MIDDLESEX-LONDON HEALTH UNIT

REPORT NO. 042-17FFC

TO: Chair and Members of the Finance & Facilities Committee

FROM: Dr. Chris Mackie, Medical Officer of Health

DATE: 2017 December 07

MIDDLESEX-LONDON HEALTH UNIT (MLHU) COLD CHAIN INCIDENT

Recommendation

It is recommended that Report No. 042-17FFC re: "MLHU Cold Chain Incident" be received for information.

Key Points

- Proper vaccine storage and handling practices play an important role in ensuring the potency of vaccines and reducing waste.
- A cold chain incident occurred in one of fridges at MLHU due to a fridge failure and limitations in the design of the fridge alarm notification system.
- The incident has been investigated, and action has been taken to reduce the risk of future occurrence.

Background

Vaccines are sensitive biological substances that can lose their potency and effectiveness if exposed to temperatures (heat and/or cold) outside their required range, or when exposed to direct sunlight. For most vaccines, this range is +2 °C to +8 °C. Vaccines must be maintained in their range at every step of their movement, from manufacture to administration. This is commonly referred to as an "unbroken cold chain." Failure to adhere to cold chain requirements may reduce vaccine potency, resulting in lack of protection against vaccine-preventable diseases and/or increased adverse reactions at the site of administration of the vaccine. Vaccines may be deemed wasted if they have been exposed to temperatures below +2 °C and/or above +8 °C, or if not used prior to the expiry date. Most vaccines are considered damaged if exposed to temperatures of 0 °C or below.

Health Units receive publicly funded vaccines from the Ontario Government Pharmacy, and are responsible for safe vaccine storage and handling as outlined in the Vaccine Storage and Handling Protocol, 2016. These requirements include:

- Using only purpose-built refrigerators to store vaccine inventory;
- Ensuring that all vaccine refrigerators are equipped with an alarm temperature monitoring system. The alarm must be either a voice or electronic message that will be telephoned or emailed to on-call staff. The alarmed temperature monitoring system must also have a back-up battery system in case of an electricity disruption;
- Ensuring regular maintenance of vaccine refrigerators at least once annually;
- Ensuring that all vaccine refrigerator batteries are replaced at least annually, or as otherwise required; and
- Checking and recording refrigerator temperatures (minimum, maximum, current) twice daily to ensure that temperatures remain between +2 °C and +8 °C.

MLHU follows the above requirements, and also conducts routine refrigerator maintenance on a semi-annual basis rather than just once per year.

MLHU Cold Chain Incident, October 6, 2017

On October 6, 2017, one of the vaccine fridges storing publicly funded vaccines malfunctioned, resulting in its temperature dropping rapidly below 0 °C. Since a fridge's temperature may rise temporarily when the door is opened for loading and unloading vaccines, there is a delay of forty minutes before the alarm is activated due to a temperature fluctuation. This delay prevents an alert being sent each time the door is opened. In this incident, the refrigerator's alarm was triggered as programmed, with a call sent to staff, but the fridge's temperature had dropped below freezing very quickly, before staff could be alerted to attend. A total of 6,070 doses of three different influenza vaccines were stored in this fridge at the time. The vaccine manufacturers were consulted to determine the viability of the three exposed vaccines. Two of the vaccine types were deemed wasted; however, the manufacturer provided data indicating that the third vaccine (500 doses) was stable under the temperatures experienced in the exposure. A total of 5,570 doses, with a value of $44,560, was wasted. In accordance with Ministry of Health and Long-Term Care (MOHLTC) requirements, the cold chain incident has been reported to the Ministry (see Appendix A).

Remediation

Repairs to the fridge were completed, and the alarm was tested and found to be working properly. Temperatures in the fridge were then monitored for ten days and found to be consistently within the +2 °C to +8 °C range. The fridge was deemed safe to re-enter service, and is now being used again for vaccine storage. Although the alarm was tested and found to be working properly, it has been replaced, as it was an older model. Currently, the only alerting options available with the existing alarm system are to provide notification of a temperature fluctuation either immediately or following a forty-minute delay. The alarms have now been set to provide immediate notification when a fridge is out of its temperature range. Alternate alarm models, which may provide more alerting options and data tracking, will be investigated and purchased if deemed appropriate.

Health Units are also able to apply for one-time funding to purchase purpose-built refrigerators, as required. A one-time funding request to replace one of the older fridges was made earlier this year. This funding was recently approved by MOHLTC, and staff will be ordering the replacement fridge immediately.

Conclusion

Despite vaccine storage and handling guidelines being followed, a cold chain incident occurred in one of the vaccine fridges at MLHU and resulted in a loss of vaccine. Efforts continue to be taken to ensure that vaccines stored in the MLHU fridges are kept within the acceptable temperature range to maintain their safety and potency.

This report was prepared by the Vaccine Preventable Diseases Team, Environmental Health Infectious Diseases Division.

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