



**Department
of Health**

COVID-19 Vaccine

What Hospitals Need to Know

12/10/20 – point-in-time document, subject to change

Howard Zucker, MD, JD

Commissioner of Health

New York State Department of Health



**Department
of Health**

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Welcome & Overview

Overview of Pfizer/BioNTech and Moderna COVID-19 Vaccines

Elizabeth Dufort, MD, FAAP

Medical Director, Division of Epidemiology
New York State Department of Health

Outline

- Pfizer/BioNTech COVID-19 vaccine overview
- Moderna COVID-19 vaccine overview
- Advisory Committee on Immunization Practices (ACIP) recommendations on COVID-19 phase 1a prioritization
- Timeline of COVID-19 vaccine approval and recommendations

Pfizer/BioNTech COVID-19 Vaccine Overview

- Vaccine candidate: BNT162b2
- Messenger RNA (mRNA) vaccine encoding the SARS-CoV-2 spike protein
- Two-dose series (30 µg dose), with 21 days between doses
- Vaccine needs to be stored at “ultra low” temperatures of -70°C (-94°F)
 - Will ship in specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain temperature conditions of -70°C±10°C
 - These shippers can be used as temporary storage units for up to 15 days by refilling with dry ice within 24 hours of receipt and every 5 days thereafter
 - Stable in refrigerator at 2-8°C (36-46°F) for up to 5 days; may not return to ultra low temperature after thawing

Pfizer/BioNTech COVID-19 Vaccine Efficacy

- Vaccine efficacy rate was **95%** ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective).
 - Based on 170 cases of COVID-19: 162 cases in placebo group vs. 8 cases in vaccine group.
 - Cases measured from 7 days after the second dose.
- Vaccine efficacy rate was 95% in participants with and without prior SARS-CoV-2 infection (second primary objective).
- Observed efficacy in adults >65 years of age was over 94%.
- Efficacy was consistent across age, gender, race, and ethnicity.
- There were 10 severe cases of COVID-19: 9 cases in placebo group and 1 case in the vaccine group.

<https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-conclude-phase-3-study-covid-19-vaccine>

Pfizer/BioNTech COVID-19 Vaccine Safety

- To date, no serious safety concerns observed
- The most common severe adverse events in the Phase 3 trial were:
 - Fatigue (3.8%)
 - Headache (2.0%)
- Most adverse events were mild to moderate and resolved in 1-2 days
- Older adults tended to report fewer and milder solicited adverse events
- Local and systemic adverse events reported in Phase 1 study:

		After Dose 1		After Dose 2	
		18-55 yo	65-85 yo	18-55 yo	65-85 yo
Local Reactions	Pain	92%	75%	83%	67%
	Redness	8%	0%	0%	0%
	Swelling	0%	0%	0%	0%
Systemic Events	Fever	17%	0%	17%	8%
	Chills	33%	0%	58%	17%
	Fatigue	42%	25%	75%	42%

Pfizer/BioNTech COVID-19 Vaccine Current Status

- The companies submitted a request for Emergency Use Authorization (EUA) to the FDA on 11/20/2020 and are submitting to other regulatory agencies around the globe
- FDA will hold a public meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) on 12/10/2020 to discuss Pfizer and BioNTech's request for EUA
- Pfizer and BioNTech expect to produce globally up to 50 million vaccine doses in 2020 and up to 1.3 billion doses by the end of 2021

Moderna COVID-19 Vaccine Overview

- Vaccine candidate: mRNA-1273
- mRNA vaccine encoding the SARS-CoV-2 spike protein, similar to the Pfizer/BioNTech vaccine
- Two-dose series (100 µg dose), with 28 days between doses
- Storage: The vaccine remains stable at:
 - -20°C (-4°F) for up to six months
 - 2° to 8°C (36° to 46°F) for 30 days
 - Room temperature for up to 12 hours
 - May not be returned to freezer after thawing, nor returned to refrigerator after brought to room temperature
- The vaccine does not require onsite dilution or special handling

<https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-longer-shelf-life-its-covid-19-vaccine>



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Moderna COVID-19 Vaccine Efficacy

- Primary efficacy endpoint, prevention of symptomatic COVID-19:
 - Vaccine efficacy rate was **94.1%**.
 - Based on 196 confirmed cases of COVID-19: 185 cases in placebo group vs. 11 cases in vaccine group.
 - Cases measured starting 2 weeks after the second dose.
 - Efficacy was consistent across age, race, ethnicity and gender groups
- Secondary endpoint: prevention of severe cases
 - 30 severe cases of COVID-19, all in placebo group and none in the vaccine group

<https://investors.modernatx.com/news-releases/news-release-details/modernas-covid-19-vaccine-candidate-meets-its-primary-efficacy>

Moderna COVID-19 Vaccine Safety

- No significant safety concerns identified by the Data Monitoring Committee
- Systemic reactions increased in frequency and severity after the second dose
- The most common grade 3 (severe) events were:
 - Fatigue (9.7%)
 - Myalgia (8.9%)
 - Arthralgia (5.2%)
 - Headache (4.5%)
 - Injection site pain (4.1%)
 - Injection site redness (2.0%)
- Most adverse events were mild to moderate:

		After Dose 1			After Dose 2		
		18-55 yo	56-70 yo	≥71 yo	18-55 yo	56-70 yo	≥71 yo
Local Reactions	Pain	93%	80%	80%	100%	90%	100%
	Redness	13%	0%	0%	13%	10%	20%
	Swelling	13%	0%	0%	7%	10%	30%
Systemic Events	Fever	0%	0%	0%	40%	10%	10%
	Chills	7%	0%	10%	80%	55%	45%
	Fatigue	27%	40%	40%	80%	75%	70%

Moderna COVID-19 Vaccine Current Status

- Moderna submitted their EUA request to the FDA on 11/30/2020
 - VRBPAC meeting 12/17/2020
- By the end of 2020, they expect to have approximately 20 million doses of vaccine ready to ship in US
- In 2021, they expect to manufacture 500 million to 1 billion doses globally

ACIP Phase 1a Prioritization Recommendations

- The CDC's Advisory Committee on Immunization Practices (ACIP) voted on December 1, 2020 to recommend that when a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) healthcare personnel* and 2) residents of long-term care facilities**

*The ACIP defined healthcare personnel as paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials.

**The ACIP defined long-term care facility residents as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

Expected Timeline of COVID-19 Vaccine Approval and Recommendations

- **Fri. Nov. 20, 2020:** Pfizer filed EUA package to the FDA
- **Mon. Nov. 30, 2020:** Moderna filed EUA package to the FDA.
- **Thurs. Dec. 10, 2020:** Public VRBPAC meeting regarding Pfizer's EUA submission
- **Fri. Dec. 11, 2020 – Mon. Dec. 14, 2020:** Window for EUA authorization and Advisory Committee on Immunization Practices (ACIP) recommendations on Pfizer's vaccine
- **Mon. Dec. 14, 2020: NYS Clinical Advisory Task Force** to meet and make a recommendation on Pfizer vaccine
- **Tues, Dec 15, 2020 (Tentative):** Possible first deliveries of COVID-19 vaccine in New York
- **Thurs, Dec 17, 2020:** Public meeting of the VRBPAC regarding Moderna's vaccine
- **Fri, Dec 18 – Mon Dec 22, 2020:** Window for EUA authorization and ACIP recommendations on Moderna's vaccine
- **Mon, Dec 22, 2020: NYS Clinical Advisory Task Force** to meet and make a recommendation on Moderna vaccine



Summary

- Pfizer/BioNTech vaccine: 95% effective, consistent across all groups
- Moderna vaccine: 94.1% effective, consistent across all groups
- Both vaccines highly reactogenic, but no serious adverse events
 - 80-100% of vaccine recipients complain of mild to moderate injection site pain
 - 25-40% report fatigue after dose 1, up to 67-80% after dose 2
 - 4-10% report severe fatigue after dose 2
- Healthcare personnel and residents of long-term care facilities prioritized for initial vaccine
- VRPBAC to meet on December 10 to discuss Pfizer vaccine and on December 17 to discuss Moderna vaccine
 - ACIP recommendations and NYS Clinical Advisory Task Force recommendations and vaccine deliveries likely to begin soon after EUA authorization

COVID-19 Vaccine Prioritization

Loretta Santilli. MPH

Director, Office of Public Health Practice
New York State Department of Health



Prioritization

- During Phase I, the Advisory Committee on Immunization Practices (ACIP) recommends that COVID-19 vaccines be provided to critical populations according to 3 sub-phases:
 - Phase 1A: Healthcare personnel (i.e. paid and unpaid personnel working in a healthcare setting), first responders in medical roles such as emergency medical services providers, Medical Examiners and Coroners, funeral workers, and persons living in and working in Long Term Care Facilities (LTCFs)
 - Phase 1B: Other essential workers
 - Phase 1C: Adults with high-risk medical conditions and people 65 years of age or older not already vaccinated in earlier phases

Prioritization

- Total number of all types of healthcare personnel in NYS (including NYC) is estimated at nearly 1.5 million
- Health care hospital personnel are a top priority because of their exposure to the virus and their critical role of keeping hospitals functioning
- Not every hospital will receive vaccine in the first allocation, however all health care personnel working in high-risk settings must have equitable access to this vaccine

Clinical Prioritization

- Hospitals must be prepared for an initial supply of vaccine that will not cover the entire health care workforce at once
- DOH issued clinical prioritization of hospital workers for the initial supply of vaccine

Employee Prioritization

- Each facility must identify personnel according to the issued prioritization guidelines, and the vaccine will be offered according to priority
- There are employed staff, voluntary staff, contractors and volunteers for whom criteria should be applied

Employee Vaccination

- The first group to be vaccinated will be high-risk health care personnel. This includes:
 - **Any staff** (not only clinicians) who work in settings where transmission is higher or who are at higher risk of transmitting the virus to patients who are at elevated risk of severe morbidity or mortality
 - **Paid and unpaid** persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials

Employee Vaccination

- Hospitals must include these considerations in determinations about which staff fit within this category:
 - Staff who work directly with COVID-19 patients, for example, by providing direct care, cleaning, handling the deceased bodies, or transport services
 - Staff who perform procedures with higher risk of aerosolization
 - Staff who have uncontrolled exposure to patients or the public in a way that may increase the risk of transmission (reception areas, cafeterias etc.)
 - Staff who are in close contact with patients who are at greater risk of morbidity and mortality if exposed (oncology, pediatrics, etc.)
- Be sure to identify these individuals and communicate your plan for offering COVID-19 vaccine to them

Employee Vaccination

- This could include medical and pediatric intensive care units, emergency departments, COVID-19 wards, if they exist, internal medicine and pediatric floors, oncology floors, bone marrow transplant units, HIV units, labor and delivery, obstetrics, operating rooms, reception, triage, cafeterias, etc.
- Rank all locations in the hospital according to volume of COVID-19 patients seen, volume of all types of patients seen, acuity, numbers of patients at risk for severe COVID-19 disease, and numbers of procedures performed
- Rank your locations from 1 (most at risk) to 5 (least at risk) using the matrix provided
- Locations will be vaccinated in order from a score of lowest to highest

Employee Vaccination

1. Identify and rank high-risk work locations within the hospital, including where:

1. Where patients with COVID-19 are provided with direct care
2. Aerosolizing procedures are performed
3. Exposure to the public occurs in an uncontrolled way (reception areas, cafeterias etc.)
4. There are patients with a greater risk of morbidity and mortality if exposed (oncology, pediatrics, etc.)
5. There are employed staff, voluntary staff, contractors and volunteers who meet the criteria.

2. Identify all job roles or job titles in each location that meet the high risk staff criteria discussed above as well as:

1. Staff who routinely touch shared surfaces or common items
2. Staff who are unable to work remotely, not providing direct patient care but are essential to the functioning of the ward such as clerks or secretaries who need to be on site and are in contact with clinicians who are routinely providing direct care

Employee Vaccination

Using the same scale of 1 (most at risk) to 5 (least at risk):

Step 1

- Score all staff who meet the above criteria and who work on the same floor or ward according to age and work or home location, using the provided matrix
- Rank the individual staff members in each location according to their score from lowest to highest
- Begin with those locations that score the lowest and proceed through all locations

Step 2

- Divide staff into 3 groups on each ward, floor or location
- Start by vaccinating staff with the lowest score, then proceed to those with higher scores, in order
- If many staff have the same score, you may prioritize staff by age or comorbidities, if known, or develop a methodology (i.e. alphabetical)
- Staff with the same score can also be randomly assigned to be vaccinated

Employee Vaccination

Step 3

- **Stop** when 1/3 of the staff on a given floor or location are vaccinated. Vaccinating in three groups is a precaution to ensure that there is more than adequate staff coverage in the event those who are initially vaccinated experience side effects that keep them from working.
- As vaccine becomes available after the first third of staff in each location are vaccinated, the second group (or third) can be vaccinated. Once all staff in group two are vaccinated, then group three can be vaccinated.

Plan immediately for the second COVID-19 dose

Employee Vaccination

- Make appointments for staff to receive the second dose 21 or 28 days (depending on which vaccine is used) later at the time the first dose is administered.
- It is important to send frequent reminders about when and where to receive the second dose.
- All vaccinated staff must be tracked to ensure they get the second matching dose on time.

Ensuring Equity

- All workers who meet criteria for vaccination must be included, regardless of job title
- For example, doctors, registered nurses, licensed practical nurses, certified nursing assistants, personal care assistants, environmental workers, ward clerks, dietary workers, and others who work on the same floor or ward and who have direct contact with COVID-19 patients should all be eligible for vaccination at the same time

Communicating the Plan

- Be sure to clearly communicate how prioritization will work to hospital staff
- Identify the individuals who meet the prioritization criteria and communicate to them your plan for offering COVID-19 vaccine
- Hospitals should consider implementing an appointment schedule to make it possible to complete the first dose of the vaccine series for your high-risk personnel within 10 days of receiving the vaccine
- All hospitals, whether it is itself an administration site or is sending staff to another hospital to receive the vaccine, must track uptake among staff and keep a record of staff that decline vaccination

Ensuring Equity

- Recipients of the first COVID-19 vaccine must also work with neighboring facilities to administer to the staff from these designated facilities
- DOH will inform each hospital of their respective allocations and partner hospital
- Need to work with neighboring hospitals and EMS, medical examiners and coroners, and nursing homes

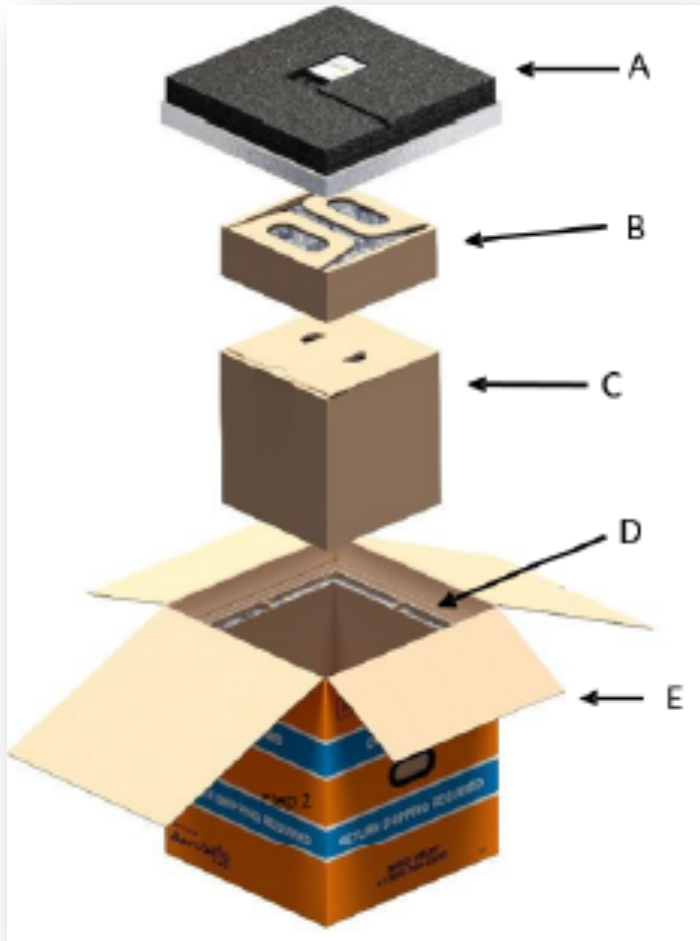
Future Deliveries

- Distribution imbalances may occur during the first week of vaccine deliveries
- Starting in the second week equal proportions of health care personnel will be covered by future allocations
- With the further deliveries, hospitals will receive sufficient vaccine allotments for all high-risk health care personnel

COVID-19 Vaccine Storage and Handling

Pfizer COVID-19 Vaccine Shipping

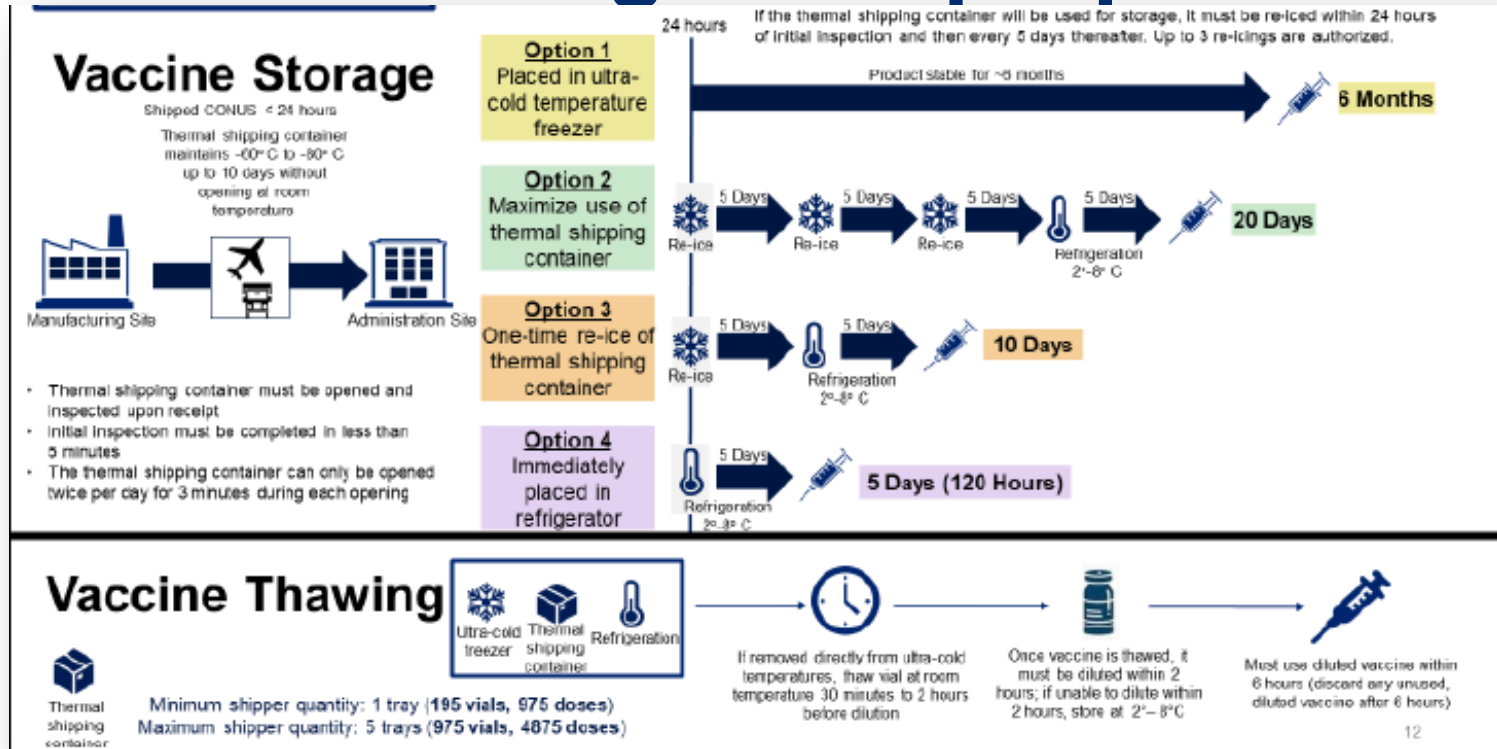
- Shipped and stored ultra-cold: dry ice/-60°C to -80°C
 - Temperature data logger & GPS tracking in transit
- With 3x dry ice replenishment, the shipping container can be used for up to 30 days
 - Minimal daily opening, 2x per day up to 3 min each
- Stored up to 5 days refrigerated



Pfizer shipping box

- Sleeve containing 1-5 trays of 195 5-dose vials
- Sleeve is surrounded by dry ice pellets
- GPS enabled data logger nested in lid

Pfizer storage and preparation



Handling Dry Ice

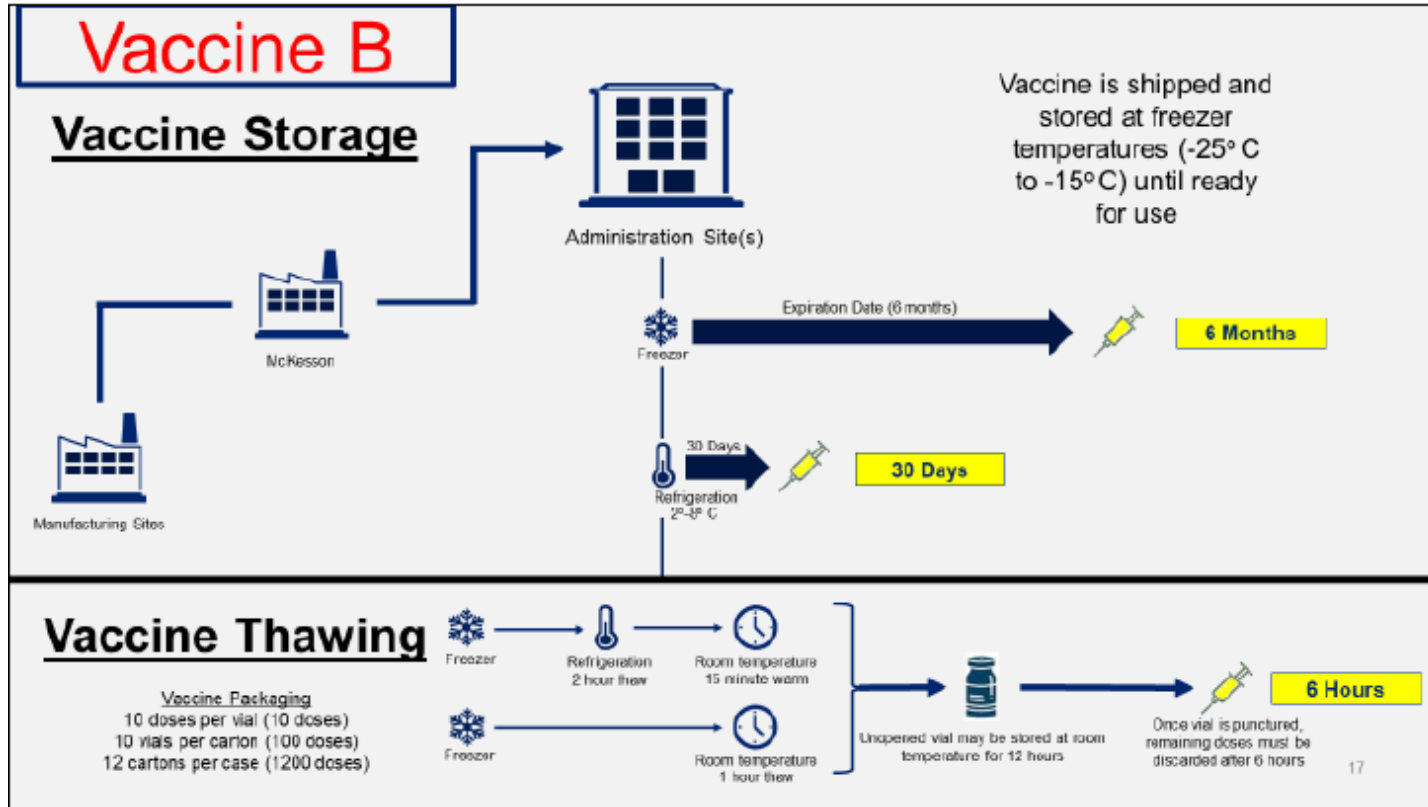
- Insulated gloves
- Eye protection
- Well ventilated storage space

- Boxes have up to 50lb dry ice, in addition to the weight of the boxes and vaccine

Moderna COVID-19 Vaccine

- Storage
 - Shipped frozen
 - Stored frozen for up to 6 months
 - Stored refrigerated up to 30 days
- Order quantity: 10 vials, 10 doses per vial

Moderna Shipping



Summary Table

The following table describes the currently known characteristics of the Pfizer and Moderna vaccines:

	Pfizer vaccine	Moderna vaccine
Minimum Order	195 vials = 975 doses (1 tray = 9 in X 9 in X 2 in)	10 vials = 100 doses (1 carton)
Freezer Storage	Ultra-Cold (-60°C to -80°C) -up to 6 months in ultra-cold temperature freezer -up to 15days in thermal shipper with dry ice replenishment	Frozen (-25°C to -20°C) -up to 6 months in freezer
Refrigerator Storage	2° to 8°C for up to 5 days	2° to 8°C for up to 30 days
Room temperature	Up to 6 hours	Up to 12 hours
Reconstitution required	Yes	No
Route of administration	Intramuscular	Intramuscular
Minimum interval between doses	21 days	28 days



Temperature Monitoring

- Required
 - Pfizer shipping box data logger can be used
 - Begin and end of day temperature checks
 - Keep record on-site

Temperature excursions/non-viable vaccine

- Verify viability with manufacturer
 - Data to support administration
- If data is not available to support, vaccine may not be administered
- Report non-viable vaccines, damaged vials or unused doses in NYSIIS

Redistribution

- Only sites that are approved may move vaccine to other sites for storage
- Must submit a notification of the vaccine being transferred, system in development.
- Pfizer vaccine should be thawed in the refrigerator before moving

Redistribution

- Redistribution is strongly discouraged for the Pfizer vaccine
- Redistribution must be approved in advance each time that vaccine is given to another location
- This includes all vaccine sent to another enrolled site for storage and administration but it does not include movement to temporary administration sites
 - Vaccine quantity moved for temporary administration should not exceed the best estimate for the number of doses to be administered in a single day at that location
- Each hospital site that has storage capacity and/or ability to use the Pfizer shipper for storage should place their prebook request to receive shipments directly

Ancillary Vaccination Supplies

- Ancillary vaccination supplies will be shipped to the facility in a separate container and will include needles, syringes, alcohol pads, vaccination cards, face shields (2 per 100 doses) and facemasks (4 per 100 doses)
- Diluent will be shipped to sites receiving the Pfizer vaccine
- In addition, facilities receiving the Pfizer vaccine will receive dry ice needed for the first recharge of the shipping container within 24 hours, should the facility be planning to use the shipping container for vaccine storage
- A kit with thermal gloves, apron and eye protection will also be provided

Training

- CDC has released a [CDC COVID-19 Vaccine Training: General Overview of Immunization Best Practices for Health Care Professionals](#)
 - This is a new, web-on-demand, self-paced module for health care providers who will be administering COVID-19 vaccine
 - This module provides healthcare providers with information about a COVID-19 vaccine EUA and safety, as well as general information about vaccine storage, handling, administration and reporting
 - Additional information and resources are available at: [CDC COVID-19 Vaccination Resources](#)

Reporting to Immunization Information Systems

- Reporting of all COVID-19 vaccinations to the NYSIIS for providers outside of NYC and to Citywide Immunization Registry for providers in NYC, within 24 hours of administration is required
- COVID-19 vaccine codes will need to be added to your electronic health record (EHR) screens and IIS interface

CVX	CPT	Sale Proprietary Name	MVX	Unit of Sale (UOS)	UOS Package
207	91301	Moderna COVID-19 Vaccine	MOD	80777-273-99	Carton, 10 multi-dose vials
208	91300	Pfizer COVID-19 Vaccine	PFR	59267-1000-2	Carton, 195 multi-dose vials

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- Due Friday at 1pm

Future Webinars

- Hub Training
- Pfizer Handling and Storage Training

QUESTIONS ?

TO NYS HOSPITALS

THANK YOU!

