

Pharmacy Protocol for COVID-19 Vaccination

- I. Introduction:** Immunization with safe and effective COVID-19 vaccine(s) authorized by the United States Food and Drug Administration (FDA) is an important public health strategy in protecting individuals from COVID-19 related illnesses, hospitalizations, and fatalities. As widely accessible healthcare professionals, pharmacists serve a critical role in expanding immunization efforts across the state of North Carolina.

Pharmacists meeting qualifications listed below in Section IV of this protocol may administer COVID-19 vaccine(s) pursuant to the NC State Health Director’s Standing Order for COVID-19 Vaccine Administration. COVID-19 vaccine providers must maintain a copy of this protocol at each location where the vaccine is administered.

- II. Authorizing Authority:** The United States Department of Health and Human Services’ issued a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) that allowed for pharmacists to “order and administer” FDA-authorized or FDA-licensed COVID-19 vaccine(s) in accordance with the Advisory Committee on Immunization Practice’s (ACIP’s) recommendations during the federally-declared COVID-19 public health emergency.

North Carolina Legal Authority: [SL 2020-3 \(SB 704\) 3D.3.\(a\)](#)

III. COVID-19 Vaccine Product Information

Pfizer-BioNTech COVID-19 Vaccine Information:

How Supplied	Pfizer-BioNTech COVID-19 Vaccine is supplied in a carton containing 25 multiple dose vials (NDC 59267-1000-3) OR 195 multiple dose vials (NDC 59267-1000-2).
Indications	Individuals 16 years of age and older
Dosing and Schedule	The Pfizer-BioNTech COVID-19 Vaccine is administered as a series of two doses (0.3 mL each), 3 weeks (21 days) apart.
Directions for use* <i>*Visual instructions found in Appendix A</i>	<u><i>Thawing Prior to Dilution</i></u> Thaw vial(s) before use by either: <ul style="list-style-type: none">- Allowing vials to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator. Thawed vials can be stored in the refrigerator for up to five days (120 hours).- Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.- Vials must reach room temperature before dilution.

	<ul style="list-style-type: none"> - Invert the vaccine vial gently 10 times (do not shake) and inspect liquid in the vial prior to dilution. Do not use if liquid is discolored or other particles are observed. <p><u>Dilution</u></p> <ul style="list-style-type: none"> - Obtain sterile 0.9% Sodium Chloride Injection, USP (use only this as diluent) and using aseptic technique, withdraw 1.8 mL of diluent into transfer syringe (21G or narrower needle). - Cleanse vaccine vial stopper with single-use antiseptic swab. - Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial. - Equalize vial pressure by withdrawing 1.8 mL air into the empty diluent syringe. - Gently invert the vial containing Pfizer-BioNTech COVID-19 Vaccine 10 times to mix; do not shake. - Inspect the vaccine in vial – it will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter. - Record the data/time of dilution on the vaccine vial label. - Store between 2°C to 25°C (35°F to 77°F) and discard any unused vaccine 6 hours after dilution. <p><u>Administration</u></p> <ul style="list-style-type: none"> - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine. - Administer immediately via intramuscular route into the deltoid muscle of the arm.
Contraindications	History of a severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine.
Precautions	<ul style="list-style-type: none"> - Severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) - Moderate to severe acute illness
Adverse Reactions	Adverse reactions following the Pfizer-BioNTech COVID-19 Vaccine that have been reported in clinical trials include

	injection site pain, fatigue, headache, muscle pain, chills, joint pain, fever, injection site swelling, injection site redness, nausea, malaise, and lymphadenopathy.		
Ancillary Supplies For individuals 16-18 years of age, 1" needle is recommended, administered in the deltoid muscle of the arm. For individuals 19 years of age and older, see table to right.	Sex and Weight of Patient	Needle Gauge	Needle Length
	Female or male fewer than 130 lbs	22-25	5/8-1"
	Female or male 130-152 lbs	22-25	1"
	Female 152-200 lbs	22-25	1-1 ½"
	Male 153-260 lbs	22-25	1-1 ½"
	Female 200+ lbs	22-25	1 ½"
	Male 260+ lbs	22-25	1 ½"
Storage	<p>Upon delivery, immediately store frozen vaccine vial trays in an ultra-low temperature freezer between -80°C to -60°C (-112°F to -76°F). Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light, in the original cartons, until ready to use.</p> <p>If an ultra-low temperature freezer is not available, the thermal container in which the Pfizer-BioNTech COVID-19 Vaccine arrives may be used as <u>temporary</u> storage when consistently re-filled to the top of the container with dry ice. Refer to the re-icing guidelines packed in the original thermal container for instructions regarding the use of the thermal container for temporary storage. The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F).</p> <p>During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Do not refreeze thawed vials.</p>		

Refer to the Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 Vaccine [Fact Sheet for Healthcare Providers Administering Vaccine](#) for additional vaccine information.

Moderna COVID-19 Vaccine Information:

How Supplied	The Moderna COVID-19 Vaccine Suspension for Intramuscular Injection, Multiple-Dose Vials are supplied as a carton of 10 multiple-dose vials (NDC 80777-273-99).
Indications	Individuals 18 years of age and older

Dosing and Schedule	The Moderna COVID-19 Vaccine is a suspension for intramuscular injection administered as a series of two doses (0.5 mL each), 1 month (28 days) apart.
Directions for use	<p><u>Thawing:</u></p> <ul style="list-style-type: none"> - Thaw vial(s) prior to use either In refrigerated conditions between 2°C to 8°C (36°F to 46°F) for 2 hours and 30 minutes or at room temperature between 15°C to 25°C (59°F to 77°F) for 1 hour - After thawing, let vial stand at room temperature for 15 minutes before administering. - After thawing, do not refreeze. - Swirl vial gently after thawing and between each withdrawal. Do not shake. Do not dilute the vaccine. - The Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Visually inspect the Moderna COVID-19 Vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered. <p><u>Administration:</u></p> <ul style="list-style-type: none"> - Using aseptic technique, withdraw 0.5 mL and administer via intramuscular injection. <p>After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F). Record the date and time of first use on the Moderna COVID-19 Vaccine vial label. Discard vial after 6 hours. Do not refreeze.</p>
Contraindications	History of severe allergic reaction (e.g., anaphylaxis) to any component of the Moderna COVID-19 Vaccine
Precautions	<ul style="list-style-type: none"> - Severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) - Moderate to severe acute illness
Adverse Reactions	Adverse reactions reported in a clinical trial following administration of the Moderna COVID-19 Vaccine include pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea/vomiting, axillary

	swelling/tenderness, fever, swelling at the injection site, and erythema at the injection site.		
Ancillary Supplies For individuals 18 years of age, 1" needle is recommended, administered in the deltoid muscle of the arm. For individuals 19 years of age and older, see table to right.	Sex and Weight of Patient	Needle Gauge	Needle Length
	Female or male fewer than 130 lbs	22-25	5/8-1"
	Female or male 130-152 lbs	22-25	1"
	Female 152-200 lbs	22-25	1-1 ½"
	Male 153-260 lbs	22-25	1-1 ½"
	Female 200+ lbs	22-25	1 ½"
	Male 260+ lbs	22-25	1 ½"
Storage	<ul style="list-style-type: none"> - Store frozen vials between -25° to -15°C (-13 to 5°F). Store in the original carton to protect from light. Do not store in dry ice or below -40°C (-40°F) - Vials can be refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to the first use. - Unpunctured vials may be stored between 8 and 25°C (46° to 77°F) for up to 12 hours. Do not refreeze. - After the first dose has been withdrawn, the vial should be held between 2 to 25°C (36° to 77°F). Discard vial after 6 hours. Do not refreeze. 		

Refer to the Emergency Use Authorization (EUA) of the Moderna COVID-19 Vaccine [Fact Sheet for Healthcare Providers Administering Vaccine](#) for additional vaccine information.

IV. Additional Clinical Considerations:

Interchangeability with other COVID-19 Vaccine products: Pfizer-BioNTech and Moderna COVID-19 Vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product. However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time.

Co-administration with other vaccines: Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Pregnancy: Available data on the Pfizer-BioNTech and Moderna COVID-19 Vaccines administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient’s personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

Lactation: There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

Immunocompromised Persons: Immunocompromised persons, including individuals receiving immunosuppressant therapy may have a diminished response to the Pfizer-BioNTech and Moderna COVID-19 Vaccines. Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all [current guidance](#) to protect themselves against COVID-19

Vaccination of persons with a SARS-CoV-2 infection: Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and [criteria](#) have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, [current evidence](#) suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

Individuals with a bleeding disorder or taking a blood thinner: COVID-19 vaccine may be given to these patients, if a physician familiar with the patient’s bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Individuals who have received passive antibody therapy as treatment for COVID-19: Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after

initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses

V. Qualifications of Person Administering Vaccine:

- *Licensure:*
 - Pharmacists must be licensed and in good standing with the North Carolina Board of Pharmacy.
- *Comply with all immunization training and continuing education requirements:*
 - Complete certificate program in vaccine administration of 20 hours approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
 - Complete a minimum of 2 hours of ACPE-approved immunization-related continuing education per State licensing period and maintain documentation.
 - Maintain valid certificate in provider-level basic cardiopulmonary resuscitation issued by the American Heart Association or the American Red Cross, or an equivalent certification.
- Notify the North Carolina Board of Pharmacy of immunizing pharmacist status.
- Enroll in the United States Federal Government COVID-19 vaccination program.
- Vaccine providers must sign and agree to the conditions in the Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Provider Agreement. Enrolled vaccination providers must also complete the *CDC COVID-19 Vaccination Provider Profile* form for each location where COVID-19 vaccine(s) will be administered, retain on file for a minimum of 3 years, and make available to CDC upon request.
- Complete COVID-19 training module, which includes information on storage/handling, vaccine indications, contraindications/precautions, administration, and documentation.

VI. Vaccine Administration

Prior to Administration:

- Provide vaccine recipient or their caregiver a copy of the current Emergency Use Authorization Fact Sheet for Recipients and Caregivers or direct the individual to the website www.cvdvaccine.com (Pfizer-BioNTech) or www.modernatx.com/covid19vaccine-eua (Moderna) to obtain the Fact Sheet.
- Review the COVID-19 Vaccine Management System (CVMS) or other vaccine records to determine if a vaccine is appropriate.
- Provide screening questionnaire to assess for any precautions or contraindications. Any individuals with contraindications to the vaccine or a history of vaccine complications should be referred to their primary care provider.
- Obtain informed consent from either the vaccine recipient or their legal representative.

- Provide vaccine recipients with an information sheet on enrolling in the V-safe survey-based surveillance program to report adverse events. V-safe also reminds patients of their second vaccine dose.

VII. Reporting Requirements:

After administering vaccine:

- Provide each vaccine recipient and/or their legal representative with a completed vaccine record card, which includes date of vaccination, product name/manufacturer, lot number, name/location of administering pharmacy, and when the recipient needs to return for the second dose of either the Pfizer-BioNTech or Moderna COVID-19 Vaccine.
- Record COVID-19 vaccination in the pharmacy record within 24 hours and record all required data elements in the COVID-19 Vaccine Management System (CVMS) or applicable reporting system as indicated by CDC agreement within 72 hours of vaccine administration.
- Notify the patient's primary care provider, if one is identified, of vaccine administration as soon as possible but no later than seventy-two (72 hours) of administration. A template letter can be found at <https://www.immunize.org/catg.d/p3060.pdf>. If the recipient does not identify a primary care provider, the pharmacist must direct the patient to information describing [benefits to having a primary care physician](#), prepared by any of the following: North Carolina Medical Board, North Carolina Academy of Family Physicians, North Carolina Medical Society, or Community Care of North Carolina and provide referrals as appropriate. (Appendix B)
- Comply with all pharmacy recordkeeping and reporting requirements of the state. Records should include at minimum:
 - Name, address, and date of birth of the patient
 - Copy of screening questionnaire
 - Date of vaccine administration
 - Administration site of injection (left deltoid, right deltoid, ect.)
 - Route of administration of the vaccine
 - Name and address of primary care provider, as identified by the patient or their legal representative
 - Name, manufacturer, lot number, and expiration date of each vaccine dose
 - Dose of vaccine administered
 - Name or identifiable initials of immunizing pharmacist, intern, or technician
- These records must be readily retrievable and be available to any federal, state, local, or territorial public health department. Records should be maintained for a minimum of 3 years following administration of the vaccine.
- Report any vaccine administration errors (whether or not associated with an adverse event), serious adverse events* (irrespective of attribution to vaccination), multisystem inflammatory syndrome in children or adults, and cases of COVID-19 that result in hospitalization or death following administration to the Vaccine Adverse Event Reporting System (VAERS) via www.vaers.hhs.gov or calling 1-800-822-7967. A copy of the VAERS form should be provided to the patient's primary care provider.

*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and require medical or surgical intervention to prevent one of the outcomes listed above.

VIII. Vaccine Follow-Up:

- Ensure a system is in place to remind vaccine recipients of their need for the second dose of the COVID-19 vaccine. A variety of methods can be utilized including personal vaccine cards, patient portals, phone calls, text messages, email, and mail.

IX. Vaccination Safety:

Infection prevention:

- Persons administering vaccines must follow appropriate precautions to minimize the spread of COVID-19 and other diseases. These precautions include:
 - Washing hands or using an alcohol-based hand sanitizer prior to each vaccine administration
 - Wearing gloves during vaccine administration
 - Wearing appropriate personal protective equipment including a surgical mask and face shield
 - Utilizing disposable sterile syringes/needles

Prevention of Needle-Stick Injuries:

- Used syringes and needles must be immediately disposed of following vaccine administration in a labeled sharps-container. Syringes should not be recapped prior to placement into containers.
- In instances of a needle-stick or sharps injury, following the steps described here: <https://www.cdc.gov/niosh/topics/bbp/emergnedl.html>

Occupational Safety and Health Administration (OSHA):

- Vaccine providers must comply with all regulations set forth by OSHA to reduce risk of bloodborne pathogens, maintain an exposure control plan, and complete annual training. <https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>

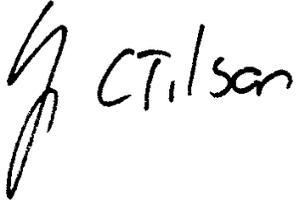
X. Emergency Procedures:

- To minimize the risk of an adverse event, it is important to screen individuals for contraindications and precautions prior to vaccine administration.

- In accordance with ACIP's General Best Practices Guidance for Immunization, all vaccine recipients should be kept under observation for 15 minutes following vaccination. Individuals with a history of any anaphylaxis should be observed for 30 minutes.
 - The following supplies should be kept in all locations where vaccines are provided and be in-date:
 - Epinephrine, aqueous 1:1000 (i.e. 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.
 - Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).
 - Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1 1/2", and 2") for epinephrine or diphenhydramine. For ampules, use filtered needles.
 - Alcohol wipes
 - Adult size pocket mask with one-way valve
 - Oxygen (if available)
 - Stethoscope
 - Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs
 - Flashlight with extra batteries (for examination of the mouth and throat)
 - Wristwatch with a second hand or other timing device
 - Cell phone or access to onsite phone
 - Optional items, if available and personnel are trained
 - Adult airways (small, medium, and large)
 - Tongue depressors
 - For medical management of allergic reactions, anaphylaxis, and other adverse events, refer to:
 - Immunization Action Coalition's (IACs) "Medical Management of Vaccine Reactions in Adults in a Community Setting"* at <https://www.immunize.org/catg.d/p3082.pdf>
 - IACs "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting"** at <https://www.immunize.org/catg.d/p3082a.pdf>
 - Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites at <https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html>
- *Appendix C
 **Appendix D

XI. Cost: The vaccine must be provided at no cost to the recipient. Health insurance issuers/plans are required to cover any ACIP-recommended COVID-19 preventive service, including vaccines, without cost sharing within 15 days of such recommendation to the CDC and can be billed for an administration fee but not the vaccine itself. [CARES Act \(Section 3203\)](#)

XII. Supply Considerations: In situations where COVID-19 vaccine supplies are limited, pharmacies should follow federal and state directives on phased prioritization approaches for vaccination.

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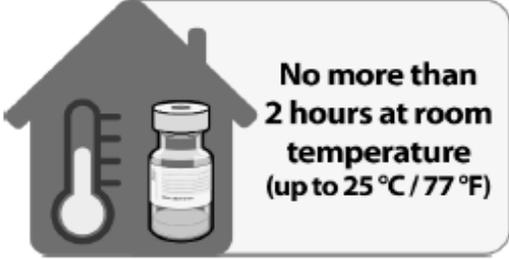
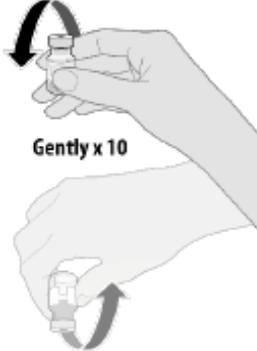
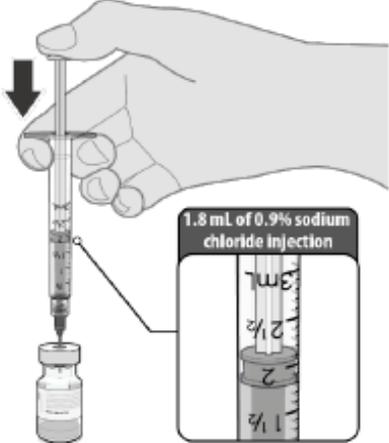
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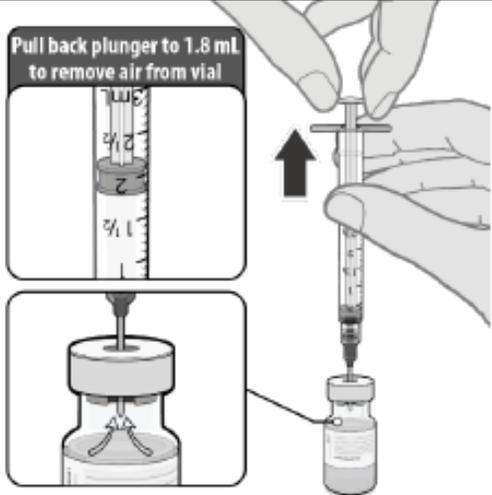
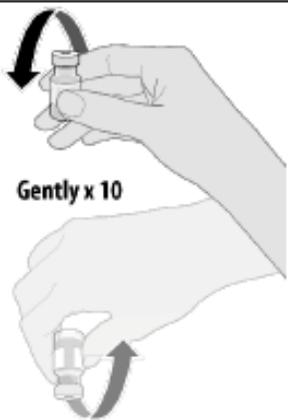
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Elizabeth Cuervo Tilson, MD, MPH
North Carolina State Health Director
NPI: 1760540421

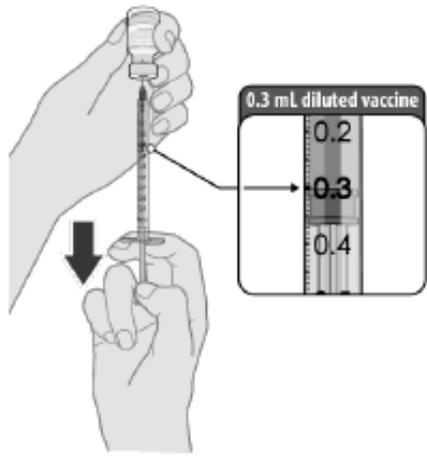
This protocol will be reviewed at least annually and revised as new or updated information becomes available.

Appendix A: Directions for thawing, dilution, and administration of Pfizer-BioNTech COVID-19 Vaccine

THAWING PRIOR TO DILUTION	
 <p>No more than 2 hours at room temperature (up to 25°C / 77°F)</p>	<ul style="list-style-type: none"> • Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by: <ul style="list-style-type: none"> ○ Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to five days (120 hours). ○ Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes. • Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours.
 <p>Gently x 10</p>	<ul style="list-style-type: none"> • Before dilution invert vaccine vial gently 10 times. • <u>Do not shake.</u> • Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles. • Do not use if liquid is discolored or if other particles are observed.
DILUTION	
 <p>1.8 mL of 0.9% sodium chloride injection</p>	<ul style="list-style-type: none"> • Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent. • Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle). • Cleanse the vaccine vial stopper with a single-use antiseptic swab. • Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

	<ul style="list-style-type: none"> • Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL air into the empty diluent syringe.
	<ul style="list-style-type: none"> • Gently invert the vial containing the Pfizer-BioNTech COVID-19 Vaccine 10 times to mix. • <u>Do not shake.</u> • <u>Inspect the vaccine in the vial.</u> • The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter.
	<ul style="list-style-type: none"> • Record the date and time of dilution on the Pfizer-BioNTech COVID-19 Vaccine vial label. • Store between 2°C to 25°C (35°F to 77°F). • Discard any unused vaccine 6 hours after dilution.

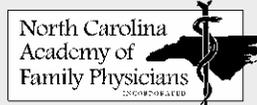
PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH COVID-19 VACCINE



- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the Pfizer-BioNTech COVID-19 Vaccine.
- Administer immediately.

Appendix B: Benefits to Having a Primary Care Physician

Information Provided by The North Carolina Academy of Family Physicians



Discover family medicine at www.ncfamilydoctor.org

All North Carolinians Need A Primary Care Physician

Benefits to Having a Primary Care Physician and Medical Home for Your Overall Healthcare

There are many benefits to having your own personal primary care physician and 'medical home' - a place you access all of your healthcare services:

You will be happier and healthier: A primary care physician helps you maintain your optimal health by helping you prevent illness and by expertly managing acute and chronic illnesses, including conditions like the flu, sinus infections, diabetes, high blood pressure, heart disease, depression, and many more. Primary care physicians help you get the right care at the right time!

You will save time and money: Primary care physicians reduce your overall healthcare costs and help you get the right care when you need it most. Patients with a primary care physician miss fewer work days, avoid costly duplicated tests/treatments, and save precious time when health issues do arise.

What is a Family Physician?

A family physician is medically trained to provide comprehensive healthcare to everyone - male and female - from birth through old age. Family physicians provide personal healthcare services that are:

- **Individualized** to you and your specific healthcare needs
- **Comprehensive** (acute conditions, chronic illnesses, and behavioral health issues)
- **Focused on prevention**, which keeps you healthier and happier
- **Coordinates your healthcare** with sub-specialists, hospitals and others when needs arise
- **Relationship-based and lifelong** - your family physician knows you, your history and your family

To learn more about the importance of having a primary care physician, please visit
www.ncfamilydoctor.org

Medical Management of Vaccine Reactions in Adults in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see “Screening Checklist for Contraindications to Vaccines for Adults” at www.immunize.org/catg.d/p4065.pdf). When adverse reactions do occur,

they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event 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 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, presyncope, and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Patient feels “faint” (e.g., light-headed, dizzy, weak, nauseated, or has visual disturbance)	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to 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 patient flat on back with feet elevated.
	Loss of consciousness	Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if 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 nasal congestion, 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 the emergency medical protocol on the next page for detailed steps to follow in treating anaphylaxis.

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Suggested Medications for Managing Anaphylaxis in a Community Immunization Clinic Setting

FIRST-LINE medication

- Epinephrine** 1.0 mg/mL aqueous solution (1:1000 dilution) in prefilled autoinjector or prefilled syringe (0.3 mg), prepackaged syringes, vials, or ampules. At least three epinephrine doses should be available onsite.

OPTIONAL medications: H₁ antihistamines

These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension, or shock.

- Diphenhydramine** (e.g., Benadryl) oral, 12.5 mg/5 mL liquid, 25 or 50 mg tablets

Additional emergency supplies you may need

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- Alcohol wipes
- Tourniquet
Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators
- Stethoscope
- Blood pressure measuring device with adult-sized and extra-large cuffs
- Tongue depressors
- Light with extra batteries (for examination of the mouth and throat)
- A timing device, such as wristwatch, for checking pulse
- Cell phone or access to onsite phone

For remote areas without EMS support

- Adult airways (various sizes)
- Adult-sized pocket mask with one-way valve
- Oxygen (if available)

REFERENCES

* American Academy of Pediatrics. *Red Book: 2018–2021*, 31st ed (p. 66).

Campbell RL, Kelso JM. Anaphylaxis: Emergency treatment. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. November 2018.

Kroger AT, Duchin J, Vazquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.

Emergency medical protocol for management of anaphylactic reactions in adults in a community setting

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. 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: EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Use epinephrine in a 1.0 mg/mL aqueous solution (1:1000 dilution). Administer a 0.3 mg dose IM using a premeasured or prefilled syringe or an autoinjector in the mid-outer thigh. If using another epinephrine formulation, the recommended dose is 0.01 mg/kg, ranging for adults from 0.3 mg to maximum dose of 0.5 mg. Administer IM, preferably in the mid-outer thigh. Epinephrine dose may be repeated 2 additional times every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
 - b **Optional treatment: H₁ ANTIHISTAMINES** relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving diphenhydramine (e.g., Benadryl) for relief of itching and hives. Administer orally 1–2 mg/kg every 4–6 hours, up to a maximum single dose of 100 mg.*
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, 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 every 5 minutes.
- 5 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.
- 6 Notify the patient's primary care physician.
- 7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the

_____ until rescinded or until _____

NAME OF CLINIC DATE

MEDICAL DIRECTOR'S SIGNATURE DATE OF SIGNING

Appendix D: “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting”

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see “Screening Checklist for Contraindications to Vaccines for Children and Teens” at www.immunize.org/catg.d/p4060.pdf). When adverse reactions do

occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event 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 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 patient sit or lie down for the vaccination.
	Paleness, sweating, coldness of the hands and feet, nausea, light-headedness, dizziness, weakness, or visual disturbances	Have patient lie flat. Loosen any tight clothing and maintain open airway. Apply cool, damp cloth to 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 patient flat on back with feet elevated.
	Loss of consciousness	Check to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if 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 nasal congestion, 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 the emergency medical protocol on the next page for detailed steps to follow in treating anaphylaxis.

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Suggested Medications for Managing Anaphylaxis in a Community Immunization Clinic Setting

FIRST-LINE medication

- Epinephrine** 1.0 mg/mL aqueous solution (1:1000 dilution) in prefilled autoinjector or prefilled syringe (various doses), prepackaged syringes, vials, or ampules. At least three epinephrine doses should be available on site, dosages as appropriate for patient population.

OPTIONAL medications: H₁ antihistamines

These relieve itching and hives only; they DO NOT relieve upper or lower airway obstruction, hypotension, or shock.

- Diphenhydramine** (e.g., Benadryl) oral, 12.5 mg/5 mL liquid; 25 or 50 mg tablets
- Hydroxyzine** (e.g., Atarax, Vistaril) oral, 10 mg/5 mL liquid, 10 mg or 25 mg tablets

Additional emergency supplies you may need

- Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") if needed for epinephrine
- Alcohol wipes
- Tourniquet
Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators
- Stethoscope
- Blood pressure measuring device with multiple-sized cuffs depending on patient population
- Tongue depressors
- Light with extra batteries (for examination of the mouth and throat)
- A timing device, such as wristwatch, for checking pulse
- Cell phone or access to onsite phone

For remote areas without EMS support

- Pediatric- and adult-sized airways (various sizes)
- Various-sized pocket masks with one-way valve
- Oxygen (if available)

REFERENCES

* American Academy of Pediatrics. *Red Book: 2018–2021 Report of the Committee on Infectious Diseases*. 31st edition, p. 64–67.

Campbell RL, Kelson JM. Anaphylaxis: Emergency treatment. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. November 2018.

Kroger AT, Duchin J, Vazquez M. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

Emergency medical protocol for management of anaphylactic reactions in children and teens in a community setting

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. 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: EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute.** Use epinephrine in a 1.0 mg/mL aqueous solution (1:1000 dilution). See page 3 to determine correct dose to be used based on child's weight. If using an autoinjector or pre-filled syringe, administer a dose of 0.1 mg, 0.15 mg, or 0.3 mg IM (as appropriate for the patient's weight) into the anterolateral thigh. If using another epinephrine format, the recommended dose is 0.01 mg/kg per dose, up to a maximum single dose of 0.5 mg. Administer IM, preferably in the anterolateral thigh. Epinephrine dose may be repeated every 5–15 minutes (or sooner as needed) while waiting for EMS to arrive.
 - b **Optional treatment: H₁ ANTIHISTAMINES** relieve itching and urticaria (hives). These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock. Consider giving **diphenhydramine** (e.g., Benadryl) or **hydroxyzine** (e.g., Atarax, Vistaril) for relief of itching or hives.
 - Administer **diphenhydramine** orally, standard dose of 1–2 mg/kg every 4–6 hours. Maximum single dose is 40 mg for children age <12 years; for children age ≥12 years, 100 mg. See dosing chart on page 3.*
 - Administer **hydroxyzine** orally; the standard dose is 0.5–1 mg/kg/dose, up to 50–100 mg maximum per day in children and adolescents. See dosing chart on page 3.
- 4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in recumbent position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, 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 every 5 minutes.
- 5 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.
- 6 Notify the patient's primary care physician.
- 7 Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

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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	
	Age group	Range of weight (lb)	Range of weight (kg)*	1.0 mg/mL aqueous solution (1:1000 dilution); intramuscular. Minimum dose: 0.05 mL	Epinephrine autoinjector or prefilled syringe (0.1 mg, 0.15 mg, 0.3 mg)
Infants and children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb†	9–14.5 kg†	0.1 mL (or mg)	0.1 mg†
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
Teens	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes (or sooner) up to 3 times while waiting for EMS to arrive.

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 to 14 kg infants and children

Optional Treatment: Diphenhydramine				Diphenhydramine dose calculations based on 1 mg/kg†	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 12.5 mg/5 mL	Tablets: 25 mg or 50 mg
Infants and children	7–36 months	20–32 lb	9–14.5 kg	10–15 mg/dose†	
	37–59 months	33–39 lb	15–17.5 kg	15–20 mg/dose†	
	5–7 years	40–56 lb	18–25.5 kg	20–25 mg/dose†	
	8–12 years	57–99 lb	26–45 kg	25–50 mg/dose†	
Teens	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg single dose)†	

► commonly known as Benadryl

Recommended dose is 1–2 mg/kg body weight every 4–6 hrs†

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

† AAP. Red Book: 2018–2021, 31st ed. (p. 66). Diphenhydramine maximum single dose for children younger than age 12 years is 40 mg, for children age 12 years and older, 100 mg.

Optional Treatment: Hydroxyzine				Hydroxyzine dose calculations based on 0.5 mg/kg	
	Age group	Range of weight (lb)	Range of weight (kg)*	Liquid: 10 mg/5 mL	Tablets: 10 mg or 25 mg
Infants and children	7–36 months	20–32 lb	9–14.5 kg	5–7.5 mg/dose	
	37–59 months	33–39 lb	15–17.5 kg	7.5–10 mg/dose	
	5–7 years	40–56 lb	18–25.5 kg	10–12.5 mg/dose	
	8–10 years	57–76 lb	26–34.5 kg	12.5–15 mg/dose	
Teens	11–12 years	77–99 lb	35–45 kg	15–25 mg/dose	
	13 years & older	100+ lb	46+ kg	25 mg/dose (50–100 mg, maximum per day)	

► commonly known as Atarax, Vistaril

Recommended oral dose is 0.5–1 mg/kg body weight every 4–6 hrs†

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

This policy and procedure shall remain in effect for all patients of the name of practice _____ <small>NAME OF PRACTICE OR CLINIC</small> effective _____ until rescinded or until _____ <small>DATE DATE</small>	Medical Director _____ <small>PRINT NAME</small> _____ <small>SIGNATURE DATE</small>
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