SECTION 7 – STORAGE AND HANDLING OF IMMUNIZATION AGENTS

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1.0 STORAGE AND HANDLING OF IMMUNIZATION AGENTS

COMPETENCY: Implements Canadian Guidelines when storing, handling or transporting vaccines

To ensure that vaccines maintain their immunogenic properties until the time of administration, appropriate handling, transport and storage of immunization agents is critical. "Cold chain" refers to all equipment and procedures used to ensure that vaccines are protected from inappropriate temperatures and light, from the time of transport from the manufacture to the time of administration.

Failure to maintain the cold chain may result in a vaccine losing its effectiveness, failure of the vaccine, and a potential for increased local reactions post administration of a vaccine. Freezing reduces the potency of inactivated vaccines. Light compromises the stability of live virus vaccines.

1.1 ORDERING PROCEDURES

- Order only enough vaccine for your client population, maintaining a two month stock of vaccine. All efforts will be made to ensure that vaccine is hand delivered to the ordering community regardless of the season. No vaccines will be "shipped" during the winter months.

- iPHIS audit reports will be run to determine pediatric quantities for the next two months.

- Vaccines are ordered on the Formulary approved order sheets.

- All vaccine orders will be reviewed by the Vaccine Program Manager or Assistant.

1.2 RECEIVING SHIPMENTS OF IMMUNIZING AGENTS

- Check the cold and warm mark monitors (refer to section on cold and warm mark monitors). Check vaccines for any damage, evidence of freezing or excessive heat.

- Place vaccines in the fridge immediately upon receipt.

- Rotate stock- Place new stock at the back of the fridge.

- Separate adult and pediatric vaccines.

- Label adult vaccines with stickers “Not For Pediatric Use”.

- Return vaccine envelope packs immediately to Whitehorse General. Never use these packs to transport lab specimens!
1.3 **COLD CHAIN BREAKS**
- **DO NOT CALL THE MANUFACTURER.**
- Report cold chain breaches to the Pharmacist at WGH or the pharmacist on call for direction.
- Contact the Vaccine Program Manager to inform of the breach and the recommendations from the pharmacist.

1.4 **VACCINE STORAGE**
- Store all vaccines between +2°C and +8°C.
- Pediatric and Adult Vaccines to be **CLEARLY** separated.
- Place vaccines at least six inches away from the cooling vent at the back of the fridge (these areas are very sensitive to temperature fluctuations).
- Place vaccines with the longest expiry dates behind shorter-dated vaccine.
- Use shorter dated product first.
- Vaccines that are light sensitive are to remain in their **original packaging** or in **light sensitive bags**.
- The following vaccines are light sensitive:
  - Fluviral
  - Rabavert
  - GARDASIL
  - Tuberosol
  - MMR II
  - Synflorix
  - Priorix
  - TYPHERIX
  - VARIVAX 111
  - Ixiaro
- Leave space between products in the refrigerator to allow air to circulate.
- Do not store drugs, food or specimens in the vaccine fridge.
- Place bottles of water on bottom shelf.
- Place two freezer packs in vaccine freezer portion.
- Vaccine Procedures are to be posted on vaccine door.
- Check vaccine door to ensure it is closed properly after each time it is opened.

1.5 **HANDLING VACCINES**
- Remove vaccines from the refrigerator just **prior** to administration.
- Vaccines will be kept in the fridge until required except for mass satellite clinics.
- Limit opening the refrigerator door unnecessarily.
- Mark the date on all multi-dose vials of vaccines and biologicals (PPD) including the box when first opened. Use within 30 days of opening unless otherwise specified by the manufacturer.
- Reconstitute products using **ONLY** the diluents for the specified products.
- Complete a refrigerator inventory **once** a month and **check** expiry dates.
1.6 **VACCINE DISPOSAL**

- Vaccines expire at the end of the month listed on the vial (i.e. Sept/09 = September 30, 2009)

  Note: Talecris products- expiry date is noted as dd-MMM-yy (day-month-year).

- Dispose of expired and unused vaccines in a sharps container or drug expiry box. Either method is acceptable and will result in incineration. Vaccines are not hazardous material.
2.0 CARE OF VACCINE FRIDGES

2.1 CARE OF STANDARD FRIDGE (WHITEHORSE GENERAL HOSPITAL-EMPLOYEE HEALTH PROGRAM)

- Store all vaccines between +2°C and +8°C.
- Record on fridge log **twice** daily temperature readings. Record minimum, maximum and current temperature on the log sheet. See Appendix A.
- Store vaccines in the middle portion of the fridge. Never store vaccines on the fridge door shelves.
- Place fridge at least 10 cm from a wall or other structures to ensure adequate ventilation.
- Protect fridge from direct sunlight.
- Ensure the door is closed tightly at all times.
- Place bottles of water on the lowest shelf to increase fridge temperature stability.
- Place freezer packs in freezer compartment to increase fridge temperature stability.
- Freezers must be defrosted when there is a build-up of 1 cm or more of ice. When defrosting the freezer the vaccines must be moved to another fridge as the fridge temperature will fluctuate during the defrosting process.
  
  **NOTE:** If you must open the fridge door for a prolonged period of time (i.e. to stock fridge), note this on your temperature log.
- Consult with WGH pharmacist for advice when vaccines have been exposed to temperatures outside of +2°C to +8°C. Do **not** call the vaccine manufacturer.
- Do not use your vaccine refrigerator to store drugs or lab specimens.
- Have the refrigerator connected to a secure power source or one with a back up supply in case of power failure.
- Ensure fridge is connected to a plug covered by the emergency generator. A sign is to be placed above the electrical outlet "**VACCINE REFRIGERATOR- DO NOT UNPLUG- DO NOT SWITCH OFF**"
2.2 CARE OF VACCINE FRIDGE (COMMUNITY NURSING FACILITIES, YCDC, KDFN HEALTH CENTRE)

- Store all vaccines between +2°C and +8°C.
- Check the temperature at minimum twice a day.
- Record on log twice daily temperature readings. Record minimum, maximum and current temperature on the log sheet. See Appendix B.
- Place fridge at least 10 cm from a wall or other structures to ensure adequate ventilation.
- Protect fridge from direct sunlight.
- Ensure the door is closed tightly at all times.
- Place bottles of water on lower shelf to increase fridge temperature stability.
- Place freezer packs in freezer to increase fridge temperature stability.
- Freezers must be defrosted when there is a build up of 1 cm or more of ice. When defrosting the freezer the vaccines must be moved to another fridge as the fridge temperature will fluctuate during defrosting the freezer.

**NOTE:** If you must open the fridge door for a prolonged period of time (i.e. to stock fridge), note this on your temperature log & reset the thermometer.

- Consult with your PHC/NIC or WGH pharmacist for advice when vaccines have been exposed to temperatures outside of +2°C to +8°C. Do not call the vaccine manufacturer.
- Do not use your vaccine refrigerator to store drugs or lab specimens.
- Leave space between products in the refrigerator to allow air to circulate.
- In the event of a prolonged power outage (more than two hours) the vaccines should be placed in an insulated cooler with ice packs. Warm and cold markers are also to be placed in the cooler.
- Ensure fridge is connected to a plug covered by the emergency generator. A sign is to be placed above the electrical outlet “VACCINE REFRIGERATOR- DO NOT UNPLUG- DO NOT SWITCH OFF”
2.3 **CARE OF VACCINE FRIDGE (WHITEHORSE HEALTH CENTRE)**

- Store all vaccines between +2°C and +8°C.
- Check the temperature at minimum twice a day.
- Record on log twice daily temperature readings. Record minimum, maximum and current temperature on the log sheet. See Appendix B.
- Place fridge at least 10 cm from a wall or other structures to ensure adequate ventilation.
- Protect fridge from direct sunlight.
- Place bottles of water on empty shelves to increase fridge temperature stability.
- Ensure the door is closed tightly at all times & check fridge seal on the door monthly.

**NOTE:** If you must open the fridge door for a prolonged period of time (i.e. to stock fridge), note this on your temperature log & reset the thermometer

- Leave space between products in the refrigerator to allow air to circulate.
- A sign is to be placed above the electrical outlet “**VACCINE REFRIGERATOR- DO NOT UNPLUG- DO NOT SWITCH OFF**”.
- Refrigerator is to be connected to alarm system.
- In the event of a prolonged power outage (more than two hours) the vaccines will be transferred to Whitehorse General Hospital. Refer to fridge alarm procedure.
- Consult with your NIC or WGH pharmacist for advice when vaccines have been exposed to temperatures outside of +2°C to +8°C. Do **not** call the vaccine manufacturer.

2.4 **TROUBLESHOOTING- VACCINE FRIDGES**

**Fridge Door Seal**

To check that the vaccine storage unit door is sealing properly:

1. Place a thin paper strip against the cabinet front.
2. Close the door.
3. Pull the paper strip. If it moves easily or falls away by itself, the door and the rubber-like seal need to be adjusted.
4. Check all the way around the door. Pay particular attention to the corners.
3.0 VACCINE THERMOMETER

3.1 CHECKING THERMOMETER PLACEMENT

If the thermometer indicates a temperature outside the recommended range, check that the thermometer is appropriately situated in the center of the fridge, adjacent to the vaccine. If the thermometer is placed near the coils, walls, floor or door, it may indicate colder or warmer temperatures than a thermometer appropriately placed in the center of the compartment where the vaccines should be kept.

3.2 CHECKING IF THE THERMOMETER WORKS

A slight variation in temperature is often seen from one thermometer reading to another, even when the vaccine storage unit thermostat is set at a particular temperature. If the thermometer reading does not fluctuate at all over several readings, temporarily remove the thermometer from the storage unit and place it outside the unit at room temperature. Check whether the temperature reading rises. If no change in the temperature reading occurs, check the batteries. Batteries are to be changed in June of each year and documented on the fridge temperature recording sheet.

If there continues to be a problem with the thermometer order a new thermometer.

Thermometers should be checked annually to ensure:

- Temperature measurement is accurate; batteries are functioning; cables or probes are not damaged.

3.3 CHECKING THE ACCURACY OF THE THERMOMETER

Slush test (Digital Thermometer)

The accuracy of a thermometer can be checked using the following test. This test is to be done every June (after new batteries have been installed in thermometer) and documented on the fridge temperature recording sheet.

- Fill a polystyrene or plastic cup two-thirds with cold water. Place the cup in the freezer until a fine layer of ice forms on top and a small section of ice forms within the fluid (about 2 hours). If ice is present, this ensures the mixture is 0°C. Place the temperature probe in the middle of the cup (do not touch the sides). Observe the temperature after 2 minutes. The temperature should drop to 0°C within 2 minutes. If the temperature does NOT drop to 0°C order a new thermometer.
4.0 VACCINE SECURITY

4.1 POWER SUPPLY

- Plug Fridge into an outlet that cannot be activated by a wall switch.
- Place a warning sign at the plug and on the storage unit alerting others not to unplug the unit. “DO NOT UNPLUG FRIDGE”.
- Ensure vaccine fridge is connected to emergency generator (outlet may have a red dot indicating connection to emergency power). Ensure back-up generator is tested monthly.

4.2 POWER OUTAGE (EXCLUDING WHITEHORSE HEALTH CENTRE)

Scheduled and time limited outage (when back up generator not in service)

- Do not open the refrigerator or freezer door until the power is restored.
- Monitor the temperatures inside the vaccine fridge to ensure they remain between +2°C & +8°C.
- If the temperature inside the refrigerator exceeds the recommended +8°C remove the vaccines from the fridge and place the vaccine in cooler packs (using freezer packs and warm/cold marks).
- Only when power has been restored and the vaccine fridge is back in the +2°C to +8°C range are vaccines to be placed back in the fridge.
- Establish at least one alternate storage facility in your community where vaccine can be appropriately, securely stored and monitored. Ideally, this facility would have a backup generator.

4.3 SECURITY OF VACCINES

- Vaccine fridges are to be placed in the Drug Storage room wherever possible to ensure a secure environment.
- Where vaccine fridges cannot be stored in the Drug Storage room they must be placed where there is minimal access by the public and are to be locked at all times and the key kept on the narcotic key ring.
Fridge Alarm Procedure- Whitehorse Health Centre

1. Disarm the alarm – Press #1

2. Note the fridge temperatures on the temperature chart and make a notation that the alarm was triggered

3. Are the fridge temperatures out of range?
   - NO
   - Is the power out?
     - YES
     - Contact Yukon Electric 633-7000
     - How long will the power be out?
       - > 2 hours or unknown
         - If only one fridge is down:
           - Transfer those vaccines to the operating fridges. Remove gel packs as needed to make room.
           - Move all vaccines (including those in freezer) into a Styrofoam container that has a gel pack from the fridge on the bottom and the top. You will likely need more than one container. Place a cold mark and a warm monitor in each container in the middle of the box.
          - If both fridges are down:
            - Contact Whitehorse General Hospital Pharmacy (08:00 – 16:00)
            - In after hours, contact main switchboard and request that they contact the pharmacist on call to come into the hospital in order to transfer vaccine to their facility. 393-8700
            - Reset the alarm Press * xxxxx

     - < 2 hours
       - Recheck in 2
Figure 1: Vaccine Fridge

VACCINE FRIDGE ALARM AND TEMPERATURE MONITORING
4.4 **INSTRUCTIONS FOR USE OF THE DIGITAL FRIDGE THERMOMETER**

- Submerge the external probe in a container of diluent (ie a blood tube filled with tap water) in the centre of the middle shelf. This is done to reduce the risk of measuring short air fluctuations when opening the refrigerator door.

- To obtain the current reading, read the current temperature showing on the thermometer.

- To obtain the minimum temperature, push the min button and read the temperature on the screen.

- To obtain the maximum temperature, push the max button and read the temperature on the screen.

- To reset the thermometer, push the reset button and both the minimum and maximum temperatures will be reset to the current temperature. **NOTE:** The Digital Thermometer is very sensitive to temperature changes. Therefore, if the door is left open for more than a few seconds reset the thermometer. Reset the thermometer after unpacking vaccines and placing them in the fridge.

**Figure 2: Min Max Thermometer- Digital**
4.5 INSTRUCTIONS FOR USE OF WIRELESS THERMOMETER/HYGROMETER

To set up unit

1. Set channel on sensing unit.
2. Set same channel on receiving unit.
3. Set alarm parameters; make sure switch on back of receiver is set to Celsius - two degrees for a low parameter, eight degrees for high parameter. Turn alarm on.
4. Place sensor unit inside refrigerator; place in centre location out in open on middle shelf.
5. Set receiver in a DEDICATED location where readings can be recorded and alarms can be heard.

To record readings

1. Read top temperature window for current temperature reading.
2. Push ‘MEM’ button to record high reading, ‘MAX’ will appear next to temperature
3. Push ‘MEM’ button again to record low reading, ‘MIN’ will appear next to the temperature.
4. Push ‘MEM’ button once more to reset.

Figure 3: Wireless Thermometer/Hygrometer
4.6 **COLD AND WARM MARK MONITORS- ACCEPTING & REJECTION SHIPMENTS**

Cold and Warm Mark Monitoring strips are to be used year round.

**Figure 4: Cold Mark Monitor**

![Cold Mark Monitor](image)

The Cold Mark will activate at -4° C.

**COLD MARK (THERMOMETER SHAPED)**

Accept vaccine shipment if color of bulb is clear or black (and Warm Mark reading is acceptable).

Reject vaccine shipment if color of bulb is black & bulb has burst.

If vaccine shipment is rejected, label “Do not use” and store the vaccines in the vaccine fridge away from other vaccines. Follow direction for Cold Chain Breaks. DO NOT CALL THE MANUFACTURER.
The Warm Mark Temperature tag has five windows. The Warm Mark will activate at 10°C (threshold temperature). The rate of blue colour movement from box 1 to 5 is dependant on the exposure time to temperatures above the threshold. i.e. box 1 is blue-exposure to a temperature over 10°C for less than 5 hours.

**Accept** vaccine shipment if:

1. All windows are clear.
2. #1 window alone is colored blue.

And Cold Mark Bulb is clear.

**Reject** vaccine shipment if:

1. #2-5 windows are blue

If vaccine shipment is rejected, label “**Do not use**” and store the vaccines in the vaccine fridge away from other vaccines. Follow direction for **Cold Chain Breaks. DO NOT CALL THE MANUFACTURER.**
5.0 REFERENCES


