Maintaining recommended temperatures of COVID-19 Vaccines is important to ensuring their quality. COVID-19 Vaccines may be transported off-site or to satellite facilities over short distances and time frames in accordance with practice setting standard operating procedures and these strategies from the The USP Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners. Learn more at www.usp.org/covid-vaccine-handling.

General COVID-19 Vaccine Transport Considerations

**Temperature and Time:** When transporting COVID-19 vaccine, validate the temperature whenever the storage container is opened. Minimize the total transport time to reduce potential risk for a temperature excursion due to a storage unit or thermal packaging system failure. A temperature monitoring device must be utilized in transport. See Table 1: Temperature and Time Considerations for Transport of COVID-19 Vaccine.

**Labeling:** When transporting COVID-19 Vaccine, labels should be adhered to the container in which the vaccine is transported in addition to the label for the pre-drawn syringes, to prevent errors during storage, transport, and administration. See Figure 1: Examples of Labels for Transport of Pfizer-BioNTech COVID-19 Vaccines (additional label examples are available in the toolkit).

**Supplies:** Ensure sufficient transport supplies (e.g., materials and equipment). These can include portable refrigerator/freezer units, qualified containers, coolant materials, insulating materials, and the required temperature monitoring device. See Figure 2: Example of How to Prepare a Pack-out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials.

**Container:** Transport the vaccine using a portable refrigerator and/or freezer unit with a temperature monitoring device. If a portable refrigerator and/or freezer unit is not available, qualified containers and pack-outs with a temperature monitoring device can be used. Only utilize the manufacturer-supplied packaging in accordance with the directions in the manufacturer’s labeling. See Figure 2: Example of How to Prepare a Pack-Out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials.

**Protection:** Secure the COVID-19 vaccine from theft and tampering, similar to other medications, when not under supervision of healthcare personnel. Use ‘tamper proof’ or ‘tamper evident’ measures (e.g., locks, tape, etc.) on these containers as appropriate per the healthcare practitioner’s judgment.

Continued on next page
Table 1
Temperature and Time Considerations for Transport of COVID-19 Vaccine

<table>
<thead>
<tr>
<th></th>
<th>Pfizer-BioNTech COVID-19 Vaccine</th>
<th>Moderna COVID-19 Vaccine</th>
<th>Janssen Ad26 COVID-19 Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature</strong></td>
<td>Maximum allowable storage time**</td>
<td>Temperature</td>
<td>Maximum allowable storage time**</td>
</tr>
<tr>
<td><strong>Frozen solid vaccine vials</strong></td>
<td>6 months</td>
<td>N/A</td>
<td>Do not freeze</td>
</tr>
<tr>
<td>Ultra-low freezer temperature at -80°C to -60°C (-122°F to -76°F)  [-96°C to -60°C (-141°F to -76°F)] is not considered an excursion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal container temperature at -96°C to -60°C (-141°F to -76°F)</td>
<td>Up to 30 days if following manufacturer re-icing instructions</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Refrigerated vaccine vials before vial dilution (Pfizer-BioNTech) or vial puncture (Moderna and Janssen)</td>
<td>Refrigerator temperature at 2°C to 8°C (35°F to 46°F)</td>
<td>Refrigerator temperature at 2°C to 8°C (36°F to 46°F)</td>
<td>Refrigerator temperature at 2°C to 8°C (36°F to 46°F)</td>
</tr>
<tr>
<td>120 hours (5 days)</td>
<td>2 weeks</td>
<td>Up to 30 days prior to first use</td>
<td>Use Janssen’s Tool to determine expiration date</td>
</tr>
<tr>
<td>Arrive at destination within 12 hours.</td>
<td></td>
<td>Use Janssen’s Tool to determine expiration date</td>
<td></td>
</tr>
<tr>
<td>Time used for transportation should be subtracted from 120 hours, the maximum allowable refrigerated storage time.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Absolute room temperature up to 25°C (77°F)</td>
<td>2 hours</td>
<td>12 hours</td>
<td>12 hours</td>
</tr>
<tr>
<td>Refrigerator to ambient room temperature at 2°C to 25°C (35°F to 77°F)</td>
<td>6 hours</td>
<td>12 hours</td>
<td></td>
</tr>
<tr>
<td>Pre-drawn syringes</td>
<td>Refrigerator to ambient room temperature at 2°C to 25°C (35°F to 77°F)</td>
<td>Refrigerator to ambient room temperature at 2°C to 25°C (35°F to 77°F)</td>
<td>Refrigerator to ambient room temperature at 2°C to 25°C (35°F to 77°F)</td>
</tr>
<tr>
<td>6 hours</td>
<td>12 hours</td>
<td>6 hours</td>
<td></td>
</tr>
</tbody>
</table>

* If the storage temperature is changed to an unmonitored temperature container, this changes the allowable storage time.
**Stability studies continue to be conducted by the manufacturer and may be subject to change.
***Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks. May be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F).

Figure 1
Examples of Labels for Transport of Pfizer-BioNTech COVID-19 Vaccine

1. Example of a pre-drawn syringe storage container label
   - Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension
   - Facility name and phone number:
   - Quantity of syringes:
   - Date & Time to discard (6 hours after dilution):
   - Lot #:
   - Initials of preparer:

2. Example of a pre-drawn syringe label
   - Pfizer-BioNTech COVID-19 Vaccine (30 mcg / 0.3 mL) IM suspension
   - Date & Time to discard (6 hours after dilution):
   - Lot #:
   - Initials of preparer:

3. Light protective zip lock container

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Figure 2
Example of How to Prepare a Pack-Out for Transportation of COVID-19 Vaccine Pre-drawn Syringes or Vials

Materials Needed

A Temperature monitoring device, with continuous monitoring being preferred
B Bubble wrap or corrugated cardboard cushioning material (at least 1" thick) to provide barrier between cooling agent and pre-drawn syringes
C Light-protected zip-lock bag or similar container for pre-drawn COVID-19 Vaccine syringes or vials
D Ice pack or other cooling agent
E Expanded polystyrene foam container to maintain temperature
F Hard-surface or hard-plastic container to protect from damage during transport

Preparing Pack-out for Transportation

1 Insulate the expanded polystyrene foam container with bubble wrap or corrugated cardboard cushioning.
2 Add ice pack or other cooling agent.
3 Add bubble wrap or corrugated cardboard cushioning.
4 Add light-protected container with pre-drawn syringes or vials to top of cushioning material and secure.
5 Secure temperature monitoring device near container with pre-drawn syringes or vials for most accurate temperature monitoring.
6 Place the expanded polystyrene foam container in the hard-plastic container to protect the vaccine during transport.
7 Close the hard-surface or hard-plastic container.

After arrival at destination(s)

1 Record date, time, and temperature every time the container is opened.

\* A container or pack-out is ‘qualified’ through laboratory testing under controlled conditions to ensure they achieve and maintain desired temperatures for a set amount of time and are available through packaging suppliers.
\* https://www.cvdvaccine-us.com
\* https://www.modernatx.com/covid19vaccine-eua/

This document is for informational purposes only. It will be updated as additional vaccines are authorized and other information becomes available.