

THE COLD CHAIN

Part Two

In spring 2012, in preparation for the administration of the influenza vaccine by pharmacists, the College published an article on protecting the cold chain, and followed up with the development of a cold chain policy in time for the launch of the Universal Influenza Immunization Program (UIIP). This follow-up article – The Cold Chain: Part Two – builds on the information presented in the last edition of *Pharmacy Connection* and focuses on a few additional areas, including:

- Patient transport of temperature sensitive medications
- What to do in the event of a cold chain breach
- Choosing between purpose-built or domestic refrigeration equipment
- Temperature-monitoring devices

PATIENT TRANSPORT OF TEMPERATURE SENSITIVE MEDICATIONS

A pharmacy has control of a drug from the moment it lands on the receiving floor to the time it is handed over to the patient. Therefore, it is critical for

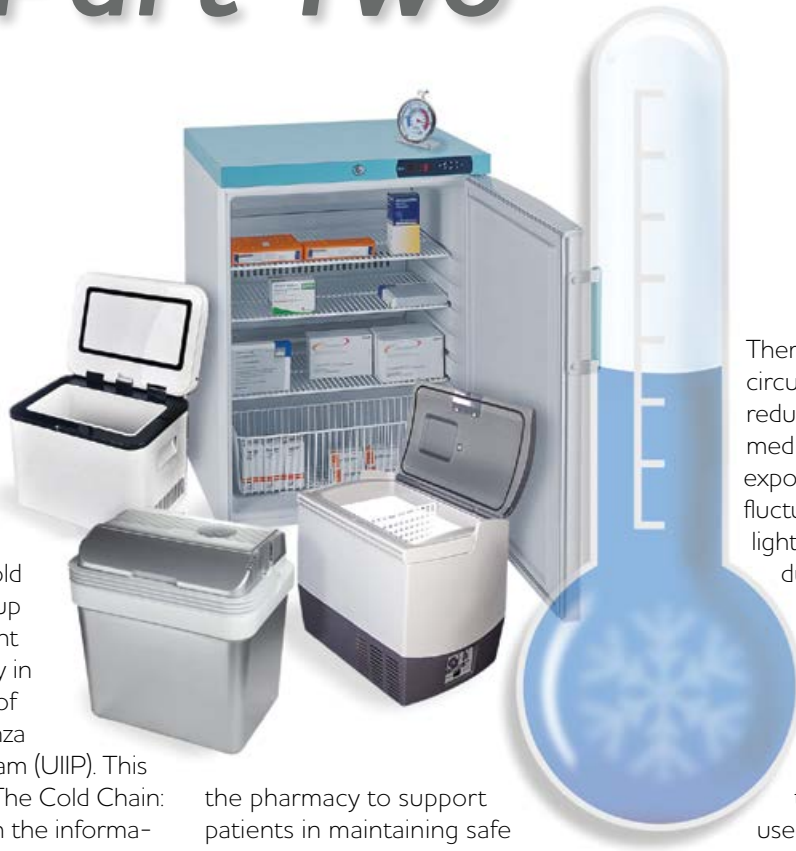
the pharmacy to support patients in maintaining safe transport of their medications. Pharmacies must establish and implement policies and procedures on receiving, storing and dispensing medications that will protect patients' safety and help maintain the potency of their medications.

It is recommended that a written protocol be developed for the transportation of each temperature-sensitive drug so that patients are clear on how they should handle the medication. It is good practice for pharmacy staff to review the information available from manufacturers or Public Health regarding the transport of vaccines to offsite locations and clinics as these principles and safeguards are similar to those for transport to a patient's home.

There are several circumstances that can reduce the shelf-life of medications including exposure to moisture, or fluctuations in oxygen, light or temperature during transportation. Some drugs require continued refrigeration once dispensed, while others can be kept at room-temperature and used until an identified expiry date.

Suggested packing materials for temporary transport of medications that must be kept cool include: insulated containers, refrigerator packs, frozen packs (tap water filled ice packs), and dry ice (where products must remain frozen). One way to assist patients in transporting their drugs is to use the packing supplies that manufacturers use to send temperature-sensitive shipments to the pharmacy.

In addition to information on proper transport and storage conditions, patients should also receive information on when unused medications should be returned to the pharmacy for disposal.



WHAT TO DO IN THE EVENT OF A COLD CHAIN BREACH

The integrity and effectiveness of pharmaceutical products are dependent upon maintaining chemical, physical, microbiological, therapeutic and toxicological stability throughout storage and use. A cold chain breach occurs when storage temperatures go outside of the recommended range, generally +2°C to +8°C for vaccines and medicines and +2°C to +6°C for blood and blood products. Some of the basic steps to ensure that products are kept safe and maintain their potency include:

- Storage under recommended environmental conditions
- Rotation of stock and observance of expiration dates
- Inspecting products for evidence of stability
- Proper treatment of products subjected to additional manipulations (repackaged, diluted, or mixed with another product)
- Informing and educating the patient


The primary environmental factors that can reduce stability include exposure to adverse temperatures, light, humidity, oxygen, and carbon dioxide. The manufacturer should provide written documentation on how to handle medications that have been exposed to adverse conditions.

Policies and procedures should clarify the protocol in the event of a cold chain breach. Policies can also address common pitfalls, for example, by including a requirement that prescriptions that need cold chain protection are returned to the refrigerator once dispensed and before being picked up by the patient; or, if the pharmacy administers the influenza vaccine, by requiring that individual doses are refrigerated until needed.

UNIVERSAL INFLUENZA IMMUNIZATION PROGRAM

In 2012, more than 580 Ontario pharmacies provided pharmacist-administered flu vaccines as part of the Universal Influenza Immunization Program. Nearly 2,500 Ontario pharmacists completed and registered their certified injection administration training programs with the College. Participating pharmacies were inspected by their local Public Health units and were approved based on the requirements in the UIIP User Agreement. Each pharmacy was required to have equipment and processes that met the established provincial standards for vaccine storage. Public Health staff indicated that many pharmacies demonstrated expert attention to cold chain management. There were, however, some pharmacies that required support from Public Health to bring their operations up to the standard required to store the publicly-funded vaccine.

Some of the issues identified through the Public Health inspections were related to thermometers, temperature documentation, inventory management, rotation of stock and maintenance of the freezer. The College's policy on Protecting the Cold Chain recommends the use of a digital-automatic temperature recording and monitoring device that indicates minimum, maximum and current temperatures in increment readings of 0.1°C. In addition to using an appropriate temperature recording device, pharmacies also need to observe and document refrigerator temperatures twice daily, as outlined in the Ministry's Vaccine Storage and Handling Guidelines (p. 9). Public Health staff observed that, in some cases, the correct refrigeration equipment was being used but the vaccine was stocked so tightly that it did not allow for adequate air circulation, proper inventory tracking or appropriate stock rotation. It is recommended that no more than one month of inventory be kept in purpose-built refrigerators, and where a smaller bar-type fridge is used, no more than two weeks worth. Finally, it was noted that some units were not self-defrosting and were not manually defrosted regularly, which could impact the stability of temperatures for vaccine storage.

The Ministry outlined the actions pharmacies should take in the event of a cold chain breach in the UIIP User Agreement. Generally, vaccines that are not stored according to the manufacturer's recommendations are considered to be 'exposed' and must be reported to Public Health for their assessment and action. 

As a priority, any medication suspected of exposure outside the recommended temperature range should be set aside and not dispensed until the stability of the drug is investigated, or not dispensed at all if there is a concern for patient safety.

CHOOSING BETWEEN PURPOSE-BUILT OR DOMESTIC REFRIGERATION EQUIPMENT

A good rule of thumb when choosing equipment is to consider the types of materials that will be stored in the pharmacy. In the event that the pharmacy is considering participating in the UIIP program, it is important to review current Health Canada (National Vaccine Storage and Handling Guidelines for Immunization Providers (2007) and MOHLTC (Vaccine Storage and Handling Guidelines) guidelines and recommendations. Both the provincial and national guidelines recommend the use of a purpose-built refrigerator (also referred to as a pharmacy, lab-style or laboratory grade refrigerator).

Purpose-Built Refrigerator:

The technical features provided by a purpose-built refrigerator ensure that temperature regulation is very sensitive, with quick reaction times to temperatures outside of the set range. These units also have a mechanism to defrost ice without raising the temperature within the unit. In addition, the units feature constant fan-forced circulation of air within the refrigerated compartments which helps maintain the temperature to a set range, even when ambient (room) temperature changes. Since these units have glass doors, extra steps must be taken to protect vaccines from light exposure. As well, the units do not provide proper insulation in the event of a power interruption.

Domestic Refrigerator:

A domestic refrigerator/freezer unit is acceptable to store temperature-sensitive products; however, there are several issues that need to be considered and addressed in advance. Thermostats have a wide temperature-tolerance and are slow to react to an increase in temperature; therefore, it can be difficult to accurately set the temperature. In addition, there is no air circulation when the compressor is off and as a result the defrost function can cause temperature fluctuations. Units may also be subject to changes in ambient temperature.

In order to address these limitations, it is critical to identify and measure the temperature 'zones' within the refrigerator so that vaccines can be stored in the optimum location. If the pharmacy is considering storing vaccines, a bar fridge (or any small single-door fridge) should not be used. The temperatures in these units are unpredictable, as the sensor in the refrigerator compartment reacts to the temperature of the evaporator, rather than to the air in the compartment, resulting in varying temperatures as the ambient temperature changes. Also, the freezer compartment is incapable of maintaining consistent temperatures to store freezer-stable vaccines.

TEMPERATURE-MONITORING DEVICES

A temperature monitoring device is essential for storing vaccines and other temperature-sensitive medications. Regardless of the type of device used, it is important to calibrate the device and ensure it is accurate. Examples of temperature-monitoring devices include:

- Data loggers – continuous temperature recording devices.

May be single-use (for transport) or multi-use (for storage). The multi-use device creates a historical record of temperatures by storing readings, which can then be downloaded onto a computer and printed out as necessary.

- Strip Monitors – single-use battery-powered units that record continuous temperature readings on a paper strip. Generally used to monitor temperatures during transport.
- Chart Recorders – utilize a wheel that records temperatures on graph paper as the wheel turns. Records continuously, 24-hours a day.
- Digital Minimum and Maximum Thermometers – measure current temperature and record minimum and maximum temperatures over a period of time. The units provide three readings: the current temperature, the maximum temperature since last reset, and the minimum temperature since last reset.

CONCLUSION

In order to protect the safety and efficacy of medications, and ultimately for the benefit of patient health and well-being, continuing vigilance to every link of the cold chain should be fully integrated into pharmacy practice. Every pharmacy needs to customize their practices to fit both the requirements of the medications that will be stored and the needs of their patients. 