Guidance and Standing Orders for COVID-19 Vaccinations

Updated: 10/19/2022

This guidance is for all COVID-19 vaccinations given under On-Site Medical Services. This guidance will be updated as new information and resources become available, including as new vaccines become available for use under a Food and Drug Administrations (FDA) Emergency Use Authorization (EUA), and after the U.S. Centers for Disease Control and Prevention (CDC) and theirAdvisory Committee on Immunization Practices (ACIP) provides medical recommendation for appropriate use of the vaccines.

If questions or issues arise during vaccine clinic operations, please refer to the contact sheet provided.

General Guidance:

Review CDC's Infection Control Guidance for Healthcare Professionals

All persons involved in handling, preparing or administering COVID-19 vaccine must read and be familiar with these NH COVID-19 vaccine clinic protocols and standing orders, and the following manufacturer-specific COVID-19 vaccine fact sheets from the FDA:

- Pfizer-BioNTech vaccine for persons 6 months through 4 years of age: Fact Sheet For Healthcare Providers Administering Vaccine
- Pfizer-BioNTech vaccine for persons 5-11 years of age: Fact Sheet for Healthcare Providers Administering Vaccine
- Pfizer-BioNTech vaccine for persons 12 years of age or older: Fact Sheet for Healthcare Providers Administering Vaccine
- Moderna vaccine 6 month-5 years of age: Fact Sheet for Healthcare Providers Administering Vaccine
- Moderna vaccine 18 years of age or older: Fact Sheet for Healthcare Providers Administering Vaccine
- Janssen vaccine: Fact Sheet for Healthcare Providers Administering Vaccine
- Novavax vaccine: Fact Sheet for Healthcare Providers Administering Vaccine

Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

All persons involved in handling, preparing or administering COVID-19 vaccines must have been provided and reviewed vaccination training material developed by On-Site Medical Services and approved by the NH Department of Health and Human Services.

Face Mask Use:

- All healthcare providers and staff supporting the COVID-19 vaccination clinic must wear a surgical face mask over their nose and mouth at all times when within the vaccination clinic facility (including in break rooms and other indoor spaces where they might encounter co-workers), when entering a facility or person's home, and when outdoors and around other people.
    - Staff should be given routine mask breaks as needed (ideally outside if weather permits) where staff are separated from others and can safely remove (and store) their face mask.
    - Staff must sanitize hands before and after removing and putting on face masks.
    - Avoid touching your face or adjust face covering without first sanitizing your hands. After touching a person's face or adjusting face coverings, hands must again be Sanitized.
- All vaccine recipients (VRs) and visitors to a COVID-19 vaccination clinic who are 2 years of age and older must wear a face mask or cloth face covering over their nose and mouth when within the vaccination facility or outdoors and around other people, unless there is a valid medical or developmental reason a child or adult cannot wear a face mask (per CDC guidance), or if a young child is unable to be compliant with face mask use even after parents/guardians and staff work to gain compliance.

- **Masking for school-based clinics (SBCs):** In alignment with NH Dept. of Education policies, children are not mandated to follow masking protocols while on school premises. Due to this policy, children are not required to wear masks within school-sponsored vaccination clinics.

Personal Protective Equipment (PPE) During a Vaccine Recipient (VR) Care Encounter:

- During VR encounters, or when interacting with members of the public, vaccination clinic staff should wear appropriate PPE, including the following:
    - Surgical face mask
    - Eye protection: face shield (preferred) or goggles (note: eye protection is optional for vaccinators operating in areas that have a low or moderate level of Community transmission of COVID-19, but should be worn in areas of "substantial" community transmission)
    - Gloves are required for healthcare workers delivering vaccine
- Staff going into a long-term care facility (LTCF) experiencing an outbreak or with concern for facility transmission must follow the facility's PPE guidance and infection control procedures.
- The above specified articles of PPE should be appropriately donned and doffed (put on and taken off) per CDC guidance on using PPE.
- Masks and face shields can be reused between VRs at fixed site (non-mobile) vaccination clinics as long as they are not contaminated; gloves should be changed in- between VRs.
    - Masks should be discarded, at a minimum, at the end of each shift, or if the mask becomes saturated or soiled.
    - Face shields and goggles can be reused and should be cleaned and disinfected at the end of each shift, or if they become soiled/contaminated; gloves should be used when cleaning and disinfecting (see cleaning and disinfection guidance below).
- For mobile clinics, or teams traveling going between facilities or households, vaccinators and staff must doff all PPE between vaccination sites – disposable masks and eye protection should be discarded after use at each vaccination site; reusable eye protection (i.e. face shield or goggles) must be cleaned and disinfected at a minimum after use at each site before traveling to the next site where clean PPE should be put on.
- Healthcare workers should practice hand hygiene immediately before AND after each VR care encounter.

Hand Hygiene:

- Alcohol-based hand sanitizer should be made readily available at the walk-in facility entrances, exists, throughout the facility, and at points of vaccination. Drive-thru clinics should also have alcohol-based hand sanitizer readily available, especially at points of vaccination for use by staff. Mobile vaccination teams should carry portable containers of alcohol-based hand sanitizer.
- All staff, visitors, and VRs should be asked to practice hand hygiene upon entry to the facility and upon exiting (even for drive-thru clinics). All household members should be asked to practice hand hygiene before a mobile vaccination team enters a household.
- All healthcare personnel delivering vaccination must practice hand hygiene immediately before and after vaccinating each VR.
- All staff should frequently perform hygiene throughout the day, including before and after taking a break or eating, before and after restroom use, etc.

Maintaining Social Distancing (COVID-19 clinics only):

- Limit and monitor points of entry to the facility.
- Drive through vaccine clinics should have personnel managing traffic flow and ensure roads and entrances/exits are not blocked. VRs and visitors to drive-thru clinics should not get out of their vehicles.
- Limit/avoid unnecessary visitors; each child/minor should be accompanied by a single parent/guardian, for example, unless others in a family are being vaccinated.

- Assign a person (e.g., a safety officer) to monitor compliance with face mask use, social distancing, clinic flow, etc.
- Maintain a unidirectional flow through the facility so people are entering and exiting through different locations to avoid close contact between VRs and visitors.
- Avoid close physical contact between staff, visitors, and VRs (i.e., avoid people coming within 6 feet of each other) unless delivering vaccine to a VR.
- Check-in and check-out process should avoid physical or prolonged close contact between VRs/visitors and staff. Consider a physical barrier (e.g., a plastic partition or barrier) at check-in/check-out separating staff and VRs, if feasible (more applicable to walk-in clinics).
- Any waiting areas at walk-in clinics should have seating for VRs and visitors spaced 6 feet or more apart. Drive-thru clinics should have people waiting in cars.
- Waiting lines should have clearly demarcated spacing for people to stand/wait 6 feet or more apart.
- Multiple vaccine delivery areas should have appropriate spacing between areas to ensure that staff, VRs, and visitors in one area are not in close contact to people in another vaccination area.
- Mobile clinics going into a household (e.g., vaccinating a homebound person) should request that a minimum number of people be present in the household at the time of vaccination, as is necessary to support vaccination of an individual in order to limit close contacts.

Screening for fever, symptoms, and risk factors for COVID-19 (COVID-19 clinics):

- Each staff member must have their temperature taken and be screened for symptoms of COVID-19, recent diagnosis of active SARS-CoV-2 infection (the novel coronavirus that causes COVID-19), and risk factors for COVID-19 prior to each shift/clinic (see screening questions below) – temperatures and responses to questions do not need to be documented or recorded
- Each VR and visitor entering a clinic (including drive thru clinics), or any household contact present for vaccination of a homebound individual must have their temperature taken and be screened for symptoms of COVID-19, recent diagnosis of active SARS-CoV-2 infection (the novel coronavirus that causes COVID-19), and risk factors for COVID-19 immediately prior, or upon entry, to the facility (see screening questions below); temperatures and responses to questions do not need to be documented or recorded.
- Staff, VRs, visitors, and household contacts who screen positive for any new or unexplained symptoms of COVID-19, have recently been diagnosed with COVID-19 and not yet meet CDC criteria for discontinuation of isolation, or who report a travel-related risk factor or close contact to a person with COVID-19 in the prior 10 days requiring quarantine* should not be allowed into the vaccination facility (including for drive-thru clinics) – see NH DHHS FAQ document for further details and rationale. Similarly, a mobile team should not enter a household if a person is present who is symptomatic or should be on quarantine due to travel outside of New England or exposure to COVID-19.*
    - * People who previously tested positive for COVID-19 by PCR or antigen testing in the 90 days prior to an exposure or travel, or who are 14 days beyond completion of a COVID-19 vaccination series at the time of an exposure or travel are not required to be quarantined. These persons can be allowed into vaccination clinics as long as they remain asymptomatic.
- Anybody with new or unexplained symptoms of COVID-19 (including fever of 100.4°F or higher) should be instructed to contact their healthcare provider for COVID-19 testing, or seek out COVID-19 testing any one of the many options for testing around the State.
- All staff, VRs, visitors, and household contacts should have their temperature taken with a touchless thermometer prior to entry to the facility (or prior to a vaccination team entering a person's home) and be asked the following screening questions (people can be asked verbally, or provided the questions in writing and asked to identify any "yes" or affirmative answers to the screening questions):
    - Do you have any symptoms of COVID-19 that are new for you, including:
        - Fever, chills, or feeling feverish;

        - Respiratory symptoms such as runny nose, nasal congestion, sore throat, cough, or shortness of breath;
        - General body symptoms such as muscle aches or severe fatigue;
        - Nausea, vomiting, or diarrhea, or Changes in your sense of taste or smell?
    - Have you recently tested positive for, or been diagnosed with, active COVID-19 in the prior 10 days (and are supposed to be isolating at home)?
    - Have you had close contact with someone who has tested positive for COVID-19 in the prior 10 days? (Note: healthcare workers caring for COVID-19 patients while wearing appropriate personal protective equipment should answer "no" because they are not considered to have exposure)
    - Have you traveled in the prior 10 days outside of NH, ME, VT, MA, RI, or CT, including domestically (within the U.S.), internationally (outside of the U.S.) or on a cruise ship?

Cleaning and Disinfection:

- Review CDC's cleaning and disinfection guidance under their Infection Prevention and Control Recommendations for Healthcare Personnel (see "Environmental Infection Control" section), and general community Cleaning and Disinfecting guidance.
- Commonly touched surfaces should be routinely cleaned and disinfected.
- Shared tools and equipment, especially shared non-disposable medical equipment used during VR care, must be cleaned and disinfected according to manufacturer's instructions between each VR use.
- Use an EPA-approved disinfectant effective against the novel SARS-CoV-2 coronavirus (EPA List N disinfectant).
- Use disposable gloves to clean and disinfect.
- Follow manufacturer instructions on PPE use, and application and contact time needed for disinfectant.

Messaging and Communication:

- All healthcare workers and supporting staff and volunteers should be informed and educated about the infection control and COVID-19 mitigation measures outlined in this and other supporting guidance documentation.
- VRs and visitors should also be informed (e.g., through use of signage) that they should not enter the facility if they have any symptoms of COVID-19, have traveled to high risk areas in the prior 10 days, or been in close contact to someone with COVID-19 in the prior 10 days (unless the person is not required to quarantine after travel or an exposure to COVID-19 due to previous infection or being fully vaccinated – see above).
- VRs, visitors, and household contacts should be instructed to wear a face mask, practice hand hygiene, and socially distance upon entering the facility, or when a mobile vaccination team enters a person's home.

Environmental Safety:

- Clinic managers and safety officers should ensure walkways and drive-up areas are safe and free of ice and snow to prevent slips and falls.
- Vaccination areas in outdoor drive-thru clinics should have space where staff can shelter from weather in a safe, socially-distanced space, and also provide a warm space for breaks and snack/lunch if needed due to cold weather.
- In the case of unsafe inclement weather (e.g., snow storm or Nor'easter), clinics should have plans for canceling and rescheduling VRs and have a plan/process in place for notification of staff.

Vaccination Clinic Work-Flow:

- Vaccine recipients (VR) should be screened before registering for an appointment at any COVID-19 vaccine clinic:
    - Screen the VR to ensure they are part of the priority vaccination population.
    - Screen the VR for any vaccine contraindications, precautions, or other specific health conditions that need additional follow-up or evaluation (see "PreRegistration Screening Questionnaire" for details and recommended actions), including:
        - Contraindications to vaccination
        - Precautions to vaccination
        - Any prior history of anaphylaxis
        - Receipt of passive antibody therapy to treat COVID-19 in the last 90 days
        - Receipt of another vaccine in the last 14 days
        - Severely immunocompromised condition
        - Current pregnancy
    - Provide the necessary documents listed below so the VR has a chance to review before their vaccine appointment.
- Documents that need to be provided to all VR's BEFORE vaccination include:
    - FDA COVID-19 vaccine "Fact Sheet for Recipients and Caregivers" (provide the specific fact sheet for the vaccine that will be administered):
        - Pfizer-BioNTech vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
        - Moderna vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
        - Janssen vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
        - Novavax vaccine: Fact Sheet for Recipients and Caregivers (for other language translations of the Fact Sheet, see the FDA website)
    - V-safe information sheet that contains background on the v-safe program and instructions for enrolling; V-safe is a new smartphone-based tool that uses text messaging and web surveys to check-in with vaccinated individuals to monitor for adverse events after a COVID-19 vaccination; v-safe will also provide second-dose reminders, if applicable.
- Before entry into the COVID-19 vaccination clinic, staff should take the temperature of all VRs and visitors using a touchless thermometer, and ask (or provide in writing) the screening questions above, to which the VR and visitors must provide an answer.
- Upon entry, staff should direct VRs to the registration area where the following should occur:
    - If VR has pre-registered and has a vaccination appointment, then registration staff verify the person's information in the Vaccine Management System (VMS).
    - If VR has NOT pre-registered, then staff register VR on-site in the VMS (it is recommended that fixed-vaccination sites require pre-registration). If registering on-site, the person registering the VR should screen the person for the above contraindications, precautions, and other health conditions using the "PreRegistration Screening Questionnaire".
    - Provide necessary documents outlined above, if not already provided
- If the VR has not been given or not reviewed the above information before the clinic, staff should direct the VR to a waiting area to review the provided information before vaccination. After reviewing the information, if the VR elects not to be vaccinated, registration staff should cancel the clinic appointment.
- Vaccinators should review information entered into the Pre-Vaccination Questionnaire, Recipient Details, and Medical Information sections of the VMS with the VR.

    - Vaccinators should use the "Vaccination Screening Checklist" to quickly screen/review for any contraindications, precautions or other health conditions.
- If no contraindications, administer the appropriate COVID-19 vaccine per standing order protocols (see attached protocols) using safe vaccination and infection prevention technique.
    - If the vaccine is dose #2 (only applies to the Pfizer-BioNTech and Moderna vaccines), ensure the same brand/manufacturer is administered as dose #1 (i.e., if dose #1 was Pfizer-BioNTech, then dose #2 needs to also be Pfizer-BioNTech)
    - Vaccinators should follow General Best Practice Guidelines for Vaccine Administration.
    - Sharps and syringes should be appropriately disposed of in a sharps container immediately after vaccination.
    - Sharps containers should be monitored and replaced when nearing capacity to prevent needle sticks when disposing of sharps.
- "Log Vaccination" and enter the necessary information in the "Vaccine Administration" section of the VMS
- Documents that need to be provided to all VR's AFTER vaccination include:
    - The "After Visit Summary (AVS) Recommendations for Vaccine Recipients" (note: this can also be provided with the information packet provided prior to vaccination if easier to implement into clinic flow).
    - "COVID-19 Vaccine Record Card" documenting the following:
        - VR's name and date of birth
        - Vaccine clinic site
        - Vaccine manufacturer and lot number
        - Date of vaccination
        - Second dose due date (if applicable)
- Encourage VRs to enroll in CDC's v-safe monitoring system.
- Vaccinators should instruct the VR to expect some side effects from the vaccine in the next few days (refer VR to the "After Visit Summary"), and to contact their primary care provider if they experience any concerning adverse reactions after leaving the vaccine clinic. If a VR doesn't have a primary care provider, they should seek medical care at a local urgent care or emergency department if they have any concerning signs/symptoms after vaccination, or call 9-1-1 for serious life-threatening symptoms or reactions (e.g., chest pains, difficulty breathing, face or throat swelling, confusion, body rash or hives, etc.)
- After vaccination, the VR should be directed to wait in an observation area for at least 15 minutes after vaccination to ensure there are no immediate serious adverse vaccine reactions (e.g., anaphylaxis) – it is not mandatory that someone wait 15 minutes, but it is strongly recommended. People with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, OR persons with a history of an immediate allergic reaction of any severity (reaction within 4 hours) after receipt of another vaccine or other injectable medication therapy, that does not meet criteria as a contraindication should be instructed to wait for 30 minutes after vaccination.
    - Waiting areas should be large rooms (for walk-in clinics) with seating spaced more than 6 feet apart, and everybody must wear masks.
    - For drive-thru clinics, waiting areas should have enough space for cars to park spaced apart so that someone can walk up to a window to check on the person without coming within 6 feet of another vehicle (e.g., space waiting vehicles so that every-other space is empty).
    - Clinic staff should monitor the waiting area wearing appropriate PPE and periodically check on VRs.
    - For vaccination of homebound persons, mobile vaccination teams should identify an area within the home where the VR can be safely observed for the appropriate time frame while the vaccination staff maintains appropriate social distance from the VR and other household members (while continuing to wear appropriate PPE).

    - Any adverse vaccine reactions should be managed according to the "Medical Management of Vaccine Reactions" protocols.
    - In the event of a serious life-altering reaction occuring, provide BLS and call emergency services (9-1-1).
- Adverse events should be reported to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.
- Scan and submit all consent forms and *End of Day Report* forms to designated OnSite Dropbox **within 1 business day**. If clinics/vaccine administrations occur over the weekend, forms need to be submitted by the end of business day the following Monday.

Additional Guidance for Vaccination Clinics in Long-Term Care Facilities:

- See recommendations below on "COVID-19 Testing for Vaccinators and COVID-19 Vaccine Clinic Staff Entering Long-Term Care and Assisted Living Facilities"
- In order to efficiently provide COVID-19 vaccination to long-term care facility (LTCF) or assisted living facility (ALF) residents, the required information and documents outlined above should be provided prior to a scheduled vaccination clinic, and at least verbal agreement (assent) should be obtained prior to the date of the clinic (written consent is not required). LTCFs/ALFs should assist in sharing of information and obtaining agreement for vaccination.
- This agreement to vaccination should be obtained:
    - Directly and verbally from residents with decision making capacity, or
    - From guardians or a person's healthcare power of attorney for residents without decision making capacity (e.g., with dementia or other cognitive impairment) – this can be obtained verbally via phone, or in writing via e-mail or fax.
- Prior to a scheduled clinic, LTCFs/ALFs should provide the vaccination clinic staff the list of residents who have agreed, or whose legal surrogates have agreed, to vaccination, and should indicate this on the provided vaccination list. Provide this list by secure fax or e-mail to the appropriate Regional Public Health Network contact.
- The LTCFs/ALFs should document in the resident's chart or medical record that the required information was provided to residents or healthcare powers of attorney, and that agreement was obtained prior to vaccination.

Additional Guidance for Vaccination of Homebound Persons

Mobile COVID-19 vaccination teams may be required to vaccinate homebound individuals. Vaccinators and staff conducting mobile vaccination clinics for homebound persons must review and follow CDC's guidelines for vaccinating homebound persons with COVID-19 vaccine, and must also review and apply the guidance in these documents and standing orders to vaccinating homebound individuals, including the following additional guidance:

- Vaccinations teams that are moving from home-to-home to vaccinate homebound individuals must plan out their routes ahead of time, including estimating time intervals of travel between vaccinations, to ensure the appropriate number of vaccine doses are available, vaccine is stored and transported at necessary temperatures, and that the vaccine is used in the necessary time period to avoid vaccine wastage.
- To efficiently vaccinate homebound individuals, the required information and documents outlined above should be provided prior to a scheduled vaccination clinic, and verbal agreement (assent) should be obtained from the vaccine recipient or guardian (written consent is not required) and documented in VMS.
- Per CDC guidance and best immunization practice, vaccines should ideally be transported in vials and not in pre-drawn syringes; vaccination teams should plan routes and schedules with this in mind. However, there may be instances when the only option is to transport vaccine in a pre-drawn syringe, which can be considered in certain situations, but vaccination teams must follow the guidance for transporting pre-drawn vaccine in syringes found in the COVID-19 Vaccine Handling Toolkit: Operational Considerations for

Healthcare Practitioners; this includes appropriate labeling of containers transporting pre-drawn syringes, and labeling of each individual pre-drawn syringe. Transporting pre-drawn syringes, however, should NOT be considered routine practice due to increased risk of administration errors.

- Before the vaccination team enters a person's home, everybody present in the home should be screened for fever, symptoms or risk factors for COVID-19 per guidance in the section above "Screening for fever, symptoms, and risk factors for COVID-19".
- Vaccination teams should request ahead of time that the minimum number of people be present in the household at the time of vaccination as is necessary to support vaccination of a homebound person.
- Everybody in the house should be asked to practice hand hygiene and everybody 2 years of age and older should wear a face mask over their nose and mouth before the vaccination team enters the home.
- Vaccination teams must develop a process for appropriate monitoring of the VR after vaccination (15 or 30 minutes), and be prepared with the necessary equipment and Supplies to manage and allergic reaction, including anaphylaxis (a minimum of 3 doses of epinephrine should be on-hand when administering vaccine).

List of Medical Providers Approved to Administer COVID-19 Vaccine through NH State-Managed Vaccination Clinics

All persons administering vaccinations through the NH State-managed COVID-19 vaccination clinics should have training and/or experience in administering vaccinations. All persons should be trained in the necessary processes and procedures outlined in this document, and provided vaccination refresher training. Any trainees (e.g., pharmacy interns, nursing students, medical students, etc.), must operate under the direct supervision of a provider/preceptor in their respective profession who is onsite, trained, experienced, and licensed/certified to provide vaccination.

The following licensed medical providers or trainees are allowed to administer COVID-19 vaccines through NH State-managed COVID-19 vaccination clinics. Note that specific personnel are allowed to vaccinate minors under the age of 12, and must meet license requirements as stated in the below standing orders:

- **MD** – Doctor of Medicine
- **DO** – Osteopathic Medicine
- **PA** – Physician Assistant
- **DMD** – Doctor of Dental Medicine
- **DDS** – Doctor of Dental Surgery
- **RDH** – Registered Dental Hygienists
- **DPM** – Doctor of Podiatric Medicine
- **ND** – Naturopathic Doctor
- **APRN** – Advanced Practice Registered Nurse
- **RN** – Registered Nurse
- **LPN** – Licensed Practical Nurse
- **RMA** – Registered Medical Assistant
- **CMA** – Certified Medical Assistant
- **Paramedic**
- **Advanced-EMT**
- **EMT** – Emergency Medical Technician (including EMT-basic)*
- **68W and 4N** – Military Medics
- **Pharmacist†**
- **Pharmacy interns† ***
- **Pharmacy Technician‡**
- **Nursing, Medical, and PA Students***

- **Ages 12+:** See above list from COVID-19 Standing Orders
- **Ages 3-11yrs:** MD, DO, APRN, APRN Student*, PA, PA Student*, RN, RN Student*, LPN, Pharmacists and Pharmacy Technicians* (If they have an immunization endorsement through NH OPLC), Paramedic, Advanced-EMT, EMT*
- **Ages 6mo-3yrs:** MD, DO, APRN, APRN Student*, PA, PA Student*, RN, LPN

** Interns and students must operate under the direct supervision of a provider/preceptor in their respective profession who is onsite, trained, experienced, and licensed/certified to provide vaccination. These individuals must all receive training on clinic processes and protocols, and training in injection safety and technique. EMTs must also conduct any training required through the NH Bureau of EMS.*
† Pharmacists & pharmacy interns require an immunization endorsement offered through OPLC.
‡ Based on NH Emergency Order #79, pharmacy technicians are allowed to vaccinate persons three years of age and older while under the supervision of a NH licensed pharmacist (see Emergency Order #79 for further details and requirements).

COVID-19 Vaccine Health Questionnaire

Administered: ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen (Johnson & Johnson)

SCREENING QUESTIONS	Yes	No	Don't Know
Are you feeling sick today?			
Have you ever received a dose of a COVID-19 vaccine before? **If yes,** which COVID-19 vaccine product(s) were you previously given? (please circle) Pfizer-BioNTech Moderna Janssen (Johnson & Johnson)			
Did you have an allergic reaction after a prior dose of COVID-19 vaccine? *Allergic reactions can include symptoms like rash, hives, swelling of face or mouth, wheezing and difficulty breathing, etc. – Please specify:*			
Do you have a known allergy to an ingredient in the Pfizer-BioNTech COVID-19 vaccine? *See the provided age-appropriate FDA Fact Sheet for a list of vaccine ingredients.*			
Do you have a known allergy to polyethylene glycol (PEG)?			
Do you have a known allergy to polysorbate?			
Have you ever had any allergic reaction within 4 hours of receiving a non-COVID-19 vaccine or other injectable medication (including medications injected into a muscle, vein, or under the skin)?			
Have you ever had a severe allergic reaction (like anaphylaxis due to any other cause, including medications taken by mouth, food, or other substances?			
Did you develop myocarditis or pericarditis after receiving a prior dose of either the Pfizer-BioNTech or Moderna COVID-19 vaccine?			
Do you have a bleeding disorder or are you taking blood thinners?			
In the last 90 days, have you been given a COVID-19 antibody therapy to either treat COVID-19, or to prevent COVID-19 from developing after you were exposed to another person with COVID-19? *(Antibody therapies include monoclonal antibodies or a blood product called "convalescent plasma")*			
In the last 90 days, did you develop an immune-related health condition that caused blood clotting AND low platelet blood counts? (T*he most common example of this is called "heparin-induced thrombocytopenia"*)			
Did you develop a health condition called "thrombosis with thrombocytopenia" (TTS) after receiving a prior dose of the Janssen vaccine? (*People with this syndrome develop blood clotting and low platelet blood counts after receiving the Janssen vaccine*)			
Did you develop Guillain-Barré syndrome (GBS) after receiving a prior dose of the Janssen vaccine?			

Vaccination Screening Checklist (For Vaccinators)

This screening checklist is to help vaccinators identify important information entered into a person's PreVaccination Questionnaire in the Vaccine Management System (VMS), which may impact the ability of a person to receive the vaccine or affect vaccine selection or management of a person after vaccination.

Review vaccine recipient (VR) information in the VMS and verify information with VR prior to vaccination:

- ☐ **Is the VR feeling sick today?**
  - Moderate or Severe Illness: Vaccination should be delayed for any person with moderate-to-severe acute illness until their illness has improved.
  - Symptoms of COVID-19: A person with any new or unexplained symptoms of COVID-19 (even mild cold symptoms) should be declined vaccination, instructed to isolate at home, and seek testing for COVID19 (person should be screened for symptoms of COVID-19 before reaching the vaccinator)
- ☐ **Has the VR previously received a dose of the COVID-19 vaccine? If yes, which one?**
  - Refer to each manufacturer guidance for direction on eligibility
- ☐ **Does the VR have a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of the COVID-19 vaccine, or to any component of the vaccine? OR Does the VR have a history of an immediate allergic reaction* of any severity after a previous dose of the COVID-19 vaccine or to a component of the vaccine (i.e., a known/diagnosed allergy to a specific component of the vaccine)?**
  - If "yes" to either, this is a vaccine **Contraindication**: Do NOT give that specific COVID-19 vaccine.
  - A person with a contraindication to one mRNA vaccine should not receive doses of either mRNA vaccine (Pfizer or Moderna)
- ☐ **Does the VR have a history of any immediate allergic reaction* to other vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections)?**
  - If "yes", this is a vaccine **Precaution**. Vaccine may be given, but VR should have received and reviewed the "Information about the COVID-19 Vaccine for Persons with Certain Health Conditions." VRs with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine (see exceptions below). Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- ☐ **If VR is receiving the Janssen vaccine:**

  1.) Did the VR have a severe allergic reaction or an immediate allergic reaction* to a previous/first dose of either the Pfizer or Moderna COVID-19 vaccine (i.e., VR has a contraindication to a second dose)?

  2.) Does the VR have a known/diagnosed allergy to polyethylene glycol?
  - If "yes" to either question, this is a vaccine Precaution for the VR getting the Janssen vaccine; above Precautions information and recommendations apply.
  - However, the CDC also recommends referral to an allergist-immunologist be considered. This is because of potential allergic cross-reactivity between polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines), and polysorbate (an ingredient in the Janssen vaccine).
  - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on the provider's risk assessment, and if

patient is aware of risks and desires to be vaccinated, then the Janssen vaccine may be given; document in VMS. VR must be monitored for at least 30 minutes after vaccination.
- If Janssen vaccine is given, it should be at least 28 days after a previous mRNA vaccine dose (if applicable).
- If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist if any concerning history.

☐ **If VR is <u>receiving the Pfizer or Moderna vaccine</u>: Does the VR have a known/diagnosed allergy to polysorbate?**
- If "yes", this is a vaccine **<u>Precaution</u>** for the VR receiving an mRNA vaccine; above Precautions information and recommendations apply.
- However, the CDC also recommends referral to an allergist-immunologist be considered. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
- If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Pfizer or Moderna vaccine may be given; document in VMS. VR must be monitored for at least 30 minutes after vaccination.
- If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist if any concerning history.

☐ **Does the VR have a history of a severe allergic reaction (e.g., anaphylaxis) due to any other cause that does not qualify as a vaccine contraindication or precaution (including other oral medications, foods, substances, environmental exposures, etc.)?**
- If "yes", vaccine may be given, but VR should have received and reviewed the "Information about the COVID-19 Vaccine for Persons with Certain Health Conditions." It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if VR did not discuss with their primary care provider, a vaccine can be given. Vaccine recipients must be monitored for at least 30 minutes after vaccination.

☐ **Does the VR have a bleeding disorder or is VR taking a blood thinner?**
- If "yes", vaccine may be given, but use a fine-gauge needle (23 gauge or smaller), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

☐ **Has VR received a passive antibody therapy to treat COVID-19 in the last 90 days (passive antibody therapy includes convalescent plasma and monoclonal antibodies)?**
- If "yes", vaccination no longer needs to be deferred after receipt of a passive antibody therapy for treatment for COVID-19. Although some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown, and the balance of benefits vs. risks favors proceeding with vaccination even considering the possibility of diminished vaccine effectiveness in this situation.

☐ **Is the VR severely immunocompromised?****
- If "yes", vaccine may be given, but VR should have received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Vaccine should be safe for VR to receive, but the vaccine may be less effective due to their immune system. If questions or concerns, recommend they discuss with their health care provider.

☐ **Is the VR currently pregnant?**

If "yes", vaccine may be given, but VR should have received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Inform VR that the COVID-19 vaccines have not been extensively studied in pregnant women, so information on vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccines to VR and unborn baby is low, and pregnant women will likely benefit from vaccination. If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.

***** An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.

** Severely immunocompromised conditions include being on chemotherapy for cancer, being within one year out from receiving a hematopoietic stem cell or solid organ transplant, untreated HIV infection with a CD4 lymphocyte count of less than 200, primary immunodeficiency disorder, high levels of steroids (e.g., receipt of prednisone >20 mg/day for more than 14 days), etc.

Standing Order for Administering the Pfizer-BioNTech COVID-19 mRNA Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.
POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics".** Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.
2. **Identify the following individuals for vaccination (i.e., the vaccine recipient, or VR):**

Primary vaccination series: Any person 6 months of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), a single dose of the J&J Janssen COVID-19 vaccine, or all recommended doses of another World Health Organization (WHO) Emergency Use listed vaccine. If administering mRNA COVID-19 vaccine dose #2, the same age- appropriate brand/manufacturer should be administered that the person received for dose #1. Monovalent vaccines should be used for all primary series vaccinations.

- **6 month - 4 years of age**:
  - **TWO DOSE PRIMARY SERIES.** A two dose primary series separated by 4-8 weeks is recommended.
  - **Immunocompromised patients**: For patients that are immunocompromised in this age group should receive a third primary series dose, eight weeks after the second dose.
  - **Booster**: currently, a booster dose using any COVID-19 vaccine is not authorized for children in this age group who receive a Pfizer-BioNTech.
- **5 years - 11 years of age:**
  - **TWO DOSE PRIMARY SERIES**. A two-dose primary series and one booster dose is recommended. The primary series doses are separated by 3-8 weeks and the booster dose is administered at least 5 months after completion of the primary series. Currently, the monovalent Pfizer-BioNTech booster dose is authorized for children in this age group who receive a Pfizer-BioNTech primary series.
  - **Immunocompromised patients**: For patients that are immunocompromised in this age group should receive a third primary series dose, 4 weeks after the second dose.
  - **Booster**: Currently, the bivalent Pfizer-BioNTech booster dose is authorized for children in this age group who receive a Pfizer-BioNTech primary series. The monovalent Pfizer-BioNTech booster will no longer be administered to children in this age group.
- **12-17 years**:
  - **TWO DOSE PRIMARY SERIES**. A two-dose monovalent primary series and one bivalent booster dose is recommended. The primary series doses are separated by 3-8 weeks.
  - **Immunocompromised patients**: For patients that are immunocompromised in this age group should receive a third primary series dose, 4 weeks after the second dose.
  - **Booster**: The bivalent mRNA booster dose is administered 2 months after completion of the primary series (for people who have not received any booster doses) or at least 2

months after the last monovalent booster dose. Currently the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive any COVID-19 vaccine primary series.

- **18 years of age and older**:
    - **TWO DOSE PRIMARY SERIES**. A two-dose monovalent primary series and one bivalent booster dose is recommended. The primary series doses are separated by 3-8 weeks.
    - **Immunocompromised patients**: For patients that are immunocompromised in this age group should receive a third primary series dose, 4 weeks after the second dose.
    - **Booster**: The bivalent mRNA booster dose is administered 2 months after completion of the primary series (for people who have not received any booster doses) or at least 2 months after the last monovalent booster dose. Currently, either the (updated) Pfizer-BioNTech bivalent or Moderna bivalent boosters are authorized for adults in this age group who receive any COVID-19 vaccine primary series.
- **Additional information about immunocompromised doses:** for persons who are moderately or severely immunocompromised: Any person 5 years of age or older who is moderately or severely immunocompromised (see CDC guidance for examples of persons who qualify; note this is NOT an all-inclusive list), and who has already received 2-doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccines. The third dose should ideally be with the same mRNA vaccine product used for the first two doses, but if the same product is not available or not known, then the alternate mRNA vaccine product can be used (i.e., the Moderna COVID-19 vaccine can be used in place of the Pfizer-BioNTech COVID-19 vaccine, and vice versa). Verify the person's age to ensure they are receiving the correct Pfizer-BioNTech vaccine formulation and dose for their age (see administration instructions below).
    - **Special situation:** For people who inadvertently received the booster dose before their third primary dose, regardless of type of vaccine received as the booster dose, administer a Pfizer-BioNTech monovalent vaccine or a Moderna monovalent vaccine (100 µg [0.5 mL, red cap vial]) as the fourth dose (third primary) at least 3 months after the third dose.
- For persons 18 years of age or older, heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. For persons 12-17 years of age, only the Pfizer-BioNTech COVID-19 vaccine may be used. Recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated. Verify the person is receiving the correct Pfizer-BioNTech vaccine formulation and dose for their age (see administration instructions below).

3. **Screen for any contraindications or precautions to vaccination (refer to the "Vaccination Screening Checklist" for vaccinators).**

Contraindications: Do NOT give the Pfizer-BioNTech COVID-19 vaccine to any person who has a history of either: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Pfizer-BioNTech COVID-19 vaccine or a component of the vaccine, or **2)** A known (diagnosed) allergy to a component of the vaccine.

- See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.
- An **"immediate allergic reaction"** is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.

- A person with a contraindication to one mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) *should not receive doses of either of the mRNA vaccines*.

Precautions: Take additional precautions if a person has a history of either: 1) An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or 2) A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either has a known/diagnosed allergy to polysorbate, the CDC recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccines. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Pfizer-BioNTech vaccine may be given; document in the Vaccine Management System (VMS).
    - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist.
- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with the vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination, and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "Vaccination Screening Checklist" for vaccinators).**
    - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Pfizer-BioNTech or Moderna vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. Before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive either the

Pfizer-BioNTech or Moderna vaccines after their episode of myocarditis/pericarditis has completely resolved.

- **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, the vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.
- **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as treatment for COVID-19 in the prior 90 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination can be given. The VR should be educated that some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown.
- **Moderate or Severe Immunosuppression**: Vaccine may be given. Vaccines should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
- **Pregnancy/Breastfeeding**: Vaccine may be given, but ensure the VR received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Inform VR that the COVID-19 vaccines have not been extensively studied in pregnant women, so information on vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccines to VR and unborn baby is low, and pregnant women will likely benefit from vaccination. If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.
- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

5. **Provide required documents listed in the "Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person,parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to:
    - This FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 6 months-5 years
    - This FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 5-11 years of age.
    - This FDA Fact Sheet for Recipients and Caregivers when vaccinating persons 12 years of age or older.
    - Fact Sheet translations into other languages can be found on the FDA's Pfizer-BioNTech COVID-19 Vaccine Website.
6. **Obtain consent for vaccination from a legal guardian for vaccine recipients under the age of 18 years, and for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves:** Follow instructions outlined in the "*Policy for Vaccinating Minors*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).
7. **Prepare to administer vaccine**: Choose the needle gauge, needle length, and injection site as outlined below. Follow manufacturer's instructions for storing and handling vaccine, and ensure the multi-dose vials of the Pfizer-BioNTech vaccine have been appropriately prepared for administration based on the following instructions:

- For Pfizer-BioNTech COVID-19 pediatric vaccine for vaccine recipients 6 months - 4 years of age (vial has an **orange cap**), follow the instructions outlined in this FDA Fact Sheet for Healthcare Providers Administering Vaccine
- For Pfizer-BioNTech COVID-19 pediatric vaccine for vaccine recipients 5-11 years of age (vial has an **orange cap**), follow the instructions outlined in this FDA Fact Sheet for Healthcare Providers Administering Vaccine.
- For Pfizer-BioNTech COVID-19 vaccine for vaccine recipients 12 years of age or older (vial has a **gray cap**), following the instructions outlined in this FDA Fact Sheet for Healthcare Providers Administering Vaccine.

Children and Adolescents (6mo - 2 years of age): Use a ⅝" or 1" needle (22-25 gauge) and administer in the vastus lateralis muscle.
Children and Adolescents (5-18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh muscle can also be used with needle gauge and length according to the table below.

Age	Needle Gauge	Needle Length	Preferred Injection Site
Children, 1-2	22-25	⅝ -1 ½ ''	Vastus lateralis muscle
Children, 3-10	22-25	⅝*-1"	Deltoid muscle of arm (preferred)
	22-25	1-1 ¼"	Anterolateral thigh (alternate)
Children 11-18	22-25	⅝* - 1"	Deltoid muscle of arm (preferred)
	22-25	1- 1 ½"	Anterolateral thigh (alternate)

** A 5/8" needle may be used in children/adolescents weighing less than 130 lbs for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh muscle can also be used for injection (use a 1.5 inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22-25	⅝*-1"	Deltoid muscle of arm (preferred)
Female or male 130-152 lbs	22-25	1"	Deltoid muscle of arm (preferred)
Female 153-200 lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Male 153-200+ lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Female 200+ lbs	22-25	1 ½"	Deltoid muscle of arm (preferred)
Male 260+	22-25	1 ½"	Deltoid muscle of arm (preferred)

** A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. Administer the Pfizer-BioNTech COVID-19 vaccine as follows:

a. **Dose #1**:
   i. For vaccine recipients 6 month-4 years of age: Give a 3 microgram dose (i.e., 0.2 mL of vaccine after MAROON cap multi-dose vial is appropriately diluted) by intramuscular (IM) injection.
   ii. For vaccine recipients 5-11 years of age: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) by intramuscular (IM) injection.
   iii. For vaccine recipients 12 years of age or older: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from monovalent GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) by intramuscular (IM) injection.

b. **Dose #2**:
   i. For vaccine recipients 6 month-4 years of age: Give a 3 microgram dose (i.e., 0.2 mL of vaccine after MAROON cap multi-dose vial is appropriately diluted) at least 21 days after dose #1 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.
   ii. For vaccine recipients 5-11 years of age: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) at least 21 days after dose #1 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.
   iii. For vaccine recipients 12 years of age or older: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from monovalent GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) at least 21 days after dose #1 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.

c. **Dose #3** (additional primary series dose for moderately or severely immunocompromised):
   i. For vaccine recipients 6 month-4 years of age: Give a 3 microgram dose (i.e., 0.2 mL of vaccine after MAROON cap multi-dose vial is appropriately diluted) at least 8 weeks after dose #2 of the Pfizer-BioNTech vaccine by intramuscular (IM) injection.
   ii. For vaccine recipients 5-11 years of age who self-attest that they are moderately or severely immunocompromised: Give a 10 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.
   iii. For vaccine recipients 12 years of age or older who self-attest that they are moderately or severely immunocompromised: Give a 30 microgram dose (i.e., 0.3 mL of vaccine from monovalent GRAY cap multi-dose vial – do NOT dilute gray cap vials prior to use) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.

d. **Booster Dose:**
   i. 5 years of age or older and meets criteria outlined for booster dose administration, then give a 30 microgram dose (i.e., 0.2 mL of vaccine after ORANGE cap multi-dose vial is appropriately diluted for ages 5-11 years).
      1. Criteria:
         a. VR is eligible in this age group, 2 months following completion of their primary series if immunocompetent. If VR is immunocompromised, administer booster dose 3 months following completion of primary series.

ii. 12 years - 17 years: give a 30 microgram dose of bivalent Pfizer-BioNTech gray cap vaccine.

1. Criteria:
    a. If the VR completed their primary series with either the Pfizer-BioNTech or Moderna COVID-19 vaccine, then give the bivalent Pfizer-BioNTech booster dose at least 2 months after the person completed their primary mRNA COVID-19 vaccine series or 2 months after the person completed their three-dose primary series because the person is moderately or severely immunocompromised.
    b. If the VR completed their primary series with the Janssen COVID-19 vaccine, then give the bivalent Pfizer-BioNTech booster dose at least 2 months (8 weeks) after the VR completed their single-dose Janssen COVID-19 vaccine or two-dose Janssen COVID-19 vaccine or moderate to severe immunocompromised individuals.

9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.
10. **Give vaccine recipient the required post-vaccination documents listed in the *"Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics"*** *(including the "COVID-19 Vaccine Record Card" and "After Visit Summary (AVS) Recommendations for Vaccine Recipients").*
11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("Medical Management of Vaccine Reactions"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of a severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.
12. Report adverse events to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order for Administering the Moderna COVID-19 Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.
POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics".** Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.
2. **Identify the following individuals for vaccination (i.e., the vaccine recipient, or VR):**
    - **PRIMARY VACCINATION SERIES:** Any person 6 month or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), or a single dose of the J&J Janssen COVID-19 vaccine.
        - **6 month - 5 years of age**:
            - Primary Series: a two dose primary series separated by 4-8 weeks is recommended.
                - Dose #1 on day 0. Dose #2 administered 4-8 weeks after dose #1.
            - Immunocompromised: a three dose primary series is recommended. The first and second doses are separated by 4 weeks and the second and third doses are separated by at least 4 weeks.
            - Booster Dose: Currently, a booster dose using any COVID-19 vaccine is not authorized for children in this age group who receive a Moderna primary series.
        - **6 years - 11 years of age:**
            - Primary Series: a two dose primary series and one age-appropriate bivalent mRNA booster dose is recommended. The primary series doses are separated by 4-8 weeks.
            - Immunocompromised: a three dose primary series and one age-appropriate bivalent mRNA booster dose is recommended. The first and second series doses are separated by 4 weeks and the second and third doses are separated by 4 weeks.
            - Booster Dose: the bivalent mRNA booster dose is administered at least 2 months after completion of the primary series (for people who have not received any booster doses) or at least 2 months after the last monovalent booster dose. Currently, the bivalent Moderna booster dose is authorized for adolescents in this age group who receive any COVID-19 vaccine primary series.
        - **12 years of age and older:**
            - Primary Series: a two dose primary series and one age-appropriate bivalent mRNA (Moderna or Pfizer-BioNTech) booster dose is recommended. The primary series doses are separated by 4-8 weeks.
            - Immunocompromised: a three dose primary series and one age-appropriate bivalent mRNA booster dose is recommended. The first and second series doses

are separated by 4 weeks and the second and third doses are separated by 4 weeks.

- Booster Dose: The bivalent mRNA booster dose is administered 2 months after completion of the primary series (for people who have not received any booster doses) or at least 2 months after the last monovalent booster dose. Currently, the bivalent Moderna booster dose is authorized for adults in this age group who receive any COVID-19 vaccine primary series.

- If administering mRNA COVID-19 vaccine dose #2, the same age-appropriate brand/manufacturer should be administered that the person received for dose #1, and doses of the Moderna COVID-19 vaccine should be separated by at least 28 days (second doses given between day 24 and 28 after the first dose are considered valid, but should not be routine). If more than 28 days have elapsed since the first dose, the second dose should be given as soon as possible and is still valid. If dose #2 is given prior to the 4 day grace period then the dose should be repeated. The repeat dose should be spaced from the date of the dose given in error by the recommended minimum interval.
- **Additional information about immunocompromised doses:** for persons who are moderately or severely immunocompromised: Any person 6 months of years of age or older who is moderately or severely immunocompromised (see CDC guidance for examples of persons who qualify; note this is NOT an all-inclusive list), and who has already received two doses of either the Pfizer-BioNTech or Moderna COVID-19 vaccines. This additional 3rd dose for people who are moderately or severely immunocompromised is only for VRs who received the Pfizer-BioNTech or Moderna vaccines for their primary series. The third dose should ideally be with the same mRNA vaccine product used for the first two doses, but if the same product is not available or not known, then the alternate mRNA vaccine product can be used (i.e., the Moderna COVID-19 vaccine can be used in place of the Pfizer-BioNTech COVID-19 vaccine, and vice versa).
  - Special situation: For people who inadvertently received the booster dose before their third primary dose, regardless of type of vaccine received as the booster dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL, red cap vial]) as the fourth dose (third primary) at least 3 months after the third dose.
- Heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. However, recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated. Verify the correct Moderna vaccine booster dose is being given (see administration instructions below).

3. **Screen for any contraindications or precautions to vaccination (refer to the "Vaccination Screening Checklist" for vaccinators).**

   Contraindications: Do NOT give the Moderna COVID-19 vaccine to any person who has a history of either: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Moderna COVID-19 vaccine or a component of the vaccine, or **2)** A known (diagnosed) allergy to a component of the Vaccine.

   - See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.
   - An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hoursfollowing administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.

- A person with a contraindication to one mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) should not receive doses of either of the mRNA vaccines.

Precautions: Take additional precautions if a person has a history of either: 1) An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or 2) A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either has a known/diagnosed allergy to polysorbate, then the CDC recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccines. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Moderna vaccine may be given; document in the Vaccine Management System (VMS).
    - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist.
- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with the vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "Vaccination Screening Checklist" for vaccinators).**
    - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID- 19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Moderna or Pfizer-BioNTech vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may

receive either the Pfizer-BioNTech or Moderna vaccines after their episode of myocarditis/pericarditis has completely resolved.

- **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, the vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.
- **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as <u>treatment</u> for COVID-19 in the prior 90 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination can be given. The VR should be educated that some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown.
- **Moderate or Severe Immunosuppression**: Vaccine may be given and should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
- **Pregnancy/Breastfeeding**: Vaccine may be given, but ensure the VR received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Inform VR that the COVID-19 vaccines have not been extensively studied in pregnant women, so information on vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccines to VR and unborn baby is low, and pregnant women will likely benefit from vaccination. If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.
- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller), followed by firm pressure on the site (without rubbing) for at least 2 minutes.

5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person, parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to, the FDA's Fact Sheet for Recipients and Caregivers (for Moderna COVID- 19 vaccine). Fact Sheet translations into other languages can be found on the FDA's Moderna COVID-19 Vaccine Website.
6. **Obtain consent for vaccination from a legal guardian for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves**: Follow instructions outlined in the "*Policy for Vaccinating Minors*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).
7. **Prepare to administer vaccine:** Choose the needle gauge, needle length, and injection site as outlined below. Ensure the multi-dose vials of the Moderna vaccine have been appropriately prepared for administration, as outlined in the FDA's Fact Sheet for Healthcare Providers Administering Vaccine (for Moderna COVID-19 vaccine). Follow manufacturer's instructions for storing and handling vaccine.

Children and Adolescents (6mo - 2 years of age): Use a ⅝" or 1" needle (22-25 gauge) and administer in the vastus lateralis muscle.

Children and Adolescents (5-18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh muscle can also be used with needle gauge and length according to the table below.

Age	Needle Gauge	Needle Length	Preferred Injection Site
Children, 1-2	22-25	⅝ -1 ½ ''	Vastus lateralis muscle
Children, 3-10	22-25	⅝*-1"	Deltoid muscle of arm (preferred)
	22-25	1-1 ¼"	Anterolateral thigh (alternate)
Children 11-18	22-25	⅝* - 1"	Deltoid muscle of arm (preferred)
	22-25	1- 1 ½"	Anterolateral thigh (alternate)

Adolescents (18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh can also be used (use a 1 – 1.5 inch needle length when injecting the anterolateral thigh).

Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh can also be used for injection (use a 1.5 inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22-25	⅝*-1"	Deltoid muscle of arm (preferred)
Female or male 130-152 lbs	22-25	1"	Deltoid muscle of arm (preferred)
Female 153-200 lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Male 153-200+ lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Female 200+ lbs	22-25	1 ½"	Deltoid muscle of arm (preferred)
Male 260+	22-25	1 ½"	Deltoid muscle of arm (preferred)

** A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Moderna COVID-19 vaccine as follows:**
    - Dose #1:
        i. 6 months - 5 years of age: Give a 0.25 microgram dose (i.e., 0.25mL of vaccine) by intramuscular (IM) injection.
        ii. 6 years- 11 years of age: Give a 0.50 microgram dose (i.e., 0.5mL of vaccine) by intramuscular (IM) injection.
        iii. 12 years of age and older: Give a 100 microgram dose (i.e., 0.5 mL of vaccine) by intramuscular (IM) injection.
    - Dose #2:
        i. 6 months - 5 years of age: Give a 0.25 microgram dose (i.e. 0.25mL of vaccine) at least 28 days after dose #1 of the Moderna vaccine by intramuscular (IM) injection.
        ii. 6 years- 11 years of age: Give a 0.50 microgram dose (i.e., 0.5mL of vaccine) at least 28 days after dose #1 of the Moderna vaccine by intramuscular (IM) injection.
        iii. 12 years of age and older: Give a 100 microgram dose (i.e., 0.5 mL of vaccine) at least 28 days after dose #1 of the Moderna vaccine by intramuscular (IM) injection.
    - Dose #3 (additional primary series dose for moderately or severely immunocompromised): After the vaccine recipient self-attests that they are moderately or severely immunocompromised.
        i. 6 months - 5 years: Give a 0.25 microgram dose (i.e., 0.25mL of vaccine) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.
        ii. 6 years- 11 years of age: Give a 0.50 microgram dose (i.e., 0.5mL of vaccine) at least 28 days after dose #1 of the Moderna vaccine by intramuscular (IM) injection.
        iii. 12 years or older: give a 100 microgram dose (i.e., 0.5 mL of vaccine) at least 28 days after dose #2 of an mRNA vaccine by intramuscular (IM) injection.
    - Booster dose (note the different dose): If a person is 6 years of age or older and meets criteria outlined above for booster dose administration.
        i. 6-11 years old: Administered 0.25mL of the bivalent Moderna vaccine.
        ii. 12 years and older:
            1. Give a 50 microgram dose (i.e., 0.5 mL of vaccine) of the Moderna bivalent vaccine by intramuscular (IM) injection at the following time interval after the person completed their primary series:
            OR
            2. Give 0.3mL of the bivalent Pfizer-BioNTech vaccine.
        iii. If the VR completed their two-dose primary series with either the Pfizer-BioNTech or Moderna COVID-19 vaccine, give the Moderna booster dose at least 2 months after the person completed their two-dose primary mRNA COVID-19 vaccine series.
        iv. If the VR completed their three-dose primary series of an mRNA COVID-19 vaccine (because they are moderately or severely immunocompromised), give the Moderna booster dose at least 2 months after the person completed their three-dose primary mRNA COVID-19 vaccine series.
        v. If the VR completed their primary series with the Janssen COVID-19 vaccine, then give the bivalent Moderna booster dose at least 2 months after the VR completed their single-dose Janssen COVID-19 vaccine or a two-dose series (because they are moderately to severely immunocompromised.
9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.
10. **Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"** (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").

11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.
12. Report adverse events to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order for Administering the J&J Janssen COVID-19 Adenovirus Vector Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC).

POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. **Follow the "Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics".** Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.
2. **Identify the following individuals for vaccination (i.e. the vaccine recipient, or VR):**

    - Primary vaccination series: Any person 18 years of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), can receive a single dose of the Janssen COVID-19 vaccine. A person who has received one prior dose of an mRNA vaccine but has an allergic reaction which prevents that person from receiving their second dose of the mRNA vaccine (i.e., person has a contraindication to receiving an mRNA COVID-19 vaccine) may be given the single-dose Janssen vaccine after at least 28 days have passed from receipt of the mRNA vaccine dose #1 to complete a primary COVID-19 vaccine series (with appropriate assessment, counseling, and precautions as outlined below).
    - Second dose / immunocompromised dose: Any person 18 years of age or older who received a previous dose of the Janssen COVID-19 vaccine and is moderately to severely immunocompromised may elect to receive a second dose of a COVID-19 vaccine at least 28 days after the first dose. mRNA COVID-19 vaccines are preferred for this dose but the Janssen COVID-19 may be given if there is a contraindication to the mRNA COVID-19 vaccines or if the VR elects to choose the Janssen COVID-19 vaccine.
        - Special situation: Many recipients of Janssen COVID-19 Vaccine may have received a booster dose (Pfizer-BioNTech, Moderna [50 µg], or Janssen vaccine), without having had the second (additional) mRNA vaccine dose. In this situation, regardless of type and timing of vaccine received as the second dose, administer a Pfizer-BioNTech vaccine or a Moderna vaccine (100 µg [0.5 mL, red cap vial]) as the third (additional) dose at least 2 months after dose 2. See Appendix D for additional dose information for Janssen COVID-19 Vaccine recipients.
    - Booster dose: Any person 18 years of age or older who is either:
        - At least 2 months (8 weeks) beyond completion of the single-dose Janssen COVID-19 vaccine or two-dose Janssen COVID-19 vaccine for moderate to severe immunocompromised individuals. Please note the mRNA vaccinations are preferred over Janssen vaccinations.
        - Any individual who received Janssen primary dose and booster dose should receive a mRNA bivalent booster vaccine (either Pfizer-BioNTech or Moderna) 2 months after their last dose (if no contraindications).

    Heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can

be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. However, recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated.

- For both primary series and booster dose vaccination, the Pfizer-BioNTech or Moderna COVID-19 vaccines should be offered to a person first before vaccination with the Janssen vaccine; the Pfizer-BioNTech or Moderna COVID-19 vaccines are recommended over the Janssen vaccine because of the rare risk of Thrombosis with Thrombocytopenia Syndrome (TTS) that can occur after Janssen vaccination. However, the Janssen vaccine can be administered to people who meet the above criteria and who have a contraindication to the mRNA COVID-19 vaccines or who request the Janssen vaccine after being informed of the risks and the recommendations (see "Vaccination Screening Checklist").

3. **Screen for any contraindications or precautions to vaccination (refer to the "Vaccination Screening Checklist" for vaccinators).**

Contraindications: Do NOT give the Janssen COVID-19 vaccine to any person who has a history of any of the following: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Janssen COVID-19 vaccine or a component of the vaccine, **2)** A known (diagnosed) allergy to a component of the vaccine, or **3)** Thrombosis with Thrombocytopenia Syndrome (TTS) development after receiving a prior dose of the Janssen or AstraZeneca COVID-19 vaccines.

- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hours following administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.

Precautions: Take additional precautions if a person has a history of either: **1)** An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or **2)** A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either 1) had a severe allergic reaction after a previous dose of the Pfizer or Moderna COVID-19 vaccine, or 2) has a known/diagnosed allergy to polyethylene glycol (PEG), then the VR has a contraindication to the mRNA COVID-19 vaccines and the CDC recommends referral to an allergist-immunologist be considered before administration of the Janssen vaccine. This is because of potential allergic cross-reactivity between polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines) and polysorbate (an ingredient in the Janssen vaccine).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Janssen vaccine may be given; document in the Vaccine Management System (VMS). If Janssen vaccine is given, it should be at least 28 days after a previous mRNA vaccine dose (if applicable).
    - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based

on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist.

- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with the vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination, and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "Vaccination Screening Checklist" for vaccinators).**
    - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID- 19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Moderna or Pfizer-BioNTech vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Janssen vaccine at a State-managed vaccination clinic. The Janssen vaccine has <u>not</u> been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Janssen vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Janssen vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Janssen vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive the Janssen vaccine after their episode of myocarditis/pericarditis has resolved.
    - **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.
    - **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as <u>treatment</u> for COVID-19 in the prior 90 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination can be given. The VR should be educated that some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown.
    - **Moderate or Severe Immunosuppression**: Vaccine may be given and should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
    - **Pregnancy/Breastfeeding**: Vaccine may be given, but ensure the VR received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Inform VR that the COVID-19 vaccines have not been extensively studied in pregnant women, so information on vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccines to VR and unborn baby is low, and pregnant women will likely benefit from vaccination. If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.

- **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller), followed by firm pressure on the site (without rubbing) for at least 2 minutes.
- **History of an immune-mediated clinical syndrome characterized by thrombosis (blood clotting) AND thrombocytopenia (low platelet counts), such as "heparin-induced thrombocytopenia" (HIT):** Persons with a history of an immune- mediated syndrome characterized by thrombosis and thrombocytopenia should not be given the Janssen COVID-19 vaccine; such persons should be offered either the Pfizer-BioNTech or Moderna COVID-19 vaccines.
- **Development of Guillain-Barré syndrome (GBS) after the first dose of the Janssen vaccine:** Development of GBS after receipt of Janssen COVID-19 Vaccine is a precaution for receiving subsequent dose(s) of the Janssen COVID-19 Vaccine. People who develop GBS within 6 weeks after receipt of Janssen COVID-19 Vaccine should not receive another dose of Janssen COVID-19 vaccine. An mRNA COVID-19 vaccine should be used for any subsequent doses. Providers should also strongly consider using an mRNA COVID-19 vaccine for subsequent doses in people who had GBS onset beyond 6 weeks after receipt of Janssen COVID-19 vaccine. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or legal representative) with a copy of the most current required information (or verify the person, parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to, the FDA's Fact Sheet for Recipients and Caregivers (for Janssen COVID-19 vaccine). Fact Sheet translations into other languages can be found on the FDA's Janssen COVID-19 Vaccine Website.
6. **Obtain consent for vaccination from a legal guardian for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves**: Follow instructions outlined in the "*Policy for Vaccinating Minors*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).
7. **Prepare to administer vaccine**: Choose the needle gauge, needle length, and injection site as outlined below. Ensure the multi-dose vials of the Janssen vaccine have been appropriately prepared for administration, as outlined in the FDA's Fact Sheet for Healthcare Providers Administering Vaccine (for Janssen COVID-19 vaccine). Follow manufacturer's instructions for storing and handling vaccine.

   Adolescents (18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh can also be used (use a 1 – 1.5 inch needle length when injecting the anterolateral thigh).

   Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh can also be used for injection (use a 1.5 inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22-25	⅝*-1''	Deltoid muscle of arm (preferred)
Female or male 130-152 lbs	22-25	1''	Deltoid muscle of arm (preferred)
Female 153-200 lbs	22-25	1- 1 ½''	Deltoid muscle of arm (preferred)
Male 153-200+ lbs	22-25	1- 1 ½''	Deltoid muscle of arm (preferred)
Female 200+ lbs	22-25	1 ½''	Deltoid muscle of arm (preferred)
Male 260+	22-25	1 ½''	Deltoid muscle of arm (preferred)

** A 5/8'' needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Janssen COVID-19 vaccine as follows**:
    a. Dose #1: Give a single 0.5 mL dose of vaccine by intramuscular (IM) injection.
    b. Dose #2: (additional primary series dose for moderately or severely immunocompromised): After the vaccine recipient self-attests that they are moderately or severely immunocompromised,
        i. Administer a second dose of an mRNA COVID-19 vaccine (either Pfizer BioNTech or Moderna) at least 28 days after dose #1.
            1. Pfizer-BioNTech: 0.3mL
            2. Moderna: 0.5mL
    c. Booster Dose: If a person is 18 years of age or older and meets criteria outlined above for booster dose administration, then give:
        i. If immunocompetent and completed the Janssen COVID-19 primary series:
            1. A 0.5 mL dose of Janssen COVID-19 vaccine by intramuscular (IM) injection at least 2 months after their last dose.
            2. OR
            3. The VR may receive, and is encouraged to receive, a mRNA COVID-19 vaccine booster dose. If VR does not have contraindications and would like a Pfizer-BioNTech booster vaccine, administer 03mL of bivalent Pfizer-BioNTech COVID-19 vaccine. If VR does not have contraindications and would like bivalent Moderna COVID-19 booster vaccine, administer 0.25mL of bivalent Moderna COVID-19 vaccine.
        ii. If immunocompromised and completed a two-dose COVID-19 primary series and is moderately to severely immunocompromised, follow the below scenarios:
            1. Both doses are Janssen COVID-19 Vaccine, administering a third dose at least 2 months after the second dose (additional bivalent mRNA dose).
                a. Bivalent Pfizer: 0.3mL or
                b. Bivalent Moderna: 0.5 mL
            2. 1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as booster dose, i.e., Pfizer 0.3mL or Moderna 0.25mL), administer a third dose (additional mRNA dose - bivalent mRNA) at least 2 months after their second dose
                a. Bivalent Pfizer: 0.3mL or
                b. Bivalent Moderna: 0.5 mL

3. 1 dose of Janssen COVID-19 Vaccine and 1 dose of an mRNA COVID-19 Vaccine (given as additional dose, i.e., Pfizer 0.3mL or Moderna 0.5mL), administer a third dose (mRNA preferred) at least 2 months after their second dose
    a. Bivalent Pfizer: 0.3mL or
    b. Bivalent Moderna: 0.25 mL or
    c. Janssen: 0.5mL (mRNA preferred over Janssen)

9. **Document vaccination**: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.
10. **Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*"** (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").
11. **Be prepared to manage medical emergencies**: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.
12. Report adverse events to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.

Standing Order for Administering the Novavax COVID-19 Protein Subunit Vaccine

PURPOSE: To reduce the burden of disease and associated morbidity and mortality from Coronavirus Disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC).

POLICY: This standing order enables eligible healthcare professionals to assess and vaccinate persons who meet the criteria outlined below and are seeking COVID-19 vaccination through the New Hampshire Department of Health & Human Services' State-managed COVID-19 vaccine clinics without the need for clinician examination or direct order from the attending provider at the time of the interaction.

PROCEDURE:

1. Follow the "Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics". Be familiar with CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines.
2. **Identify the following individuals for vaccination (i.e., the vaccine recipient, or VR):**

- **Primary vaccination series:** Any person 12 years of age or older who has not already received two prior doses of an mRNA COVID-19 vaccine (i.e., Pfizer-BioNTech or Moderna), or a single dose of the J&J Janssen COVID-19 vaccine.
    - 12-17 years:
        - Primary Series: 2-dose primary series and one age-appropriate bivalent mRNA booster dose is recommended, The primary series doses are separated by 3-8 weeks and the bivalent booster dose is administered at least 2 months after completion of the primary series.
        - Immunocompromised: 2-dose primary series and one age-appropriate bivalent mRNA booster dose is recommended, The primary series doses are separated by 3 weeks and the bivalent booster dose is administered at least 2 months after completion of the primary series.
        - Booster: The bivalent mRNA booster dose is administered at least 2 months after completion of the primary series. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Novavax primary series.
    - 18 years or older:
        - Primary Series: 2-dose primary series and one age-appropriate bivalent mRNA booster dose is recommended, The primary series doses are separated by 3-8 weeks and the bivalent booster dose is administered at least 2 months after completion of the primary series.
        - Immunocompromised: 2-dose primary series and one age-appropriate bivalent mRNA booster dose is recommended, The primary series doses are separated by 3 weeks and the bivalent booster dose is administered at least 2 months after completion of the primary series.
        - Booster: The bivalent mRNA booster dose is administered at least 2 months after completion of the primary series. Currently, the bivalent Pfizer-BioNTech booster dose is authorized for adolescents in this age group who receive a Novavax primary series.

- Heterologous (i.e., mix-and-match) booster dosing is allowed, so any of the COVID-19 vaccines can be used for booster doses regardless of the vaccine product used for a VR's primary vaccination. However, recommendations about the timing of booster dose administration is based on which vaccine the VR received for their primary vaccine series. If a booster dose is given earlier than the recommended time period, the booster dose does NOT need to be repeated. Verify the correct vaccine booster dose is being given (see administration instructions below).

3. **Screen for any contraindications or precautions to vaccination (refer to the "Vaccination Screening Checklist" for vaccinators).**

Contraindications: Do NOT give the Novavax COVID-19 vaccine to any person who has a history of either: **1)** A severe allergic reaction (e.g., anaphylaxis) after a previous dose of the Novavax COVID-19 vaccine or a component of the vaccine, or **2)** A known (diagnosed) allergy to a component of the Vaccine.

- See CDC's "Interim Clinical Considerations for Use of COVID-19 Vaccines", Appendix C for a list of COVID-19 vaccine ingredients.
- An "immediate allergic reaction" is defined as any hypersensitivity related signs or symptoms consistent with urticaria (hives), angioedema, respiratory distress, or anaphylaxis that occurs within 4 hoursfollowing administration. Allergic reactions after vaccination should be differentiated from non-allergic reactions, such as vasovagal episodes and normal vaccine side effects. CDC has created a table (Appendix D) to assist providers in differentiating.

Precautions: Take additional precautions if a person has a history of either: 1) An immediate allergic reaction to other non-COVID-19 vaccines or injectable medication therapies (including intramuscular, intravenous, or subcutaneous injections), or 2) A non-severe, immediate allergic reaction after a previous dose of a COVID-19 vaccine.

- Vaccine may be given, but persons with a vaccine "precaution" are recommended to discuss their allergy histories with their primary care provider so their provider can help perform a risk assessment and discuss the potential risks/benefits of the COVID-19 vaccines with the VR. If the VR chooses not to discuss their allergy history with their primary care provider before vaccination, the VR can still be administered the vaccine. Inform the VR about the potential increased risk of an allergic reaction to the COVID-19 vaccine. VR must be monitored for at least 30 minutes after vaccination.
- If VR either has a known/diagnosed allergy to polysorbate, then the CDC recommends referral to an allergist-immunologist be considered before administration of the Pfizer-BioNTech or Moderna vaccines. This is because of potential allergic cross-reactivity between polysorbate (an ingredient in the Janssen vaccine) and polyethylene glycol (an ingredient in both the Pfizer and Moderna vaccines).
    - If VR has consulted with their primary care provider and/or an allergist-immunologist, and vaccination was determined to be appropriate based on provider's risk assessment, and if patient is aware of risks and desires to be vaccinated, then the Novavax vaccine may be given; document in the Vaccine Management System (VMS).
    - If VR has not consulted with their primary care provider or an allergist-immunologist, consult with vaccine clinic medical lead to determine if vaccination is appropriate based on VR's allergy history. Consider declining vaccination until the patient is evaluated by their primary care provider or an allergist-immunologist.
- If there is any question about whether a VR has a COVID-19 vaccine contraindication vs. precaution, consult with the vaccine clinic medical lead to help determine if vaccination is appropriate. If there are concerns about whether a VR is appropriate to be vaccinated with available COVID-19 vaccines, then the VR should be declined vaccination and instructed to seek assessment and vaccination in a more appropriate medically monitored setting.

4. **Screen for other health conditions listed below (refer to the "Vaccination Screening Checklist" for vaccinators).**
    - **Development of myocarditis or pericarditis after receiving an earlier dose of an mRNA COVID- 19 vaccine (Pfizer-BioNTech or Moderna)**: If the VR developed myocarditis or pericarditis after receipt of an earlier dose of the Moderna or Pfizer-BioNTech vaccine, then the VR should not receive an additional dose of an mRNA vaccine or the Novavax vaccine at a State-managed vaccination clinic. The Novavax vaccine has not been associated with development of myocarditis/pericarditis. Therefore, VR could be considered for the Novavax vaccine to either complete their primary vaccine series or receive a booster, if VR is eligible. However, before administration of the Novavax vaccine after an episode of myocarditis/pericarditis associated with receipt of an mRNA COVID-19 vaccine, the VR should be fully recovered with no evidence of ongoing heart inflammation, as determined by a VR's clinical team. Therefore, in a VR who developed myocarditis/pericarditis after receipt of an mRNA vaccine, such persons should be referred to their healthcare provider for further assessment and administration of additional COVID-19 vaccine doses (including Novavax vaccine) to ensure appropriate counseling and risk assessment, monitoring, and to ensure that signs/symptoms of myocarditis/pericarditis have completely resolved before another dose is given. People with a history of myocarditis or pericarditis that is NOT related to receipt of a prior dose of an mRNA COVID-19 vaccine may receive either the Pfizer-BioNTech or Moderna vaccines after their episode of myocarditis/pericarditis has completely resolved.
    - **Severe allergic reaction (e.g., anaphylaxis) due to any cause that does not qualify as a vaccine contraindication or precaution (including to other oral medications, food, environmental exposures, etc.)**: Vaccine may be given. It is recommended that the VR discuss their allergy history with their primary care provider before vaccination, but even if the VR did not discuss with their primary care provider, vaccine can be given. VR must be monitored for at least 30 minutes after vaccination.
    - **Receipt of passive antibody therapy (e.g., convalescent plasma or monoclonal antibody therapy) as <u>treatment</u> for COVID-19 in the prior 90 days**: As a precautionary measure to avoid interference of the antibody treatment with the vaccine-induced immune response, COVID-19 vaccination can be given. The VR should be educated that some reduction in vaccine-induced antibody titers was observed in people who previously received antibody products, the clinical significance of this reduction is unknown.
    - **Moderate or Severe Immunosuppression**: Vaccine may be given and should be safe for VR to receive, but the vaccine may be less effective due to their immune system. Counsel the person to continue to take steps to protect themselves from COVID-19 after vaccination. If questions or concerns, recommend the VR discuss with their health care provider.
    - **Pregnancy/Breastfeeding**: Vaccine may be given, but ensure the VR received and reviewed the *"Information about the COVID-19 Vaccine for Persons with Certain Health Conditions."* Inform VR that the COVID-19 vaccines have not been extensively studied in pregnant women, so information on vaccine safety and effectiveness during pregnancy is limited, but we believe that the risk of the vaccines to VR and unborn baby is low, and pregnant women will likely benefit from vaccination. If the person has questions or concerns, recommend they discuss with their pregnancy provider before vaccination.
    - **Bleeding disorder or taking blood thinner**: Vaccine may be given, but use a fine-gauge needle (23 gauge or smaller), followed by firm pressure on the site (without rubbing) for at least 2 minutes.
5. **Provide required documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (or ensure vaccine recipient has already received the documents)**: Provide all vaccine recipients (or, in the case of minors or people who lack decision making capacity, their parent or

legal representative) with a copy of the most current required information (or verify the person, parent/guardian, or legal representative received and had the opportunity to review the information), including, but not limited to, the FDA's Fact Sheet for Recipients and Caregivers (for Novavax COVID- 19 vaccine). Fact Sheet translations into other languages can be found on the FDA's Novavax COVID-19 Vaccine Website.

6. **Obtain consent for vaccination from a legal guardian for vaccine recipients 18 years of age or older who lack decision making capacity and cannot legally consent to vaccination themselves**: Follow instructions outlined in the "*Policy for Vaccinating Minors*". Any new vaccine dose administration requires a new consent form (if the parent/guardian is not in attendance).
7. **Prepare to administer vaccine:** Choose the needle gauge, needle length, and injection site as outlined below. Ensure the multi-dose vials of the Moderna vaccine have been appropriately prepared for administration, as outlined in the FDA's Fact Sheet for Healthcare Providers Administering Vaccine (for Moderna COVID-19 vaccine). Follow manufacturer's instructions for storing and handling vaccine.

   Children and Adolescents (12-18 years of age): Use a 1-inch needle (22-25 gauge) and administer in the deltoid muscle of the arm. Alternatively, the anterolateral thigh muscle can also be used (use a 1 – 1.5inch needle length when injecting the anterolateral thigh).

   Adults (19 years of age and older): Use needle size, gauge, and injection location as outlined in the table below based on a person's sex and weight. The deltoid muscle of the arm/shoulder is the preferred injection site, but if necessary due to a medical condition, the anterolateral thigh can also be used for injection (use a 1.5 inch needle length for males and females of any weight when injecting the anterolateral thigh).

Sex and Weight	Needle Gauge	Needle Length	Preferred Injection Site
Female or male <130 lbs	22-25	⅝*-1"	Deltoid muscle of arm (preferred)
Female or male 130-152 lbs	22-25	1"	Deltoid muscle of arm (preferred)
Female 153-200 lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Male 153-200+ lbs	22-25	1- 1 ½"	Deltoid muscle of arm (preferred)
Female 200+ lbs	22-25	1 ½"	Deltoid muscle of arm (preferred)
Male 260+	22-25	1 ½"	Deltoid muscle of arm (preferred)

** A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.*

8. **Administer the Novavax COVID-19 vaccine as follows:**
   - Dose #1:
     i. 12 years of age and older: Give 0.5 mL of Novavax vaccine by intramuscular (IM) injection.
   - Dose #2:
     i. 12 years of age and older: Give 0.5 mL of Novavax vaccine by intramuscular (IM) injection.

- Booster dose:: If a person is 12 years of age or older and meets criteria outlined above for booster dose administration.
    i. **12-17 years:** Administer 0.3mL of the bivalent Pfizer-BioNTech vaccine. Please note that Moderna products are not authorized for booster doses in this age group.
    ii. 18 years and older:
        1. Give a 50 microgram dose (i.e., 0.25 mL of vaccine) of the Moderna bivalent vaccine by intramuscular (IM) injection at the following time interval after the person completed their primary series:
        OR
        2. Give 0.3mL of the bivalent Pfizer-BioNTech vaccine.

9. Document vaccination: Document each person's vaccine administration immediately in the Vaccine Management System (VMS) and enter required information.

10. Give vaccine recipient the required post-vaccination documents listed in the "*Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics*" (including the "*COVID-19 Vaccine Record Card*" and "*After Visit Summary (AVS) Recommendations for Vaccine Recipients*").

11. Be prepared to manage medical emergencies: Be prepared to manage medical emergencies related to the administration of vaccine by following the emergency medical protocols ("*Medical Management of Vaccine Reactions*"). To prevent syncope, vaccinate patients while they are seated. Observe vaccine recipient for at least 15 minutes after vaccination; persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause, a history of a non-severe immediate (onset less than 4 hours) allergic reaction after a previous dose of a COVID-19 vaccine, or a history of any immediate allergic reaction of any severity to other non-COVID-19 vaccines or injectable medication therapies that do not qualify as a vaccine contraindication should be observed for 30 minutes after vaccination.

12. Report adverse events to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at: https://vaers.hhs.gov/reportevent.html.

On-Site Medical Services Policy for Vaccinating Minors

For All Vaccine Recipients Under the Age of 18

It is the policy of On-Site Medical Services that each vaccine recipient under the age of 18 years must have a signed consent form associated with each vaccination dose. The parent or guardian of each child must sign a physical copy of the consent form as well as give a verbal consent prior to any vaccine being administered. The consent form can be found below. If the legal parent or guardian is not present at the time of vaccine administration, please see the section below on *Clinics When a Parent or Guardian is NOT in Attendance. *Consent forms are valid for **5 days** from the date of parent/guardian signature. **Please note, if consent forms have parent/guardian signatures dated more than 5 days from date of vaccination, verification in NHIIS is required prior to administration to ensure the correct dose listed on vaccine consent form is the correct dose being administered. If unable to verify in NHIIS, verbal consent can be obtained by parent/guardian within 5 days prior to the scheduled vaccination clinic date. Verification must be documented in writing on the consent forms, including date of verification and means of verification (i.e. through NHIIS or verbal consent).***

Guidance for Conducting School-Based Clinics When a Parent or Guardian is NOT in Attendance

For vaccine recipients under the age of 18 years and *without a legal parent or guardian present* there will need to be extra documentation. For each vaccine given to a minor without a parent or guardian present, a consent form must be signed by the legal parent or guardian prior to any vaccine administration.

1. On-Site Medical Services Pediatric Consent **or** RPHN COVID-19 Vaccination Record and Consent

** Consent must be completed correctly. If the consent form is not completed in its entirety (i.e. missing an answer to a question, signed/dated by a parent/guardian, etc.), vaccination will need to be declined.*

For international students or recipients whose parent or guardian is not local, they will need a copy of proof of guardianship that has been individually signed by the parent authorizing medical rights to a named individual. If possible, having a signed consent form from the parent along with the proof of guardianship would be preferred.

The medical screening questionnaire (on pediatric consent form) should be used to screen children for any serious adverse reactions or side effects that might have occurred after a prior dose. The vaccinator should also verify and inquire of the VR whether they had any serious adverse side effects after a prior dose of the vaccine. **If a parent/guardian reports on the consent form that their child did experience serious/severe side effects or allergic reactions after an earlier vaccine dose, then the vaccinator should seek additional information from the parent/guardian to clarify (if needed), or decline vaccination if it is not medically appropriate.**

For VRs who are 5 years of age or older who are seeking a 3rd additional dose because they are moderate-severely immunocompromised, in addition to the consent form, the form "Third Dose Vaccine Administration for People who are Immunocompromised" also needs to be filled out, signed, and returned with the consent form prior to dose #3 administration.

Guidance for Minors in New Hampshire Division for Children, Youth, and Families Custody

For vaccine recipients under the age of 18 years and in the custody of Children, Youth and Families of NH (DCYF), there is additional information and documentation needed.

1. Letter from medical provider recommending the COVID-19 vaccine for the VR
2. Medical Authorization Form for the VR
3. On-Site Medical Services consent form **or** RPHN COVID-19 Vaccination Record and Consent signed by the DCYF case coordinator for that minor

   Consents must be completed correctly. If **any of the consent forms are not completed in their entirety (i.e. missing an answer to a question, signed/dated by a parent/guardian, etc.), vaccination will need to be declined.*

The medical screening questionnaire (on pediatric consent form) should be used to screen children for any serious adverse reactions or side effects that might have occurred after a prior dose. The vaccinator should also verify and inquire of the VR whether they had any serious adverse side effects after a prior dose of the vaccine. **If a parent/guardian/foster parent reports on the consent form that the VR did experience serious/severe side effects or allergic reactions after an earlier vaccine dose, then the vaccinator should seek additional information from the parent/guardian/foster to clarify (if needed). If further information is not available, the vaccinator is to seek advice from the clinic supervision, or decline vaccination if it is not medically appropriate.**

If all of the above requirements are present, then the VR may be vaccinated with the appropriate COVID-19 vaccine and documented accordingly.

Blood Borne Pathogen Exposure

Blood-borne pathogens (BBPs) include Human Immunodeficiency Virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV). A healthcare worker can be exposed to these viral pathogens when exposed to an infected person's blood or other potentially infectious body fluids* through a percutaneous exposure (i.e., needle stick), or when blood or body fluids are exposed to a break in the skin or mucous membranes (i.e., eyes, nose, and mouth). In the setting of a COVID-19 vaccination clinic, the primary route of exposure to BPPs is from a contaminated needle stick; the risk of mucous membrane exposure should be minimal given brief patient contact, limited care targeting vaccine delivery, and the provider and clinic staff wearing eye protection (full face shield preferred over goggles). Clinic staff should follow the Interim Guidance for NH State-Managed COVID-19 Vaccination Clinics and follow the Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Vaccine Administration to minimize the risk for a needle stick and BBP exposure.

In the event of a potential exposure to a source patient's (i.e., the person who is the source of exposure) blood or other potentially infectious body fluid, the healthcare provider or clinic staff should take the following steps:

1. Immediately and thoroughly wash with soap and water any needle stick, other sharp wounds, or broken skin that has been exposed to another person's blood or body fluids.
2. Copiously flush and irrigate any exposed mucous membranes with clean water or sterile saline.
3. Once the wound is cleaned or mucous membranes are flushed, immediately report any exposure to the onsite clinical lead/supervisor.
4. Evaluation and testing should be offered to both source patient and staff member via a local urgent care utilizing personal health insurance.
5. Clinical lead/supervisor shall discuss the situation with the source patient and ask if the source patient can get blood borne pathogen testing to help inform care/management of the staff member who was stuck with a needle.
    a. The source patient should be advised to seek blood borne pathogen testing at a local urgent care using their personal insurance if they choose to.
6. Clinical lead/supervisor shall discuss the situation with the staff member with injury and advise them to seek blood borne pathogen testing at a local urgent care using their personal insurance if they choose to.
    a. Staff member should also seek follow up testing via urgent care or PCP utilizing personal insurance outlined by their provider.
7. Fill out the "Incident Report Form" below. This is critical to complete to ensure appropriate coordination between public health, On-Site Medical Services, the staff member, and the source patient. Be sure to document:
    a. Staff name, date of birth, and contact information (including phone number and email address)
    b. Date, time, and clinic location of incident and exposure
    c. Description of the exposure, including:
        i. Nature of the exposure (i.e., percutaneous needle stick, non-intact skin, mucosal, human bite, etc.)
        ii. Type of body fluid involved
        iii. Body location of exposure and contact time with the body fluid

iv. For percutaneous needle stick injuries, include a description of the injury including, type of needle used (solid vs. hollow bore needle), depth of wound, use in source patient
v. Actions taken after the exposure

d. Source patient's name, date of birth, and contact information (including phone number, mailing address, and email)
e. Source patient's pertinent medical history (including known HIV, HBV, or HCV infection status)

8. Supervisor should notify On-Site Medical Services by phone, and submit the Incident Report Form by secure email. All staff and source patient information must be kept confidential.
9. Staff should follow-up with their agency occupational medicine group or primary care provider.

**Body fluids considered potentially infectious include: blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, or any body fluid contaminated with visible blood. HBV and HCV can be detected in saliva, so these viruses could potentially be transmitted through bite wounds, although uncommon. Fluids generally NOT considered infectious (unless they contain blood) include feces, nasal secretions, sputum, sweat, urine, and vomit.*

NH COVID-19 Vaccination Clinic: Blood Borne Pathogen Exposure Report

Date of Incident: _____ **Time of Incident**:_____

Clinic Name/Location: _____

STAFF INFORMATION:

Name:_____ Date of Birth: _____

Phone Number: _____

E-mail Address: _____

Employer/Staff Type (circle all that apply):

National Guard PHN Hospital Fire/EMS Volunteer Other:_____

Clinic Supervisor Name and Contact Information: _____

Phone Number: _____ Email: _____

DESCRIPTION OF EXPOSURE/INCIDENT:

Type of Exposure (circle all that apply):

Needle Stick Non-intact skin Mucous membrane Bite Other: _____

Type of Body Fluid: **Blood Other:_____**

Body location of exposure:_____

Estimated Contact Time: _____

Describe the injury (for a needle stick: describe the type of needle, depth of wound, etc.):

Actions Taken:_____

Location of Medical Evaluation: _____

Name & Contact information of healthcare provider following staff after needle stick:

_____

SOURCE PATIENT INFORMATION (person who is the source of the exposure):

Name: _____ Date of Birth: _____

Phone Number: _____

Mailing Address: _____

E-mail address: _____

Source Patient Has a Known History of Infection with (circle all that apply):

HIV Hepatitis C Virus Hepatitis B Virus None Unknown

Call On-Call Provider to report.
Upload this form to On-Site Medical Services Secure Dropbox

COVID-19 VACCINATION CLINIC INCIDENT REPORT FORM

Note: for blood borne pathogen incident (needle stick, etc.), use the incident form in the current COVID-19 Standing Order document

Today's Date: _____

Date of Incident: _____ Time of Incident: _____

STAFF REPORTING:

Staff Name: _____ Phone Number: _____

E-mail Address: _____

Clinic Name/Location: _____

TYPE OF INCIDENT:

_____ Vaccine administration error ____ Vaccine reaction ____ Seizure

_____ Other (brief description_____)

Reported through VAERS? If so, report number: _____

Name of Vaccine:_____ Site: _____ Lot Number: _____

Patient Name: _____DOB: _____

Patient Phone Number: _____

E-mail Address: _____

DESCRIPTION OF EXPOSURE/INCIDENT:

Actions Taken:

Outcome:

Health Care Provider Contacted: Yes ____ No_____ If so, date/time:

Name and phone number of provider: _____

Call On-Call Provider to report.
Upload this form to On-Site Medical Services Secure Dropbox

Medical Management of Vaccine Reactions in Adults

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered (see www.immunize.org/catg.d/p3072.pdf, guidance in provided clinic protocols, and vaccine standing orders). Even with careful screening, reactions may occur. These reactions can vary from minor (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). Vaccine providers should be familiar with identifying allergic reactions, including anaphylaxis, and must be competent in managing these vaccine events at the site of vaccine administration. Providers should also have a plan in place to immediately contact emergency medical services (EMS) in the event of a severe vaccine reaction. Maintenance of the airway, oxygen administration, and administration of intravenous medications might be necessary. The table below describes procedures to follow if various reactions occur.

REACTION	SIGNS and SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply Pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place a thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have the patient sit or lie down for vaccination
	Patient feels "faint" or has paleness, sweating, nausea, lightheadedness, dizziness, weakness, or visual disturbances.	Have the patient lie flat. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloth to the patient's face and neck. Keep them under close observation until full recovery.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place the patient flat on back with feet elevated.

	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place the patient flat on back with feet elevated. Call 911 if the patient does not recover immediately.
Anaphylaxis	**Skin and mucosal symptoms** such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. **Respiratory symptoms** such as change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. **Gastrointestinal symptoms** such as nausea, vomiting, diarrhea, cramping abdominal pain. **Cardiovascular symptoms** such as collapse, dizziness, tachycardia, hypotension.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.
Cardiac Arrest	**Symptoms leading up to cardiac arrest**: syncope, dizziness, rapid heart rate, palpitations, shortness of breath. **Cardiac arrest**: collapse, pulselessness.	See "Emergency Medical Protocol for Management of Cardiac Arrest in Adults" on the next page for detailed steps to follow in treating cardiac arrest.

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS) Updated 12/20/2020

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

1. If itching and swelling are confined to the injection site where the vaccination was given, observe the patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. **Drug dosing information: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**
    a. **First-line treatment**: Use **epinephrine** 1.0 mg/mL aqueous solution (1:1,000 dilution). Administer 0.01 mg/kg per dose intramuscularly (adult dose ranges from 0.2 mg to 0.5 mg; maximum single dose is 0.5 mg). Prefilled autoinjector use is preferred. Repeat every 5-15 minutes in the absence of clinical improvement. Administration should preferably occur in the mid-outer thigh; administer through clothing if necessary. Follow manufacturer instructions for autoinjector use – hold the device/needle in the thigh for at least 3 seconds. Never reinsert the needle. Do not administer repeated injections at the same site.
    b. **Optional treatment: H_1 antihistamines** – for hives or itching use **diphenhydramine**. Administer 25 mg orally every 4–6 hours or 50 mg every 6-8 hours (maximum single dose is 50 mg). H1 antihistamines do NOT relieve upper or lower airway obstruction, hypotension, or shock.
4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep the patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, the patient's head may be elevated, provided blood pressure is adequate

to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse at least every 5 minutes.

5. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 5–15 minutes for up to 3 doses, depending on the patient's response.
6. Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Report adverse event to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.
8. Notify the patient's primary care provider. If unable to contact, notify the patient that they will need to follow up with their primary care provider as soon as possible.

Emergency Medical Protocol for Management of Cardiac Arrest in Adults

1. If the patient is found to be in cardiac arrest, a medical emergency is under way.
2. Activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. Feel for carotid pulse. Keep pulse check to 10 seconds or less
4. If no pulse or if unsure if a pulse is felt, being CPR.
5. Place eel of hand on lower half of sternum
6. Place other hand on top and interlock fingers
7. Keep arms straight and press down, compressing the chest 2 inches
    a. If alone, the compressions to breaths ratio are 30:2
    b. If two healthcare providers are present, the compressions to breaths ratio are 15:2
8. Let the chest completely recoil between compressions
9. Have an assistant gather the nearest AED.
10. As compressions are being done, attach the AED.
    a. Once AED is on and active, follow directions of AED.
11. Continue with compressions until EMS arrives.

Updated: 09/20/2022

Medical Management of Vaccine Reactions in Children & Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered (see www.immunize.org/catg.d/p3072.pdf, guidance in provided clinic protocols, and vaccine standing orders). Even with careful screening, reactions may occur. These reactions can vary from minor (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). Vaccine providers should be familiar with identifying allergic reactions, including anaphylaxis, and must be competent in managing these vaccine events at the site of vaccine administration. Providers should also have a plan in place to immediately contact emergency medical services (EMS) in the event of a severe vaccine reaction. Maintenance of the airway, oxygen administration, and administration of intravenous medications might be necessary. The table below describes procedures to follow if various reactions occur.

REACTION	SIGNS and SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply Pressure and an adhesive compress over the injection site.
	Continuous bleeding	Place a thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.

Psychological fright and syncope (fainting)	Fright before injection is given Patient feels "faint" or has paleness, sweating, nausea, lightheadedness, dizziness, weakness, or visual disturbances. Fall, without loss of consciousness Loss of consciousness	Have the patient sit or lie down for vaccination Have the patient lie flat. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloth to the patient's face and neck. Keep them under close observation until full recovery. Examine the patient to determine if injury is present before attempting to move the patient. Place the patient flat on back with feet elevated. Check the patient to determine if injury is present before attempting to move the patient. Place the patient flat on back with feet elevated. Call 911 if the patient does not recover immediately.
Anaphylaxis	**Skin and mucosal symptoms** such as generalized hives, itching, or flushing; swelling of lips, face, throat, or eyes. **Respiratory symptoms** such as change in voice, sensation of throat closing, stridor, shortness of breath, wheeze, or cough. **Gastrointestinal symptoms** such as nausea, vomiting, diarrhea, cramping abdominal pain. **Cardiovascular symptoms** such as collapse, dizziness, tachycardia, hypotension.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.
Cardiac Arrest	**Symptoms leading up to cardiac arrest**: syncope, dizziness, rapid heart rate, palpitations, shortness of breath. **Cardiac arrest**: collapse, pulselessness.	See "Emergency Medical Protocol for Management of Cardiac Arrest in Adults" on the next page for detailed steps to follow in treating cardiac arrest.

Adapted from www.immunize.org and online.lexi.com by the New Hampshire Division of Public Health Services (DPHS) Updated 12/20/2020

Emergency Medical Protocol for Management of Anaphylactic Reactions in Children

1. If itching and swelling are confined to the injection site where the vaccination was given, observe the patient closely for the development of generalized symptoms.
2. If symptoms are generalized, activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. **Drug dosing information: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.**

a. **First-line treatment**: Use **epinephrine** 1.0 mg/mL aqueous solution (1:1,000 dilution). Administer 0.01 mg/kg per dose intramuscularly (adult dose ranges from 0.2 mg to 0.5 mg; maximum single dose is 0.5 mg). Prefilled autoinjector use is preferred. Repeat every 5-15 minutes in the absence of clinical improvement. Administration should preferably occur in the mid-outer thigh; administer through clothing if necessary. Follow manufacturer instructions for autoinjector use – hold the device/needle in the thigh for at least 3 seconds. Never reinsert the needle. Do not administer repeated injections at the same site. B.

b. **Optional treatment: H_1 antihistamines** – for hives or itching use **diphenhydramine**. Administer 25 mg orally every 4–6 hours or 50 mg every 6-8 hours (maximum single dose is 50 mg). H1 antihistamines do NOT relieve upper or lower airway obstruction, hypotension, or shock.

4. Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep the patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, the patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse at least every 5 minutes.
5. If EMS has not arrived and symptoms are still present, repeat the dose of epinephrine every 5–15 minutes for up to 3 doses, depending on the patient's response.
6. Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.
7. Report adverse event to VAERS: Report adverse events following administration of vaccine to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or online at https://vaers.hhs.gov/reportevent.html.
8. Notify the patient's primary care provider. If unable to contact, notify the patient that they will need to follow up with their primary care provider as soon as possible.

For your convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine					**Epinephrine Dose**	
					1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose is 0.05 mg	Epinephrine autoinjector (0.1 mg 0.15 mg or 0.3 mg)
Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.		**Age group**	**Range of weight (lbs)**	**Range of weight (kg)***		
	Infants and children	1–6 months	9–19 lbs	4–8.5 kg	0.05 mg (or mL)	Off label
		7–36 months	20–32 lbs	9–14.5 kg	0.1 mg (or mL)	0.1 mg†
		37–59 months	33–39 lbs	15–17.5 kg	0.15 mg (or mL)	0.15 mg/dose
		5–7 years	40–56 lbs	18–25.5 kg	0.2–0.25 mg (or mL)	0.15 mg/dose
		8–10 years	57–76 lbs	26–34.5 kg	0.25–0.3 mg (or mL)	0.15 mg or 0.3 mg/dose
	Teens	11–12 years	77–99 lbs	35–45 kg	0.35–0.4 mg (or mL)	0.3 mg/dose
		13 years & older	100+ lbs	46+ kg	0.5 mg (or mL) – max. dose	0.3 mg/dose

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.
* *Rounded weight at the 50th percentile for each age range*
† 0.1 mg autoinjector is licensed for use in 7.5 kg to 14 kg infants and children

Optional Treatment: Diphenhydramine					Diphenhydramine Dose
Commonly known as Benadryl		Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg
Recommended dose is 1-2 mg/kg body weight every 4-6 hours	Infants and children	7–36 months	20–32 lbs	9–14.5 kg	10 –15 mg/dose
		37–59 months	33–39 lbs	15–17.5 kg	15–20 mg/dose
		5–7 years	40–56 lbs	18–25.5 kg	20–25 mg/dose
		8–12 years	57–99 lbs	26–45 kg	25–50 mg/dose
	Teens	13 years & older	100+ lbs	46+ kg	50 mg/dose (single dose maximum is 50 mg)

Note: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.
***** *Rounded weight at the 50th percentile for each age range*

Emergency Medical Protocol for Management of Cardiac Arrest in Children

1. If the patient is found to be in cardiac arrest, a medical emergency is under way.
2. Activate the emergency medical system (i.e., call 911). This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
3. Feel for carotid pulse. Keep pulse check to 10 seconds or less
4. If no pulse or if unsure if a pulse is felt, being CPR.
5. Place eel of hand on lower half of sternum
6. Place other hand on top and interlock fingers
7. Keep arms straight and press down, compressing the chest 2 inches
    a. If alone, the compressions to breaths ratio are 30:2
    b. If two healthcare providers are present, the compressions to breaths ratio are 15:2
8. Let the chest completely recoil between compressions
9. Have an assistant gather the nearest AED.
10. As compressions are being done, attach the AED.
    a. Once AED is on and active, follow directions of AED.
11. Continue with compressions until EMS arrives.

Updated: 10/19/2022

These standing orders shall remain in effect for all patients being vaccinated under the direction of On-Site Medical Services, effective 10/03/2022 and until rescinded.

Medical Director:
Aimee N. Herron, DNP, APRN, FNP-BC

signature Aimee N Herron date 09/29/2022