



TO: Chair and Members of the Board of Health

FROM: Christopher Mackie, Medical Officer of Health
Emily Williams, Chief Executive Officer (Interim)

DATE: 2021 March 18

VACCINE COLD CHAIN INCIDENT RESULTING IN PRODUCT LOSS

Recommendation

It is recommended that the Board of Health receive Report No. 14-21 re: “Vaccine Cold Chain Incident Resulting in Product Loss” for information.

Key Points

- Storage and handling of publicly funded vaccine is prescribed by the Ministry of Health.
- Public health units play a key role in the distribution and administration of vaccines.
- A “cold chain” incident as a result of a refrigerator failure on February 9th resulted in the loss of \$132,891.50 worth of vaccine. None of the vaccine was COVID-related.
- Staff have reported the incident to the Ministry of Health and are currently replacing the refrigerator.

Background

Public Health Units are responsible for the administration and distribution of Ontario’s publicly funded vaccines. These vaccines are delivered to health units from the Ontario Government Pharmacy (OGP) and are administered through on-site or mobile clinics, or distributed onward to third parties such as family physicians or Long-Term Care homes. The process of transporting vaccine is regulated through the [Vaccine Storage and Handling Protocol](#) of the Ontario Public Health Standards.

To ensure vaccine safety for patients, a key element of vaccine storage and handling is the “vaccine cold chain”. This describes the strict adherence of keeping the vaccine within its proper temperature range from the point of manufacture to the point of delivery to a patient. For most of the vaccines handled by public health units, this temperature range is from 2°C to 8°C. Throughout the cold chain, temperatures are continuously monitored and recorded.

At the Middlesex-London Health Unit (MLHU), cold chain monitoring is achieved by confirming the temperature logs for vaccines received at MLHU from couriers, using redundant thermometers and alarms on health unit refrigerators, adhering to proper transport techniques and monitoring when delivering vaccines in mobile clinics, logging temperatures during distribution to third parties such as family doctors’ clinics, and inspecting the receiving refrigerators and logs at those clinics.

Each refrigerator at MLHU is purpose built and maintains a precise temperature within a range of +/- 0.5°C. Preventative maintenance and calibration is performed on the refrigerators on a regular basis. The refrigerators have internal audible alarms to warn of temperature excursion from the set range of 2°C to 8°C, auxiliary thermometers which show current temperature as well as the minimum and maximum temperature attained. This is augmented by a cellular/wifi redundant, continuously web-monitored thermometer which sends text and email alerts to staff should temperature excursion or signal inactivity occur. This is further backed up by an after-hours answering service who will call identified managers when an alarm is activated.

Electricity to the refrigerators is secured by backup generators which ensures an uninterrupted supply of power. Storing vaccine in multiple refrigerators also helps to mitigate the risk of loss if one should fail.

Cold Chain Incident at MLHU

At 9:34 pm on February 9, 2021, a temperature alarm was triggered on the refrigerator used to store the vaccine that is distributed to community health care providers. A sudden drop in temperature below 0°C had occurred. Staff were alerted by the answering service and responded back to the health unit to investigate arriving at the malfunctioning refrigerator within approximately 40 minutes. The temperature in the refrigerator was confirmed to be at -10°C at that point. Staff removed and transferred all vaccine from the refrigerator to another operable refrigerator and quarantined the vaccine pending further investigation.

The total value of vaccine in the refrigerator at the time of the excursion was \$233,761.66 ([Appendix A](#)). After discussions with the vaccine manufacturers and the Ontario Government Pharmacy, it was determined that \$100,870.16 of vaccine was able to be salvaged without compromising its viability however \$132,891.50 of vaccine was deemed not salvageable and was returned to the OGP. The value of the loss is borne by the Province and is not a liability to MLHU.

The refrigerator that malfunctioned had been serviced and inspected on January 4th of this year. It has since been removed from service and a replacement has been ordered. One-time funding for the replacement of vaccine refrigerators can be requested from the Province through the Annual Service Plan and Budget Submission process.

While vaccines have some tolerance to temperature excursions above the prescribed range, they are very sensitive to temperatures below freezing, providing very little time to respond and intervene should the latter occur. Temperature drops in refrigerators, which may be attributable to faulty sensors or overactive compressors, are much less common than temperature increases which can be caused by power interruptions or doors left ajar.

Conclusion and Next Steps

The Ministry of Health was satisfied that appropriate action had been taken in response to the incident and that all reasonable precautions had been in place to ensure the security of vaccine and proper maintenance of cold chain. Staff will evaluate the remaining refrigerators and determine whether they should be replaced in light of this event.

This report was prepared by the Environmental Health and Infectious Disease Division.



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