Date: 8th June 2021
Document Code: 73-01
Version: 01

Guidelines

COVID-19 Vaccination
Pfizer-BioNTech Vaccine Interim Guidelines

Objective

To provide guidelines for the Pfizer-BioNTech vaccine storage, handling, administration and safe disposal along with recommendations for vaccine recipients.

Rationale

Vaccines are important part of strategies to curtail the devastating Covid-19 pandemic. Pfizer-BioNTech vaccine needs special handling to maintain its effectiveness. Safe transportation, storage, administration and disposal of vaccine waste must be ensured at all vaccination facilities.

Instructions

Vaccine Storage & Handling

Storage & Temperature monitoring

1. Upon delivery, inspect the outside of the thermal shipping container for damage. Do **NOT** stack or place anything on top of the thermal shipping container.
2. Do **NOT** open the vial trays or remove vials until you are ready for thawing, transportation, or use
3. Store vaccine in an ultra-cold freezer, thermal shipping container, freezer, or refrigerator.
4. Check and record storage unit temperatures each workday.

See Annex A for detailed guidance about different storage units and temperature monitoring.

Deliveries

Vaccine

Use CDC's Delivery Checklist for Pfizer-BioNTech Vaccine when accepting a delivery and unpacking vaccine[1]. When vaccine is delivered:

1. Open the thermal shipping container. Press the stop shipment button on the temperature monitoring device for 5 seconds.
2. The LED indicator light will change to a solid color and a temperature status report will be e-mailed to the person who ordered the vaccine.
3. Proceed based on the color of the LED indicator light:
   No color or red: Wait for the status report.
   Green: Unpack the vaccine.
4. Follow the manufacturer's guidance for unpacking the vaccine. Inspect the trays.
   - Do not open the vial trays or remove vials until ready to thaw/use the vaccine.
   - If storing the vaccine at ultra-cold temperatures, return vaccine to frozen storage within 5 minutes.
5. If not using the thermal shipping container to store vaccine, return the thermal shipping container as per the manufacturer's instructions.
   - Ensure ALL the vaccine has been removed before returning the container.

Dry Ice Safety

1. Dry ice is needed to maintain proper temperatures in the thermal shipping container.
2. Ensure staff has proper PPE and is trained to handle dry ice safely.
3. Do **NOT** use or store dry ice in confined areas, walking refrigerators, environmental chambers, or rooms without ventilation. A leak in such an area could cause a depletion of oxygen in the atmosphere, which may lead to asphyxiation

Ancillary Supply Kit

An ancillary supply kit will be delivered separately from the vaccine and includes:

1. **Mixing supplies:** Diluent, needles, syringes, and sterile alcohol prep pads
   - Mixing supplies are packaged separately with a green identification label.
   - Do NOT use mixing supplies to administer vaccine.
2. **Administration supplies:** Needles, syringes, sterile alcohol prep pads, vaccination record cards, and some PPE.
   - Ancillary supply kits have been reconfigured to support the number of doses ordered.

Who should receive the Vaccine?

[1] Refer to annex-B

Individuals aged **18** years and older who are clinically extremely vulnerable (**CEV**)[2] being at a high risk of severe illness from COVID-19, who have not received other currently available Covid-19 vaccines are eligible for Pfizer-BioNTech vaccine. These include;

1. Solid Organ Transplant (SOT) recipients:
   - Pre-transplant patients: complete vaccine course at least 2 weeks prior to transplantation if possible.
   - Post-transplant patients may receive vaccine 1 month after transplantation.
   - No adjustment of immunosuppressive medications required prior to vaccination
2. Hematopoietic Stem Cell Transplant (HSCT) recipients and those being planned for HSCT
3. Those suffering from Primary Immune Deficiency Diseases (PIDDS)[3]
4. Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, patients undergoing radical radiotherapy, HIV infection at all stages and multiple myeloma.
5. Individuals who are receiving immunosuppressive or immunomodulating biological therapy including, but not limited to, anti-TNF, alemtuzumab, ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, and individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil.
6. Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at **20mg** or more per day for adults (if they have not received other currently available vaccines)
7. Anyone with a history of haematological malignancy, including leukaemia, lymphoma, and myeloma and those with systemic lupus erythematosus and rheumatoid arthritis, and psoriasis who may require long term immunosuppressive treatments.
8. Asplenia or dysfunction of the spleen. This also includes conditions that may lead to splenic dysfunction, such as homozygous sickle cell disease, thalassemia major and coeliac syndrome.
9. Other severe chronic conditions where Pfizer-BioNTech vaccine may be recommended by the treating physician:
   - Chronic respiratory disease: Individuals with a severe lung condition, including those with asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, and chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).
   - Chronic heart disease and vascular disease: Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischemic heart disease. This includes individuals with atrial fibrillation, peripheral vascular disease or a history of venous thromboembolism.
   - Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome.
   - Chronic liver disease Cirrhosis, biliary atresia, chronic hepatitis.

[2]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/984310/Greenbook_chapter_14a_7May2021.pdf
[3] https://www.niaid.nih.gov/diseases-conditions/types-pidds

- Chronic neurological disease Stroke, transient ischemic attack (TIA).
- Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). This includes individuals with cerebral palsy, severe or profound learning disabilities, Down's syndrome, multiple sclerosis, epilepsy, dementia, Parkinson's disease, motor neuron disease and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability.

Women who are pregnant and lactating, falling under all above listed categories **CAN** receive Pfizer-BioNTech Vaccine.

Who should NOT receive Vaccine?

- Individuals having **fever at the time of coming for vaccination** (Can be rescheduled after the illness is settled)
- Patients with **active COVID-19**
  - Those with mild COVID-19 can receive the vaccine once the isolation period complete.
  - Those with severe COVID-19 can receive the vaccine once they become stable
- **Those who have already received any other COVID-19 vaccine** regardless of CEV or antibody levels.
- **Those with history of severe allergic reaction (anaphylaxis) or an immediate allergic reaction**, even if it was not severe, **to any ingredient in an mRNA COVID-19 vaccine** (such as polyethylene glycol) or to first dose of **an mRNA COVID-19 vaccine**

Vaccine Preparation

Thaw Frozen Vaccine

Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use under one of the following conditions:

1. **Thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]**
   - A single tray of vials may take up to **3 hours** to thaw; fewer vials will thaw more quickly
   - Thawed vials can be stored in the refrigerator for up to **120 hours (5 days)**
2. **Thaw at room temperature [up to 25°C (77°F)] for 30 minutes**
   - Vials thawed at room temperature are for immediate use

Equilibrate and dilute multiple dose vial

Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours (including thaw time). Do NOT refreeze thawed vials.

1. **Before dilution invert vaccine vial gently 10 times.**

- Do not shake
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles
- Do not use if liquid is discolored or if other particles are observed

2. **Dilute the vaccine.**
    - Obtain sterile **0.9%** Sodium Chloride Injection, USP. Use only this as the diluent
    - Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle)
    - Cleanse the vaccine vial stopper with a single-use antiseptic swab
    - Add **1.8 mL** of 0.9% Sodium Chloride Injection, USP into the vaccine vial
3. **Equalize vial pressure.**
    - Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL of air into the empty diluent syringe
4. **Gently invert the diluted vial 10 times to mix.**
    - Do not shake
    - Inspect the vaccine in the vial
    - The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter
5. **Record and restore.**
    - Record the date and time of dilution on the Vaccine vial label
    - Store between **2°C to 25°C (35°F to 77°F)**
    - Avoid exposure to direct sunlight and ultraviolet light.
    - Discard any unused vaccine 6 hours after dilution

Vaccine Administration

- Route of Administration: **Intra-muscular**
- Site of Administration: **Lateral Deltoid Muscle (Upper Arm), Non-dominant side**
- Dose: **30 mcg (0.3 mL)**
- Diluent: **0.9% sodium chloride (normal saline, preservative-free)**
- Presentation after dilution: **Multidose vial (6 doses/vial)**
- Regimen: **2 shots, 21 days (3 weeks) apart**

Steps of Administration

1. Wear mask and observe COVID-19 **SOPs**
2. **Greet** the client
3. Complete **verification** process in the NIMS
4. Ensure **consent** by stating “that you are receiving this COVID-19 vaccine because you have registered yourself into the system”
5. Expose site (**deltoid** of non-dominant arm) for administration

6. **Explain the procedure and inform** that some pain on giving injection, discomfort at the site of injection or fever after the injection may happen
7. Swab the injection site with an alcohol swab for **30 seconds**, then let the area dry for another 30 seconds so that the alcohol doesn't enter the puncture and sting
8. Take mixed vaccine vial out of the vaccine carrier.
9. Cleanse the stopper on the vial of mixed vaccine with a new, sterile alcohol prep pad.
10. Withdraw **0.3 mL** of mixed vaccine preferentially using low dead-volume syringes and/or needles.[4]
11. Remove air bubbles if any while the needle is still in the vial to avoid loss of vaccine.
12. Irrespective of the type of syringe and needle, ensure final dosing volume of 0.3 mL of vaccine.[5]
13. Inject intra muscularly at the site of injection at an angle of 90º (right angle)
14. Dispose the syringe in the safety box
15. Complete entry in the **NIMS**
16. Observe recipients after vaccination for an immediate adverse reaction.

    30 minutes: Persons with a:
    - History of an immediate allergic reaction of any severity to a vaccine or injectable therapy
    - Contraindication to Janssen COVID-19 Vaccine who receive Pfizer-BioNTech vaccine
    - History of anaphylaxis due to any cause

    15 minutes: All other persons
17. After monitoring, if no acute adverse event is experienced by the client, send the client home. Also, advise the client to **report to health facility /1166 helpline** if any adverse event is experienced.
18. Also, ensure the vaccine recipient understands that a 2nd dose must be received **3 weeks** after the 1st dose to complete the series.

Vaccine Waste Management

- Used vials and syringes must be **collected safely** by the vaccinator
- **Syringes must be disposed through environment friendly incinerators** where available.
- In case of non-availability of incinerators, follow the under mentioned link for proper disposal of the vaccine waste.
  https://apps.who.int/iris/bitstream/handle/10665/43476/9241594284_eng.pdf?sequence=1&isAllowed=y

[4] If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
[5] If the amount of vaccine remaining in the vial cannot provide a full 0.3 mL dose, discard the vial and contents. **Do NOT** combine vaccine from multiple vials to obtain a dose.

- The **vaccinator under supervision of the health facility in-charge** of the concerned health facility will ensure proper disposal of COVID-19 vaccination waste
- **Daily waste generation and disposal record** must be maintained by the vaccinator

During vaccination, Do NOT

- Touch the rubber pad of vaccine vial (causes contamination and can result in an AEFI)
- Recap needle of syringes (to prevent needle stick injuries)

Please refer to "Annex B & C" for vaccine delivery & vaccine administration checklist

Note: The above recommendations are being regularly reviewed by the Ministry of National Health Services, Regulations & Coordination and will be updated based on the international & national recommendations and best practices.

The Ministry acknowledges the contributions of Dr Ifrah Javaid, Dr Mehreen Arshad, Dr Sabeen Khurshid Zaidi, Syed Shamim Raza,, EPI Team and HSA/ HPSIU/ NIH team to compile these guidelines.

References

1. CDC's Pfizer-BioNTech COVID-19 Vaccine materials https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
2. CDC's Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
3. CDC's Pfizer Beyond-Use Date (BUD) labels https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/bud-tracking-labels.pdf
4. CDC's Delivery Checklist https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/delivery-checklist.pdf
5. CDC's Freezer and Refrigerator Temperature Logs https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html
6. https://www.cvdvaccine-us.com/images/pdf/How-To-Prepare-and-Administer-the-Vaccine-Poster.pdf
7. https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prep-and-admin-summary.pdf
8. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/984310/Greenbook_chapter_14a_7May2021.pdf
9. https://www.fda.gov/media/144414/download
10. https://bsbmtct.org/wp-content/uploads/2021/03/BSBMTCT-SARS-CoV-2-vaccination-statement-15Mar2021.pdf
11. https://www.niaid.nih.gov/diseases-conditions/types-pidds
12. https://apps.who.int/iris/bitstream/handle/10665/43476/9241594284_eng.pdf?sequence=1&isAllowed=y

Annex-A

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary

Thermal Shipping Container

CDC recommends providers consider using the thermal shipping container for **temporary storage** only. The container requires significant support to store vaccine at proper temperatures, including trained staff, a regular supply of dry ice, and standard operating procedures for regular maintenance. Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature.

- Review contact information.
  - If the contact for your order (inVTrckS) is not valid, you will NOT be notified in the event of a temperature excursion. Contact your jurisdiction's immunization program for assistance.
  - If your contact is valid and you are not receiving e-mails or cannot load email hyperlinks, refer to Controlant for troubleshooting (https://in.controlant.com/ onsitemonitoring).
  - Identify up to 4 contacts to receive e-mails and text alerts on the container's temperature status.
- Review **DAILY** e-mails on the status of the container.
- Click the link in daily e-mails to access and download all temperature data. Save the Excel file summarizing all temperature data for at least 3 years.
- Save the return shipping label provided in your shipping container at delivery. Use the shipping label to return the thermal shipping container with Controlant TMD after **30 days**.
- Replenish dry ice pellets (10 mm to 16 mm) within **24 hours** of delivery and every **5 days** thereafter. Follow manufacturer's guidance for adding dry ice.
- Dry ice will be sent for the first re-icing unless you opt out when placing the vaccine order.
- Additional dry ice shipments will **NOT** be provided. Arrange for dry ice to maintain the temperature of the container after the first re-ice.

Removing vaccine vials/doses for use:

- Determine the number of vials needed before opening the thermal shipping container.
- Open the thermal shipping container no more than **2 times per day for up to 3 minutes each time**. Use packaging tape to reseal the outer carton after each entry.
- Store vaccine vials upright in the tray and protect from light.

Ultra-Cold Freezer

Before mixing, the vaccine may be stored in an ultra-cold freezer between **-80°C and -60°C (-112°F and -76°F).**

- Store vaccine vials upright in the tray or box.

- Protect from light.
- Vaccine may be stored until the expiration date.
- As the expiration date approaches, contact the manufacturer to determine if it has been extended. Do not discard vaccine without ensuring the expiration date has passed.

Freezer

Before mixing, the vaccine may be stored in the freezer between **-25°C and -15°C (-13°F to 5°F)** for up to **2 weeks**. This beyond-use date replaces the manufacturer's expiration date. The total time vials are stored at these temperatures should be tracked and should not exceed 2 weeks.

- These temperatures are within the appropriate range for routinely recommended vaccines, BUT the temperature range for this vaccine is tighter.
- If storing the vaccine in a freezer with routinely recommended vaccines, carefully adjust the freezer temperature to the correct temperature range for this vaccine.
- Use CDC's freezer storage temperature log for COVID-19 vaccine to document storage unit temperatures.
- Monitor how long the vaccine has been in the freezer using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Store the vaccine in the tray or box.
- Protect from light.
- Do not use dry ice for freezer storage.
- Vials stored in the freezer may be returned one time to ultracold temperature storage **(-80ºC to -60ºC [-112ºF to -76ºF]).**
    - Once returned to ultra-cold storage, the 2-week time frame is suspended.
- Vaccine stored in the freezer can be transferred to refrigerator storage where it can be stored for up to **1 month (31 days)**.

Refrigerator

Before mixing, the vaccine may be stored in the refrigerator between **2°C and 8°C (36°F and 46°F)** for up to 1 month (31 days). After 31 days, contact the manufacturer for guidance. If directed to discard any remaining vials, follow the manufacturer's and your jurisdiction's guidance for proper disposal.

- Monitor how long the vaccine has been in the refrigerator using CDC's beyond-use date labels for Pfizer-BioNTech COVID-19 vaccine.
- Store the vaccine in the tray or box.
- Protect from light.
- Do **NOT** refreeze thawed vaccine.

Temperature Monitoring

Ultra-cold freezer, freezer, and refrigerator: Storage unit temperatures must be monitored regularly, checked, and recorded at the beginning of the workday to determine if any temperature excursions have occurred since the last temperature check. For accurate temperature monitoring, use a digital data logger (DDL) with a detachable probe that best reflects vaccine temperatures.

- Ultra-cold temperatures: Use a probe designed specifically to measure ultra-cold temperatures.
- Frozen and refrigerated storage: Use a probe buffered with glycol, glass beads, sand, or Teflon®.

Check and record the temperature daily using CDC's temperature log. Use one of the options below:

- **Option 1 (preferred): Minimum/Maximum (Min/Max) Temperature**
  Most DDLs display min/max temperatures. Check and record the min/max temperatures at the start of each workday.
- **Option 2: Current Temperature**
  If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday. Review the continuous DDL temperature data daily.

Thermal Shipping Container: Use the Controlant temperature monitoring device (TMD) included with the thermal shipping container to monitor the temperature. See thermal shipping container information above.

Diluent

0.9% sodium chloride (normal saline, preservative-free) diluent is included in the ancillary supply kits. Follow the manufacturer's guidance for storing the diluent.

Mixed Vaccine

- Once mixed, vaccine can be left at room temperature **(2°C to 25°C [35°F to 77°F])** for up to **6 hours.**
- Discard any remaining vaccine after **6 hours.**
- Mixed vaccine should **NOT** be returned to freezer storage.
- Minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Annex-B

Pfizer-BioNTech COVID-19 Vaccine Delivery Checklist	
COVID-19 vaccine (Pfizer) requires ultra-cold temperatures during shipment and will arrive in a thermal shipping container with dry ice. To unpack the vaccine, staff will need proper personal protective equipment (PPE) and should know how to handle dry ice safely. Training materials from the manufacturer, including videos, are available at www.cvdvaccine.com. Use the following checklist to ensure the vaccine is received, stored, and handled appropriately.	
Staff name/Signatures	
1. Examine the shipping container for signs of physical damage. • If the thermal shipping container appears damaged — **STOP**. Contact Pfizer with questions or concerns. • If the thermal shipping container appears to be in good condition, continue to Step 3.	☐
2. Place the thermal shipping container on the floor to unpack (may weigh up to ~80 pounds).	☐
3. The thermal shipping container contains dry ice Before opening: Collect PPE, including goggles and insulated gloves. Place the thermal shipping container in an area with proper ventilation. A leak in a confined area may create an oxygen-deficient environment and result in suffocation.	☐
4. Open the thermal shipping container.	☐
5. Press and hold the "Stop Shipment" button on the temperature monitoring device (TMD) for 5 seconds. • This triggers an e-mail report from the manufacturer on the temperature status of the container during transit. The report will be sent to the provider (facility) e-mail address associated with the order. • The LED indicator light on the TMD will change from blinking to a solid light	☐
6. Proceed based on the color of the LED indicator light. • **Green:** Vaccine can be unpacked. Continue to step 8. • **Red or no color:** STOP! Wait for the status report on the vaccine. • Contact the manufacturer immediately if the status report indicates a temperature excursion has occurred. • Continue to step 8 if the vaccine can be used.	☐

7. Wearing PPE, continue to unpack the shipping container following the manufacturer's guidance. Materials outlining the unpacking process can be found inside the container immediately after opening the lid. 1. Inspect the tray(s) of vaccine for damage. Ensure the correct number of trays were delivered. 2. Place the tray(s) or box (es) with the vials upright in the storage unit. • If storing vaccine at ultra-cold temperatures between -80°C and -60°C (-112°F and -76°F), do NOT open the tray(s) or touch the vials. Return tray to ultra-cold storage within 5 minutes. • If storing the vaccine at freezer temperatures between -25°C and -15°C (-13°F to 5°F), the vaccine may be stored for up to 2 weeks. o Vials stored in the freezer may be returned one time to ultra-cold temperature storage (-80ºC to -60ºC [-112ºF to -76ºF]). o Once returned to ultra-cold storage, the 2-week time frame is suspended. • If storing the vaccine at refrigerator temperatures between 2°C and 8°C (36°F and 46°F), the vaccine must be used within 1 month (31 days). o Thawed vaccine cannot be refrozen. 3. Dispose of the dry ice according to the manufacturer's directions.	☐
8. If using the thermal shipping container to store vaccine,* replenish the container with dry ice pellets (sized 10 mm to 16 mm) within 24 hours of delivery. Unless you have opted out of receiving dry ice when the order was placed, dry ice will be provided for the first re-icing.† Close the container using packing tape.	☐
9. Respond to the manufacturer's status report email regarding ongoing temperature monitoring of the thermal shipping container. • If storing vaccine in an ultra-cold freezer or refrigerator, click on the link to opt out of ongoing temperature monitoring. • If storing vaccine in the thermal shipping container,* an additional e-mail will be sent. Add additional contacts to be notified of the temperature status of the container. Include after-hours phone numbers.	☐

*CDC recommends using the thermal shipping container for temporary storage only.
† Dry ice will not be provided for Pfizer 450 COVID-19 vaccine orders.

Annex-C

CHECKLIST FOR COVID-19 VACCINE ADMINISTRATION	
Client Name:	**Age:**
ID Card:	**Gender:**
Address:	
Staff name/Signatures	
1. Greet the Client	☐
2. Make sure that you and client are wearing face mask	☐
3. Complete the 2-step verification of client	☐
4. Ensure consent by stating that "you are receiving this COVID-19 vaccine because you registered yourself in the system"	☐
5. Prepare dose	☐
6. Explain the procedure and inform that some pain on giving injection, and discomfort or fever after the injection can occur	☐
7. Sterilize injection site with alcohol swab	☐
8. Administer injection	☐
9. Properly dispose the injection waste	☐
10. Send the client to observation section for 30 minutes	☐
11. After 30 minutes, and with no acute AEFI, client is ready to be sent home.	☐
12. Respond to Qs if any, as the last step.	☐