Appendix Q: Vaccines

- Below are the NYC REMAC approved vaccinations recommended by the Centers for Disease Control and Prevention (CDC). This appendix will be updated as new vaccines are approved by the NYC REMAC and is to be used as a reference. The type of vaccine, including concentration and dose, is to be determined by an agency Medical Director

INFLUENZA

1. Indications: assess the need of vaccination against influenza
    - **ADULT:**
        - All adults are recommended to receive influenza vaccination each year
        - Women who are or will be pregnant during the influenza season: administer any recommended, age-appropriate trivalent or quadrivalent inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV4) to pregnant women in any trimester
        - People who do not recall whether they received influenza vaccine in the current vaccination season should be vaccinated
    - **PEDIATRIC:**
        - All children and teens 6 months of age and older are recommended to receive the influenza vaccination each year
        - A second dose of influenza vaccine is recommended 4 weeks or more after the first dose for children age 6 months through 8 years of age if they have not or do not know if they have received 2 doses in prior years (not necessarily in the same season)
        - A second dose is needed for a 9-year-old child who received one dose in the current season when they were age 8 years, if they have not or do not know if they have received 2 doses in prior years
2. Screen for Contraindications and Precautions:
    - **Contraindications for use of all influenza vaccines**

      Do not administer the influenza vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of any influenza vaccine or to any of its components (except egg). For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or

      www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states
    - **Contraindications only for use of live attenuated influenza vaccine (LAIV4, FluMist® Quadrivalent, nasal spray)**
        - Do not administer LAIV4 to a person who is:

- Pregnant
- Functional or anatomic asplenia, CSF leak, cochlear implant, or is immunocompromised due to any cause (including immunosuppression caused by medications or HIV infection)
- Age 50 years or older
- Received influenza antivirals *before* scheduled vaccination (Zanamivir or Oseltamivir within 48 hours; Peramivir within 5 days; Baloxavir within 17 days). If any of these antiviral drugs are taken within 14 days *after* LAIV, revaccinate with IIV or RIV4.
- In close contact of or who provides care for a severely immunosuppressed person who requires a protective environment
- Age 2 through 4 years who has received a diagnosis of asthma or who has experienced wheezing or asthma within the past 12 months, based on a healthcare provider's statement or medical record
- Age 6 months through 17 years and is receiving aspirin- or salicylate-containing medicine

- **Precautions for use of all influenza vaccines**
  - Moderate or severe acute illness with or without fever
  - History of Guillain-Barré syndrome within 6 weeks of a previous influenza vaccination
- **Precautions for use of LAIV4 only**
  - Age 5 years or older with Asthma
  - Other chronic medical conditions that might predispose the person to complications of influenza infection (e.g., other chronic pulmonary, cardiovascular [excluding isolated hypertension], renal, hepatic, neurologic, hematologic, or metabolic disorders [including diabetes mellitus])

For patients with egg allergy: People with egg allergy of any severity can receive any recommended and age-appropriate influenza vaccine (i.e., any IIV, RIV4, or LAIV4) that is otherwise appropriate for their health status. Most influenza vaccines (except RIV4 and cell-cultured IIV4) are egg cultured and may have trace amounts of egg protein. If a vaccine other than cell-cultured IIV (Flucelvax® Quadrivalent; Seqirus) or RIV (Flublok® Quadrivalent; Sanofi Pasteur) is used, people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema or swelling, respiratory distress, lightheadedness, or recurrent emesis), or who required epinephrine or another emergency medical intervention, the selected vaccine should be administered in a medical setting (e.g., health department or physician office). Vaccine administration should be super- vised by a healthcare provider who is able to recognize and manage severe allergic conditions

Note: For children aged 6 months-8 years who are receiving influenza vaccine for the first time; have had fewer than two prior doses of influenza vaccine in all previous years; or don’t know their influenza vaccine history, administer two doses separated by at least 4 weeks

ADULT				
Vaccine	**Age**	**Dose**	**Route**	**Administration**
Inactivated influenza vaccine (IIV)	All ages	0.5 ml	IM	Deltoid muscle
IIV-high dose	≥ 65 years old	0.7 ml	IM	
Adjuvanted inactivated influenza vaccine (aIIV4)		0.5 ml	IM	
Cell culture-based IIV (ccIIV4)	All ages	0.5 ml	IM	
Recombinant influenza vaccine (RIV4)	≥18 years old			
Live attenuated influenza vaccine (LAIV4)	< 50 years old (except pregnant women)	0.2 ml	IN	Spray 0.1 ml into each nostril while the patient is in an upright position

PEDIATRIC				
Vaccine	**Age**	**Dose**	**Route**	**Instructions**
Inactivated influenza vaccine (IIV)	6–35 months	Afluria®: 0.25 ml Fluarix®: 0.5 ml FluLaval®: 0.5 ml Fluzone®: 0.25 ml or 0.5 ml	IM	Anterolateral thigh; alternatively, children aged 12-35 months old may receive injections in deltoid muscle
Inactivated influenza vaccine (IIV)	≥ 3 years	0.5 ml	IM	Deltoid muscle or anterolateral thigh
Cell culture-based IIV (ccIIV4)	≥ 4 years			Deltoid muscle
Recombinant influenza vaccine (RIV4)	≥ 18 years			
Live attenuated influenza vaccine (LAIV4)	≥ 2 years	0.2 ml	IN	Spray half of vaccine into each nostril while the patient is in an upright position

PFIZER BIO-N-TECH COVID-19 VACCINE

Pfizer-BioNTech COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

1. Indications: assess the need of vaccination against COVID-19
    - **ADULT:**
        - FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 vaccine in individuals 12 years of age or older
2. Screen for Contraindications and Precautions:
    - **Contraindications for use**

      Do not administer the Pfizer-BioNTech COVID-19 vaccine to a person who has experienced a serious systemic or anaphylactic reaction to any component of the Pfizer-BioNTech COVID-19 vaccine. For a list of vaccine components, refer to the manufacturer's package insert
    - **Precautions for use**
        - Severe allergic reaction
        - Fever
        - Bleeding disorder or are taking anticoagulants
        - Immunocompromised
        - Pregnancy
        - Breastfeeding
        - Having received another COVID-19 vaccine
3. Dosage and Administration
    - The Pfizer-BioNTech COVID-19 vaccine is administered intramuscularly of a 0.3 ml prepared solution to be administered as two doses three weeks apart. There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series

4. Preparation for Administration

4.1 Prior to dilution

- The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed and diluted prior to administration
- Pfizer-BioNTech COVID-19 vaccine may be thawed by either:
  - Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)]. 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 25ºC (77ºF)] for 30 minutes
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours

4.2 Dilution

- Before dilution, invert vaccine vial gently 10 times. Do not shake
- 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 the liquid is discolored or if other particles are observed
- Dilute the vial contents using 1.8 ml of 0.9% Sodium Chloride Injection, USP to form the Pfizer-BioNTech COVID-19 Vaccine
- ONLY use 0.9% Sodium Chloride Injection, USP as the diluent. This diluent is not packaged with the vaccine and must be sourced separately. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent
- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 ml air into the empty diluent syringe
- Gently invert the vial containing the Pfizer-BioNTech COVID-19 vaccine ten times. Do not shake
- Inspect the vaccine in the vial. The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulates
- Record the date and time of dilution on the vial label
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 6 hours after dilution

5. Administration

- Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. Confirm there are no particulates and that no discoloration is observed. Do not administer if vaccine is discolored or contains particulates

- 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 the vaccine intramuscularly immediately

6. Adverse reactions
   - Reported adverse reactions 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 (see Full EUA Prescribing Information)
   - Severe allergic reactions have been reported following the Pfizer-BioNTech COVID-19 vaccine during mass vaccination outside of clinical trials
   - Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 vaccine

MODERNA COVID-19 VACCINE

Moderna COVID-19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older

1. Indications: assess the need of vaccination against COVID-19
    - **ADULT:** FDA has authorized the emergency use of Moderna COVID-19 vaccine in individuals 18 years of age or older
2. Screen for Contraindications and Precautions:
    - Contraindications for use:
    - Do not administer the Moderna COVID-19 vaccine to a person who has experienced a serious systemic or anaphylactic reaction to any component of the Moderna COVID-19 vaccine. For a list of vaccine components, refer to the manufacturer's package insert
    - Precautions for use
    - Severe allergic reaction
    - Fever
    - Bleeding disorder or are taking anticoagulants
    - Immunocompromised
    - Pregnancy
    - Breastfeeding
    - Having received another COVID-19 vaccine

3. Dosage and Administration
    - The Moderna COVID-19 vaccine is administered intramuscularly of a 0.5 ml solution to be administered as two doses four weeks apart. There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series

4. Preparation for Administration

    4.1 Thawing
    - The Moderna COVID-19 Vaccine Multiple Dose Vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.
    - Moderna COVID-19 vaccine may be thawed by either:
        - Allowing vial(s) to thaw in the refrigerator [2ºC to 8ºC (35ºF to 46ºF)] for 2.5 hours. After thawing, allow vial(s) to stand at room temperature for 15 minutes before administering

        - Allowing vial(s) to sit at room temperature [15ºC to 25ºC (59ºF to 77ºF)] for 1 hour
    - 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 particulates. Visually inspect the Moderna COVID-19 vaccine vials for other particulate matter and/or discoloration prior to administration. If either of these conditions exist, the vaccine should not be administered
    - After the first dose has been withdrawn, the vial should be stored between 2ºC to 25ºC (35ºF to 77ºF). Record the date and time of first use on the Moderna COVID-19 vaccine vial label. Discard vial after 6 hours. Do not refreeze

5. Administration
    - Visually inspect each dose in the dosing syringe prior to administration. The white to off-white suspension may contain white or translucent particulates. Do not administer if vaccine is discolored or contains other particulate matter
    - Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab and withdraw 0.5 ml of the Moderna COVID-19 vaccine
    - Administer the vaccine intramuscularly
6. Adverse reactions
    - Reported adverse reactions in clinical trials include injection site pain, fatigue, headache, myalgia, arthralgia, fever/chills, nausea/vomiting, axillary swelling/tenderness, swelling at the injection site, and erythema at the injection site (see Full EUA Prescribing Information)
    - Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Moderna COVID-19 vaccine