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pharmacy
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The Vaccine Cold-Chain

By Kathy Moscou, B.Sc.Ph., RPh MPH

Statement of objectives

Upon completion of this lesson, the pharmacy technician should be able to:

1. Discuss and understand the importance of maintaining the "cold-chain," and identify vaccines that require cold storage.
2. Outline the pharmacy technician's role in maintaining the cold-chain.
3. List procedures that must be followed if the cold-chain is broken.

Introduction

Vaccines are biological substances administered to prevent disease.¹ They must be protected from temperature fluctuations because exposing them to extreme cold or heat can destroy their integrity and render them unusable. This lesson emphasizes the pharmacy technician's role in maintaining vaccine effectiveness and provides guidelines to deal with circumstances when a vaccine may have been compromised.

What is the cold-chain?

The cold-chain refers to a set of safe handling practices that ensure vaccines are maintained at a constant temperature (between 2°C-8°C) from the time of manufacture until the time of administration to patients.^{2,3,4} To ensure the appropriate temperature is maintained when vaccines reach the pharmacy, they must be placed in appropriate storage units immediately. In addition, transport from the pharmacy to the point of administration by a nurse or physician must also follow the cold-chain protocol. Failure to maintain vaccines at this constant temperature constitutes a "breach" (disruption) in the cold-chain that can result in a loss of vaccine potency.

Why the cold-chain is important

Disruption of the cold-chain poses a public health threat. When the cold-chain is disrupted, a vaccine's effectiveness and shelf life can be reduced. Vaccine stability decreases exponentially each time

the vaccine is exposed to temperatures outside 2°C-8°C.³ Once a vaccine is compromised, it cannot be restored, and each time a cold-chain breach occurs, the vaccine's effectiveness is reduced; the loss of potency is cumulative.² In addition to vaccine failure, the number of localized reactions at the injection site may increase.³ The severity of problems linked to breaches in the cold-chain depends on whether the vaccine is a chemical or biological, and whether the dosage form is an aqueous solution, suspension or dry powder.² Dry powders and chemicals are least affected by cold-chain breaches. Biological solutions and suspensions are most sensitive to cold-chain breaches.²

Disruptions to the cold-chain are also very costly. It is estimated that, in Ontario alone, up to 20% of physician offices and clinics fail to maintain vaccines under required storage conditions.⁴ Once these vaccines are compromised, they must be destroyed. This costs the province of Ontario an estimated \$3 million annually.⁴ The actual cost is undoubtedly higher because only a proportion of vaccine waste is reported to the Ministry of Health.⁴

What is a vaccine?

Vaccines prevent disease by taking advantage of the body's ability to make antibodies and release "killer" cells to destroy disease-causing microbes and viruses that attack it.

Live, attenuated vaccines are a living but weakened version of the invader, so they do not cause

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Table 1: Vaccines that require refrigeration (2°C-8°C)⁴

- Diphtheria toxoid, polysaccharide conjugate vaccine
- Diphtheria and tetanus toxoids (DT)
- Diphtheria and tetanus toxoids, and pertussis (acellular) (DPT)
- Diphtheria and tetanus toxoids, adsorbed pertussis vaccine (acellular) and inactivated polio vaccine
- Diphtheria and tetanus toxoids, adsorbed pertussis vaccine (acellular), inactivated polio vaccine and Haemophilus influenzae type b (Hib) conjugate vaccine
- Hepatitis A vaccine, Hepatitis B vaccine and combined Hepatitis A and Hepatitis B vaccine
- Hib conjugate vaccine
- Inactivated polio vaccine
- Influenza vaccine
- Measles, mumps and rubella (MMR) vaccine
- Meningococcal vaccine (groups A, C, Y and W-135)
- Pneumococcal 7-valent conjugate vaccine
- Pneumococcal polysaccharide 23-valent vaccine
- Rabies vaccine
- Varicella vaccine

disease (non-virulent).¹ They can mutate to a virulent strain of the virus. Polio, measles, mumps and rubella are live vaccines. Inactivated, killed vaccines are advantageous because they cannot mutate but they produce less immunity than live vaccines.¹ For inactivated, killed vaccines, booster shots are usually required to ensure continued immunity. Flu, hepatitis A and polio are inactivated, killed vaccines. Toxoid vaccines stimulate the immune system to produce antibodies to the toxins that cause illness (e.g. tetanus and diphtheria).¹ Conjugate vaccines link antigens or toxoids to the polysaccharide or sugar molecules that certain bacteria use to disguise themselves and stay in the body.¹ Conjugate vaccines allow the immune system to recognize and attack these “disguised” bacteria. Haemophilus influenzae type b (Hib) is a conjugate vaccine.

Maintaining the cold-chain

Nearly all vaccines must be refrigerated between 2°C-8°C. Refer to Table 1 for a list of common vaccines requiring refrigeration.

Health Canada publishes the National Guidelines for Vaccine Storage and Transportation in Canada for Disease Control. Download the pdf at www.phac-aspc.gc.ca/publicat/ccdr-rmtc/95pdf/cdr2111e.pdf.⁵

Maintaining the chain involves choosing and using proper refrigerators and transport containers capable of storing drug products at required temperatures. It

also requires strict adherence to Health Canada protocols for receiving, stocking, storing and transporting of drugs requiring refrigeration and complying with protocols for cold-chain breaches.

Refrigeration units

When feasible, pharmacy personnel should place vaccines in a refrigerator designated solely for vaccines.⁵ If a separate refrigerator is not feasible, vaccines should be segregated from other refrigerated pharmaceuticals. Pharmacies that handle a large volume of vaccines (e.g., a hospital) should purchase a walk-in refrigeration unit.⁵ If the refrigerator is overstocked, air will not circulate enough to maintain constant temperatures.^{4,5} The refrigeration unit should be equipped with a thermometer, to monitor temperature fluctuations and a temperature recording device.^{4,5} An alarm that signals when the refrigeration unit is out of range should be installed.⁵ Monitoring devices should be calibrated regularly.⁵

It is important to keep the refrigerator away from heat as this can affect the unit's performance.⁴ The refrigerator cord should also be strategically placed to avoid accidental unplugging from the electrical outlet.⁴

Receiving, stocking and storage

Establishing and adhering to protocols for receiving, stocking and storage vaccines is an important component of cold-chain maintenance. These protocols must com-

ply with Health Canada's National Guidelines, and include assessing a vaccine's condition when it's received by the pharmacy and ensuring vaccines are immediately attended to and stored properly. Pharmacy staff must also be alert for warning signs that the cold-chain has been broken during shipment. This might be as simple as noticing that freezer packs have thawed or dry ice placed in the transport container has evaporated.³ Unfortunately, damage to the vaccines themselves, by exposure to heat or freezing is not easy to detect. No changes in colour or appearance occurs so visual indicators are unavailable.² Shaking the vaccine may reveal clumps that indicate freezing; however, often no clumps are visible, making this method of detection unreliable.⁶

Procedures for stock rotation should also be established to ensure that vaccines are rotated to avoid waste due to outdated supplies. Expiry dates should be checked and vaccines stocked so those that expire soon are placed in front of vaccines that expire later.⁴ Once stocked, vaccines should not be removed from the refrigerator until they're dispensed.^{4,5}

Transportation

Pharmacy staff in charge of transporting vaccines must make sure that vaccines arrive at their destination at the proper temperature.⁵ How long the vaccine will be out of the refrigerator must be considered when determining the type of transport container.³ In most cases, vaccines should be transported in an insulated container with ice packs.⁵ Vaccines should always be positioned to avoid direct contact with the ice packs.² Heat or cold monitors should also be included in the transport container, if possible.⁵

Vaccines should be dispensed to patients with labelling for transport and storage. The pharmacist should provide advice about ways to avoid exposure to extreme heat and cold. For example, vaccines should never be placed in the glove compartment of a car. If the travel time between the pharmacy and the patient's destination is less than 20 minutes, the vaccine can be dispensed in an insulated bag. If travel time is longer or outside temperatures are excessively warm, Health Canada and manufacturer shipment guidelines should be followed and

vaccines should be transported with ice packs in an insulated container.

Cold-chain maintenance checklist

To maintain the cold-chain, techs must:

- Identify vaccines that must be refrigerated.
- Assess vaccine transport materials for potential breaches in the cold-chain.
- Refrigerate vaccines ASAP, when required.
- Rotate stock to minimize waste.
- Store vaccines on the middle shelves of the refrigerator with adequate air circulation rather than on the door (where they will be exposed to warm air each time the door is opened).
- Store vaccines away from the freezer element and away from direct contact with ice or frozen cooler packs.
- Place water bottles on top shelf, bottom shelf and door shelves, if possible, to aid in maintaining consistent fridge temperature in case of a power failure.
- Make sure the refrigerator door is securely sealed each time it is opened and closed.
- Check and record the temperature range in the refrigerator twice a day.
- Screen for outdated vaccines frequently.
- Check the freezer frequently and defrost it if more than 1 cm of ice is visible.
- When transporting vaccines, place them in an insulated vaccine bag or in a cooler if transportation time is more than 20 minutes or if it's really hot or cold outside.
- Report refrigeration problems right away.

Refer to Figure 1 for a summary of the technician's role in cold-chain storage.

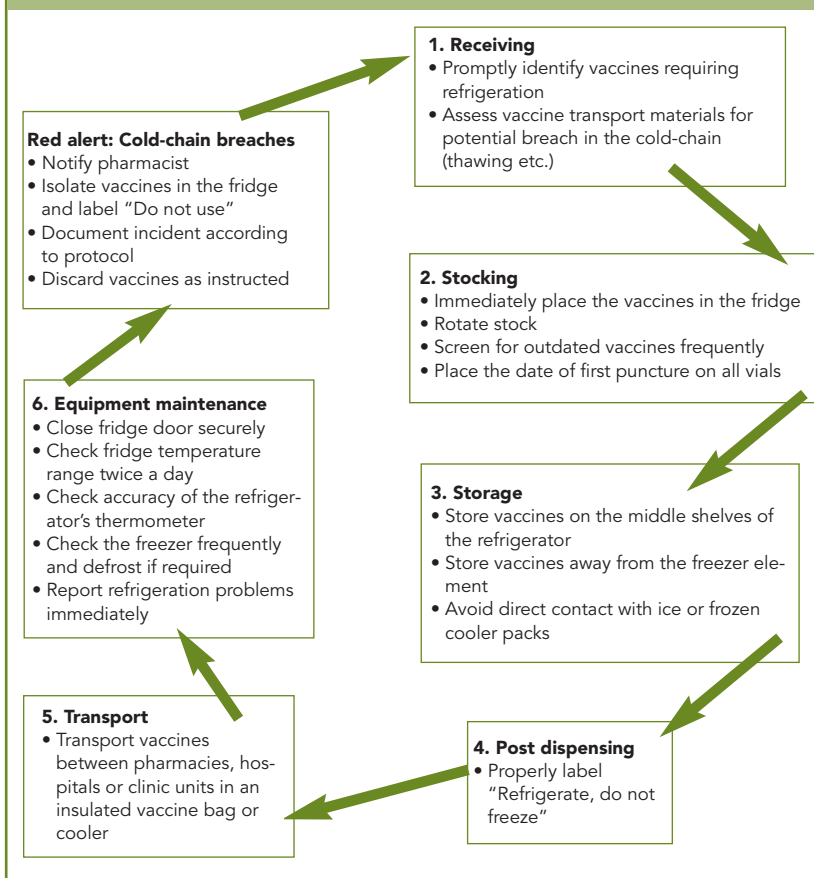
If a cold-chain breach occurs

The cold-chain can be disrupted anywhere along the path between the vaccine manufacturer and the patient. Significant disruptions can occur during periods of power loss. Power outages of less than 20 minutes are unlikely to cause a loss of vaccine effectiveness or stability as long as the refrigerator remains closed. In fact, most domestic refrigerators will retain temperatures between 2°C-8°C for up to two hours, if unopened.³ Beyond two hours, temperatures begin to steadily rise and can reach 21°C or higher within 4 hours.³ Other causes of cold-chain disruptions involve errors made by pharmacy staff, including improper shipping and han-

Table 2: Managing cold-chain breaches

- **ISOLATE** the vaccines in the refrigerator and label "DO NOT USE"
- **DOCUMENT**
 - Date of incident
 - Estimated range of temperatures vaccine was exposed to
 - Duration of exposure
 - Manufacturer expiry date and lot number
- **NOTIFY** pharmacy administration and all other appropriate authorities
- **ASSESS** usability of vaccine, by pharmacist in consultation with the manufacturer
- **DISCARD** exposed vaccine if necessary
- **EVALUATE** pharmacy procedures to determine how to avoid future cold-chain disruptions
- **MAKE POLICY CHANGES** as necessary and monitor changes for effectiveness

Figure 1: Technician's role in cold-chain storage



dling, delays in storing vaccines after they are received in the pharmacy, overstocking the refrigerator, which reduces needed air circulation and leaving the refrigerator door ajar.²

If there's a cold-chain breach, proper procedures should be posted in an area that is readily visible to all pharmacy staff. The event must also be documented for future reference and follow-up. The estimated temperature the vaccine was exposed to, duration of exposure, manufacturer expiry date and lot num-

ber should be recorded.³ Vaccines that have been exposed to temperature extremes should be isolated in the refrigerator and labelled "DO NOT USE," with the date clearly marked on the package.^{2,3,5} Pharmacy administration and all other appropriate authorities should be notified.³ The pharmacist may contact the vaccine manufacturer to assist in the determination of usability of the exposed vaccine.² Vaccines should be appropriately discarded if necessary. The pharmacy should review operating procedures to determine

how future breaches can be avoided. Policy changes should be instituted as necessary and changes should be monitored for effectiveness.³ These steps are outlined in Table 2.

The pharmacy technician's role

Technicians are actively involved in inventory management in the pharmacy, and play a key role in receiving and stocking pharmaceutical products under proper storage conditions. Techs must be able to readily identify shipments of vaccines and any other pharmaceuticals requiring refrigeration. They must also stay up-to-date with all changes in storage requirements, which may change if the drug product is reformulated.³ Drugs are reformulated to increase shelf-life (e.g., Blenoxane®) or improve stability (e.g., Zithromax Z-pak®). Storage requirements may differ between manufacturers of the same active drug due to formulation differences. Drug packaging can also influence storage requirements.³

REFERENCES:

1. National Institute of Allergy and Infectious Disease, Understanding Vaccines: What They Are, How They Work, Bethesda (MD): NIAID, National Institutes of Health, US Department of Health and Human Services; Published July 2003. 55 pages. NIH Publication No. 03-4219 Available at: <http://www.niaid.nih.gov/>
2. Seto, J., Marra, F., Keeping it Cool: A Pharmacist's Guide, Executive Summary, University of British Columbia, Continuing Pharmacy Professional Development, Home Study Program, Feb. 2005. Rogers Publishing Ltd., pp 1-7
3. Murdoch, J., Chill Out: What pharmacists need to know about the room temperature stability of refrigerated pharmaceutical products, *Pharmacy Practice*, Vol. 22, No. 6 pp 32-42
4. Weir, E., Hatch, K., Preventing cold-chain failure: vaccine storage and handling, *JAMC* Oct 2004; 171(9)
5. Canada Communicable Disease Report, National Guidelines for Vaccine Storage and Transportation, Vol. 21-11, dated 15 June 1995 F1-3
6. Canada Communicable Disease Report, Effects of Freezing on DPT and DPT-IPV Vaccines, Adsorbed, Vol. 21-11, dated 15 June 1995 F-6

► QUESTIONS

Please select the best answer for each multiple choice question.

1. Most vaccines must be maintained at a constant temperature between:

- a. -5°C-0°C
- b. 20°C-25°C
- c. 2°C-8°C
- d. 27°C-40°C

2. When the cold-chain is disrupted:

- a. Vaccines may become toxic
- b. Vaccines may lose their effectiveness
- c. No change in vaccine potency occurs
- d. Vaccines become cloudy

3. Please select the answer that is false. According to Canadian National Guidelines...

- a. Vaccines should be stored separately in a designated refrigerator
- b. Overstocking interferes with temperature regulation of refrigerators
- c. Refrigeration units should be equipped with a minimum/maximum thermometer
- d. Vaccines should be stored on the shelf of the refrigerator door

4. Pharmacy technicians should store vaccines that have been received in the pharmacy...

- a. Within 3 hours of receipt
- b. Within 2 hours of receipt
- c. Immediately upon receipt
- d. No time requirements are necessary

5. Damage to vaccines due to exposure to heat or freezing...

- a. Cannot be easily detected by visual inspection
- b. Is easily detected because the vaccine changes colour
- c. Is easily detected because clumps always are formed
- d. Is easily detected because the vaccine changes from clear to cloudy

6. Please select the false statement. Live, attenuated vaccines...

- a. Must be stored in the refrigerator
- b. Are used to vaccinate against polio, measles, mumps and rubella
- c. Are less effective than vaccines made from killed virus
- d. May mutate to a virulent strain of the virus

7. Please select the false statement. Pharmacy technicians ...

- a. Must be able to readily identify vaccines that require refrigeration
- b. Help assess vaccine transport materials for potential breaches in the cold-chain
- c. Rotate stock to minimize wastage due to outdates
- d. May not prepare vaccines for transport between pharmacies, hospital or clinic units
- e. Must report refrigeration problems immediately

8. If power is lost to the refrigerator for 20 minutes or less...

- a. Vaccines should be immediately removed from the refrigerator and placed in insulated bags
- b. Vaccines should be isolated and labelled with date of incident
- c. Vaccine effectiveness will not be compromised so long as the refrigerator door remained closed
- d. All vaccines should be immediately discarded
- e. B and C are true

9. All of the following are responsibilities of the pharmacy technician in cold-chain management EXCEPT:

- a. Assess vaccine transport materials for potential breach in the cold-chain
- b. Screen for outdated vaccines frequently
- c. Properly label vaccines
- d. Counsel patients about proper handling and storage of vaccines

10. All of the following are responsibilities of the pharmacy technician in cold-chain management EXCEPT:

- a. Notify pharmacist of breaches in the cold-chain
- b. Make final determination regarding usability of vaccines that have been exposed to unsuitable temperatures
- c. Check fridge temperature range routinely
- d. Defrost freezer as required

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