot distance from others and promote use of hand hygiene, respiratory hygiene, and cough etiquette.
12. 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.
13. Ensure staff is wearing identification cards or other identification (vests, shirts, etc.), as appropriate.
14. Communicate clinic updates and wait times.
15. 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





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available. It is more important to use all available doses than to strictly adhere to individuals who meet the current phase.

c. Staffing

1. 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 [here](#). Employ a variety of staff and define roles and responsibilities clearly. Consider implementing the following:
 - a. Appoint a clinic lead to facilitate overall operations and communications who can also troubleshoot as needed.
 - b. Assign 1-2 support staff to focus on paperwork and data input.
 - c. Utilize local government and volunteer organizations for additional support or administrative tasks.
 - d. Assign a staff member to ensure vaccine is subject to acceptable storage and handling to prevent wastage.
2. Ensure staff is properly trained to administer vaccine. VDH resources can be found [here](#). CDC COVID-19 Vaccine Training Modules can be found [here](#).
3. Create physical vaccine clinic calendars in addition to regular emails to align staff and disseminate key information to employees.
4. Provide relevant staff with handouts and information regarding proper storage and handling of COVID-19 vaccines (see [Supplies & Materials section](#) for more details).
5. 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.
6. Additional staff may be needed to:
 - a. Help enforce physical distancing measures.
 - b. Clean the facility frequently.



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- c. 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. Supplies & Materials

1. Ensure clinic is stocked with an adequate number of vaccination cards, EUA Fact Sheets for Vaccine Recipients, consent forms, and educational materials daily. Provide staff with detailed lists of supplies and equipment needed daily for staff.
2. If using paper, compile patient packets with educational material and required documents before the clinic opening.
3. Share this [Satellite, Temporary, and Off-Site Vaccination Clinic Supply Checklist](#) with clinic staff.
4. During the COVID-19 pandemic, protection must be available for staff and patients. [Supplies](#) required during the COVID-19 pandemic include:
 - a. Alcohol-based hand sanitizer with at least 60% alcohol and hand soap.
 - b. Cleaning supplies for more frequent cleanings, using [EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2](#).
 - c. [Masks](#) for patients who arrive without one.
 - d. [Personal protective equipment \(PPE\)](#) for staff, including face masks, gloves, and eye protection, based on [current guidance for the safe delivery of vaccination services](#).
 - e. Thermometers for checking patients' temperatures before they [enter the clinic](#), if required.
 - f. Tissues.
5. Ancillary kits for Moderna vaccine will contain supplies to administer **100 doses**. The Pfizer-BioNTech ancillary kit will contain supplies to administer **975 doses**. Ancillary kits will contain needles (22-25G x 1" and 22-25G x 1.5"), syringes, alcohol pads, vaccination record cards, needle gauge and length chart, face shields, and surgical masks, and diluent vials (for Pfizer-BioNTech only).
6. **Ancillary kits for Janssen (J&J) vaccine Ancillary supply kits include enough supplies to administer 100 doses.** They will include administration needles and syringes (22–25-gauge, 1–1.5" (adult)), sterile alcohol preparation pads, PPE (surgical masks and face shields for staff), COVID-19 vaccination record



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cards, and needle gauge and length chart detailing the appropriate length/gauge for injections based on route, age (children), gender, and weight (adults).

7. Ancillary supply kits **will not include** sharps containers, gloves, and bandages. Additional personal protective equipment may be needed depending on vaccination provider site needs.
8. Use 3mL syringes for optimal performance when mixing Pfizer-BioNTech vaccine.
9. Anaphylaxis after vaccination is rare but can occur. It is mandatory that all vaccination providers have supplies immediately available to address acute anaphylactic reactions.
 - a. 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.**
 - b. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found [here](#).
 - c. Each health district should have a well-developed [plan for addressing anaphylaxis](#). Yearly emergency procedures drills are mandatory for all staff.
 - d. **A minimum of three doses of epinephrine must be available at each clinical site.**
 - e. Consider requesting EMS personnel to assist with monitoring for post vaccination anaphylaxis.
10. Have a means of measuring blood pressure and, if available and staff are trained, a pulse-ox machine in the post-vaccination observation area.
11. Take the following actions to avoid wasting doses.
 - a. 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.



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- b. Create standby lists of prioritized persons to receive any unused doses and call individuals on the list if there are extra doses.
- c. 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.**
 - i. Once thawed, unopened vials of [Pfizer-BioNTech vaccine](#) can be used up to 120 hours (5 days) if stored properly in the refrigerator. [Pfizer-BioNTech vaccine can also be stored in a conventional freezer \(-25°C and -15°C \(-13°F to 5°F\)\) for up to two weeks.](#) Labels for Pfizer-BioNTech are available [here](#).
 - ii. Unopened vials of [Moderna vaccine](#) can be stored in the refrigerator for up to 30 days. Labels for Moderna vaccine storage and handling are available [here](#).
 - iii. [Janssen \(J&J\) vaccine will arrive refrigerated and may be stored in the refrigerator \(between 2°C and 8°C \(36°F and 46°F\)\) until it’s expiration date.](#) Vials that have not been punctured may be kept at 9° C to 25° C (47° F to 77° F) for a total of 12 hours. Do not freeze this vaccine. Upon receipt and as end of expiration approaches, check the expiration date through one of three options: Scan the QR code on the outer carton, call 1-800-565-4008, or go to www.vaxcheck.jnj.
 - iv. **Punctured** vials of the Janssen (J&J) vaccine can also be kept at 2°C to 8°C (36°F to 46°F) for up to 6 hours or room temperature (maximally 25°C or 77°F) for up to 2 hours. Discard any unused vaccine after 2 hours at room temperature or 6 hours at refrigerated temperature. Do NOT combine residual vaccine from multiple vials to obtain a dose.
 - v. Punctured vials of Pfizer-BioNTech and Moderna vaccine **must be discarded after 6 hours.**
 - vi. CDC’s COVID-19 vaccine refrigerator temperature monitoring log can be found [here](#).
- d. Consider using a portable refrigerator to store vaccine in PODs.
- e. Use the recommended syringe type by the vaccine manufacturer. Some sites have reported VanishPoint syringes losing doses.



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- f. Report wasted doses using the [Vaccine Wastage Reporting Tool](#).
12. As of February 16th, in support of the [Pfizer-BioNTech EUA](#) update, the **CDC is officially recording Pfizer-BioNTech COVID-19 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 [Vaccine Wastage Reporting Tool](#).

II. Pre-Vaccination Patient Intake & Education

1. 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. Package the [EUA Fact Sheet for Recipients and Caregivers](#), [VaxText](#), [v-safe](#), 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.
3. 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](#).
4. Address patient's questions and gather patient information, such as contraindications, before the visit to expedite the screening process.
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 [met the criteria to discontinue isolation](#).
 - b. Explain to patients this is a two-shot series (**unless they are receiving the Janssen (J&J) vaccine**) and they will need to return if this is their first shot (after 21 days for Pfizer-BioNTech COVID-19 vaccine and after 28 days for the Moderna COVID-19 vaccine).
 - c. Provide the [EUA Fact Sheet for Recipients and Caregivers](#) 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.
 - d. Screen all recipients for contraindications and precautions. Review for appropriate vaccination or deferral. **Those with a [contraindication](#) should not be vaccinated. A [COVID-19](#)**



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[prevaccination questionnaire](#) is available to assist with screening. Refer to [Appendix A](#) for the triage form from CDC.

- i. CDC currently recommends the following observation periods after vaccination:
 - ii. 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.
 - iii. 15 minutes for:
 1. All other persons. Some examples are below:
 - a. An immunocompromised person without any contraindications or history of immediate allergic reactions.
 - b. A person with other allergies such as to peanuts or oral medications (without any history of anaphylaxis or other precautions or contraindications)
 - iv. * 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).
 - v. Persons who have had a severe allergic reaction to a first dose of a COVID-19 vaccine should **not** receive the second dose.
 - vi. Refer to the [CDC Clinical Considerations](#) for guidance for vaccinating patients who are pregnant or have underlying medical conditions.
- e. Capture date of birth.



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- f. Ensure patients are ≥ 16 years if receiving the Pfizer-BioNTech vaccine or ≥ 18 years if receiving the Moderna or Janssen (J&J) vaccine.
6. Make sure patient education is accessible to all.
 - a. If working in 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 [here for Pfizer-BioNTech](#) and [here for Moderna](#).
 - b. Ensure that a language line is available to assist patients for whom an interpreter is not available.
 - c. Obtain handouts in larger fonts to make information more accessible to elderly and visually impaired populations.
 - d. Modify [VaxText](#) and [v-safe](#) 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 [EUA Fact Sheet for Recipients and Caregivers](#)** to connect patients with key information, to reduce printing time, and to eliminate paper waste.
8. 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.
9. 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 [VaxText](#).

III. Vaccine Storage & Handling

1. Ensure plans are in place for maintaining vaccine at appropriate temperatures while stored and throughout the clinic day based on [vaccine storage and handling guidance](#). Monitor and document vaccine temperatures as required throughout the day.
2. CDC's [Vaccine Storage and Handling Toolkit](#) provides guidance on safe and effective vaccine management practices for all healthcare providers.



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3. 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.
4. A contingency plan should also be in place, in case vaccines are delayed or compromised and need to be replaced.
5. **Finalize your plan for administering the second dose before the initial doses are administered.**

IV. Vaccine Preparation & Administration

a. Vaccine Preparation

1. [Pfizer-BioNTech](#) and [Moderna](#) COVID-19 vaccines must be thawed before mixing (Pfizer-BioNTech) or administration.
 - a. Pfizer-BioNTech: Thaw at room temperature between 30 minutes and 2 hours before mixing.
 - b. Moderna: Thaw at room temperature (59 to 77 °F) for 1 hour **or** in refrigerated conditions between (36 to 46 °F) for 2 hours and 30 minutes then at room temperature for 15 minutes.
2. Dilution required using 0.9% Sodium Chloride for Pfizer-BioNTech vaccine.
3. **Do not dilute** Moderna vaccine.
4. **Do not shake** [Pfizer-BioNTech](#), [Moderna](#), and [Janssen \(J&J\)](#) vaccine vials.
 - a. Pfizer-BioNTech: Gently invert and evert vials ten times to mix.
 - b. Moderna: Swirl vial gently after thawing and between each withdrawal. **Do not** use and contact the manufacturer if vials are shaken instead of swirled.
 - c. [Janssen \(J&J\)](#): Gently swirl the vaccine vial for 10 seconds prior to administration.
5. [For Moderna and Janssen \(J&J\) vaccines](#), all doses will need to be used within 6 hours of opening a vial. [For Janssen \(J&J\) vaccine specifically](#), opened vials need to be used within 6 hours in the refrigerator or **only two hours at room temperature**.
6. For Pfizer-BioNTech vaccine, all doses must be used within 6 hours of dilution.
7. Do not re-freeze thawed vials.



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8. Vaccines are not interchangeable. A patient must receive the second dose using the same vaccine used for the first dose. For example, if Moderna was used for the first dose, it must be used for the second; you cannot use the Pfizer-BioNTech vaccine for the second dose.
9. In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time. More guidance is available [here](#).

b. Vaccine Administration

1. 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.
2. Follow the “seven rights” of vaccine administration: right patient, right vaccine/diluent, right time, right dose, right route, right site, and right documentation.
3. 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. 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.





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- 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.
 - v. Ensure vaccinators understand the need to contact a supervisor immediately if a needlestick occurs.
4. Additional information and safety measures to avoid NSIs can be found at the following links.
- i. [NIH: Injection Safety for COVID-19 Vaccinators & Vaccine Administrators Preventing Needlesticks and Blood Exposures](#)
 - ii. [CDC NIOSH Science Blog: Preventing Needlestick Injuries at COVID-19 Vaccination Sites](#)

V. Post Vaccination

1. Ensure patients know that CDC has recommended that no other vaccines be given 2 weeks before or after a COVID-19 vaccine. This means if they just received their first COVID-19 vaccine, they should not get any other vaccines until they receive their second COVID-19 vaccine. If this is their second COVID-19 vaccine, they should not get another vaccine for 2 weeks.
2. Have patient education handouts available if patients would like to read during their observation period.
3. Place nervous patients or those with concerns for adverse reactions closer to a clinical observer.
4. 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. Details for signing up for VaxText. Consider using this [handout](#).
 - c. A filled in second dose card, including a scheduled follow up appointment. Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 21 days [Pfizer-BioNTech] or 28 days [Moderna]). However, second doses administered within a grace period



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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 the first and second doses for either vaccine. Therefore, if the second dose is administered >21 days after the first Pfizer-BioNTech vaccine dose or >28 days after the first Moderna vaccine dose, there is no need to restart the series. Vaccine administration errors should be reported to the [Vaccine Adverse Event Reporting System \(VAERS\)](#), a national early warning system to detect possible safety problems in U.S.-licensed vaccines.

5. People who have been vaccinated 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](#).
 - a. Ensure all patients are wearing a mask or cloth face covering throughout the entire observation period.
 - b. Choose an area with no foot or vehicle traffic.
 - c. Adhere to 6 feet physical distancing.
 - d. Ensure people feel safe and comfortable.
 - e. 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.

6. You are required to report the following to VAERS:
 - a. Vaccine administration errors (whether associated with an adverse event [AE] or not)
 - b. [Serious AEs](#) (irrespective of attribution to vaccination)
 - c. Multisystem inflammatory syndrome (MIS)



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- d. Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
7. You are encouraged to report any clinically significant AEs that occur after vaccine administration.
8. Adverse events should be reported even if the cause of the AE is uncertain.
9. Immediately treat suspected cases of anaphylaxis with intramuscular injection of epinephrine. More information from the CDC about preparing for the potential management of anaphylaxis after COVID-19 vaccination can be found [here](#).

VI. Record Keeping

1. This process is critical, and time-sensitive but will likely also be time-consuming. Ensure adequate staff, time, and resources are allotted.
2. **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 [VDH VIIS Website](#).
 - 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 [COVID-19 Vaccine Redistribution Process](#). Also, remember to use [this survey link](#) to report when you redistribute COVID-19 vaccine to another provider or facility.





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3. Have a designated check out area to make sure all forms are filled out and vaccination is recorded.
4. Enter data at the clinic site and document in real time.
 - a. If using paper, dedicate a support staff member to enter data.
 - b. Assign 1-2 staff to data entry for real-time record keeping.
5. Fully document vaccine in the patient chart: date, lot number, expiration, manufacturer, injection site, vaccinator, EUA vaccine fact sheet date.
6. It is essential to track the lot numbers of the vaccines in case of adverse reactions.
7. Have a copier nearby in case you need to duplicate cards, paperwork, etc.
8. Attend updated trainings to understand systems used for record keeping, such as PrepMod and VIIS.
9. Ensure you have maintained [required documentation from the Board of Pharmacy](#).
10. Identify an IT point of contact or specialist to help troubleshoot if systems issues arise.
11. If you are using PrepMod, refer to [this VDH webpage](#) to review resources (e.g., quick reference guides) that walk through using PrepMod at a VDH-sponsored clinic.

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

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> 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† 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction* to other vaccines or injectable therapies‡ <p>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.#</p>	<p>Among people without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> 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
<p>Actions:</p> <ul style="list-style-type: none"> Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.† 	<p>Actions:</p> <ul style="list-style-type: none"> Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>Actions:</p> <ul style="list-style-type: none"> 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people

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

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

‡ Includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which



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is a vaccine component, but in whom it is unknown which component elicited the immediate 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.





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Appendix B: Resources & References

1. CDC Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations: <https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html>
2. VDH Nursing directive: Emergency Treatment of Anaphylaxis (2020): <https://vdhweb.vdh.virginia.gov/nursing/directives-guidelines/>
3. VDH COVID-19 Vaccination Response Resources for Healthcare Professionals: <https://www.vdh.virginia.gov/covid-19-vaccine/healthcare-professionals/>
4. CDC Clinical Considerations for COVID-19 Vaccination: <https://www.cdc.gov/vaccines/covid-19/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>

