

**CITY OF HAMILTON  
INTERNAL AUDIT REPORT 2013-01  
PUBLIC HEALTH SERVICES (PHS) – COLD CHAIN / BIOS PROGRAM  
FOLLOW UP**

#	OBSERVATIONS OF EXISTING SYSTEM	RECOMMENDATION FOR STRENGTHENING SYSTEM	MANAGEMENT ACTION PLAN	FOLLOW UP (SEPTEMBER 2014)
1.	<p><u>Physical Security – Access Via Proximity Card</u></p> <p>Vaccines received from the Ontario Government Pharmaceutical and Medical Supply Service (OGPMSS) are stored in locked refrigerators in a secure room (lab). Access to the lab is restricted through the use of proximity cards.</p> <p>As at January 30, 2013, proximity card reports provided by Facilities showed 399 individuals with access to the lab. The access list includes cleaners, custodians, contractors, building security and City employees who no longer work in Public Health Services. Although the vaccine refrigerators are locked, access to the refrigerator keys is not controlled.</p> <p>Having the vaccine supply accessible to a large number of individuals presents the potential risk of improper handling, waste and misappropriation.</p>	<p>That management arrange for employees' proximity cards to be programed to restrict access to the vaccine room to only staff whose regular job duties require such access. The proximity card reports should be requested from Facilities and reviewed by management on an annual basis.</p> <p>That the refrigerator keys be kept secure at all times.</p>	<p>Agreed. This work has already been completed. Access restricted to those deemed by managers as requiring access to vaccines (i.e. regular business; after hours on-call). Expected implementation: completed but will review access on an annual basis.</p> <p>Agreed. We will look at the best place to secure the keys in consultation with program staff and on-call staff. Expected implementation: Q2 2013.</p>	<p>In Progress. Management has taken steps to ensure that the number of individuals with access to the vaccine room has been significantly reduced. Only 2 staff are accessing the vaccine fridges in the day. Management reviews access on an annual basis and when significant changes occur. However, some individuals who do not require access for their regular job duties (e.g. no longer work in the area) still have access to the vaccine room. Expected Completion: December 2014.</p> <p>In Progress. The key is stored inside the vaccine room, restricting access to the same number of individuals as above. Some individuals who do not require access for their regular job duties still have access to the vaccine room and thus, the key. Expected Completion: December 2014.</p>

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2.	<p><u>Vaccine Wastage Rates</u></p> <p>The Ministry of Health and Long-Term Care issues program and topic specific protocols to guide public health units in meeting the <i>Ontario Public Health Standards</i>. The <i>Vaccine Storage and Handling Protocol, 2010</i> stipulates that:</p> <ul style="list-style-type: none"> <li>• Wastage rates should not exceed five percent for any one product; and</li> <li>• If wastage exceeds this level, inventory control measures should be taken to reduce it.</li> </ul> <p>Public Health Services reports the wastage rates for human papillomavirus and influenza vaccines that are stored and administered by the City on a semi-annual basis. However, Public Health Services does not evaluate wastage rates for vaccines provided to all health care providers by the City.</p>	<p>That management calculate wastage rates on a product basis for all vaccines distributed to all health care providers. Measures should be taken to reduce wastage rates to at least the Ministry's five percent threshold.</p>	<p>Agreed. Management will create a report that looks at vaccine wastage on an annual basis by products distributed and returned (for various reasons). Any products that exceed Ministry recommendations for wastage (i.e. 5% for single dose vials; 20% for multi-dose) will be investigated further to identify issues and create a follow-up plan. Expected implementation: Q1 2014 (for 2013 wastage) and annually thereafter.</p>	<p>Initiated. Public Health Services reports the wastage rates for human papillomavirus and influenza vaccines that are stored and administered by the City. However, it does not evaluate wastage rates for vaccines provided to external health care providers. Expected Completion: September 2015.</p>

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	<p><u>Vaccine Wastage Rates (Cont'd)</u>  Based on calculations performed by Internal Audit, wastage rates for 14 of 29 vaccines types distributed during the 2012 calendar year exceeded the Ministry's five per cent threshold.</p> <p>Public Health Services is responsible to meet <i>Protocol</i> requirements by ensuring wastage does not exceed the threshold which may reduce vaccine costs, mitigate the risk of shortages and allow a more robust inventory management process.</p>			

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3.	<p><u>Non-compliance with the Protocol</u></p> <p>In addition to vaccine wastage rates outlined above, Public Health Services is not in compliance with other provisions stipulated in the <i>Vaccine Storage and Handling Protocol, 2010</i>. For example:</p> <p>a) A time lag exists between when Public Health Services receives waste vaccine and when the returns are actually entered into the Biological Inventory Ordering System (BIOS). In excess of two months may pass before waste is returned to OGPMS.</p> <p>b) Vaccine inventory is counted each month as opposed to before the weekly order is placed.</p> <p>c) The standard level of vaccine inventory held by the City is based upon staff experience. Public Health Services does not formally plan or forecast vaccine supplies for the coming year.</p>	<p>That management address the non-compliant <i>Protocol</i> provisions. If requirements cannot be addressed due to capacity or efficiency constraints, management should seek advice or amnesty from the Ministry. Communication with the Ministry should be documented and retained.</p>	<p>Agreed. Steps have already been taken to ensure that returns are entered into BIOS more frequently. This has included consultation with the Ministry to determine a more efficient process. Expected implementation: Q3 2013.</p> <p>Agreed. Inventory counts will be done prior to each vaccine order. Expected implementation: Q1 2014.</p> <p>Agreed. Management is committed to consulting with other health units to see how they meet this provision and with the PHS Surveillance Unit to determine how this may be done. Expected implementation: Q1 2014.</p>	<p>Initiated. A review of comparable guidelines published by the Ontario Ministry of Health and Long Term Care, the Public Health Agency of Canada, and the US Centers for Disease Control and Prevention was completed as well as a survey of five other health units. However, the development and implementation of processes based on the review has not yet begun. A key lock has been installed on the Dundas site refrigerator. Expected Completion: September 2015.</p>

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	<p data-bbox="142 305 596 370"><u>Non-compliance with the Protocol (Cont'd)</u></p> <p data-bbox="142 391 596 570">d) Public Health Services does not calculate each health care provider's one-month supply in order to monitor vaccine requests.</p> <p data-bbox="142 748 596 889">e) The vaccine refrigerator at the Dundas site is not equipped with lockable doors.</p> <p data-bbox="142 911 596 1084">As a public health unit, the City is responsible for complying with requirements set out in the <i>Vaccine Storage and Handling Protocol, 2010</i>.</p>		<p data-bbox="1098 402 1575 686">Agreed. Management is committed to consulting with other health units to see how they meet this provision and with the PHS Surveillance Unit to determine how this may be done. Expected implementation: Q1 2014.</p> <p data-bbox="1098 748 1575 854">Agreed. This issue will be corrected in May of 2013 during annual refrigerator maintenance.</p>	

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4.	<p><u>Inventory Count Adjustments</u> Vaccines received from OGPMS and stored in the refrigerator are counted on a monthly basis. Inventory quantities recorded in BIOS are compared to the physical counts. Unexplained differences between recorded and counted inventory are adjusted through the shrinkage account in BIOS.</p> <p>Vaccine inventory count results and adjustment explanations are not documented by staff or reviewed and approved by management. Management oversight over inventory adjustments is an important control in order to:</p> <ul style="list-style-type: none"> <li>• Compensate for lack of segregation of duties between vaccine custodianship, record keeping and reconciliation functions;</li> <li>• Control and monitor the number and dollar value of adjustments posted to the inventory shrinkage account; and</li> <li>• Ensure items are investigated, explained and resolved appropriately in a timely manner.</li> </ul>	<p>That staff summarize the vaccine inventory count results, including quantities recorded, quantities counted, differences calculated and explained and any corrective action taken. Management should review and approve inventory count adjustments and sign off on the inventory count documentation.</p>	<p>Agreed. Management is committed to having a monthly report as recommended with management reviewing and addressing any issues with adjustments. Expected implementation: Q2 2013.</p>	<p>In Progress. Vaccine inventory is being counted and reconciled on a monthly basis. Management reviews and approves adjustments that are made. However, not all inventory adjustments are reported on the reconciliation and the review is not always performed in a timely manner. Expected Completion: December 2014.</p>

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5.	<p><u>Measures to Maintain Stable Temperatures</u></p> <p>Temperature fluctuations in the refrigerated storage units are the main threat to vaccine potency. Vaccines may become ineffective if stored at suboptimal temperatures for defined periods of time. Not only does this represent waste of product and tax dollars but administering ineffective vaccine may increase the risk of illness and disease and can result in diminished trust in the health care system.</p> <p>Refrigerator maintenance, monitored temperature alarms, backup power, alternate storage locations and documented emergency procedures are controls implemented by Public Health Services to prevent and mitigate the risk of temperature fluctuations at City vaccine storage facilities. Deficiencies that place the effectiveness of management's controls at risk were identified as:</p>			

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	<p><u>Measures to Maintain Stable Temperatures (Cont'd)</u> a) Refrigerator maintenance services are performed by contracted technicians on an annual basis. A review of the 2012 refrigeration maintenance inspection checklists indicated that not all maintenance services appeared to be performed on the vaccine refrigerators. A Public Health Services staff member did not sign off on the maintenance checklists to verify that all work was performed.</p>	<p>That a Public Health Services staff member sign the maintenance checklist after verifying that technicians have completed all services.</p>	<p>Agreed. All maintenance checklists will be brought to the manager for review and signature.</p>	<p>Not Completed. PHS is not verifying that the actual work was performed appropriately as reported by the vendor and service forms are not signed off by a PHS staff member. Expected Completion: December 2014.</p>

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	<p><u>Measures to Maintain Stable Temperatures (Cont'd)</u></p> <p>b) The leased building where the refrigerators are located is outfitted with a backup generator in the event of a power outage. Management does not obtain reports from the property manager to corroborate that the generator is maintained and tested on a periodic basis. There have been instances of the backup generator not working during power outages at this location.</p> <p>c) Public Health Services entered into an agreement with McMaster University Medical Centre (MUMC) in May 2004 to store vaccine at their facility in the event that stable temperatures could not be maintained at City vaccine storage premises. The terms within the agreement should be updated to reflect current capacity and insurance requirements.</p>	<p>That management obtain and review generator maintenance reports from the property manager on a periodic basis.</p> <p>That management update the storage agreement with MUMC.</p>	<p>Agreed. We will consult with the Emergency Response Planner within PHS to determine how to request, receive and action any issues with this report. Expected implementation: Q3 2013.</p> <p>Agreed. This recommendation was already identified during the 2013 operational planning process. Expected implementation: Q4 2013.</p>	<p>Not Completed. PHS currently does not receive information regarding maintenance or test results. Expected Completion: December 2014.</p> <p>In Progress. A vaccine storage agreement has been drafted and is currently under review. Expected Completion: December 2014.</p>

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	<p><u>Measures to Maintain Stable Temperatures (Cont'd)</u></p> <p>d) Procedures for emergencies during and after business hours are documented in Public Health Services' policies and procedures manual. However, these documents are in draft form, have not been formally approved by the Associate Medical Officer of Health and are not posted in vaccine storage facilities. In addition, the procedures do not include periodic controlled emergency scenarios to test staff preparedness and the integrity of the contingency plan.</p>	<p>That management finalize the policies and procedure manual and conduct periodic emergency scenarios to test all aspects of the contingency plan.</p>	<p>Agreed. Five out of six policies have been updated and signed off. An emergency test scenario has been drafted to test the policy for the evacuation of vaccine after-hours. Expected implementation for both components: Q2 2013.</p>	<p>In Progress. Procedures for emergencies during and after business hours have been developed. However, they have not yet been approved. Provisions for emergency testing still need to be included in the procedure. A test of emergency plans was conducted in May 2013 and a further test at the new location is being tentatively planned for January 2015. Expected Completion: September 2015.</p>

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6.	<p><u>Cold Chain Inspections</u> Public Health Services is responsible for ensuring health care providers who receive vaccine in Hamilton are maintaining the cold chain. The cold chain includes all materials, equipment and procedures used to maintain vaccines in the required temperature range until they are administered to individuals. In order to fulfill this mandate, Public Health Services:</p> <ul style="list-style-type: none"> <li>• Investigates cold chain incidents reported by health care providers or identified by City staff;</li> <li>• Inspects each health care provider's site on an annual basis; and</li> <li>• Provides on-site orientation and assists setting up new facilities.</li> </ul>			

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	<p><u>Cold Chain Inspections (Cont'd)</u> Internal Audit identified the following areas that may be improved in order to strengthen Public Health Services' inspection processes.</p> <p>a) A formal cold chain inspection is not carried out in a timely manner after a new facility receives its first vaccine order. Additional follow up should be performed to ensure inexperienced health care providers understand and implement cold chain procedures.</p> <p>b) Files maintained by Public Health Services do not always contain sufficient documentation to verify that corrective action was implemented by the health care provider and corroborated by Public Health Services' staff. In addition, Public Health Services' staff members do not ensure vaccines identified as waste during cold chain investigations and inspections are returned by the health care provider.</p>	<p>That Public Health staff perform a formal cold chain inspection of new facilities within one month of releasing vaccines.</p> <p>That Public Health Services' staff carry out follow up activities to ensure corrective action was taken and the return of waste vaccines was completed. Notes or other documentation should be placed in the health care provider's file to indicate follow up activities were performed</p>	<p>Agreed in principle. We will ensure the policy reflects a two month requirement (rather than one month) for an inspection to be completed, given the number of new facilities and new fridges that require service (i.e. new pharmacies for influenza vaccine). Expected implementation: Q2 2013.</p> <p>Agreed. We will meet with staff to discuss solutions to ensure that corrective actions and return of waste have been completed. Expected implementation: Q3 2013.</p>	<p>In Progress. A policy has been approved which includes a requirement for an inspection to occur one month after the set up visit. However, staff are not consistently carrying out these inspections. Expected Completion: December 2014.</p> <p>Completed. Staff are consistently following up to verify that corrective action was implemented by the health care provider. New vaccine orders are put on hold until wastage is returned.</p>

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	<p><u>Cold Chain Inspections (Cont'd)</u></p> <p>c) Eleven health care providers were assessed fail or conditional ratings on their 2012 annual cold chain inspections. Re-inspections were performed for only three of these facilities. Staff members did not document why re-inspections were not carried out. There are no approved guidelines to help staff decide when a re-inspection is warranted to ensure consistency across all health care providers.</p>	<p>That Public Health Services' staff document and justify why a re-inspection is not carried out. Management should create a guideline to promote consistent treatment by all inspectors.</p>	<p>Agreed. This policy has been updated and clearly outlines the requirements for a re-inspection for conditional and failed inspections and the requirements for documentation should they not be completed. Expected implementation: Q2 2013.</p>	<p>Completed. Staff are consistently performing re-inspections for health care providers with fail ratings and calling or inspecting those with conditional passes. Actions taken are being documented in the progress reports.</p>

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	<p><u>Cold Chain Inspections (Cont'd)</u> d) There are no formal guidelines or processes in place to identify, track or action problematic health care providers who incur high numbers of cold chain incidents or large losses for wasted vaccines. Without punitive measures, there are no incentives for health care providers to improve their cold chain processes.</p>	<p>That management create formal guidelines and processes to identify, track and action challenging health care providers, where appropriate.</p>	<p>Agreed in principle. Management is committed to ensuring that health care providers are accountable for vaccine wastage. We will consult with other health unit colleagues and with the Ministry of Health. Expected implementation: Q2 2014.</p>	<p>In Progress. The Vaccine Cold Chain Incident Follow-up Policy which includes guidelines for managing problematic health care providers has been developed but not approved by the AMOH. However, the dollar value threshold being utilized does not equate to the Ministry's recommended 5% wastage guideline. Additional measures will be examined after consulting with other health units and the Ministry of Health and Long Term Care. Expected Completion: September 2015.</p>