Health Forum of West Michigan

February 5th, 2021

COVID-19 Vaccines

- Hospital Infrastructure Requirements
- Clinical Considerations

Pete Haverkamp R.Ph., Director of Pharmacy Services

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Vaccine Support Infrastructure

- Proper vaccine storage and handling is vital in ensuring that vaccines are effective when administered.
- The Pfizer-BioNTech COVID-19 vaccine must be kept in an ultra-low freezer between -80°C to -60°C (-112°F to -76°F).
- If an ultra-low temperature freezer is not available, a thermal shipping container in which the vaccine arrives can be used when consistently refilled with dry ice as a **temporary** storage location.
- The thermal shipping container will maintain a temperature range if -90°C to -60°C (-130°F to -76°F) and storage in this temperature range is not considered an excursion.
- Handling the vaccine and at these temperatures requires special personal protective equipment including gloves, a face shield.
- These storage requirements present a challenge as many locations lack ulta-low freezers.

ref: https://www.cvdvaccine-us.com/product-storage-and-dry-ice

Thermal Containers

- Pfizer-BioNTech ships the COVID-19 vaccine to sites using a **thermal container** that will ensure that the vaccine remains frozen.
- The thermal container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage within this temperature range is not considered an excursion from the recommended storage condition.
- To function correctly, the thermal container must consistently **re-filled to the top of the container with dry ice**.
    - 24 hours: The thermal shipping container must be replenished with dry ice within 24 hours of delivery.
    - 2x/Day: It is recommended that the thermal shipping container not be opened more than 2 times a day.
    - 3 Minutes: The thermal shipping container should not be opened more than 3 minutes at a time
    - 5 Days: The thermal shipping container should be re-iced every 5 days

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Facts About Dry Ice

- Dry ice is the **frozen form of carbon dioxide**. When it is warmed it transforms directly into a gas. This process is called sublimation. Dry ice sublimes at temperatures at or above -78°C (-109°F).
- Staff working with the vaccine as it arrives in a thermal container that contains dry ice must use **special handling precautions** to prevent harm or damage to infrastructure.
- The main hazards our dry ice include **asphyxiation** and **burns.**
- Dry ice if not properly dispose of can also lead to **explosions** if placed in a sealed container.
- Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation.
- Exposed skin should be protected from contact with dry ice.

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

ref: https://www.cvdvaccine-us.com/images/pdf/Shipping_and_Handling_Guidelines.pdf

Do not touch and avoid eye contact

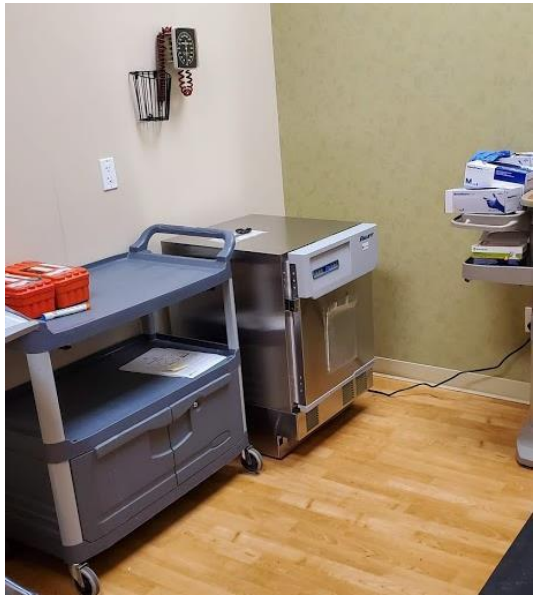
Do not eat

Do not store in confined spaces

Do not place in airtight containers

Staff Training is Key

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH



Temperature Management

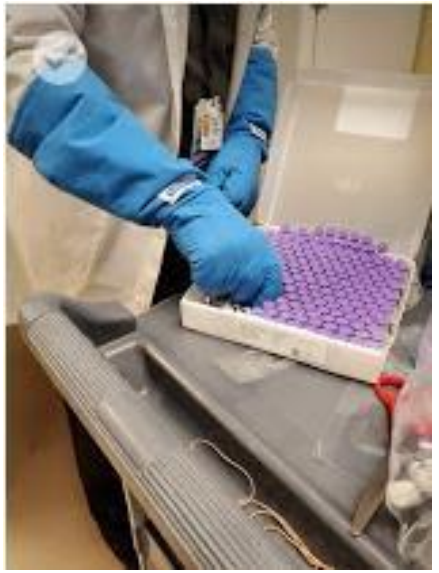
- Vaccines require storage within the correct temperature at each point along its journey.

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Temperature Requirements – Pfizer-BioNTech
Ultra-low Freezer, Thermal Container, and Vial Tray and Vials

- **Frozen Vials Prior to Use**
  - Cartons vaccine Multiple Dose Vials arrive in thermal containers with dry ice. Once received, remove the vial cartons immediately from the thermal container **and store in an ultra-low-temperature freezer between -80°C to -60°C (-112°F to -76°F)**. **Vials must be kept frozen between -80°C to -60°C (-112°F to -76°F) and protected from light until ready to use**
  - If an ultra-low-temperature freezer is not available, the **thermal container** in which the vaccine arrives may be used as **temporary storage** when consistently re-filled to the top of the container with dry ice. The thermal container maintains a temperature range of **-90°C to -60°C (-130°F to -76°F)**.

- **Vial Tray and Vial Handling:**
  - Closed-lid vial trays containing 195 vials removed from frozen storage [-80°C to -60°C (-112°F to -76°F)] may be at room temperature [up to 25°C (77°F)] for **up to 5 minutes** for transfer between ultra-low-temperature environments
  - Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage [-80°C to -60°C (-112°F to -76°F)] may be at room temperature [up to 25°C (77°F)] for **up to 3 minutes**
  - After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for **at least 2 hours** before they can be removed again
  - Once an individual vial is removed from a vial tray at room temperature, it **should not be returned to frozen storage** and should be thawed for use



METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Temperature Requirements – Pfizer-BioNTech
Thawed Vials and Vials After Dilution

- **Thawed Vials Before Dilution**
- **Thawed Under Refrigeration**
  - Thaw and then store undiluted vials in the **refrigerator [2°C to 8°C (35°F to 46°F)] for up to 5 days (120 hours**). A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, to thaw in the refrigerator, whereas a fewer number of vials will thaw in less time
- **Thawed at Room Temperature**
  - **For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes**. Thawed vials can be handled in room light conditions. Vials must reach room temperature before dilution
  - Undiluted vials may be stored at room temperature for no more than 2 hours
- **Vials must reach room temperature before dilution**

- **Vials After Dilution**
- **After dilution, store vials between 2°C to 25°C (35°F to 77°F)** and **use within 6 hours** from the time of dilution
- During storage, **minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light**
- **Any vaccine remaining in vials must be discarded after 6 hours**
- **Do not refreeze**

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Pfizer-BioNTech COVID-19 Vaccine
Clinic Planning, Dilution and Dose Preparation

- **Plan ahead**. Sites need to have a system to estimate closely the number of doses needed for the immunization clinic to avoid vaccine wastage.
- The vaccine should be administered using **low dead-volume syringes and/or needles**. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- **Prepared syringes should be administered immediately**. Administer the vaccine intramuscularly.
- **Ensure the vaccine recipient understands that a 2nd dose must be received 3 weeks after the 1st dose to complete the series**.

1. Before dilution invert vaccine vial gently 10 times. Do not shake.
2. Dilute the vaccine with 1.8mL of sodium chloride 0.9%.
3. Gently invert the diluted vial 10 times to mix. Do not shake.

   Record the date and time of dilution.
4. Prepare individual 0.3 mL doses from the diluted multiple dose vial.

   With careful technique staff can remove 6 vaccine doses per vial.

ref: https://www.cvdvaccine-us.com/images/pdf/How-To-Prepare-and-Administer-the-Vaccine-Poster.pdf

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Vaccine Clinic Design and Flow

- Clinics spaces must be designed to have good flow characteristics to ensure an efficient and safe experience.
- Vaccination can occur in individual physician offices, pharmacies, hospital-based locations, drive through clinics, and large area size mass vaccination locations.
- Station based designs function efficiently and keep patient traffic moving.
- Stations may include welcome, registration, check-in, vaccination bays, nursing support areas, dose preparation, observation, and check-out.

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Clinical Considerations
mRNA COVID-19 Vaccines

Reactogenicity (side effects)

- mRNA COVID-19 vaccine recipients should be made aware of likelihood that they will experience some effects from the vaccine:
- **Localized** - pain, swelling, redness at the injection site, localized arm pit soreness on the same side as the vaccinated arm.
- **Systemic** - fever, fatigue, headache, chills, muscle and joint pain.
- Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, **approximately 80–89% of vaccinated persons develop at least one local symptom and 55–83% develop at least one systemic symptom following vaccination**.
- **Side effects are a sign that the immune system is working**.
- Symptoms **typically go away on their own within a week**.

ref: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Clinical Considerations

Adverse Event Incidence and Treatment

- **Most systemic post-vaccination symptoms are mild to moderate** in severity, **occur within the first three days** of vaccination, and **resolve within 1–3 days** of onset.
- These **symptoms are more frequent and severe following the second dose** and **among younger persons.**
- Persons **should be encouraged to complete the series even if they develop local or systemic symptoms following the first dose** to optimize protection against COVID-19.
- In clinical trials, **hypersensitivity-related adverse events were similar to the placebo groups**.
- **Anaphylaxis following vaccination was not observed in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials**. **However, anaphylactic reactions have been reported following receipt of mRNA vaccines outside of clinical trials**.
- Antipyretic or analgesic medications (e.g., **acetaminophen, non-steroidal anti-inflammatory drugs**), if medically appropriate. **may be taken for the treatment of post-vaccination local or systemic symptoms**

ref: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Clinical Considerations
Pregnancy and Lactation

- While the absolute risk is low**, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, or death**.
- Additionally, they might be at an **increased risk of adverse pregnancy outcomes, such as preterm birth**.
- Based on current knowledge, **experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus because mRNA vaccines are not live vaccines**.
- The **mRNA in the vaccine is degraded** quickly by normal cellular processes and **does not enter the nucleus of the cell**.
- However, the **potential risks of mRNA vaccines to the pregnant person and the fetus are unknown** because these vaccines have not been studied in pregnant people.
- A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine
- There are **no data** on the safety of COVID-19 **vaccines in lactating people** or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. **mRNA vaccines are not thought to be a risk to the breastfeeding infant**.

photo credit: argus leader

ref: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

depositphotos.com

METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH

Clinical Considerations

Who Should Not Get The Pfizer-BioNTech or Moderna COVID-19 vaccines?

- **Contraindications:**
  - A history of the following:
    - **Severe allergic reaction** such as **anaphylaxis after a previous dose of an mRNA COVID-19 vaccine or any of its components**.
    - **Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components i**ncluding polyethylene glycol [PEG] *
    - **Immediate allergic reaction of any severity to polysorbate***

* These persons should not receive mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna) at this time (**unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine** under observation, in a setting with advanced medical care available.

ref: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Should I Get the Vaccine?

- **Concerns:**
  - Some people with COVID-19 can have very mild symptoms.
  - Some people may see natural infection as preferable to receiving a new vaccine.
  - Others may be concerned that getting a COVID-19 vaccine could make a later illness worse.
  - Others may question if the vaccine is that helpful having heard statements that getting COVID-19 gives you better and longer immunity than the protection a vaccine can give.
- **Response:**
  - There are **potential serious risks that a COVID-19 infection poses to individuals and their loved ones. Unvaccinated people could give the disease to loved ones who may get very sick or could die**. There is also a potential that COVID-19 will **cause long-term health issues after recovery**.
  - Scientists are still learning more about the virus that causes COVID-19. And it is not known whether getting COVID-19 disease will protect everyone against getting it again, or, if it does, how long that protection might last.
  - The vaccines have been tested in large clinical trials.
- **Conclusion:**
  - Getting a COVID-19 vaccine is a safer choice.

Covid-19 Myths

Pneumonia and flu vaccines.

- Vaccines against pneumonia, such as the pneumococcal vaccine, **don't provide protection against the COVID-19 virus**. The flu shot also won't protect you against the COVID-19 virus. However, annual flu vaccinations are recommended for everyone age 6 months and older.

Saline nasal wash.

- There is **no evidence that rinsing your nose with saline protects against infection with the COVID-19 virus**.

High temperatures.

- **Exposure to the sun or to temperatures higher than 77 F (25 C) doesn't prevent the COVID-19 virus or cure COVID-19**. You can get the COVID-19 virus in sunny, hot and humid weather. Taking a hot bath also can't prevent you from catching the COVID-19 virus. Your normal body temperature remains the same, regardless of the temperature of your bath or shower.

Low temperatures.

- **Cold weather and snow also can't kill the COVID-19 virus**.

Antibiotics.

- **Antibiotics kill bacteria, not viruses**. However, people hospitalized due to COVID-19 might be given antibiotics because they also have developed a bacterial infection.

Alcohol and chlorine spray.

- **Spraying alcohol or chlorine on your body won't kill viruses that have entered your body**. **These substances also can harm your eyes, mouth and clothes.**

COVID-19 Vaccine Scams to Avoid

1. You can't pay to put your name on a list to get the vaccine.
2. You can't pay to get early access to the vaccine.
3. Nobody should call you about the vaccine and ask for your Social Security number, bank account information or credit card number.

BE SAFE
BE READY
BE INFORMED

FEDERAL TRADE COMMISSION

NATIONAL ASSOCIATION OF ATTORNEYS GENERAL

Covid-19 Vaccine Facts

- **FACT:** COVID-19 vaccines can cause a short fever, headache, fatigue, sore arm or chills, especially after the second dose. **Other reactions are extremely rare**.
- **FACT:** The COVID-19 vaccines **do not contain a live or whole coronavirus, microchips, tracer technology, fetal tissue, stem cells, mercury, aluminum, luciferase, the Mark of the Beast, pork products or preservatives.**
- **FACT:** The **mRNA-based vaccines do not change a person's DNA**.
- **FACT: The COVID-19 vaccine can end the pandemic much sooner, and with fewer lives lost. This could especially help people in the highest risk groups, including people of color**.

ref: https://healthblog.uofmhealth.org/wellness-prevention/not-sure-about-covid-19-vaccine-get-facts-then-decide


METRO HEALTH
UNIVERSITY OF MICHIGAN HEALTH