Division of Public Health
Clinical Guidelines and Standing Orders
for the Administration of COVID-19 Vaccine

BACKGROUND

The Division of Public Health will be providing access to the COVID-19 vaccine to persons in accordance with the State of Delaware vaccine safety and monitoring found at https://coronavirus.delaware.gov/vaccine/vaccine-safety-and-monitoring/. This clinical guideline and standing order serves to provide information related to the administration of the COVID-19 vaccine manufactured by Pfizer, Moderna and Johnson & Johnson.

SCOPE

This standing order applied to all staff administering the COVID-19 vaccine as a representative of Division of Public Health (full-time, part-time, contractual, or volunteer).

PROCEDURES - for Pfizer BioNTech Manufactured Vaccine

Supplies:
1 vial 0.9% Sodium Chloride Injection (at least 2ml vial).
1 diluent syringe/needle (3ml or 5ml syringe/21G needle).
1 mL syringe/IM injection needle.
Other items – alcohol swabs, gloves, PPE, and emergency response supplies.

Preparation:
5 years to <12 years old: Each thawed vial must be diluted with **1.3mL** of sterile 0.9% Sodium Chloride for Injection. After dilution, 1 vial contains 10 doses of 0.2mL.
12 years old and older: Each thawed vial must be diluted with **1.8mL** of sterile 0.9% Sodium Chloride for Injection. After dilution, 1 vial contains 6 doses of 0.3mL.
Optimal diluent vial is 2mL.
One 3 mL syringe can be used to withdraw the required amount of diluent.
One 21 gauge or narrower needle should be used to withdraw the diluent.

IF using a larger diluent vial – once the 1.3mL or 1.8 mL is withdrawn from the vial– the diluent vial must be discarded. It cannot be used for another withdraw of diluent.

Administration:

- Gather five 1 mL syringes for each vaccine vial and the appropriate needle for an IM injection.
- 1 syringe is used for each of the:
  - **0.2mL** dose/patient **(5 years to < 12 years old)**
  - **0.3mL** dose/patient **(12 years old and older)**
- All injections should follow the acceptable standards for site location and IM vaccine administration established by DPH in the DPH Flu vaccine training*.
- IMPORTANT NOTE: There are reports of vials containing more than 5 doses after reconstitution. The clinician can provide every full dose (0.2mL or 0.3mL) in the vial. It is a strong contraindication to combine vial fluids to obtain a dose of 0.2mL or 0.3mL. At no point should remaining vaccine in vials be combined with other vials to obtain a full dose.

Dosage and Route:

• The standing order dosage and route for the Pfizer BioNTech vaccine, once reconstituted per above, is:

o **0.2mL** dose per patient **(5 years to < 12 years old)**, IM.
o **0.3 mL** dose per patient **(12 years old and older)**, IM.

• Schedule (Primary Series):

- Dose #1: initial dose
- Dose #2: given 3 – 8 weeks after dose #1
  - 8-week interval is optimal for some individuals 12 years old and older, especially males ages 12 years old to 39 years old.
  - Shorter interval (3-weeks) between the first and second doses is the recommended interval for
    - Individuals who are moderately to severely immunocompromised
    - Adults 65 years old or older
    - Others who need rapid protection due to increased concern about community transmission or risk of severe disease
    - Or any other group or age that does not fit within the above recommended 8-week interval.
- Dose #3: (Additional Primary Dose) minimum of 4weeks after dose #2, for those moderately to severely immunocompromised individuals.

Booster Dose:

- **Booster Dose Indications**: (may “mix and match” per below under interchangeability section).
- **Booster Dose #1:**

- For individuals ages 5 years old to <12 years old:
  - Single booster dose given at least 5 months after completion of primary series.
- For individuals ages 12 years old and older:
  - For those moderately or severely immunocompromised – administer booster dose at least 3 months after administration of the additional primary dose of the COVID-19 mRNA vaccine series
  - For those who are not moderately or severely immunocompromised – administer booster dose at least 5 calendar months after the last dose of COVID-19 mRNA vaccine primary series.

- **Booster Dose #2:**
  - Eligibility:
    - Individuals 50 years old and older, regardless of health status
    - Individuals 12 years old and older who are moderately or severely immunocompromised.
    - Individuals 18 years old and older who received 2 doses of Janssen vaccine.
    - See Additional Clinical Considerations from the CDC in determining other possible conditions or situations that may warrant a second COVID-19 vaccine booster: https://www.cdc.gov/vaccines/covid-19/downloads/Clinical-Considerations-Second-COVID-19-Booster-508.pdf
  - Administer the second booster dose at least 4 months after the previous dose.
  - Only Pfizer-BioNTech or Moderna COVID-19 vaccine products can be administered for the second booster dose.

Storage and Stability of Pfizer BioNTech Vaccine

Vial stability and storage before dilution:

- Undiluted vials may be held at room temperature for up to 2 hours before dilution.
  - This 2-hour timeframe includes the 30-minute timeframe for thawing.

Vial stability and storage after dilution:

- Refer to Emergency Use Authorization (EUA) for specifics for vial storage prior to use and during use for each variation of the Pfizer BioNTech vaccine.

PROCEDURES - for Moderna Manufactured Vaccine

Supplies:

- Moderna Vaccine vial.
  - NOTE: there are no additional preparation requirements for the Moderna vaccine.
- 10-12 dosing syringes/needles (1mL syringe/IM injection needle).
- Other items – alcohol swabs, gloves, PPE, and emergency response supplies.

Administration:

- Gather 10 1 mL syringes for each vaccine vial and the appropriate needle for an IM injection.
- 1 syringe is used for each of the 0.5 mL dose/patient.
- All injections should follow the acceptable standards for site location and IM vaccine administration established by DPH in the DPH Flu vaccine training*.

Dosage and Route:

• The standing order dosage and route for the Moderna vaccine is:

o **0.5 mL** dose per patient (18-years-old or older), IM, for primary series and those receiving third dose due to being moderately to severely immunocompromised.

o **0.25 mL** dose per patient (18-years-old or older), IM, for booster dose: 3 months after completing primary series, f**or those moderately to severely immunocompromised**, otherwise 5 months after their primary series.

• Schedule (Primary Series):

- Dose #1: initial dose
- Dose #2: minimum of 4-weeks after dose #1
  - 8-week interval is optimal for some individuals 12 years old and older, especially males ages 12 years old to 39 years old.
- Dose #3 (Additional Primary Dose): minimum of 4-weeks after dose #2, for those moderately to severely immunocompromised individuals.

  For those who completed the 2 dose primary series or the two dose primary series with the third additional primary dose, due to being moderately to severely immunocompromised, a **booster dose** may be given.

- **Booster Dose Indications:** (may “mix and match” per below under interchangeability section)
- **Booster Dose #1:**
  - For individuals ages 18-years-old or older.
  - Booster dose is to be given at least 12-weeks after completion of the primary **series for those who are moderately to severely**

immunocompromised. Otherwise, booster dose is to be given at least 5 months after completion of the primary series

- **Booster Dose #2:**
  - Individuals 50 years old and older regardless of health status
  - Individuals 18 years old and older who are moderately or severely immunocompromised.
  - Individuals who received 2 doses of Janssen vaccine.
  - See Additional Clinical Considerations from the cdc in determining other possible conditions or situations that may warrant a second COVID-19 vaccine booster dose: https://www.cdc.gov/vaccines/covid-19/downloads/Clinical-Considerations-Second-COVID-19-Booster-508.pdf
  - Booster dose is to be given at least 12-weeks after receipt of the first booster dose of any authorized or approved COVID0-19 vaccine.

Storage and Stability of the Moderna Vaccine

- Vials may be held at room temperature for up to 12 hours.

Any vaccine not used after 12 hours must be discarded.

PROCEDURES - for Janssen/Johnson & Johnson (J&J) Manufactured Vaccine

Supplies:

- J&J Vaccine vial.
  - NOTE: there are no additional preparation requirements for the J&J vaccine.
- 10-12 dosing syringes/needles (1 mL syringe/IM injection needle).
- Other items – alcohol swabs, gloves, PPE, and emergency response supplies.

Administration:

- Gather 5, 1 mL syringes for each vaccine vial and the appropriate needle for an IM injection.
- 1 syringe is used for each of the 0.5 mL dose/patient.
- All injections should follow the acceptable standards for site location and IM vaccine administration established by DPH in the DPH Flu vaccine training*.

Dosage and Route:

- The standing order dosage and route for the J&J vaccine is: 0.5 mL dose per patient (18-years-old or older), IM

Schedule:

- Dose #1: Initial dose of J & J vaccine.
- Dose #2/Booster dose #1: administered at least 2 months after administration of dose #1.

- **Booster dose indications**: (may "mix and match" per below under interchangeability section).

- Dosing for those who are **moderately to severely immunocompromised**.
  - Dose #1: Initial dose of Janssen/Johnson & Johnson vaccine.
  - Dose #2: mRNA vaccine (Pfizer/Moderna) to be administered at least 28 days after dose #1.
  - Booster dose: A booster dose at least 2 months after administration of dose #2. This booster dose may be a Janssen/Johnson & Johnson COVID-19 vaccine, but administration of an mRNA (Pfizer or Moderna) is the preferred vaccine for this dose.

- **Booster Dose #1:**
  - Individual ages 18-years-old and older.
  - May follow the heterologous (or "mix and match" per below under interchangeability) booster dose approach. This allows for those individuals who received the Janssen/Johnson & Johnson vaccination as their primary series to receive any FDA approved and authorized COVID-19 vaccine for this dose.
  - 2 months after the primary Janssen/Johnson & Johnson vaccine.

- **Booster Dose #2:**
  - Individuals ages 18-years-old and older.
  - For those who have received a primary vaccine dose and booster vaccine dose of the Janssen/Johnson & Johnson COVID-19 vaccine product.
  - Administer any approved mRNA vaccine, Pfizer or Moderna, at least 4 months after booster dose of the Janssen/Johnson & Johnson vaccine.
  - See dosing booster dosing details for the mRNA vaccine product that is going to be administered.

Storage and Stability of the J&J Vaccine

- Vials may be held at room temperature for up to 2 hours.

All vaccine must be used (once vial is punctured) within 6 hours.

DOCUMENTATION

The documentation requirements for administration of the COVID-19 Vaccine - for all manufactures are:

- Document the vaccine administration in accordance with DPH clinical documentation standards for vaccines.
- In compliance with the EUA, complete the vaccination card and provide it to the client with a copy of the manufacturer FAQ.
- Report the vaccination administration in DelVAX.

INTERCHANGABILITY OF VACCINE MANUFACTURERS

NOTE: It remains strongly recommended that clients receive vaccines from the same manufacturer. The CDC recommendations now allow for a mix and match of dosing for the booster shot. If there is an availability restriction related to one manufacturer, the nurse may administer the booster dose from an alternative manufacturer. While an individual may prefer or request a vaccine from a different manufacturer, it remains strongly recommended to encourage dosages within the same manufacturer series. Should either situations occur, the nurse may "mix and match" vaccine manufacturers based on the CDC recommendations referenced herein, by providing a booster dose for Pfizer or Moderna, or the second dose of Johnson and Johnson.

SCREENING and CONTRAINDICTIONS

ALGORITHM FOR THE TRIAGE OF PERSONS PRESENTING FOR VACCINE

	PROCEED WITH VACCINATION	USE CAUTION WITH VACCINATION	CONTRAINDICATED
CONDITIONS	**CONDITIONS:** *Immunocompromised conditions *Pregnancy *Lactation **ACTIONS:** *Additional counseling *15-minute observation period	**CONDITIONS:** *Moderate to severe acute illness **ACTIONS:** *Risk assessment *Potential deferral of vaccination *15-minute observation period	**CONDITIONS:** *None **ACTIONS:** *N/A
ALLERGIES	**ALLERGY:** *History of food, pet, insect, venom, environmental, latex etc. allergy **ACTION:** 15-minute observation period	**ALLERGY:** *History of severe allergic reaction (e.g., anaphylaxis) to another vaccine not including the manufacturer's vaccine) *History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication **ACTION:** Risk assessment Potential deferral of vaccine 30-minute observation period	**ALLERGY:** *History of severe allergic reaction (e.g., anaphylaxis) to any component of the COVID-19 vaccine) **ACTION:** Do not vaccinate

Persons Vaccinated Outside the United States

See CDC *Summary Documentation for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized or Approved in the United States*, page 3: https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf

REFERENCES & RESOURCES

(the below references and guidance documents are incorporated by reference herein)

CDC's Healthcare Professional COVID-19 Vaccine Resources:

- https://www.cdc.gov/vaccines/covid-19/index.html
- https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-5yrs-older.pdf
- https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

MODERNA:

- Vaccine Safety & Overview: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html
- CDC Product Information: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html
- FDA Updates: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine
- Fact Sheet for Healthcare Providers Administering Vaccine/Emergency Use Authorization (EUA): https://www.fda.gov/media/144637/download
- CDC Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

PFIZER/BIONTECH:

- Vaccine Safety & Overview: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html
- CDC Product Information: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
- FDA Updates: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine
- Fact Sheet for Healthcare Providers Administering Vaccine/Emergency Use Authorization (EUA): https://www.fda.gov/media/144413/download
- 5 years old to < 12 years old Pfizer-BioNTech Factsheet: https://www.fda.gov/media/153714/download
- 12 years old or older Pfizer-BioNTech Factsheet (dilute vaccine): https://www.fda.gov/media/153713/download
- 12 years old or older Pfizer-BioNTech Factsheet (do not dilute vaccine): https://www.fda.gov/media/153715/download
- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

JANSSEN/J&J:

- Vaccine Safety & Overview: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html

- CDC Product Information:
  https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

- FDA updates:
  https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

- Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States:
  https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Immunocompromised resource/guide:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/immuno.html

Booster information resource:

Eligibility:
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html

Mix and Match information:

https://www.cdc.gov/media/releases/2021/p1021-covid-booster.html

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/04-COVID-Atmar-508.pdf

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/12-COVID-Reddy-508.pdf

COVID-19 Vaccination Administration Error & Deviation Guide:

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-errors-deviations.pdf

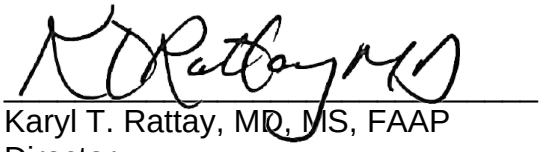
Training Resources:

To obtain further training related to IM injection skill, please refer to the skills in-service via DE TRAIN:

1. Enter: https://www.train.org/detrain/home into your web browser.
2. Log in to your account. If you do not have an account, you will need to follow the instructions on the website to create one.
3. Click on the magnifying glass to search.
4. Enter the corresponding course ID (see above) and click search.
5. Click on the course.
6. Click on Launch.
7. Enter registration code: DPHFLU21.
8. Click on “Launch”. The video should start in a new window.
9. When you complete the first video, close the video window.
10. Compete items #3 through #8 for the next segment.
11. All the handouts we discuss in the video are available in the “Resources” tab on each of the Launch pages.

SIGNATURE PAGE

The preceding procedures and guidelines for the administration of the COVID-19 vaccine are approved for use by the Division of Public Health Registered Nurses, and any other nurses working under the direction of the Division of Public Health, including any qualified personnel designated by the Delaware Emergency Management Agency as permitted by 20 *Del. C.* §3137.



Karyl T. Rattay, MD, MS, FAAP
Director

05/19/2022
Effective Date
(updated: 05/19/2022)