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| Saskatchewan | **Name of Activity:** | Transportation of Pfizer Comirnaty® COVID-19 Vaccine in Ultra-Frozen or Thawed State | |
| | **Role Performing Activity:** | Saskatchewan Health Authority, Athabasca Health Authority, Northern Intertribal Health Authority, First Nations and Inuit Health Branch Staff, Ministry of Health | |
| **WORK STANDARD** | **Location:** COVID-19 Immunization Manual | | **Department:** Population Health Branch |
| | **Document Owner:** Vaccine Management Team | | **Region/Organization where this Work Standard originated:** Ministry of Health Population Health Branch |
| | **Date Prepared:** 2021-01-21 | **Last Revision:** 2024-09-25 | **Date Approved:** |

**Work Standard Summary:** This work standard outlines the guidelines for transportation of:

- Pfizer Comirnaty® 12+ years COVID-19 mRNA vaccine (0.3ml [30mcg] **Grey Cap/Label**)

**IMPORTANT NOTE: Pfizer Comirnaty® vaccines cannot be stored or transported between -25°C to -15°C.**

**Saskatchewan Health Authority work standards on the transportation of COVID-19 vaccine can be accessed on their Vaccine Storage and Handling-COVID-19 website and include:**

- *Packing and Temperature Monitoring of Vaccine work standard*
- *Documentation and Reconciliation Process when Transporting Pfizer BioNTech and Moderna COVID-19 Vials work standard*

| | **Essential Tasks:** |
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| 1. | **Transportation Recommendations**<br>• Pfizer Comirnaty® COVID-19 vaccines are transported in either an ultra-frozen (-90˚C to -60˚C) or thawed state (+2˚C to +8˚C), subject to additional transport precautions which is outlined in this work standard. This applies to all current vaccine formulations.<br>• When the required cold chain equipment is not available for ultra-frozen transport, the vaccine can be transported in a thawed or thawing state as outlined in this work standard.<br>• As required, Pfizer COVID-19 open vials may be transported as outlined in this work standard.<br>  ○ Pfizer has stability data from studies using monovalent formulations that shows open vials and syringes transported between 6 and 12 hours has no expected impact on quality.<br>• For additional information on vaccine storage and handling, refer to:<br>  ○ Ministry of Health's *Vaccine Storage and Handling and Cold Chain Break Procedures for COVID-19 Vaccines work standard* and *Appendix A* on the COVID-19 Immunization Manual website.<br>  ○ Saskatchewan Immunization Manual, Chapter 9: Management of Biological Products https://www.ehealthsask.ca/services/Manuals/Documents/sim-chapter9.pdf |
| 2. | **Prior to Redistributing the Vaccine**<br>• Confirm the number of vaccine doses that are required at the receiving site.<br>• Ensure the receiving site has the appropriate storage equipment, ability, and capacity to store vaccine at the necessary temperature.<br>  ➢ If transporting the vaccine in an ultra-frozen state, the site requires a temperature monitored ultra-low temperature freezer or refrigerator.<br>  ➢ If transporting the vaccine in a thawed or thawing state, the site requires a temperature monitored refrigerator.<br>  ➢ If transporting using dry ice (ultra-frozen state): |

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| | ○ Dry ice personal protective equipment and trained staff to handle dry ice is required.<br>○ Transportation of dangerous goods certification (HAZMAT Class 9-UN1845) is required when transporting excessive dry ice by aircraft. Consultation with Transport Canada may be needed to help determine if dry ice load is considered excessive.<br>○ Transportation of dangerous goods certification is not required when transporting with dry ice by ground as long as the shipment does not include other dangerous goods.<br><br>• Ensure the receiving site has the appropriate ancillary supplies and staff education/information materials to support vaccine storage and administration.<br>**NOTE:** education materials and resources are available on the following sites:<br>➢ Pfizer: https://www.cvdvaccine.ca/<br>➢ SHA: COVID-19 Vaccine Information for Health Care Providers<br>• Ensure each receiving site has patient vaccine handouts including vaccine fact sheets and vaccine screening questions.<br>• Communicate clearly with each receiving site on exact time of vaccine delivery to ensure their readiness. |
| 3. | **Guidelines for Transporting Pfizer Comirnaty® in an Ultra Frozen State (-90 ˚C to -60 ˚C)**<br>• Only a full tray/carton of vaccine is permitted to be transported in an ultra-frozen state (i.e. do not repackage vaccine and transport individual vials).<br>➢ Pfizer Comirnaty 12+ (**Gray Cap/Label**) full carton= 10 vials (60 doses)<br>• Transport vaccine between -90˚C to -60˚C in the original carton/box.<br>• Vaccine must be shipped in a validated shipping container (i.e. intended to transport ultra-frozen vaccine or drugs).<br>➢ Shipping containers used may include a portable freezer capable of ultra-frozen temperature, a validated dry ice shipping container, or the Pfizer thermal shipper (Note: Pfizer does not recommend using their thermal shipper for further distribution due to risk of damage or delayed return of the shipper).<br>○ If transporting in a container with dry ice, avoid direct contact of paperboard materials with dry ice. **Vials should never be in direct contact with dry ice.**<br>○ Avoid liquid nitrogen as a coolant, which can damage the vials and stoppers.<br>○ Consider inner thermal packaging material that can withstand the condensation of dry ice.<br>➢ Condition the shipping container according to manufacturer instructions.<br>➢ Maximum transport time is based on the type of shipping container.<br>➢ Pack vaccine securely to protect the product from damage during transportation.<br>➢ Label the shipping container with a cautionary statement pertaining to temperature control (e.g. Freeze in a ULT freezer/Refrigerate Vaccine Immediately on Arrival) and required dry ice labelling according to transportation of dangerous goods requirements (“Dry Ice UN1845”) if applicable.<br>➢ A data logger is placed in the middle of the vaccine cartons at the centre of the shipping container and programmed to alert cold chain excursions warmer than -60° C and colder than -90° C.<br>**NOTE:** data logger must be compatible for ultra-frozen temperatures and dry ice (if applicable).<br>➢ Additional vaccine packing information is outlined in #5.<br>• If transporting vaccine in an ultra-frozen state by air transport:<br>➢ Follow Transport Canada Civil Aviation (TCCA)/IATA (International Association of Transportation Authorities) guidelines for shipping dry ice on aircraft. |

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| | ➢ The equilibrium temperature of dry ice changes because of air pressure. Unpressurized aircraft transporting the vaccine on dry ice should not exceed an altitude of 25,000 feet to maintain the vaccine within the labeled storage condition.<br>• Upon arrival at the destination, keep the tray/carton closed and immediately place in a temperature monitored ultra-low temperature freezer between -90°C to -60°C or temperature monitored refrigerator between +2°C to +8°C.<br>• Immediately analyze the data logger for cold chain excursion outside of -90°C to -60°C. If a cold chain excursion occurred, follow the Ministry of Health's cold chain management work standard: Vaccine Storage & Handling and Cold Chain Break Procedures for COVID-19 Vaccines.<br>• Allow vaccine to thaw prior to reconstitution. Follow the thawing instructions outlined in the Vaccine Storage & Handling and Cold Chain Break Procedures for COVID-19 Vaccines. |
| 4. | **Guidelines for Transporting Pfizer Comirnaty® in a Thawed State (+2 ˚C to +8˚C)**<br>**NOTE:** The stability timeline between 2° C to 8° C begins once Pfizer vaccine is removed from the freezer. **DO NOT REFREEZE THAWED VACCINE.**<br>• Either a full tray/carton or individual vials are permitted to be transported in a thawed state.<br>• Transport of open vials:<br>➢ Open vials may be transported as required between +2°C to +8°C but vaccine must be utilized within the stability period of 12 hours from the time of first vial puncture.<br>• **Transport thawed vaccine at temperature between +2° C to +8° C.**<br>➢ Place the vaccine directly from the freezer or refrigerator into a vaccine insulated container/cooler (container/cooler bag typically used to transport vaccine at +2° C to +8˚C in current practice may be used. Follow local/organizational work standard for packing vaccine bag). **Record the date and time vaccine is removed from the freezer**.<br>➢ Transport vaccine in the original carton/box. The container must be able to maintain vaccine between +2° C to +8° C for at least the duration of the intended transport.<br>• A label saying **DO NOT REFREEZE** or equivalent must be on the transport container.<br>• A label saying **FRAGILE-HANDLE WITH CARE** or equivalent must be on the transport container.<br>**NOTE:** It is acceptable to transport vaccine while thawing during transport (i.e. when vaccine is placed directly from freezer into container/cooler), however ensure not to refreeze vaccine.<br>• Vials should be stored upright whenever possible.<br>• Take measures to ensure thawed vaccine does not contact any frozen or cold packs within the container.<br>• Take measures, including use of bubble wrap or similar material, to ensure thawed vaccine does not contact any frozen packs within the container.<br>• Transport vaccine in the original carton/box whenever possible. The carton should be surrounded by dunnage (padding material) inside the container to minimize product/carton movement during transport.<br>• Add a temperature monitoring device to the centre of the cooler.<br>➢ **It is strongly recommended to use a data logger for temperature monitoring**. Program the device to alert cold chain excursion under 2°C and over 8°C.<br>○ If a data logger is not available, a minimum/maximum thermometer may be used. It is important to manually reset the minimum and maximum temperatures to the current temperature immediately prior to being used for transport. |

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| | • See #6 below for additional vaccine packing information.<br>• Special precautions must be taken during transport to **prevent excessive movement/"jostling" of the vaccine**.<br>➢ The vaccine should be handled with care and protected as much as possible from shocks, drops, vibration, etc.<br>○ Pack vaccine securely within the shipping container to protect the product from rolling and breaking during transportation.<br>➢ An appropriate container should be used to minimize the potential to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials which are temporarily knocked over may still be used.<br>➢ Container must be secured (strapped/braced) when being transported to prevent unnecessary movement.<br>• **Closed Vial Transport Time Considerations:**<br>➢ There is no limit on the transportation time as long as the product is within the approved stability period and temperature.<br>• If transporting vaccine in a thawed state by air transport:<br>➢ Vials must be securely packed in a +2°C to +8°C temperature-controlled container appropriate for use on an aircraft.<br>➢ On unpressurized flights, temperature-controlled containers must maintain +2°C to +8°C even if the outside air temperature is less than 2˚C to prevent the vials from refreezing.<br>• Upon arrival to destination, immediately place the vaccine in a temperature monitored refrigerator between +2°C and +8°C. **DO NOT REFREEZE.**<br>• Immediately analyze the temperature monitoring device for cold chain excursion outside of +2°C to +8°C.<br>➢ If a cold chain excursion occurred, follow the Ministry of Health's cold chain management work standard: Vaccine Storage & Handling and Cold Chain Break Procedures for COVID-19 Vaccine.<br>**NOTE:** The data logger reading following transportation in a thawing state (i.e. vaccine removed from the freezer and placed directly into the container/cooler) may show a temperature lower than +2° C initially with gradual stabilization between +2° C to +8°C. This would be an expected reading and does not need to be considered a cold chain excursion. When using a min/max thermometer, any temperature excursion under +2°C must be reported since this device does not distinguish the time of temperature readings. |
| 5. | **Vaccine Packing Considerations**<br>• Once an individual vial is removed from a vial tray at room temperature, it cannot be returned to frozen storage and should be thawed for use.<br>• Vaccine packing should occur quickly where the vaccines are taken directly from the freezer/fridge and immediately placed into the shipping container/cooler.<br>➢ **For transport in ultra-frozen state**:<br>○ Full cartons/boxes that arrive in ultra-frozen condition are to be kept closed and should not be at room temperature for longer than **5 minutes** for transfer between ultra-low temperature environments. Before repacking vials into another thermal shipping container for transport, bring vials back to -90 to -60° C before transferring to new container.<br>➢ **For transport in thawed state**:<br>○ Repackaging should be done in a 2-8˚C environment whenever possible.<br>○ When packing vaccine at room temperature, time of exposure should be minimized. |
| | • Pick vaccine with the shortest expiry date (if applicable).<br>• Fill empty spaces within the shipping container with bubble wrap/paper to prevent shifting in the container/cooler.<br>• **For transport in thawed state only**- If vaccine vials are separated from a full carton/box, refer to #6. |

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| 6. | **Packing Vaccines from Original Packaging**<br><br>**NOTE:** Please also refer to the Ministry of Health work standard *Repacking Vaccines from Original Packaging* on the COVID-19 Immunization Manual website: https://www.ehealthsask.ca/services/Manuals/Documents/WS-Repacking-of-vaccines-from-original-packaging.pdf<br>• It is a Health Canada requirement that a licensed healthcare professional (e.g., registered pharmacist, registered nurse) oversee the packing of vaccines into new packages (e.g., cardboard boxes, opaque or amber bags) from their original packages (written communication from Health Canada to the Ministry of Health, 2020-11-13).<br>• Vaccine must be placed into a package that will protect the vaccine from light (e.g. opaque or amber bag).<br>• Remove the exact or rounded up vaccine doses from their original package and place them directly into the new package under the required frozen storage conditions.<br>• Remove as much air as possible from the amber bag before sealed to minimize the possibility of jostling.<br>• Securely seal the new package.<br>• Place a label stating the vaccine name, number of vial/syringe units and corresponding doses, and a reference to the product monograph onto the new packaging. (COVID-19 vaccine specific labels are created by the Ministry of Health and posted on the COVID-19 Immunization Manual website).<br>• The package containing the vial(s) should be placed in insulation or bubble wrap or similar padding to protect the product.<br>**NOTE:** Ensure dunnage material (e.g. bubble wrap) is conditioned +2° C to +8° C for thawed transport prior to placing in container/cooler with vaccine.<br>• The newly prepared package(s) are stored under the required storage conditions until they are ready to be shipped. |