



COVID-19 VACCINE CLINIC PLAYBOOK

REVISED 5/20/2021

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Note: Revised Sections Highlighted

Key Contacts

CLIFTON SPRINGS HOSPITAL: 585-260-5792

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Amy Carey	585-698-5425	Christi Rollo	315-945-0817
Security	Joseph Alampi	315-576-1542	Sabrina Peters	315-759-8417
Pharmacy	William (Bill) Patterson	315-651-5720	Sylvia Manly	585-755-5466
Supply Management	Adam LaBounty	315-830-6585	Amanda Tyler	585-867-1021
Employee Health	Rebecca Goodman	315-462-1560		
Environmental Services	Tiffany Nelson	315-759-4151	Eddie Rodriguez	585-730-0986
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

NEWARK-WAYNE HOSPITAL: 585-260-4275

Department/Role	Primary Contact	Number	Secondary Contact	Number
Clinic Leader	Christi Rollo	315-945-0817	Amy Carey	585-698-5425
Security	Don Wentworth	585-507-1558	Security guard	315-332-2221
Pharmacy	Joan Hurley	315-573-1147	David Verdine	315-332-2205
Supply Management	Amanda Tyler	585-867-1021	David Hammond	315-945-7566
Employee Health	Rebecca Goodman	315-462-1560		
Environmental Services	Deb Sanford	315-945-8834	Maura Snyder	585-259-6211
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

ROCHESTER GENERAL HOSPITAL: 585-771-7358

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Casey Wilbert	315-796-5852	Nick Manning	801-499-9155
Security	Aaron Springer	585-705-5888	Chuck St. John	585-732-1680
Pharmacy	Casey Wilbert	315-796-5852	Nancy Nicoletta	
Supply Management	John Fazio	585-278-3597	Jennifer Sato	585-290-1775
Employee Health	Bonnie Mott	585-922-9098		
Environmental Services	Jamie Seals	585-260-9450	Scott Sleeper	585-732-2659
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

UNITED MEMORIAL MEDICAL CENTER: 585-755-1663

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Shane Nickerson	585-471-4604	Stacey Pastuszynski	585-344-5656
Security	Dave Hetrick	585-727-8185	Brad Hilchey	585-409-6029
Pharmacy	Michael (Mike) Koncilja	585-344-5495	Korey Brauen	585-344-5321
Supply Management	Josh Wallace	585-344-5417	Jennifer Brooks	585-409-9029
Employee Health	Sherry Watkins	585-344-5403		
Environmental Services	Chris Dehaven	716-984-6864	Dave Hetrick	585-727-8185
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

UNITY HOSPITAL: 585-417-0237

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Shaw-Ree Chen	585-481-3795	Evan Tinder	607-743-1318
Security	Paul Donahue	585-683-5961	Paul Staub	585-298-2875
Pharmacy	Robert (Bob) Adams	585-455-2448	Shashi Patel	585-451-5302
Supply Management	Maria Rosario	585-613-6423	Cedria Wright	585-723-7058
Employee Health	Kelly Kuczynski	585-723-7882	Shannon McCarty-Leone	585-363-0491
Environmental Services	Vic Zeno	585-752-3941	Will Smith	585-738-5901
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

Acute Care Clinic Locations

CLIFTON SPRINGS HOSPITAL & CLINICS COVID-19 VACCINE CLINIC

<p>ADDRESS: 2 Coulter Road Clifton Springs, NY 14432 315-462-9571</p>	<p>PARKING: Upon arrival, park in the Coulter road parking lot in front of the main entrance and enter the hospital through the main entrance for screening.</p>	<p>VACCINE CLINIC LOCATION: The clinic is located in the cafeteria. After screening, proceed to the right and take the stairway to the second floor. You will see the clinic on your left. If you prefer the elevator, proceed to the left in the lobby. The elevator is on the left across from the rest rooms. Take the elevator to the second floor, turn right off the elevator, the clinic will be the first hallway to the left.</p>
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NEWARK-WAYNE COMMUNITY HOSPITAL COVID-19 VACCINE CLINIC

<p>ADDRESS: 1200 Driving Park Avenue Newark, NY 315-332-2204</p>	<p>PARKING: Upon arrival, park in the South West lot in front of the main entrance and enter the hospital through the main entrance for screening.</p>	<p>VACCINE CLINIC LOCATION: The clinic is located in the cafeteria. After screening, proceed to the left of the main desk and take the elevator on the right to the basement. Take the hall to your right and the cafeteria is immediately on your left.</p>
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ROCHESTER GENERAL HOSPITAL COVID-19 VACCINE CLINIC

<p>ADDRESS: 1425 Portland Ave Rochester, NY 14621</p>	<p>PARKING: Upon arrival to the hospital, please park in the Portland Ave garage. Valet is available.</p>	<p>VACCINE CLINIC LOCATION: After checking in, continue straight past the staircase, past the grey elevators, to the Atrium on the left side of the hall (Twig Gift Shop). Vaccines will be administered in the Atrium with post administration monitoring next door in the Twig auditorium.</p>
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UNITED MEMORIAL MEDICAL CENTER COVID-19 VACCINE CLINIC

<p>ADDRESS: 127 North St Batavia, NY 14020 585-344-5263</p>	<p>PARKING: Upon arrival, park in the front of the main entrance and enter the hospital through the main entrance for screening.</p>	<p>VACCINE CLINIC LOCATION: The clinic is located in the administrative hallway on the first floor. After screening, proceed to the administrative hallway for registration. You will be vaccinated in the medical staff office. Post vaccination you will be in the boardroom / hallway for observation and then discharged.</p>
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UNITY HOSPITAL COVID-19 VACCINE CLINIC

<p>ADDRESS: 1555 Long Pond Rd Rochester, NY 14626 585-455-2448</p>	<p>PARKING: Upon arrival to the hospital, please park near the main entrance.</p>	<p>VACCINE CLINIC LOCATION: After entering the Hospital from the Main Entrance, follow the signage straight through the main corridor. You will find a waiting area and check in on the right just past the family birth place.</p>
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Clinic Set Up and Flow

Initial Setup

- » Each clinic space should provide a large enough area to provide appropriate social distancing
- » Four distinct areas should be setup: registration, vaccine preparation, vaccine administration and post-administration monitoring
- » Refrigerator to store vaccine will be in place and at temperature prior to clinic start time
- » Place a copy of the COVID-19 Refrigerator Log on the clinic refrigerator
- » Registration will be set up with one table and appropriate forms and documentation
- » There will be socially distanced vaccine administration areas
- » Sharps containers and waste baskets will be provided at administration and preparation areas
- » Supplies will be provided on a rolling cart

Daily Setup

- » All clinic staff to report to clinic at least 30 minutes prior to start time
- » Document refrigerator temperature on log prior to start of clinic (see appendix)
- » Each day pharmacy will bring vaccine, Vaccine Preparation Log, and emergency medication boxes to clinic at least 30 minutes prior to clinic start time and document vaccines placed in the refrigerator on the clinic Vaccine Refrigerator Log
- » The clinic staff will wipe down all surfaces prior to start of clinic
- » All contact areas should be cleaned / disinfected between patients
- » Materials management will ensure all supplies are stocked

Daily Breakdown

- » The clinic staff will wipe down all chairs and tables after last patient has been administered vaccine
- » Pharmacy will return all unused vaccine to central pharmacy and update both the clinic and central pharmacy Vaccine Refrigerator Logs indicating any returns to the central pharmacy
- » Materials management will ensure supplies remain in a secure location at the close of clinic
- » Security will lock clinic location(s)
- » Document refrigerator temperature on log at the end of each clinic

End of Clinic Breakdown

- » Clinic will be returned to original state
- » All trash and sharps will be removed from area(s)
- » Refrigerator will be transported to facility/department of origin
- » Supplies and supply cart will be removed from clinic location
- » Any COVID Vaccine Clinic signage will be removed
- » Emergency medication boxes will be returned to pharmacy

Clinic Supplies

Privacy screens	Future appointment reminder card	COVID-19 vaccine	Supplies
Computers	Tables	Gloves	Hand sanitizer
Cleaning wipes	Bandages	Sharps containers	Trash cans
Face shields	Masks	Vaccine labels	Needles

CLINIC AREAS

Patient Registration

- Table (2)
- Computer
- Vaccine appointment reminder cards
- Hand sanitizer stations
- Consent forms

Vaccine Preparation

- Table
- Reconstitution supplies
- Gloves
- Alcohol/ cleaning supplies

Vaccine Administration

- 5 vaccination areas
- COVID19 vaccine
- Needles
- Table and chair
- Alcohol swabs
- 1 emergency drug box

Post-Administration Monitoring

- Chairs, socially distanced
- Clock
- 1 emergency drug box

CLINIC STAFF

Primary Assignment	Team Member
Registration	Access Associate
Assessment/Monitoring	RN and APP
Vaccine Preparation	Pharmacist
Patient Transport	Access Associate
Vaccine Escort	Security Officer
Supply Replenishment	Materials Management (on call)
Medical Director	Dr. Dieter Afflen (on call)

Detailed Roles and Responsibilities

ACCESS ASSOCIATES + VOLUNTEERS:

- » Register vaccine recipients
- » Provide EUA Fact Sheet & any necessary consent forms
- » Schedule follow-up vaccine appointment
- » Transport

LPN/STUDENT STAFF

- » Administer vaccine

VACCINE ADMINISTRATION:

- » Visually inspect each dose in the dosing syringe before administration.
 - Verify the final dosing volume of 0.3 mL for the Pfizer vaccine
 - Pfizer vaccine - confirm there are no particulates and no discoloration (will be an off-white color normally)
 - Verify the final dosing volume of 0.5 mL for the Moderna vaccine
 - Moderna vaccine will be white to off white suspension
 - Verify the final dosing volume of 0.5 mL for the Janssen vaccine
 - Janssen vaccine is a colorless to slightly yellow, clear to very opalescent suspension
- » Administer intramuscularly into the deltoid muscle
- » **For the Pfizer vaccine** administer a single 30 mcg/0.3 mL dose to patients 12 years and older followed by a second dose 21 days later
- » **For the Moderna vaccine** administer a single 100 mcg/0.5 mL dose to patients 18 years and older followed by a second dose 28 days later
- » **For the Janssen vaccine** administer a single 0.5 mL dose to patients 18 years and older

RN STAFF/APP STAFF

- » Complete patient assessment
- » Administer vaccine
- » Post administration monitoring
- » Review vaccine information sheet
- » Answer questions

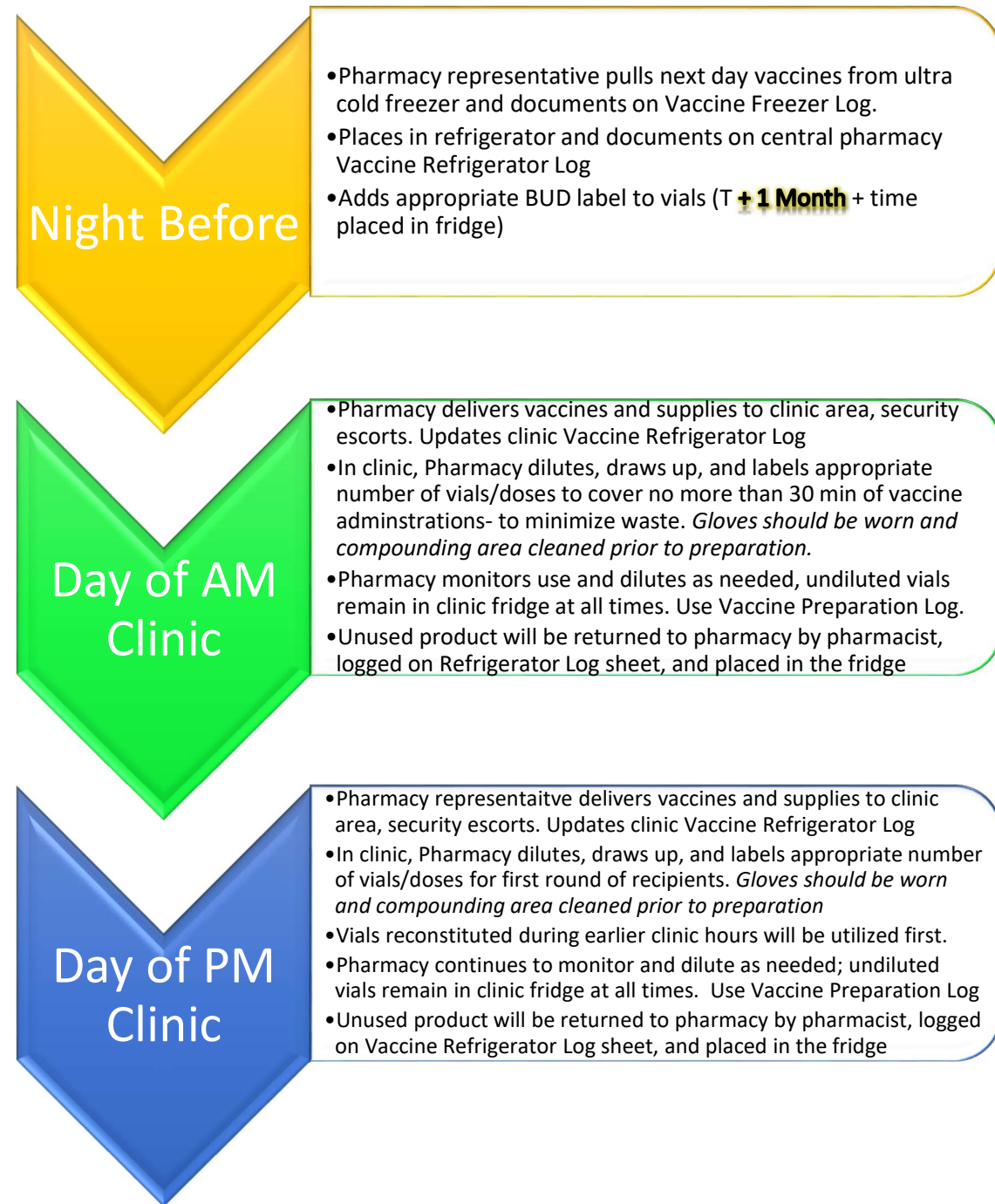
APP STAFF

- » Supervise clinic

PHARMACY STAFF

RRH Pharmacy Department – Pfizer Vaccine Clinic Process Monitor

vaccine scheduling to remove appropriate number of doses from freezer evening prior to clinic. One vial provides up to 6 doses. Security will always accompany transportation of vaccine



Pfizer Vaccine Storage Requirements

Storage Location	Requirements
Freezer	Ultra-Cold (-60° C to -80° C) <ul style="list-style-type: none"> Until the expiry date printed on the label. Up to 15 days in thermal shipper with dry ice replenishment on Day 0, 5, and 10. Please reference Policy S91: Safe Handling of Dry Ice. -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. May then be returned one time to ultra cold storage.
Refrigerator	2° C to 8° C (35° to 46°F) for up to 1 month
Room temperature	2° C to 25°C (35° to 77°F) Up to 6 hours diluted

VACCINE TRANSPORT

Beginning of Clinic

(arrive at least 30 minutes prior to start)

- Pharmacist packs appropriate number of refrigerated vaccines into cooler
- Pharmacist documents on central pharmacy Refrigerator log sheet # of vials removed and transported to clinic
- Loads vaccine onto cart
- Call security to escort to clinic location

End of Clinic

- Pharmacist packs any remaining doses of vaccine into cooler and updates clinic Refrigerator Log Sheet.
- Pharmacist loads remaining supplies and vaccine onto cart
- Call security to escort to central pharmacy
- Pharmacist places vaccines and supplies in designated storage area(s) and documents # of vials returned and wasted on Refrigerator and Preparation Log sheets

Pfizer Vaccine Preparation

Supplies (for each vaccine vial to make 5 or 6 doses, if available in vial)

- 1 vial of *Pfizer BioNTech COVID-19 vaccine*
- 1 vial of diluent (2 mL vial of Preservative Free 0.9% Sodium Chloride Injection, USP)
- 1 diluent syringe/ needle (3mL or 5mL syringe/ 21-25 gauge needle)
- 5 dosing syringes/ needles (1mL syringes and IM injection needles: 22-25 gauge- 1 to 1.5 inches)
- Ancillary supplies: alcohol swabs, bandages, gloves, PPE

Vials

- Remove a thawed vial from the refrigerator and allow it to come to room temperature
- If using a frozen vial, thaw for 30 minutes at room temperature. Do not use before 30 minutes because the rubber stopper inside the vial may still be frozen and may crack with the insertion of a needle.
- Vials at room temperature must be diluted within 2 hours.

Dilution Procedure

- Invert vial gently 10 times to mix- **do NOT shake**
- Cleanse the vial stoppers with an alcohol swab
- Using a 3 mL or 5 mL syringe, withdraw **1.8 mL** from diluent vial - discard any remaining diluent
- Add **1.8 mL** of the diluent into the vaccine vial using a 21-25 gauge needle
- Withdraw **1.8 mL** of air into the empty diluent syringe before removing the needle from the vial to equalize the vial pressure.
- Gently invert the reconstituted vial 10 times to mix – **do NOT shake**
- Record the date and time on the vial label
- Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge). Label with 6 hour expiration time.
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 6 hours after dilution

Managing Pfizer COVID-19 Vaccine Overfill

Effective 12/17/2020, RRH will follow FDA, DOH, and CDC guidance to utilize available overfill to create a 6th Pfizer COVID-19 vaccine dose when available in a single vial. We will not allow combining of overfill from more than one vial to create a 6th dose. No 7th doses will be allowed even if sufficient overfill appears to exist.

PREPARATION:

Thaw a select number of vials based on the assumption that each will yield more than 5 doses. Continue to thaw on demand as needed and store under refrigeration.

Pull from the refrigerator and prepare doses on demand to minimize waste.

Continue to follow manufacturer dilution and expiration dating guidance as outlined in the COVID-19 Clinic Playbook.

Use the COVID-19 Vaccine Preparation log included in the Playbook Appendix to track the number of doses yielded from each vial.

RRH Pharmacy Department – Moderna Vaccine Process

Monitor vaccine scheduling to remove appropriate number of doses from freezer evening prior to clinic. One vial provides 10 doses. Security will always accompany transportation of vaccine

Night Before

- Pharmacy representative pulls next day vaccines from freezer and documents on Vaccine Freezer Log.
- Places in refrigerator and documents on central pharmacy Vaccine Refrigerator Log
- Adds appropriate BUD label to Moderna vials (T + 30 days)

Day of AM Clinic

- Pharmacy delivers vaccines and supplies to clinic area, security escorts. Updates clinic Vaccine Refrigerator Log
- In clinic, Pharmacy draws up, prepares and labels appropriate number of vials/doses to cover no more than 30 min of vaccine administrations- to minimize waste. *Gloves should be worn and compounding area cleaned prior to preparation.*
- Pharmacy monitors use and prepares as needed, unused vials remain in clinic fridge at all times. Use Vaccine Preparation Log.
- Unused product will be returned to pharmacy by pharmacist, logged on Refrigerator Log sheet, and placed in the fridge

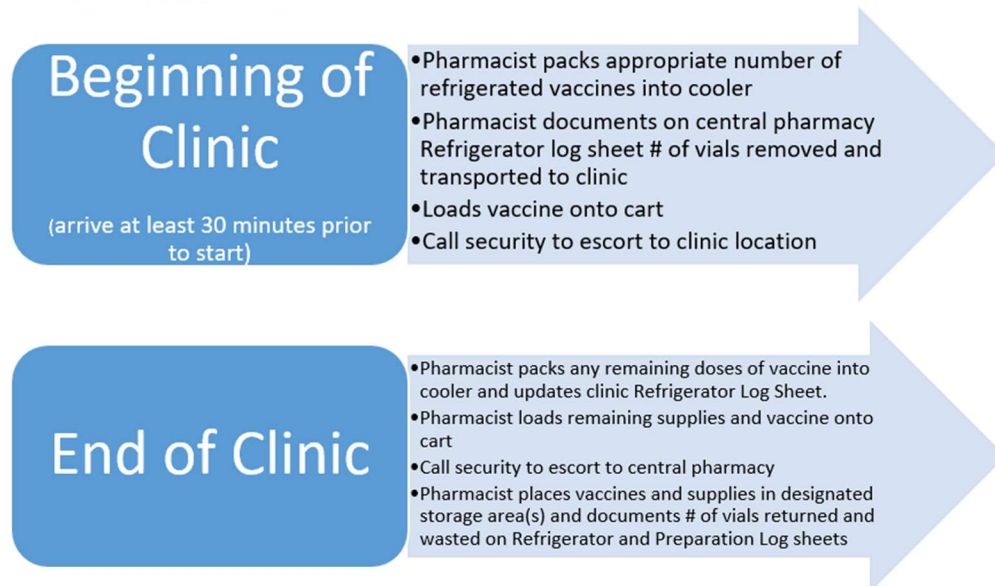
Day of PM Clinic

- Pharmacy representative delivers vaccines and supplies to clinic area, security escorts. Updates clinic Vaccine Refrigerator Log
- In clinic, Pharmacy draws up, prepares and labels appropriate number of vials/doses for first round of recipients. *Gloves should be worn and compounding area cleaned prior to preparation*
- Vials thawed during earlier clinic hours will be utilized first.
- Pharmacy continues to monitor and prepare as needed; unused vials remain in clinic fridge at all times. Use Vaccine Preparation Log
- Unused product will be returned to pharmacy by pharmacist, logged on Vaccine Refrigerator Log sheet, and placed in the fridge

Moderna Vaccine Storage Requirements

Storage Location	Requirements
Freezer	-50° to -15°C (-58° to 5°F). The vaccine must be thawed prior to administration.
Refrigerator	2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
Room temperature	<p>Unopened vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.</p> <ul style="list-style-type: none"> After the first dose has been withdrawn, the vial should be held between 2° to 25°C (36° to 77°F) and discarded after 12 hours.

VACCINE TRANSPORT



Moderna Vaccine Preparation

Supplies

- **2 vial sizes available**
 - **Maximum 11 dose vial – range 10 to 11 doses**
 - **Maximum 15 dose vial – range 13 to 15 doses**
 - NYS assumes these vials will contain 14 doses and will send ancillary kits to support this number
 - If only 13 doses are able to be withdrawn from a maximum 15 dose vial, the 14th dose must be reported as wastage
- 1 vial of Moderna COVID-19 vaccine
- 10 to 15 dosing syringes/ needles (1 mL or 3 mL syringes and IM injection needles: 22-25 gauge 1 to 1.5 inches)
- Ancillary supplies: alcohol swabs, bandages, gloves, PPE

Vials

Vial	Thaw in Refrigerator	Thaw at Room Temperature
Maximum 11-Dose Vial	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
Maximum 15-Dose Vial	Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 3 hours. Let each vial stand at room temperature for 15 minutes before administering.	Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.

- Unopened vials may be stored between 8° to 25°C (46° to 77°F) for a total of 24 hours.
- After the first dose has been withdrawn, the vial should be stored between 2° to 25°C (36° to 77°F) and discarded after 12 hours.

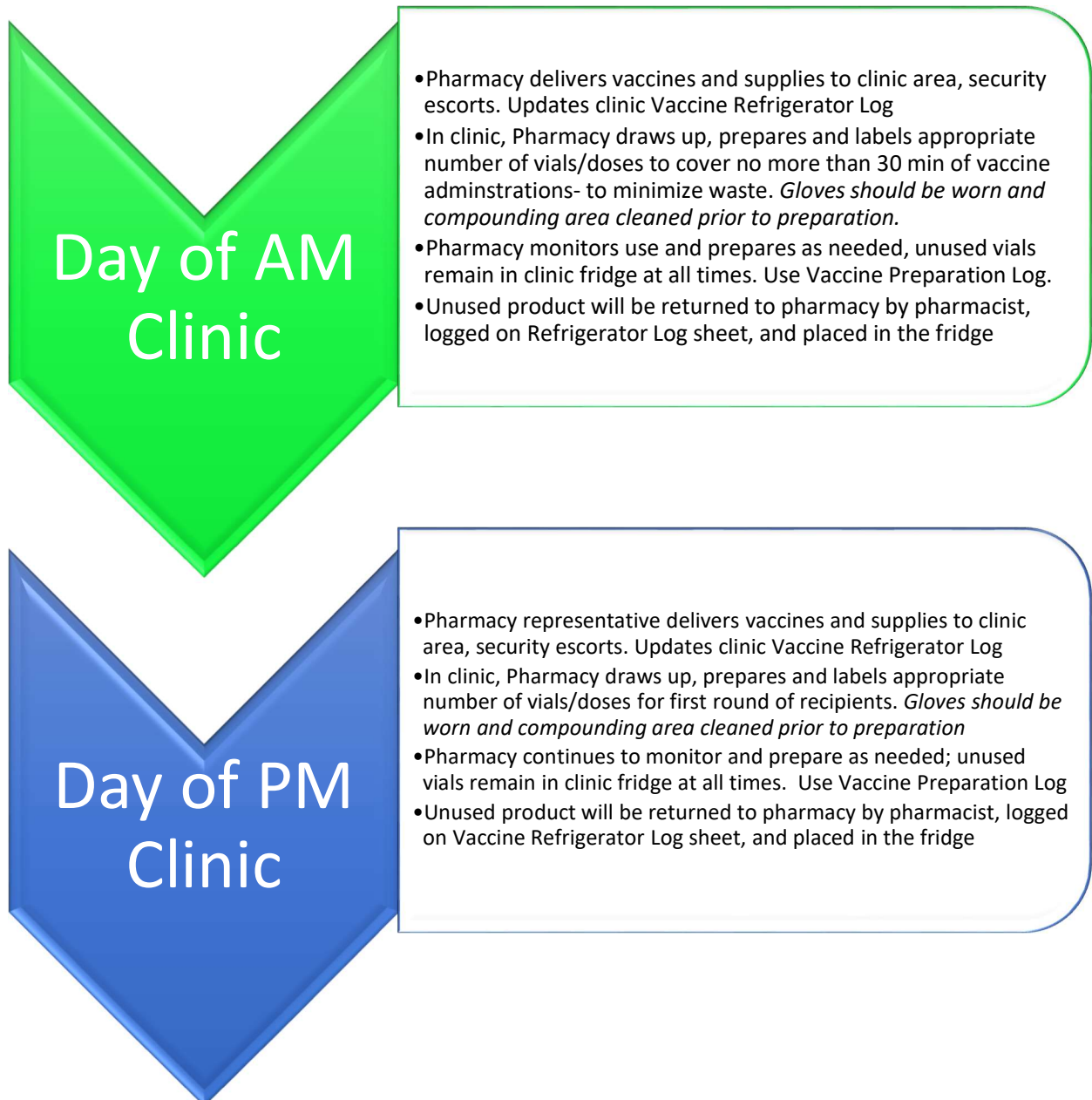
Procedure

- Cleanse the vial stoppers with an alcohol swab
 - Record the date and time on the vial label
 - With the vial upright, gently swirl the vaccine. Do NOT shake. If the vial is shaken, contact the manufacturer.
- Note: Gently swirl the vaccine before withdrawing subsequent doses.

- Draw up 0.5 mL (100 mcg) of the suspension in a 1 mL or 3 mL sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge).
- If only 13 doses are able to be withdrawn from a maximum 15 dose vial, the 14th dose must be reported as wastage
- Label with 6 hour expiration time
- Store between 2°C to 25°C (36°F to 77°F)

RRH Pharmacy Department – Janssen Vaccine Clinic Process (TBD)

One vial provides 5 doses. Security will always accompany transportation of vaccine.



VACCINE TRANSPORT

Beginning of Clinic

(arrive at least 30 minutes prior to start)

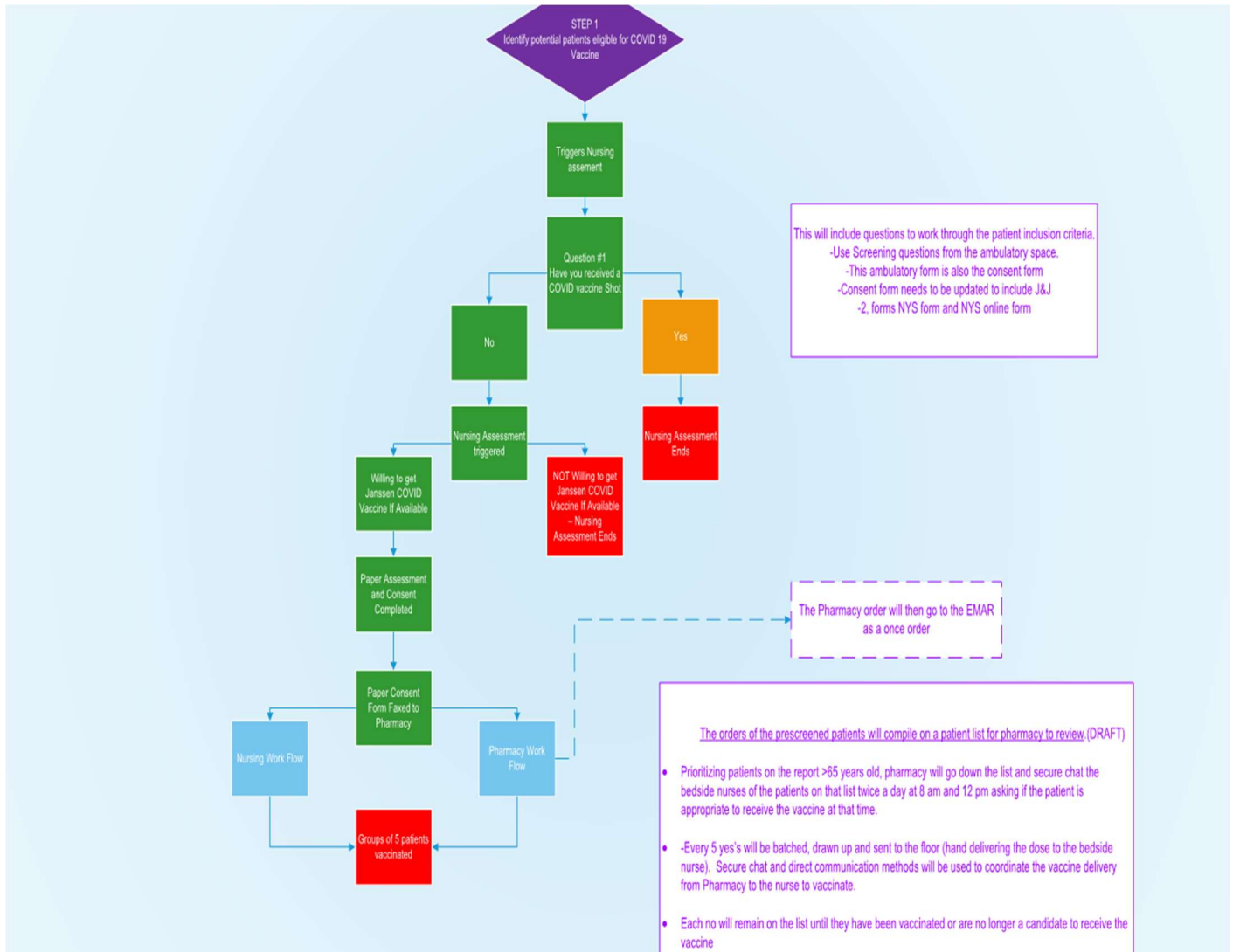
- Pharmacist packs appropriate number of refrigerated vaccines into cooler
- Pharmacist documents on central pharmacy Refrigerator log sheet # of vials removed and transported to clinic
- Loads vaccine onto cart
- Call security to escort to clinic location

End of Clinic

- Pharmacist packs any remaining doses of vaccine into cooler and updates clinic Refrigerator Log Sheet.
- Pharmacist loads remaining supplies and vaccine onto cart
- Call security to escort to central pharmacy
- Pharmacist packs remaining doses and supplies in designated refrigerator and documents # of vials returned and updates Refrigerator Preparation Log sheets

TBD

Affiliate Hospital Inpatient Pharmacy Workflow for COVID-19 Vaccine Screening and Ordering



Janssen Vaccine Storage Requirements

Storage Location	Requirements
Freezer	The vaccine is initially stored frozen by the manufacturer, then shipped at 2° to 8°C (36° to 46°F). If the vaccine is still frozen upon receipt, thaw at 2° to 8° C (36° to 46° F). If needed immediately, thaw at room temperature (maximally 25°C/77° F). A carton of 10 vials will take approximately 2 hours to thaw, and an individual vial will take approximately 1 hour to thaw. Do not refreeze once thawed.
Refrigerator - Unpunctured vials	2° to 8° C (36° to 46° F) and protect from light. Do not freeze.
Room temperature	Unpunctured vials may be stored between 9° to 25°C (47° to 77°F) for up to 12 hours. <ul style="list-style-type: none"> • After the first dose has been withdrawn, the vial should be held between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature for (maximally 25° C/77° F) for up to 2 hours.

Janssen will provide access to the vaccine expiration date via the following website. Enter the lot number found on the product carton or vial to obtain its expiration date.

Janssen will also provide vaccine stability data for temperature excursions at the same website.

[Janssen COVID-19 Vaccine Product Quality Checker \(vaxcheck.jnj\)](https://www.janssen.com/vaxcheck)

Janssen Vaccine Preparation

Supplies

(For each vaccine vial to make 5 doses)

- 1 vial of Janssen COVID-19 vaccine
- 5 dosing syringes/ needles (1 mL or 3 mL syringes and IM injection needles: 23 -25 gauge 1 to 1.5 inches)
- Ancillary supplies: alcohol swabs, bandages, gloves, PPE

Vials

- Unpunctured vials are stored at refrigerated temperatures between 2° to 8°C (36° to 46°F).
- After the first dose has been withdrawn, store the vial between 2° to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.
- Discard vaccine if not used within these times.

Procedure

- Record the date and time on the vial label
- Cleanse the vial stoppers with an alcohol swab
- Visually inspect the Janssen COVID-19 Vaccine vials for particulate matter and discoloration prior to administration.
- If either of these conditions exists, do not administer the vaccine
- With the vial upright, gently swirl the vaccine for 10 seconds. Do NOT shake. If the vial is shaken contact the manufacturer.
Note: Gently swirl the vaccine before withdrawing subsequent doses.
- Draw up 0.5 mL of the suspension in a 1 mL or 3 mL sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge).
- Label with 6 hour expiration time of first vial puncture & store under refrigeration (36° to 46°) or label with a 2 hour expiration time from first vial puncture and store at room temperature up to 77°F.

Vaccine Tracking

Vaccine primary coordinators will utilize the Vaccine Freezer, Refrigerator, and Preparation logs included in the appendix to track all COVID-19 vaccine doses thawed, dispensed, prepared, and returned to the primary storage location. In addition, vaccine primary coordinators will be responsible for tracking the number of individuals vaccinated daily and the number of individuals scheduled to receive vaccine the next day. This information should remain readily available as state agency representatives may request these details at any time.

Post Administration Monitoring/Adverse Event Reporting

- » Recommend 15 minute monitoring
- » In case of emergency: please utilize emergency medication box and follow local emergency response protocol (see appendix)
 - » **Adverse reactions should be entered into SafeConnect and also reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be filed at <https://vaers.hhs.gov/> or by calling 1-800-822-7967**
 - » Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report the following to VAERS:
 - » Vaccine administration errors (whether associated with an AE or not),
 - » Serious AEs (even if they are not sure if the vaccination caused the event)
 - » Multisystem inflammatory syndrome (MIS) in children or adults, and
 - » Cases of COVID-19 that result in hospitalization or death to VAERS.
 - » They are also required to report to VAERS any additional AEs and/or adhere to any revised safety reporting requirements per FDA's conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA, as applicable.
 - » Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure if the vaccination caused the event.

Managing Downtime Procedures

- » If loss of power: return vaccine to central pharmacy to be stored under refrigeration
- » If EMR goes down: move to paper forms
- » Document all downtime administrations in EMR once it becomes available

Managing Declinations, No Show's, & Extra Prepared Vaccine

- » Clinic leaders and clinic pharmacy teams will work closely to ensure limited doses of vaccine are prepared in advance to minimize waste.
- » Recognizing that some candidates may decline the vaccine or not be eligible after the dose has already been prepared, the clinic lead will work with their local SLT member to identify on call/ standby team members to receive the vaccine prior to expiration.
- » Clinic leaders should escalate all questions and concerns to Margie Lim-Morison and Emily O'Banion as needed.

Partner Hospital Clinic Process

RRH STAFF:

RRH security, pharmacy, and registration support will be available for each partner hospital vaccine clinic held at an RRH facility. Security will allow access to and monitor the clinic venue, pharmacy will transport vaccine to the clinic location, materials management will provide supplies, and registration support will be available to assist with scheduling second doses.

VACCINE ALLOCATION:

The state has partnered select hospitals across the state to share certain allocations of the Pfizer COVID-19 vaccine. These dose allocations are based on the FDA EUA-approval with labeling of 5 doses contained in each vial.

When pharmacy prepares the partner hospital's dose allocation, the pharmacy must use a 5 dose per vial assumption when allocating vials. ***This applies to RRH partner hospitals as well.*** This guidance is based on directive from RRH legal who is aware of the recent advice from the NYSDOH, FDA, and Pfizer to use vial overfill to obtain 6 doses per vial.

PARTIAL VIAL ALLOCATION:

For partial vial allocations, the RRH allocation will be administered to RRH employees at the beginning of the partner clinic. For example, if a partner clinic is allocated 2 doses out of 1 vial, 3 RRH on call/ standby employees will be vaccinated and the remaining 2 doses will be left for the partner clinic. This will be managed locally by the clinic leader, employee health, pharmacy, and Senior Leadership Team (SLT) member.

VIAL PREPARATION FOR PARTNER CLINICS:

Partner clinics will provide the number of scheduled vaccinations to the RRH hospital pharmacy leadership no later than 3pm the day before the clinic.

Thaw enough vials to meet the partner hospital dose allocation based on the assumption that each vial will yield ***only 5 doses***. Document on the Vaccine Freezer and central pharmacy Vaccine Refrigerator Logs.

1 hour before the scheduled partner clinic, pharmacy will transport the partner hospital vial allocation, emergency drug boxes, and Vaccine Preparation Logs to the clinic site with security escort. Vials will be placed in the clinic refrigerator and the clinic Vaccine Refrigerator Log will be updated and signed. Materials Management will provide supplies.

Partner hospital is responsible for bringing their own PPE, sharps containers, cleaning supplies, and extra supplies (i.e. syringes, etc) that exceed what was provided by McKesson.

The partner clinic will prepare and administer vaccine to their team members.

TRACKING & REPORTING:

NYSIIS Reporting

Partner clinics must complete the COVID-19 Vaccine log included in the Playbook Appendix to track the patient vaccination information.

HERDS Reporting

At the end of the clinic, Partner Clinic Leaders shall provide to the RRH registration associate the COVID-19 Vaccine log which includes the patient vaccination information, the total number of doses administered and vials used.

This information will be passed on to the RRH pharmacy leaders and Dorothy Day. Dorothy Day will complete the NYSIIS upload process.

CLOSING PARTNER CLINIC:

Once the partner's dose allocation is reached and the clinic is over, the partner clinic lead is to notify the security officer to initiate clinic closure. Security will contact central pharmacies at Rochester General Hospital (585-922-4481) and Unity Hospital (585-723-7330) and the nursing supervisor at Newark-Wayne Hospital (315-945-8903) to retrieve any leftover vaccine and to secure supplies.

RRH will manage the partner clinic waste.

If there is leftover diluted vaccine available, the partner hospital is required to document this as waste on the Preparation Log. If there are refrigerated vials remaining, these should be removed from the clinical refrigerator (logged on the clinical Refrigerator Vaccine Log), returned to pharmacy under security escort, placed in the refrigerator, and central pharmacy Refrigerator Log updated.

Appendices

- Vaccine Screening Questions
- Emergency Use Authorization (EUA) Patient Fact Sheets
- Emergency Use Authorization (EUA) Provider Fact Sheets
- RRH COVID-19 Vaccine Consent Form
- CareConnect Knowledge Builder: Ambulatory COVID-19 Vaccination Administration
- Health Care Worker Post Vaccine Management Plan
- Pfizer BioNTech COVID-19 Vaccine Fast Facts
- Moderna COVID-19 Vaccine Fast Facts
- Janssen COVID-19 Vaccine Fast Facts
- Vaccine Comparison
- Emergency Drug Box Contents
- Medical Management of COVID-19 Vaccine Reactions in Adults
- Safe Handling of Dry Ice Policy & Attestation
- Temperature logs
- Vaccine Freezer, Refrigerator, and Preparation Logs
- Clinic Signage & Marketing Materials
- Quick Reference Guide for Comparing General Information, Storage and Handling Information, and Vaccine Administration Information
- Handling Vaccine Administration Errors and Deviations
- Interim Clinical Considerations Summary

Vaccine Clinic Screening Questions

12.15.20 V4

- **RRH QUESTION: Have you been diagnosed with COVID-19 infection in the last 90-days?**
 - **YES** → defer vaccination until 90days from last (+) test.
 - **NO** → proceed with remaining risk assessment.

New York State Department of Health Consent Form Questions: Guidance

- **Are you feeling sick today?**
 - **YES** → refer to vaccination site healthcare provider for assessment of current health status.
 - If patient is feeling moderately or severely ill, **do not vaccinate** at this time and ask the patient to return when symptoms improve.
- **In the last 10 days, have you had a COVID-19 test or been told by a healthcare provider or health department to isolate or quarantine at home due to COVID-19 infection or exposure?**
 - **YES** → return to isolation/quarantine, and reschedule for after isolation or quarantine ends
 - If patient was diagnosed with COVID-19 greater than 10 days ago and has been asymptomatic for 24 hours or more, patient may be vaccinated. *** Refer to RRH Question above, defer for 90 days form positive test. ***
 - If the patient has had a test in the last 10 days, ask the result. If positive send them home, if negative they can proceed to vaccination. If the result is unsure or unknown advise the patient to return once a negative test has been confirmed or 10 days have passed since a positive test.
- **Have you been treated with antibody therapy for COVID-19 in the past 90 days (3 months)?**
 - **If YES, when did you receive the last dose?**
 - **Last Dose within 90-days:** **defer** vaccination and reschedule after least 90-days from last dose of treatment to avoid interference of treatment with vaccine-induced immune responses.
 - **Last dose more than 90-days:** **proceed** with vaccination
- **Have you ever had a serious or life-threatening allergic reaction, such as hives or difficulty breathing, to any vaccine or shot?**
 - **If YES – refer to the vaccination site healthcare provider for assessment of allergic reaction.**
 - **COUNSEL PATIENT, patient may choose to proceed with vaccination**
 - Choice to defer or decline vaccine at this time

- 30 minute observation if patient chooses to proceed with vaccination
 - *** A severe allergy to a component of the Pfizer-BioNTech vaccine is a contraindication to receiving vaccine.**
- **Have you had any vaccines in the past 14 days (2 weeks) including flu shot?**
 - **If YES, how long ago was your most recent vaccine?**
 - **Do not vaccinate** with COVID-19 vaccine and reschedule for 14 days after most recent vaccine.
 - **COUNSEL PATIENT:** avoid getting another vaccine for 14 days before or after any COVID-19 vaccine doses.
- **Are you pregnant or considering becoming pregnant?**
 - **YES then COUNSEL PATIENT** to talk with her healthcare provider before vaccination.
 - If a woman is part of a group (ex. HCP) who is recommended to get vaccine and is pregnant, **she may choose to be vaccinated after discussing with her healthcare provider.**
 - Considerations:
 - Level of COVID-19 community transmission risk
 - her personal risk of getting COVID-19 due to occupation or other activities
 - Risks of COVID-19 to her and potential risks to the fetus
 - The efficacy of the vaccine
 - The known side effects of the vaccine
 - The lack of data about the vaccine during pregnancy
 - Pregnant women with fever after vaccination should take acetaminophen as fever has been associated with adverse pregnancy outcomes.
 - Routine testing for pregnancy prior to getting COVID-19 vaccine is not recommended.
- **RRH: If a woman is lactating or breastfeeding and is part of a group (ex. Healthcare personnel) she may choose to be vaccinated. There are no data on safety of COVID-19 vaccine in lactating women or effects of mRNA vaccine on breastfed infant or milk production/excretion. mRNA vaccines are not considered live vaccines and are not thought to be risk to breastfeeding infant.**
- **Do you have cancer, leukemia, HIV/AIDS, a history of autoimmune disease or any other condition that weakens the immune system?**
 - **YES then refer to the healthcare provider onsite or the patient's healthcare provider for additional counseling.**
 - **Patient may choose to proceed with vaccination.**
 - **COUNSEL PATIENT, that if they are immunocompromised or are on a medicine that affects their immune system, they may have a less strong immune response to the vaccine but may still get vaccinated.**
 - Vaccine safety and efficacy profiles in this population is unknown in this population of patients.
 - There is a potential for reduce immune responses
 - Patients need to continue to follow all current guidance to protect themselves against COVID-19

- **Do you take any medications that affect your immune system, such as cortisone, prednisone or other steroids, anticancer drugs, or have you had any radiation treatments?**
 - **YES then refer patient for counseling.**
 - **COUNSEL PATIENT, patient may choose to proceed with vaccination**
 - Patient may have less strong response to the vaccine but may still choose to be vaccinated.
 - Vaccine safety and efficacy profiles in this population is unknown in this population of patients.
 - There is a potential for reduce immune responses
 - Patients need to continue to follow all current guidance to protect themselves against COVID-19
 - **NO**
 - Proceed with vaccination

Pfizer Vaccine Ingredients:

- This vaccine contains polyethylene glycol/macrogol (PEG) as part of ALC-0159. ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride, disodium hydrogen phosphate dihydrate, sucrose, water for injections

Moderna Vaccine Ingredients:

- This vaccine contains a synthetic messenger ribonucleic acid (mRNA) encoding the pre-fusion stabilized spike glycoprotein (S) of SARS-CoV-2 virus. The vaccine also contains the following ingredients: lipids (SM-102, 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

Janssen Vaccine Ingredients:

- Each 0.5 mL dose of Janssen COVID-19 Vaccine is formulated to contain 5×10^{10} virus particles (VP) and the following inactive ingredients: citric acid monohydrate (0.14 mg), trisodium citrate dihydrate (2.02 mg), ethanol (2.04 mg), 2-hydroxypropyl- β -cyclodextrin (HBCD) (25.50 mg), polysorbate-80 (0.16 mg), sodium chloride (2.19 mg). Each dose may also contain residual amounts of host cell proteins (≤ 0.15 mcg) and/or host cell DNA (≤ 3 ng).

References:

- CDC and Pfizer Webinar 12.13.20: What Clinicians Need to Know about the COVID-19 Vaccine
- NYSDOH December 2020: Information for Healthcare Professionals about the Screening Checklist for the COVID-19 Vaccine
- Moderna COVID vaccine FDA Briefing Document
- Janssen COVID-19 FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE

Insert Copy of EUA Patient Fact Sheet Here

Insert Copy of EUA Provider Fact Sheet Here

Insert Copy of Consent Form Here

Insert CareConnect Knowledge Builder: Ambulatory COVID-19 Vaccination Administration

Insert COVID 19 Vaccination HCW Post-Vaccination Management Plan

Pfizer BioNTech COVID-19 Vaccine Fast Facts

Vaccine Packaging

- 2 mL type 1 glass vial (preservative-free)
- MDV has 0.45 mL frozen liquid drug product
- Five doses per vial after dilution
- Single tray (box it is delivered in)
 - Holds 195 vials; 975 doses per tray (each vial has five doses)
 - A smaller tray contains 25 vials (125 doses)
 - Weights close to 75 pounds with dry ice and packaging
 - Has a GPS enabled temperature monitoring device which will be enabled upon shipment
 - Should be disabled by pressing the stop button when received and unpackaged



Vaccine handling

- Vials must be taken out of the package and transferred to a ULT freezer within five minutes to prevent premature product thawing.
- Store as a frozen liquid at -75 Celsius
- Can be stored 2 to 8 Celsius for up to **1 month**
- Can be stored no more than two hours at room temperature
- Post-dilution in use period is six hours.

Vaccine Dosing

- Must be diluted with 0.9% Preservative Free Sodium Chloride Injection (normal saline) before use.
- After dilution with 1.8 mL of normal saline, the vial contains sufficient volume to deliver five 30 mcg doses in 0.3 mL injections; after dilution, the concentration is 0.1 mg/mL
- Schedule: two 30 mcg doses given 21 days apart (can be stretched to 19 -23 days)

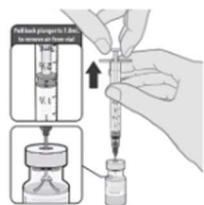
Vaccine

Point of Use

- THAW
 - Remove vial for every five recipients
 - Vials must be stored in a refrigerator for up to **1 month**

○ DILUTE

- Use 0.9% Sodium Chloride Injection, USP for use as a diluent.
- Dilute the thawed vial by adding 1.8 mL of 0.9% Sodium Chloride Injection into the vial.



- Ensure the vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.
- Diluted vials must be used within six hours from the time of dilution and stored between 35 degrees F to 77 degrees F

○ PREPARE

- Gently invert the vial ten times to mix; DO NOT SHAKE.
- Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge).
 - For each additional dose, use a new sterile syringe and needle; ensure the vial stopper is cleansed with antiseptic before each withdrawal.



○ ADMINISTER

- Visually inspect each dose in the dosing syringe before administration.
 - Verify the final dosing volume of 0.3 mL
 - Confirm there are no particulates and no discoloration (will be an off-white color normally)
- Administer intramuscularly into the deltoid muscle
- Administer a single 30 mcg/0.3 mL dose followed by a second dose 21 days later.
 - The second dose must be the same vaccine; Pfizer BioNTech COVID-19 vaccine is not interchangeable with other COVID-19 vaccines.

Vaccine Cost

- Per the NYSDOH, providers are required to administer the COVID-19 vaccine to individuals regardless of insurance or ability to pay.
- Providers may not bill for the cost of the vaccine but can bill the individual's health insurance for an administration fee.

- Providers vaccinating individuals with no health insurance or insurance that does not cover the administration fee can request reimbursement for the administration of the COVID-19 through the [Provider Relief Fund](#).

Moderna COVID-19 Vaccine Fast Facts

Vaccine Packaging

- 5 mL type 1 glass vial (preservative-free)
- Ten to fifteen doses per vial, dependent on size
- Each shipping box contains 10 multidose vials (140 doses)
- Each shipping box has a temperature monitoring device that needs to be checked and disabled upon arrival.

Vaccine handling

- Vials can be stored frozen -50°C to -15°C (-58° to 5°F) for up to 6 months. Store in original carton to protect from light.
- Can be stored 2° to 8° C (36° to 46° F) for up to thirty days
- Unpunctured vials can be stored no more than twenty four hours at room temperature after thawed
- After first dose is withdrawn discard vial in twelve hours.

Vaccine Dosing

- 0.5 mL/100 mcg dose
- Two vial sizes
 - Maximum 11 dose vial
 - Maximum 15 dose vial
- Schedule: two 100 mcg doses given 28 days apart

Vaccine Point of Use

- THAW
 - Remove vial for every 10 recipients
 - Vials must be stored in a refrigerator for up to 30 days
 - Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes for maximum 11 dose vial. For maximum 15 dose vial thaw refrigerated 2° to 8°C (36° to 46°F) for 3 hours.
 - After thawing, let vial stand at room temperature for 15 minutes before administering

- Alternatively, thaw maximum 11 dose vial at room temperature between 15° to 25°C (59° to 77°F) for 1 hour and maximum 15 dose vial at room temperature 15° to 25°C (59° to 77°F) for 1 hour and 30 minutes.
 - Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 24 hours. Do not refreeze.
 - PREPARE
 - Swirl vial gently after thawing and between each withdrawal. **Do not shake.** Do not dilute the vaccine.
 - Draw up 0.5 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge).
 - For each additional dose, use a new sterile syringe and needed; ensure the vial stopper is cleansed with antiseptic before each withdrawal.
 - ADMINISTER
 - Visually inspect each dose in the dosing syringe before administration.
 - Verify the final dosing volume of 0.5 mL
 - Confirm white to off white suspension which may contain white to translucent product related particulates
 - Administer intramuscularly into the deltoid muscle
 - Administer a single 100 mcg/0.5 mL dose followed by a second dose 28 days later.
 - The second dose must be the same vaccine; Moderna COVID-19 vaccine is not interchangeable with other COVID-19 vaccines.

Vaccine Cost

- Per the NYSDOH, providers are required to administer the COVID-19 vaccine to individuals regardless of insurance or ability to pay.
- Providers may not bill for the cost of the vaccine but can bill the individual's health insurance for an administration fee.
- Providers vaccinating individuals with no health insurance or insurance that does not cover the administration fee can request reimbursement for the administration of the COVID-19 through the [Provider Relief Fund](#).

Janssen COVID-19 Vaccine Fast Facts

Vaccine Packaging

- 2.5 mL vial (preservative-free)
- Five doses per vial
- Each box contains 10 multiple dose vials (50 doses)

Vaccine handling

- Vials can be stored refrigerated 2° to 8° C (36° to 46° F). Store in original carton to protect from light.
- Unpunctured vials can be stored between 9°C to 25°C (47° to 77°F) for up to 12 hours.
- After the first dose is withdrawn, hold the vial between 2°C to 8°C (36° to 46°F) for up to 6 hours or at room temperature (maximally 25°C/77°F) for up to 2 hours.

Vaccine Dosing

- 0.5 mL
- Vial contains 5 doses
- Schedule: one dose

Vaccine Point of Use

- Refrigerate:
 - Remove vial for every 5 recipients
 - Vials must be stored in a refrigerator
- Unpunctured vials may be stored between 9° to 25°C (47° to 77°F) for up to 12 hours. Do not refreeze.
- PREPARE
 - Swirl vial for 10 seconds gently before first withdrawal and before each subsequent withdrawal. **Do not shake.**
 - Draw up 0.5 mL of the suspension into a new sterile dosing syringe with a needle appropriate for intramuscular injection (23 to 25 gauge).

- For each additional dose, use a new sterile syringe and needle; ensure the vial stopper is cleansed with alcohol before each withdrawal.
- ADMINISTER
 - Visually inspect each dose in the dosing syringe before administration.
 - Verify the final dosing volume of 0.5 mL
 - Confirm the vaccine is colorless to slightly yellow, clear to very opalescent suspension.
 - Administer intramuscularly into the deltoid muscle
 - Administer a single 0.5 mL dose

Vaccine Cost

- Per the NYSDOH, providers are required to administer the COVID-19 vaccine to individuals regardless of insurance or ability to pay.
- Providers may not bill for the cost of the vaccine but can bill the individual's health insurance for an administration fee.
- Providers vaccinating individuals with no health insurance or insurance that does not cover the administration fee can request reimbursement for the administration of the COVID-19 through the [Provider Relief Fund](#).

Vaccine Comparison

Per NYSDOH and Janssen/Johnson & Johnson and respective EUAs:

	Janssen vaccine	Pfizer vaccine	Moderna vaccine
Minimum order	20 vials = 100 doses	195 vials = 975 doses (1 tray = approximately 9 in X 9 in X 2 in)	10 vials = 140 doses (1 carton)
Freezer storage	N/A	Ultra-Cold (-60° C to 80° C) <ul style="list-style-type: none"> Up to expiry date printed on label Up to 15 days in thermal shipper with dry ice replenishment -25°C to -15°C for up to two weeks. May then be returned to ultra cold storage one time. 	Frozen (-25° C to -20° C) <ul style="list-style-type: none"> Up to 6 months in a freezer
Refrigerator storage	2° C to 8° C	2° C to 8° C for up to 1 month	2° C to 8° C for up to 30 days
Room temperature	Up to 12 hours – if not punctured	Up to 6 hours – if diluted	Up to 12 hours – if not punctured
Reconstitution required	No	Yes	No
Route of administration	Intramuscular	Intramuscular	Intramuscular
The minimum interval between doses	N/A	21 days	28 days
Patient Age Indication	18 years and older	12 years and older	18 and older

RRH Emergency Drug Boxes

Emergency Box Contents

MEDICATIONS	SUPPLIES
Epinephrine 1:1,000 (1mg/mL) 1mL vials (4) <i>(IM injection only)</i>	Syringes 1 mL tuberculin syringes (4)
Diphenhydramine liquid 25mg/10 mL unit dose cups (2)	Needles: <ul style="list-style-type: none">• 22 gauge, 1 inch (4)• 22 gauge , 1 ½ inch SafetyGlide (4)
Diphenhydramine 25 mg capsules (2)	Alcohol Prep pads (6)
	Ice pack (1)

ROCHESTER REGIONAL HEALTH

4



Reminder: the box contains medications, syringes and needles. It will need to be stored in a locked area when not in use.

Medical Management of COVID 19 Vaccine Reactions in Adult Patients

Purpose

To provide registered nurses independent directions and guidelines in the management of COVID-19 vaccine reactions in adult patients.

Performed by

Registered nurses following a non-patient specific order for the medical management of COVID-19 vaccine reactions in adult patients.

Background

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 vaccines are administered. Vaccine reactions are classified as local, systemic or allergic. If reactions occur, staff should be prepared with procedures for their management.

Signs and symptoms of *anaphylactic reaction* are the sudden or gradual onset of generalized:

- itching, erythema (redness)
- urticarial (hives)
- angioedema (swelling) of the lips, face or throat)
- bronchospasm (wheezing)
- shortness of breath
- shock
- abdominal cramping and /or diarrhea
- cardiovascular collapse

REACTION	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 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.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	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 the patient 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	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults

1. If itching and swelling are confined to the injection site where the vaccine was given, observe closely for the development of generalized symptoms. Apply ice pack (cold compress) to injection site.
2. If symptoms are generalized, call 911 and notify the physician. This should be done by a second person when possible, while the primary healthcare professional evaluates and manages the patient.
3. **First line treatment:** Use epinephrine in an aqueous solution (1:1000 dilution). For patients weighing more than 30kg, **administer a 0.3 mg dose IM in the mid-outer thigh.**

4. **Optional treatment for hives and itching ONLY.** *These medications DO NOT relieve upper or lower airway obstruction, hypotension, or shock.* For patients weighing more than 40kg, administer diphenhydramine 50 mg orally.
5. Monitor the patient closely until EMS arrives. If necessary, perform basic life support (BLS).
6. If EMS has not arrived and symptoms are still present, repeat doses of epinephrine every 5 to 15 minutes for up to 3 doses, depending on the patients response.
- 7.
8. Record the patient's reaction to the vaccine, all vital signs, and medications administered to the patient (including dose, time, response and name of personal who administered it).
9. Notify the patient's primary care physician.
10. Report the incident to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

References

Immunization Action Coalition: Managing Vaccine Reactions

<https://www.immunize.org/handouts/vaccine-reactions.asp>

Medication management of vaccine reactions in adult patients

https://www.health.ny.gov/prevention/immunization/providers/docs/management_of_vaccine_reactions_in_adults.pdf

Vaccine Recommendations and Guidelines of the ACIP

[https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html#:~:text=Local%20reactions%20\(e.g.%2C%20redness\),are%20the%20least%20frequent%20reactions.](https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html#:~:text=Local%20reactions%20(e.g.%2C%20redness),are%20the%20least%20frequent%20reactions.)

Insert Copy of Policy: Safe Handling of Dry Ice & Attestation

Insert Vaccine Freezer Log

Insert Vaccine Refrigerator Log

Insert Vaccine Preparation Log

Insert Quick Reference Guide for Comparing General Information, Storage and Handling Information, and Vaccine Administration Information

Insert Handling Vaccine Administration Errors and Deviations

Insert Interim Clinical Considerations Summary