Chapter 3 Section **3.04**

Ministry of Health and Long-Term Care

3.04 Immunization

Background

Immunization with vaccines can reduce or eliminate the prevalence of many infectious diseases and therefore help maintain a healthier population and reduce the health-care costs associated with the treatment of these diseases.

The publicly funded immunization schedule currently includes vaccines that protect against 16 different diseases. Eligible persons in Ontario can be immunized against these infectious diseases at no cost. The eligibility criteria vary by vaccine, with most vaccines being available only to people within certain age groups. Individuals may purchase vaccines for which they are not eligible, as well as other vaccines that are approved for sale in Canada but are not publicly funded, such as the vaccine for shingles. Most vaccines are administered by family physicians, but other health-care providers, including public health unit nurses and pharmacists, also administer certain vaccines, such as the influenza (flu) vaccine.

Responsibility for Ontario's immunization program is shared among various parties, as shown in **Appendix 1**:

• The federal government is responsible for approving new vaccines prior to their use in Ontario and elsewhere in Canada and also arranges vaccine purchasing agreements in which provinces may choose to participate.

- The Ministry of Health and Long-Term Care (Ministry) has overall responsibility for Ontario's immunization program, including immunization policy development, implementation and oversight. This includes advising the government on which vaccines to publicly fund and the related eligibility criteria.
- Under Ontario's *Health Protection and Promotion Act*, 36 public health units across the province are responsible for administering the Ministry's publicly funded immunization programs in their respective areas. The Ministry has established protocols with which public health units are required to comply. Each public health unit is led by a local medical officer of health and is governed by a municipally controlled board of health.
- The Ministry's Ontario Government Pharmaceutical and Medical Supply Service (Ontario Government Pharmacy) is responsible for purchasing vaccines and distributing them to health-care providers, such as physicians in Toronto who administer vaccines, and to public health units in the rest of the province, which in turn distribute the vaccines to health-care providers.

 Public Health Ontario, a Ministry-funded agency, is responsible for monitoring, among other things, the percentage of Ontarians who receive vaccines, and adverse events following immunization.

In 2012, the Chief Medical Officer of Health commissioned a review to identify opportunities to improve the effectiveness and efficiency of Ontario's publicly funded immunization system in order to address the system's growth, both in cost and complexity in the last several years, the corresponding low vaccination coverage rates, and the associated reasons. The resulting report, Ontario's Publicly Funded Immunization System: Building on Today's Strengths, Innovating for the Future—Report of the Advisory Committee for Ontario's Immunization Review (referred to as the 2014 Immunization System Review) was submitted to the Ministry in March 2014. It identified a number of issues, many of which we also identified and discuss in this report.

The Ministry does not track or monitor the total costs of delivering the immunization program in Ontario. We estimated that operational funding for Ontario's immunization program was about \$250 million in both the 2012/13 and the 2013/14 fiscal years, as shown in **Figure 1**. In addition to these costs, the total costs to develop, between 2007 and 2016, a new public-health information system that includes a new immunization registry are expected to exceed \$160 million.

Audit Objective and Scope

Our audit objective was to assess whether there are effective governance, information technology systems, and policies and procedures in place to ensure that Ontario's immunization program protects against vaccine-preventable diseases in an efficient and cost-effective manner and is in compliance with legislative requirements. Our last audit of immunization in Ontario was conducted in 2003 as part of a larger audit of Ontario's Public Health Activity. Senior ministry management accepted our audit objective and associated audit criteria.

Our audit work was primarily conducted at the Ministry, including work at its Ontario Government Pharmacy. We also visited three public health units—Toronto Public Health, Oxford County Public Health, and the Sudbury and District Health Unit to review their processes for administering immunization programs, including how they ensure that vaccines are kept at the appropriate temperature to maintain potency. Our fieldwork was conducted between December 2013 and April 2014.

We also spoke with representatives from: Public Health Ontario (the government agency responsible for, among other things, evaluating the immunization program, conducting research, surveillance of the percentage of people that are immunized-that is, immunization coverage-and investigating adverse events following immunization) and its Provincial Infectious Diseases Advisory Committee—Immunization; the Ontario Medical Association; and selected other public health units in Ontario. As well, we obtained information on the delivery of immunizations by immunization programs in other jurisdictions, including other Canadian provinces (British Columbia, Manitoba, and Alberta), New York State, Australia, and the United Kingdom.

In conducting our audit, we also reviewed relevant documents and administrative policies and procedures; analyzed information; interviewed appropriate staff from the Ministry and public health units; and reviewed relevant research from Ontario, various other North American jurisdictions, Australia and the United Kingdom. In addition, we asked the Ministry to run a number of computer reports in order for us to gain a greater understanding of vaccine wastage among public health units. We also obtained and analyzed ministry data on physician claims from the Ontario Health Insurance Plan (OHIP) system and on pharmacist claims from the Health Network System to identify duplicate patient billings for the influenza

Figure 1: Estimated Total Operating Costs of the Immunization Program, 2013/14 and 2012/13 (\$ million)¹ Source of data: Ministry of Health and Long-Term Care

Nature of Immunization-related Expenditures	2013/14	2012/13
Vaccine procurement	118.1	124.8
Public health units' operating costs—Ministry-funded ¹	56.4	54.9
Public health units' operating costs—municipally funded ¹	17.6	17.0
Vaccine administration costs ²	50.0	46.1
Ministry costs to administer program ³	4.2	4.4
Ontario Government Pharmacy ³	1.1	1.1
Public Health Ontario	2.1	2.0
Total	249.5	250.3

1. All costs are for the fiscal year, except for "Public health units' operating costs—Ministry-funded" (row 2) and "Public health units' operating costs municipally funded" (row 3). These estimates are primarily based on budgeted amounts for the calendar year.

2. Includes amounts paid to physicians and pharmacists for administering vaccines. The amounts paid to public health units for administering vaccines are included in the Ministry funding provided to public health units.

3. Excludes occupancy costs, which are not tracked.

vaccine. As well, we engaged two independent consultants, each of whom has expert knowledge of immunizations, to advise us.

Summary

Although there have been no significant outbreaks in Ontario, good information will always be needed to identify potential risks and, especially in a time of fiscal restraint, to evaluate program cost-effectiveness. The Ministry lacks good information to monitor whether Ontario's immunization program and delivery mechanisms operate in a cost-effective manner. For example, the Ministry does not track information on the total costs of delivering the immunization program in Ontario and therefore cannot ensure that the program is being delivered cost-effectively. Furthermore, information on children's immunization coverage rates relies on parents reporting information to public health units often years after their child is vaccinated, rather than health-care providers reporting information when they administer the vaccines. As such, immunization coverage information that could be used for decision-making is not reliable.

The Ministry also does not obtain good information on a timely basis about which federally recommended vaccines are cost-effective in Ontario. Since 2003, the Ministry has doubled the number of publicly funded vaccines, but does not have reliable information on their impact on Ontario's health system. Other significant issues noted during our audit include the following:

- Minimal provincial co-ordination of public health units: There is minimal provincial co-ordination of the 36 municipally governed public health units in Ontario over the immunization programs they deliver. Each public health unit acts independently and is not responsible to Ontario's Chief Medical Officer of Health. Further, over a third of the public health units each have a population that represents less than 1% of Ontario's population. The Ministry has not studied what could be the most cost-effective model or governance structure for delivering Ontario's immunization program.
- The Ministry does not track total costs: The Ministry does not track or monitor the total costs of delivering the immunization program in Ontario. We estimated, with assistance from the Ministry, these costs to be significant

at about \$250 million in the 2013/14 fiscal year (a total that includes \$74 million spent by public health units, \$118 million in vaccine costs, \$50 million in costs paid to health-care providers to administer vaccines, and \$7 million in Ministry and Public Health Ontario administration costs).

- No assessment of reasonableness of immunization costs incurred by public health units: We noted significant variations in Ministry funding to public health units, ranging from a low of \$2 per person living in one public health unit's area to a high of \$16 per person living in another's. However, the Ministry does not compare the immunizationrelated costs among the 36 public health units to determine whether patient needs are met cost-effectively, and it has not analyzed the reasons for these funding variations.
- Ontario's child-immunization rates are below federal targets: Low immunizationcoverage rates can increase the risk of disease outbreaks. Public Health Ontario data indicates that Ontario's childhood immunization-coverage rates (that is, the percentage of children immunized) are below federal immunization-coverage targets and, in almost all cases, below the level of immunization coverage that is necessary to prevent the transmission of disease. In fact, one public health unit reported that outbreaks would occur if its measles immunization-coverage rate decreased by as little as 10%. Ontario has not set its own provincial immunization targets, and there are geographic differences in immunization rates in the province.
- Ministry lacks information on immunization coverage in licensed daycares: Ministry policy requires daycare centres to report annually to their local public health unit on the immunization status of children. The public health units are then to report information on daycare centres' immunization coverage rates to the Ministry. However, public health

units do not report this information to the Ministry, and the Ministry does not request it. As a result, the Ministry is not aware of immunization-coverage levels in daycare centres or even the number of immunized children in daycare centres.

- Thousands of questionable payments for flu immunizations in 2013/14: We noted almost 21,000 instances where the Ministry paid physicians and pharmacists for administering the flu vaccine more than once to the same person over nine years of age during the 2013/14 flu season. The Ministry needs to introduce controls to prevent and identify duplicate vaccinations, and investigate the reasons for any duplicate billings made to the Ministry.
- Many doses of influenza (flu) vaccine unaccounted for: The Ministry did not have information on what happened to almost one million doses of the flu vaccine that it purchased.
- Over-ordering of vaccines results in wastage: Health-care providers and public health units reported \$3 million in vaccines expiring before use. There is no cost to public health units or health-care providers who over-order the free Ministry funded vaccines, and no Ministry system is in place to consistently identify unreasonable orders. Moreover, five of the six public health units we reviewed expressed concerns regarding excess and expired inventory at health-care providers.
- New \$160-million system will not reach full value until all vaccinations are recorded at the time of immunization: Ontario is in the process of implementing a new system (Panorama), which includes a vaccination registry, at an estimated cost that has escalated by over \$85 million and is now expected to exceed \$160 million. However, similar to the older system it is replacing, vaccinations are still not being electronically recorded by most health-care providers at the time they are administered. Parents must still report their

children's vaccinations to their local public health unit. This practice continues to result in problems with data accuracy and completeness. Furthermore, there are no plans to track vaccinations administered to adults. Until immunization information is registered by health-care providers at the time a vaccination is given, Panorama will not provide the data needed to identify areas of the province with low immunization-coverage rates, which could help prevent future outbreaks and identify vulnerable people during an outbreak. The Ministry indicated that the potential of Panorama for eventual point-of-care documentation of immunization (for example, physicians entering information electronically at the time a vaccination is given) would be an improvement over the existing system. However, the full benefit of Panorama cannot be recognized until all providers can update the registry at the time of vaccination.

- There is no process to ensure vaccination of adult immigrants: According to the Public Health Agency of Canada, immigrants are often not immunized prior to arriving in Canada, and may come from countries where vaccine-preventable diseases are more prevalent. This makes them more likely to acquire a vaccine-preventable disease and spread the disease to unimmunized Ontarians. However, no federal or provincial processes are in place to ensure that new immigrants are immunized before or soon after arriving in Ontario.
- Ontario has not fully assessed the costeffectiveness of funding some federally recommended vaccines: There are financial impacts on the health-care system that result from decisions to either fund or not fund vaccines in the province. For example, publicly funding cost-effective vaccines can save money (by reducing health-care costs) and reduces the incidence of vaccine-preventable diseases. By assessing the cost-effectiveness of funding vaccines, the Ministry would have

evidence to support its decision on whether or not to publicly fund a vaccine.

OVERALL MINISTRY RESPONSE

The Ministry of Health and Long-Term Care (Ministry) welcomes the recommendations contained in the Auditor General's report as important inputs to further strengthen Ontario's immunization program and continue building confidence in both the safety and effectiveness of vaccines.

Ontario has had a long history as a leader in the prevention and control of infectious diseases through immunization. To highlight some recent examples:

- Ontario was the first jurisdiction in North America to implement the Universal Influenza Immunization Program, which was further expanded in 2012 to improve access through pharmacist-administered flu shots.
- Ontario has continued to improve the quality of its immunization program through the creation of Public Health Ontario in 2007, which, among other things, has strength-ened Ontario's processes relating to vaccine safety surveillance.
- Ontario is one of the only Canadian jurisdictions that require children attending school and licensed daycare to be immunized against particular diseases.
- Under the Public Health Accountability Agreement first established in 2011, Ontario's public health units continue to demonstrate their commitment to excellence in the delivery and management of immunization programs at the local level.
- Ontario is currently implementing Panorama, the provincial immunization repository, with 35 out of 36 public health units now using its immunization component. The Ministry's vision is to expand Panorama's current focus on school-aged

children to include, in future phases, all immunizations for all Ontarians.

Parents are of particular importance in the immunization environment, as children have a high degree of susceptibility to disease and the greatest need for immunization. Although it is easy to forget the ravages of vaccine-preventable diseases from the past (for example, measles, diphtheria and meningitis), Ontario continues to work particularly with parents to improve access to vaccines and to ensure they understand the diseases, the risks and benefits of immunization, and how to protect their children.

In fall 2012, the Ministry initiated a comprehensive Immunization System Review, the findings of which were submitted to the Ministry in March 2014. The Ministry is currently developing a five-year Immunization Program Renewal action plan informed by these findings. We are pleased to note the close alignment of the Immunization System Review with the Auditor General's recommendations. These recommendations will be a significant contribution to the action plan, which aims to shape the future of Ontario's immunization system and improve the health of all Ontarians for generations to come.

Detailed Audit Observations

Complex Program Delivery Structure

Responsibility for Immunization

Under the *Health Protection and Promotion Act* (Act), the Chief Medical Officer of Health is responsible for dealing with risks to public health in Ontario, and reports on, among other things, immunization issues. The Act makes 36 boards of health (one for each public health unit) responsible for ensuring that publicly funded immunization programs are provided in each of their areas. (Appendix 1 highlights selective key responsibilities for Ontario's immunization program.) Each public health unit has a medical officer of health, who is required under the Act to control infectious diseases, including vaccine-preventable diseases, within that public health unit's boundaries. Each medical officer of health reports to its local board of health on issues related to public health, including publicly funded immunizations. The boards of health are all municipally controlled to varying degrees, with three types of board structures set out in legislation:

- At 25 boards of health, the majority of members are appointed by municipalities, with the remaining members provincially appointed.
 Although provincially appointed representatives are expected to provide the province's perspective to the board, they are not required to report back to the province.
- At nine boards of health, all members are elected municipal councillors.
- At two boards of health, membership is a mix of elected councillors and the general public.

No Analysis of Most Cost-effective Governance Model

The Ministry has an accountability agreement with each board of health that sets out, among other things, each board's reporting requirements to the Ministry. However, there are minimal requirements with respect to reporting on a given public health unit's vaccine-preventable disease program. Further, although the Ministry funds the majority of costs of the 36 public health units (the Ministry funds 75% and municipalities fund 25%), the public health units are municipally controlled, and in most situations are not responsible to the Chief Medical Officer of Health or the Ministry. As well, while the Act requires boards of health, and therefore the public health units, to comply with Ministry-created Ontario Public Health Standards and related protocols, including those on immunization, there are few requirements to report results

to the Ministry. Even where there are requirements, this information, for the most part, is not reported. Consequently, although the Ministry has overall responsibility for immunizations in Ontario, the Ministry does not have sufficient information on local public health unit issues regarding immunizations to make informed funding or policy decisions.

Many stakeholders are involved in the delivery of Ontario's immunization program, and some of them have a vested interest in retaining the current structure. As a result, there is a wide range of views on the best delivery model for Ontario's immunization program. In 2012, the provincially funded Commission on the Reform of Ontario's Public Services (the Drummond Report) recommended integrating the public health system into other parts of the health system (that is, Local Health Integration Networks), as well as considering uploading public health to the provincial level to ensure better integration with the health-care system.

We asked four local medical officers of health in Ontario for their views on an effective model of governance for the immunization program in Ontario. One medical officer of health told us that a good model of governance would be to have a provincial board of health that was chaired by Ontario's Chief Medical Officer of Health and to which all local medical officers of health would report. (This is similar to the model used in British Columbia, where the local medical officers of health report to the Provincial Health Officer.) This local medical officer of health indicated that such a model of governance would allow for more consistent practices across Ontario and enable more collaboration between medical officers of health, because the current structure involves each medical officer of health working in relative isolation. The three other medical officers of health disagreed with this approach, stating that it could undermine their ability to respond quickly to health matters in their local public health units. They believed that the current approach was the best governance model.

Although it is beneficial to have public health close to the community, the Ministry should in this

time of fiscal constraint review potentially more cost-effective options, including a review of the immunization program delivery structure.

Immunization Program Costs Not Monitored

The Ministry does not track or monitor the total costs of delivering the immunization program in Ontario. Given the significant expenditures on the immunization program, we believe that the Ministry should be more closely monitoring these costs to ensure that the immunization program is being delivered in a cost-effective manner.

Although each public health unit's budget submission to the Ministry indicates the expected expenditures on its vaccine-preventable diseases program, the Ministry has never required public health units to report actual spending, or compared immunization program costs or vaccine expenditures across public health units. Further, although the Ministry had information in most cases on the amount paid for each instance in which a health-care provider administers a vaccine, it had not tracked the total amounts paid to each provider or overall. Without complete and accurate cost information, it is difficult for the Ministry to determine whether services are being delivered cost-effectively.

Because the Ministry does not track the total costs of Ontario's immunization program, we requested information to determine these costs. As shown in **Figure 1**, we estimated the total operating costs for the 2013/14 fiscal year to be about \$250 million. The operating costs include costs incurred by public health units, boards of health, Public Health Ontario, and the Ministry. The Ministry's costs include vaccine costs, associated Ontario Government Pharmacy costs, and amounts paid to health-care providers to administer vaccines. The costs associated with implementing the new immunization registry—the main component of the Ministry's new information technology system, Panorama—are not included here and are discussed in the section titled *New Information System Yet to Realize Full Benefit* later in this report.

Ministry funding to each public health unit for the immunization program is not based on an assessment of the demand for services and does not consider, for example, the size or age composition of a public health unit's population. Rather, the funding to public health units is on a historical basis, with increases averaging 2% each year since 2010. However, the Ministry has not analyzed whether this is the appropriate level of funding to meet patient needs in each public health unit.

Our analysis indicated that the Ministry's historical-funding approach has resulted in large variances in per capita funding among the public health units. In fact, ministry funding for 2012/13 varied by public health unit from a low of \$2 per person in one public health unit to a high of \$16 per person at another, with a median funding of \$6 per person. Since municipalities fund 25% of public health unit costs, municipalities that can afford to spend more money on public health receive more ministry funding. The Ministry had not analyzed the reasons for the regional variations or assessed the impact that such funding variations have had on immunization programs across Ontario. For instance, the Ministry has not assessed whether higher per capita funding to public health units resulted in better immunization programs.

Ministry Needs to Review Number and Size of Public Health Units

The Ministry has not analyzed the number of public health units to determine the most cost-effective delivery structure. The 2003 Walker Report, by the Expert Panel on SARS (Severe Acute Respiratory Syndrome) and Infectious Disease Control, recommended consolidating the number of public health units to between 20 and 25, and retaining local presence through satellite offices, to allow for a critical mass to support comprehensive expertise and capacity at the public health unit level. Further, the 2006 report by the Ministry's Capacity Review Committee (established to review the organization and capacity of public health units) recommended reducing the number of public health units from 36 to 25 to ensure sufficient resources and staff expertise, and to reduce vacancies in small public health units. In 2009, the Ministry surveyed stakeholders, including boards of health, medical officers of health and other public health unit staff. About a third of respondents were against any merger to build capacity, primarily because they wanted to retain their autonomy in order to best respond to the unique needs of their specific communities. Another third generally supported a merger, while the remainder had no preference. Despite the evidence indicating the benefits of a reduced number of public health units, the Ministry had not undertaken any subsequent analyses to determine the most cost-effective model of service delivery. Our review of the program structure in larger provinces indicated two had significantly fewer health units, with Quebec having 18 regions, each with a medical officer of health, while British Columbia has five regional health authorities, each with a local chief medical officer of health.

We noted that 13 of the current public health units in Ontario have populations of fewer than 135,000 each, which is less than 1% of Ontario's population. Of these, five had a part-time medical officer of health as of May 2014, with four of these qualified and one in the process of completing specialized education required under a regulation to the *Health Protection and Promotion Act*. Merging smaller public health units may better enable them to recruit and retain a full-time medical officer of health and ensure that sufficient time and expertise is readily available to respond to public health needs, including occurrences of disease and outbreaks.

RECOMMENDATION 1

To ensure that Ontario's immunization program is delivered in an efficient and cost-effective manner, the Ministry of Health and Long-Term Care should review the immunization program

delivery structure, including total funding and the allocation of funding to public health units. Such a review should consider alternative delivery options.

MINISTRY RESPONSE

The Ministry agrees that the delivery of Ontario's publicly funded immunization program in an efficient and cost-effective manner is an important priority, and is pleased to receive advice and recommendations from the Auditor General on this area. The Ministry is currently developing a five-year Immunization Program Renewal action plan to be released in 2015.

As part of its mandate for accountability and transparency, the Ministry will also undertake a review of public health units, targeted to begin in the 2015/16 fiscal year. The outcomes of this review will support improvements in the delivery of public health programs and services, including immunization, within a transformed health system. The Ministry's considerations relating to the structure and organization of public health program and service delivery, including funding models and allocation, will be informed by the findings of the Immunization System Review and the Auditor General's recommendations, and will be built on previous Ministry-commissioned reviews of these topics.

Cost and Reliability Concerns with New Information System

New Information System Yet to Realize Full Benefit

After the 2003 outbreak of Severe Acute Respiratory Syndrome (SARS), the federal government identified a need for a nation-wide disease surveillance system, because contagious diseases, including vaccine-preventable ones, cross provincial/territorial boundaries. As a result, a computer system called Panorama was commissioned by the federal government in conjunction with the government of British Columbia. In 2007, Ontario decided to replace the Immunization Records Information System (IRIS)-its immunization registry software—with Panorama and subsequently approved plans to customize and implement three of Panorama's components: an immunization registry, a vaccine inventory tracking system, and one other component to assist public health units in managing outbreaks. In 2010, a fourth component was approved to assist public health units in investigating cases of vaccine-preventable disease.

As shown in **Figure 2**, the cost of implementing Panorama rose from the 2007 estimate of \$79 million to implement three components by March 2011, to \$158 million to implement four components by March 2014, and then to \$165 million to implement just two components

	Proposed		Estimated		_
	Project	Costs	Total Project	Expected	
Date	Components ¹	to Date	Cost (\$ million)	Implementation Period	Project Status
May 2007	1,2,3	0.7 ²	79.4	May 2007–Mar. 2011	Approved
Nov. 2009	On hold	45.0	On hold	On hold	On hold
Aug. 2010	1,2,3,4	45.0	158.0	Aug. 2010-Mar. 2014	Revisions approved
Dec. 2010	1,2,3,4	45.1	165.3	Dec. 2010-Mar. 2014	Revisions approved
Mar. 2014	1,2	138.6	165.3	Dec. 2010-Mar. 2016	Awaiting approval

Figure 2: Panorama Timelines, Cost Estimates, and Extent of Functionality Source of data: Ministry of Health and Long-Term Care

1. There are four project components: 1-Immunization registry; 2-Inventory management; 3-Outbreak management; and 4-Vaccine-preventable disease investigations.

2. These are the preliminary planning costs since the project began in the 2005/06 fiscal year.

by March 2016. As a result, the estimated cost increased by 110%, even though it included implementing fewer components of Panorama than originally planned.

As of March 2014, \$139 million had been spent to date on implementing Panorama in Ontario (\$126 million funded by the Ministry and \$13 million funded by the federal government). By July 2014, \$142 million had been spent. At that time, the Ministry had implemented the immunization registry component in 35 public health units (with the last one expected to be implemented by summer 2015) and the inventory tracking component at the Ontario Government Pharmacy. The Ministry expected the inventory tracking system components to be implemented in all 36 public health units by fall 2015. However, the Ministry indicated that all reporting capabilities of these components would not be fully operational until March 2016. Further, the Ministry had not yet developed a cost estimate or timeline, nor obtained associated approvals, for implementing Panorama's outbreak and investigation components, although it still plans to implement them.

Although Panorama is being adopted in many larger provinces, including Ontario, it is not being adopted in all provinces. Furthermore, although Panorama is replacing Ontario's 36 separate IRIS immunization registries (one in each public health unit) with one immunization registry, it still has certain limitations similar to those of IRIS: that is, vaccinations will still not be electronically recorded by physicians at the time they are administered. Because Panorama does not address this key deficiency of IRIS, it, too, will not provide complete or accurate information. As a result, Panorama will not contain information that can be used to accurately identify areas of the province with low immunization coverage rates that require tailored immunization strategies to help prevent future outbreaks, and to identify vulnerable people during an outbreak. Despite its high and rising costs, until such time as all vaccinations are contained in

Panorama, the completeness of the data is limited, similar to IRIS.

Vaccination History Not Complete

In Ontario, the public health units are responsible for maintaining immunization registry information. We noted in our 1997 and 2003 Annual Reports that they update the registry based on vaccination information reported by children's parents when the child enters school, which may not be reliable because the reporting usually occurs between four and six years after the child receives most vaccinations. The public health units then manually enter the information into the immunization registry, which is time-consuming and also increases the risk of error. As a result, the vaccination history on the registry may not be reliable. In 2003, the Ministry indicated it was working toward a registry that would more effectively monitor children's immunization status.

Immunization registries are an accepted best practice to track the vaccination history of each person in a jurisdiction. Since most immunizations are given to children, registries are primarily used to track childhood vaccines, but they can also be used to track adult vaccines (for example, adults should have a combination tetanus and diphtheria booster ever 10 years). With accurate and complete immunization information, a registry can be used to send reminders to individuals, including parents of children, who have not yet had the recommended publicly funded vaccinations. It can also be used to track areas of a jurisdiction in which a low percentage of the population has been vaccinated and, during an outbreak, to quickly identify and notify persons who have not been immunized and are therefore more vulnerable. As well, providing physicians or others who administer vaccines with access to such a registry can help prevent people from receiving duplicate immunizations in error.

Panorama includes a new immunization registry. The Ministry indicated that the new system is creating efficiencies because it is replacing

36 separate Immunization Records Information System (IRIS) immunization registries (one in each public health unit) with one central registry. This enables public health units to more quickly access the immunization records of a child who has moved from one public health unit area to another. However, public health units will still rely on information reported by parents years after their children's immunizations, and public health units will still need to manually enter this information into Panorama.

There is no ministry requirement for tracking information on all vaccinations given to each adult and no current plans to track such information. As a result, there will still be minimal information available on vaccinations received by adults.

Having physicians and other health-care providers update the registry at the time a vaccine is administered would provide more reliable information. In fact, Manitoba, Alberta, New York State, Australia, and the United Kingdom all have processes whereby, at the time a vaccination is given, physicians or other health-care providers submit information, usually electronically, that updates an immunization registry. In 2007, the Ministry envisioned that, in the longer term, physicians and other health-care providers would be able to update Panorama at the time a vaccine is administered. However, by summer 2014, the Ministry had not yet established its plan or associated timelines to enable physicians to update the immunization registry. The Ministry indicated that a key reason for this delay was that it needed to implement international data standards as part of Panorama's registry component prior to implementing processes to enable physicians to update immunization information at the time a vaccine is given.

RECOMMENDATION 2

Prior to proceeding with the implementation of Panorama's outbreak and investigation components, the Ministry should assess the current data completeness and accuracy deficiencies of Panorama. In this regard, to ensure that public health units have access to reliable immunization registry information in the event of an outbreak, and to send reminders to those who are due for immunizations (for example, for children according to the immunization schedule and for adults every 10 years for their tetanus booster), the Ministry of Health and Long-Term Care (Ministry) should develop processes, as part of its implementation of Panorama, that enable physicians and other health-care providers to electronically update the immunization registry each time they provide a vaccine, including those provided to adults.

As well, to better contain the escalation of costs to implement all four components of Panorama, the Ministry should review the costs and benefits of implementing the system's outbreak and investigation components to determine whether they will meet the Ministry's needs. If they are assessed to be cost-beneficial, the Ministry should develop a plan, including a budget and timelines, to implement these components in a cost-effective and timely manner.

MINISTRY RESPONSE

The Ministry agrees that incorporating immunization information from all health-care providers who administer vaccines in Ontario (including physicians and pharmacists) will be important to ensure a robust provincial immunization repository. This will, among other things, support outbreak management and immunization reminders. The Ministry will leverage its existing investment in Panorama, including its use of international immunization data standards, its capacity to support electronic linkages to other systems, and its capacity to record and track immunizations for all ages. This is in support of the Ministry's vision that all immunizations for all Ontarians will be housed in the provincial immunization repository. The Ministry will continue to develop options and

recommendations to inform governmental decisions going forward.

The Ministry also agrees with the second part of the recommendation and will review the costs/benefits of implementing Panorama's outbreak management and investigations components. Recognizing that these components of Panorama address the business needs in public health, and also building on the implementation of Panorama's immunization component in 35 public health units, the Ministry will analyze the costs/benefits of proceeding with the outbreak management and investigations components. The Ministry will also develop options and recommendations to inform future government decisions.

Better Tracking of Immunization Coverage Rates Needed

Ontario's Immunization Coverage Rates Below National Targets

Vaccinating an individual works to protect just that person against the associated disease. However, vaccinating a sufficient number of people can reduce or stop the spread of infectious diseases transmitted between people within a population (because few susceptible people remain to be infected). Such a population is considered to have herd immunity with regard to that disease.

Establishing and achieving a targeted immunization coverage rate—that is, the desired percentage of a given population to be vaccinated against a disease—can help a population achieve herd immunity. The targeted rate is usually set higher than the associated herd immunity level, in part because some people who are vaccinated against a disease do not become immune and because in others, immunity diminishes over time.

The 2006 National Immunization Coverage Survey, conducted by the Public Health Agency of Canada, noted that adult coverage rates are an important health indicator that can be used to target public health interventions to populations identified as having low rates of immunization. National immunization coverage rate targets were initially established in 1996 for most childhood vaccines, with some of these targets updated and the targets for most newer vaccines—that is, human papillomavirus (HPV), varicella (chicken pox) and pneumococcal—set in 2005 and 2007. However, no national targets have been established for rotavirus vaccine (which is administered before a child is a year old). For adults, national targets were set to achieve the following for three groups of people by 2010:

- 80% pneumococcal coverage for those aged 65 or older;
- 95% pneumococcal coverage for certain highrisk groups, such as persons with HIV; and
- 100% varicella coverage for post-partum women without evidence of immunity and 99% rubella coverage for post-partum women prior to discharge from hospital.

There are no other national targeted immunization coverage rates for adults, expect for some targets for influenza.

As shown in Figure 3, the immunization coverage rates achieved in Ontario are all lower than the national targets, and coverage rates vary greatly across public health units. Furthermore, the coverage rates are almost all lower than the herd immunity threshold levels recommended by the National Advisory Committee on Immunization (NACI) and other authoritative sources. For example, the overall measles coverage rate was 88% in the 2012/13school year, which is well below the recommended herd immunity threshold level of 96%-99%. In fact, in one public health unit, the measles coverage rate was just 61%. When herd immunity threshold levels are not achieved, there may not be enough people vaccinated to reduce or stop the spread of these infectious diseases to unimmunized people in Ontario. This is of particular concern in the public health units that have fewer immunized people.

Although the Ministry participated in establishing most of the national immunization coverage targets for children and adults, it did not adopt

Figure 3: Comparison of Ontario Immunization Coverage Rates to National Targets, by School Year (%)

Source of data: Ministry of Health and Long-Term Care

	National Coverage						2012/13 Range of Coverage among 36 Public
	Target	2008/09	2009/10	2010/11	2011/12	2012/13 ¹	Health Units
Early-childhood Vaccinations	2,3						
Diphtheria	99	84	75	81	80	75	38-97
Measles	99	83	76	86	89	88	61-98
Mumps	99	83	76	86	89	88	61-98
Polio	99	83	75	80	79	74	38-97
Rubella	97	83	76	95	95	95	71-99
Tetanus	99	84	79	81	80	75	38-97
Meningococcal (1st dose)	97	_4	_4	_4	72	82	60-95
Pertussis	95	80	76	77	76	73	38-97
Varicella (chicken pox 1st dose)	85	_4	_4	_5	75	78	49-85
Haemophilus influenzae type b (Hib)	97	_5	_ ⁵	_5	_5	85	59-98
Pneumococcal	90	n/a⁵	n/a⁵	n/a⁵	n/a⁵	80	55-92
Rotavirus	n/a ⁶	_4	_4	_4	_4	_4	<u> </u>
Grade 7/8 Vaccinations							
Hepatitis B	95	78	74	77	87	87	79-96
Human papillomavirus (HPV)	90	53	55	58	70	89	69-87
Meningococcal (2nd dose)	90	87	83	_5	84	80	79-96

1. Most recent results available from Public Health Ontario.

 Until June 30, 2014, Ontario's Immunization of School Pupils Act required children starting school to have been vaccinated against six diseases: diphtheria, measles, mumps, polio, rubella, and tetanus. As of July 1, 2014, the legislation requires these children to have been vaccinated against three additional diseases (for a total of nine): meningococcal disease, pertussis (whooping cough), and varicella (chicken pox).

3. Immunization coverage rates for the early-childhood vaccinations are measured at age 7 except for varicella (reported at age 5) and pneumococcal and Hib (both reported at age 4). Seven-year-olds are considered immunized if they have received all the vaccinations required by that age according to Ontario's immunization schedule.

4. No data collected during these school years due to recent introduction of public funding for these vaccines.

5. Coverage rate not available, because Immunization Records Information System (IRIS) does not calculate this information correctly or comparably.

6. There is no recommended Canadian coverage target for rotavirus vaccine.

these targets. Further, no province-wide immunization coverage targets have been established. Despite the fact that the Ontario Public Health Standard on Vaccine Preventable Diseases (which sets out the desired outcomes and associated requirements that boards of health must follow) indicates that each public health unit is to achieve targeted coverage rates, the Ministry has established only a few targeted rates over the last several years for the public health units. For example, a target was established for only one vaccine for each public health unit in 2013, and none were established for 2014. The Ministry indicated that no targets have been set because the data being collected by the public health units was not comparable.

The 2014 Immunization System Review also suggested that program performance measures and targets should be in place for each vaccine, including immunization coverage targets based on the uptake required to achieve herd immunity. The review also noted that it was difficult to obtain adult and senior immunization coverage data for Ontario. Tracking coverage rates can assist in assessing a population's risk of instances or outbreaks of vaccine-preventable diseases. Except for the influenza vaccine, the Ministry does not have information on the coverage rates actually achieved for adults, because this information is rarely tracked in the Ministry's immunization registry. The Ministry has not yet developed a plan to implement changes necessary to address key issues identified in the Immunization System Review. The Ministry expected to have such a plan developed in 2015.

One of the desired societal outcomes in the Ontario Public Health Standard on Vaccine Preventable Diseases is reduced incidence of disease. Low immunization coverage rates increase the risk of disease outbreaks. In fact, a 2013 Toronto Public Health report noted that if Toronto's measles coverage rates "drop by as little as 10%, outbreaks will occur." At the time of our audit, Public Health Ontario, which is responsible for monitoring immunization coverage rates in Ontario, indicated to us that the lack of information being tracked in Ontario's immunization registry made it difficult to relate low immunization coverage rates to any outbreaks that occur. Further deficiencies in the way registry data is captured can contribute to inaccurate information on immunization rates. Therefore, Public Health Ontario had not analyzed outbreaks by their location (such as whether they occur in a daycare centre, a school or a workplace) or by the age of those infected, which can help reduce the incidence of disease and outbreaks. Public Health Ontario expected to be able to conduct such analysis for school-age children once the new immunization registry, part of Panorama, is fully operational.

RECOMMENDATION 3

To promote higher vaccination coverage rates, including the achievement of herd immunity levels, and thereby protect against the spread of vaccine-preventable diseases, the Ministry of Health and Long-Term Care should establish targeted provincial immunization coverage rates for all vaccinations, and monitor, in conjunction with Public Health Ontario, whether they are being achieved.

MINISTRY RESPONSE

The Ministry agrees that the formal establishment and monitoring of immunization coverage targets is an element of immunization system performance management. To ensure that immunization coverage targets are as robust and up-to-date as possible, the Ministry will work with Public Health Ontario and other partners in reviewing the existing nationally established targets and setting new provincial immunization coverage targets as needed for all publicly funded vaccines in Ontario. The Ministry, in conjunction with Public Health Ontario, will continue to monitor coverage rates at the provincial and public health unit level, and will assess achievement against the provincial targets once established.

Inadequate Processes to Track and Address Low Immunization Coverage Rates for Children

Vaccination Requirements Different for Daycares and Schools

In Ontario, children are required to have certain immunizations to attend daycare centres and schools. (See **Appendix 2** for a comparison of different provinces' immunization schedules for publicly funded vaccines.) However, under the Ministry's policy on licensed daycare centres and the requirements under the *Immunization of School Pupils Act*, exemptions from immunizations are permitted for medical, conscience or religious reasons. Medical exemptions require a letter from a physician. For daycare centres, an exemption for conscience or religious reasons is allowed if a parent provides the daycare centre with a letter stating

their reason. However, the Act states that once a child reaches school, parents wishing to obtain a similar exemption must swear a statement before certain individuals, such as a lawyer, a member of the Assembly, or certain court clerks.

In 2014, California began requiring parents who wanted their children to be exempt from a vaccination due to personal beliefs to obtain a statement signed by a health-care practitioner indicating that the parent received information about the benefits and risks of the vaccine, in addition to an exemption document similar to the one used in Ontario. Australia requires all exemptions to be signed by a health-care provider to ensure that parents understand the benefits and risks of immunization. The 2014 Immunization System Review suggested that the Ministry consider working with public health units to develop "consistent strategies for ensuring parents are aware of the risks of not having their children immunized before they submit a statement of exemption."

In Ontario, daycare centres must ensure that children have had the appropriate vaccinations for their age at the time they start attending the daycare centre. While daycare centres are required from time to time thereafter to ensure children obtain age-appropriate vaccinations, there is no authority for public health units to suspend children for this reason once they start attending the daycare centre. However, under the Immunization of School Pupils Act, the local medical officer of health may suspend students or cause their parents to be fined if they do not provide information on the student's immunization history. The 2014 Immunization System Review stated that the Ministry should consider "exploring the potential to develop one overall piece of legislation to address disease prevention and infection control in school and daycare settings."

We noted that neither the Ministry nor Public Health Ontario has information on whether parents of unimmunized children have been fined or the children suspended for not being vaccinated or having filed an exemption with the public health unit. The three public health units we visited had not fined any parents during the latest school year for which data was available. However, in compliance with the Act, all three had suspended unimmunized students: one (with more than 700 schools in the area) had suspended more than 6,600 students during the 2013/14 school year; another (with about 100 schools in the area) had suspended more than 580 students in the 2012/13 school year; and the third (with more than 50 schools in the area) had suspended fewer than five children in the 2012/13 school year. Without information on the number of children that have been suspended, as well as information on the outcome of these suspensions (for example, whether the child was subsequently immunized), the Ministry cannot evaluate the effectiveness of the actions taken by the public health units to ensure compliance with legislated immunization requirements.

Better Identification Needed of Areas with Low Coverage Rates

Both IRIS and its replacement, Panorama, provide information on the percentage of children with religious, conscience or medical exemptions. These exemptions are claimed relatively infrequently, totalling between 1% and 2% of children provincewide for all vaccines in 2012/13. However, these rates vary significantly among the public health units. Public Health Ontario noted for 2012/13 that the exemptions for measles, by public health unit, ranged from a low of less than 1% of children at one public health unit to a high of over 7% of children at another. Public Health Ontario has indicated that even public-health-unit-specific rates "likely conceal important variations in immunization exemptions across communities within public health units." For example, the public health unit with an average exemption rate of over 7% would have certain schools where exemption rates were much higher than 7%.

However, neither Public Health Ontario nor the Ministry has information on which geographic areas within the boundaries of each public health unit have low immunization coverage rates, even though such areas are at a higher risk of a disease outbreak. Instead, public health units are responsible for identifying those geographic areas within their boundaries that have low coverage rates, but these results are rarely reported to the Ministry or to Public Health Ontario.

Ministry policy requires licensed daycare centres to report annually to their local public health unit on the immunization status of children. The public health units are then to report information on daycare centres' immunization coverage rates to the Ministry. However, public health units do not report this information to the Ministry, and the Ministry does not request it. As a result, the Ministry is not aware of immunization coverage levels in daycare centres or even the number of immunized children in daycare centres. One of the three public health units we visited did not ensure that data was received for all children attending daycare centres, due to resource constraints. As a result, the public health unit would not be able to quickly assess which children are at risk in the event of an outbreak. Since IRIS could not produce a rotavirus coverage report, the public health units were not able to easily determine how many children were at increased risk of acquiring this disease, even though a number of rotavirus outbreaks occurred in daycare centres in the last couple of years (seven outbreaks occurred in daycare centres in 2013 and two in 2012). Panorama is expected to track rotavirus, but at the time of our audit, it was too early to assess how effectively it would do so.

Overall childhood immunization coverage rates are reported publicly in Public Health Ontario's annual coverage report. However, this public report does not include any coverage rates by public health unit or changes in coverage rates over time. Publicly disclosing this information would provide Ontarians with information on immunization coverage rates in their area and would help show whether coverage rates are increasing or decreasing, especially in areas with historically low coverage rates. Furthermore, the report does not provide any information on coverage or exemption rates by school or daycare centre. We calculated one public health unit's coverage rate in daycare centres and found that 15% of children did not have all required measles vaccinations, with one daycare centre as high as 42% (eight of the 19 children in the daycare centre) and another at 31% (18 of the 59 children in the daycare centre); such immunization coverage rates increased the risks of outbreaks at these daycare centres. If this information were publicly available, parents of children who cannot be immunized could choose to send their child to a daycare centre with a larger percentage of vaccinated children, where an outbreak would be less likely.

RECOMMENDATION 4

To help prevent outbreaks by ensuring that a sufficient percentage of Ontario's population, including children, is vaccinated, the Ministry of Health and Long-Term Care should— together with improving the completeness and accuracy of the data tracked by Panorama's immunization registry—do the following:

- harmonize the immunization requirements, including the vaccination, exemption and suspension processes, between schools and daycare centres by exploring the possibility of developing one overall piece of legislation to address disease prevention and infection control in daycares and schools, as recommended in the 2014 Immunization System Review;
- review options for ensuring that parents who exempt their children from vaccinations for non-medical reasons are aware of the risks and benefits of being immunized, such as by requiring a signed statement from a physician stating that the parent received information on the risks and benefits of the vaccine;
- ensure that public health units are taking appropriate actions to identify and address areas of the province, including daycare

centres and schools, with low immunization coverage rates; and

 publicly report immunization coverage rates by daycare and school so that parents of children who cannot be immunized can choose to send their child to a daycare centre or school with a larger percentage of vaccinated children, where an outbreak is less likely.

MINISTRY RESPONSE

The Ministry agrees that, to help prevent outbreaks, concerted efforts are needed across the system to improve vaccine uptake, especially in areas of low immunization coverage. Building on Panorama as an important tool for adhering to immunization data standards and for continually improving immunization data completeness and accuracy, the Ministry will:

- develop strategies to improve alignment and consistency of immunization processes across schools and daycare centres, including a review of existing legislation for schools and daycare centres to explore whether legislative changes are required to achieve this aim;
- consider opportunities to increase awareness and improve understanding among parents of the risks of exempting their children for non-medical reasons;
- work with public health units and Public Health Ontario to clarify and strengthen processes, strategies and requirements for identifying and addressing areas of low immunization coverage; and
- develop a plan for expanding public reporting of immunization coverage rates, building upon work already underway in some health unit areas, including consideration of public reporting of rates on a geographical basis (for example, for daycare centres and/or schools).

Processes Needed to Better Deal with Vaccine-Preventable Diseases Entering Canada

The Canadian Immunization Guide published by the Public Health Agency of Canada notes that over one-third of new immigrants are susceptible to measles, mumps or rubella. Further, immigrants from tropical countries are five to 10 times more susceptible to varicella (chicken pox). We noted that the Ontario government, in conjunction with the federal government, offers Settlement Services to help newcomers adjust to life in Canada. Immigrants receive information about immunization, such as requirements for children, but not about most immunizations recommended for adults. The 2014 Immunization System Review also noted that imported cases of vaccine-preventable diseases pose a threat. It indicated that the Ministry could work with groups that represent the major new-Canadian communities to promote awareness of the need for immunizations among those who visit friends and family in countries where such vaccinepreventable diseases are still endemic.

The Canadian Immunization Guide recommends that persons without proof of immunization be immunized. However, there is neither provincial nor federal monitoring to ensure that immigrants have an opportunity to receive required immunizations. New immigrants to the United States are required to have their vaccinations updated as part of their mandatory pre-arrival medical screening. Evidence-based clinical guidelines for immigrants and refugees posted online by the *Canadian Medical* Association Journal recommend that all adult immigrants without immunization records, and all children at vaccine-appropriate ages with missing or uncertain vaccination records, receive the vaccine for measles, mumps, rubella, diphtheria, tetanus and polio. Without these vaccinations, new immigrants are susceptible to vaccine-preventable diseases, and may import cases of vaccine-preventable diseases to Ontario.

RECOMMENDATION 5

To reduce the risks of importing cases of vaccine-preventable disease into Ontario, the Ministry of Health and Long-Term Care, in conjunction with provincial stakeholders, including the Ministry of Citizenship and Immigration, should explore, in discussions with the federal government, the possibility of providing immigrants the opportunity to receive required vaccinations before arriving in Ontario. This would include consistently providing information on immunization to new immigrants.

MINISTRY RESPONSE

The Ministry agrees that all Ontarians, including new immigrants entering the province, and especially children, should be immunized according to the Publicly Funded Immunization Schedules for Ontario and given access to the information, tools and supports needed to facilitate this process. As a component of the Immunization Program Renewal action plan currently under development, the Ministry will work with stakeholders, including the Ontario Ministry of Citizenship and Immigration, Public Health Ontario and the federal government, to review and update the Ministry's current risk-based approach for identifying priority groups for immunization and consider opportunities to further improve the immunization status of immigrants.

Improvements Needed to Promotion of Immunization

Physicians Require More Information and Effectiveness of Incentives Needs Review

One of the desired societal outcomes in the Ontario Public Health Standard on Vaccine Preventable Diseases is increasing the immunization knowledge of health-care providers. A 2013 Ministrycommissioned survey of physicians indicated that 40% of the 264 physicians responding required more information on the recommended timing of vaccinations and 61% needed more information on updates or clarification on changes to the schedule. The 2014 Immunization System Review noted that because Ontario's publicly funded immunization schedule changes over time, it may be difficult for parents and physicians to ensure that children are adequately immunized.

The survey of physicians also indicated that twothirds wanted more information to help address parental concerns about common vaccine myths and misconceptions. In British Columbia, a reference guide for physicians presents both clinical and technical evidence on vaccines, and provides simple terms that physicians can use when providing explanations to patients.

To promote immunization, the Ministry pays bonuses to certain physicians—who work in certain groups or organizations with other physicianswho report that they have immunized a required minimum percentage of their patients in the last year. For example, a physician will receive \$2,200 for immunizing 95% of the children in his or her practice; \$1,100 for immunizing 90%; and \$440 for immunizing 85%. The total of these bonuses paid in the 2013/14 fiscal year was almost \$11 million. The Ministry does not verify the number of children immunized. In addition, over \$6 million in bonuses was paid to physicians who provided the influenza vaccine to at least 60% of their patients. In New York State, the local health departments do not pay bonuses but do validate physicians' immunization rates. The Ministry has not evaluated whether its bonus payments to physicians are resulting in higher immunization rates in Ontario, nor has it considered other options for improving physicians' immunization rates.

Public Education about Benefits and Risks of Vaccination Not Co-ordinated

Another desired societal outcome in the Ontario Public Health Standard on Vaccine Preventable Diseases is increased public knowledge of immunization. The 2014 Immunization System Review notes growing hesitancy to have children vaccinated due to concerns about the safety and effectiveness of vaccines and a sense that vaccinepreventable diseases are no longer a threat. Since the 2010/11 fiscal year, over 80%, and in some years up to 100%, of the Ministry's immunizationrelated advertising funding went toward specifically promoting the influenza vaccine. Public health units also use some funding for local campaigns such as posters, fridge magnets and radio ads. The Ministry conducted several awareness campaigns about the HPV vaccine during the 2009/10 fiscal year (for example, online ads and magazines) because HPV had the lowest coverage rate for childhood vaccinations. Subsequently, the percentage of immunized Grade 8 girls increased from 55% in 2009/10 to 70% in 2011/12.

We noted that the Immunize British Columbia website offers residents a live webchat with a nurse to discuss vaccines and any associated concerns. One public health unit we visited indicated that this approach could be used in Ontario to effectively respond to parental concerns and reduce duplication of effort. While the Ministry's Telehealth phone line enables Ontarians to talk to a nurse about health-related matters, at the time of our audit, they could not provide information to address vaccine hesitancy issues and related parental concerns. We further noted that the state of Maine, after starting to target its public health campaigns to specific population groups, increased its child immunization rates by 40%, with minimal impact on overall cost.

A federal website maintained by the Public Health Agency of Canada advises Canadians travelling abroad of the recommended immunizations they should receive before travelling. Although many of these immunizations are not publicly funded, they can be essential to protecting the health of people travelling to countries where certain diseases are prevalent. The 2014 Immunization System Review also recognized the risk to travellers and noted that Ontario could assess ways to enhance and support the provision of travel vaccines, in order to reduce the threat posed by travellers bringing cases of measles and other vaccine-preventable diseases back to Ontario.

RECOMMENDATION 6

To ensure that Ontarians can easily access information on the risks and benefits of immunizations, the Ministry of Health and Long-Term care should:

- in conjunction with stakeholder such as the College of Physicians and Surgeons of Ontario, ensure that physicians have easy access to clinical and technical evidence on vaccines, and to materials that provide simple terms for physicians' use when providing explanations to patients;
- determine whether the bonus payments currently made to certain physicians are resulting in improved immunization rates in a cost-effective manner; and
- help reduce duplication of effort by public health units in addressing concerns locally, by considering a more co-ordinated approach to public education regarding all vaccines, including a website that provides clear and understandable information on vaccine hesitancy issues.

MINISTRY RESPONSE

The Ministry agrees with the importance of providing timely, relevant and reliable information about vaccines to both health-care providers and the public, including easily accessible information on the risks and benefits of immunization. Building on the current proactive efforts of public health units, the Ministry develops communication campaigns and educational material to increase knowledge and awareness regarding publicly funded immunization programs and to promote immunization as part of a healthy lifestyle. As part of the Immunization Program Renewal action plan currently under development, the Ministry will be expanding these efforts to further promote immunization and build public confidence including:

- working with Public Health Ontario, public health units, the College of Physicians and Surgeons of Ontario, the Ontario Medical Association, and other key stakeholders to ensure the development of comprehensive, user-friendly online resources for providers to support their efforts in communicating about vaccines with their patients;
- reviewing available evidence to determine if immunization bonus payments lead to improvements in immunization rates; and
- developing a comprehensive and coordinated immunization promotion strategy for the public, aligned with local promotion efforts of public health units, to provide the information, tools and supports the public needs—when and how they need them—to make informed immunization decisions.

Cost/Benefit Analysis Needed of Some Federally Recommended Vaccines

The process for approving publicly funded vaccines for use in Ontario starts with Health Canada, which approves which vaccines can be sold in Canada. The National Advisory Committee on Immunization (NACI) then issues advice, based on scientific evidence, on the use of the approved vaccines, such as which age group(s) should receive each vaccine. As well, the Canadian Immunization Committee (which has federal/provincial/territorial representation) provides advice on program implementation, such as cost-effectiveness considerations. In Ontario, the Provincial Infectious Diseases Advisory Committee—Immunization (PIDAC) advises Public Health Ontario, which in turn advises the Ministry, on which vaccines should be publicly funded and for whom. The Ministry then advises the government on which vaccines to fund and for whom.

In our 2003 Annual Report, we noted several vaccines that were recommended by NACI but not publicly funded by the Ministry. Since then, the Ministry has increased the number of vaccines it funds for the general population, such that the number of diseases protected against increased from 10 to 16. At the time of our current audit, all but one of the vaccines recommended by NACI were being publicly funded (the exception being shingles), although four others (HPV, meningococcal, pertussis and varicella) were not funded for all persons, as recommended by NACI (as shown in **Appendix 3**).

The Ministry indicated that there is limited or no eligibility for these vaccines due to the cost of purchasing the vaccines and difficulties in assessing the cost-effectiveness of the vaccines in Ontario. However, PIDAC has indicated that the shingles vaccine is cost-effective for people 60 to 70 years old. At the time of our audit, the Ministry did not have sufficient analysis concluding on the cost-effectiveness of expanding eligibility for the other vaccines.

RECOMMENDATION 7

The Ministry of Health and Long-Term Care should implement a consistent process for examining the costs and benefits for Ontario of publicly funding vaccines recommended by the National Advisory Committee on Immunization. This process should include an examination of situations in which the vaccination costs are found to be less than the health-care costs of treating people who acquire a vaccine-preventable disease.

MINISTRY RESPONSE

The Ministry agrees with the importance of assessing cost-effectiveness as a key factor to inform government decision-making related to new or expanded publicly funded immunization programs. In developing its policy advice, the Ministry uses a nationally recommended analytic framework for immunization programs in Canada. This framework includes costeffectiveness as a key consideration, in addition to factors such as scientific evidence, frequency and severity of disease in Ontario, acceptability including public and stakeholder perspectives, and equity, ethical and legal considerations.

The Ministry will further strengthen its cost-effectiveness analysis and advice to inform decision-making, including working with Public Health Ontario and other partners to develop a standardized approach for assessing cost-effectiveness, including the use of Ontario-specific data and modelling assumptions where possible.

Better Oversight of Influenza Immunization Program Needed

In 2000, Ontario introduced a Universal Influenza Immunization Program, under which anyone older than 6 months can receive the influenza (flu) vaccine at no cost. Unlike other vaccines, the flu vaccine lasts only about four to six months before the immune protection diminishes. Therefore, a new vaccine is offered each year. The Ministry estimates, based on net doses of the vaccine distributed (that is, total doses distributed less reported wastage), that about 30% of the Ontario population is immunized each year. In the 2013/14 flu season (from about September 2013 to March 2014), ministry data supported that about 3.1 million doses were administered, as shown in **Figure 6**.

The Ministry has not conducted any recent assessment of the overall impact of Ontario's universal influenza program on patients and their use of health-care resources.

Inconsistent Influenza Immunization Policies for Health-care Workers

In 2012, the Provincial Infectious Diseases Advisory Committee—Immunization (PIDAC) recommended that annual influenza vaccinations be a condition of employment for all Ontario health-care workers, including all hospital staff, primary-care physicians, long-term-care home workers and paramedics. The federal target is to have 80% of these workers immunized. However, Ministry documents indicate that, for the 2013/14 flu season, only about 70% of long-term-care home workers and 50% of hospital workers were immunized. There is an even higher federal target of 95% for workers who have extensive contact with patients at long-term-carehomes; however, the Ministry does not measure the immunization rate of these workers.

In 2013, the National Advisory Committee on Immunization (NACI) indicated that the influenza vaccination of health-care workers was an "essential component of standard of care" to protect patients from disease. British Columbia requires health-care workers who have not been immunized to wear a surgical mask during flu season. This change resulted in an increase in vaccination uptake from 40% to about 75% in acute-care hospitals. Saskatchewan plans to implement a similar policy for the 2014/15 flu season. Although not a requirement in Ontario, 13 Ontario hospitals (9% of hospitals) have implemented a policy requiring staff to either be vaccinated or wear a mask. According to the Ontario Hospital Association, nearly all of these hospitals experienced significant increases in their immunization rates. Therefore, such a requirement can be a good step in protecting vulnerable patients and reducing influenza outbreaks in hospitals.

RECOMMENDATION 8

If there is support for the efficacy of the influenza vaccine to reduce the transmission of influenza, to help reduce the risk of hospitalized patients contracting influenza, the Ministry of Health and Long-Term Care (Ministry) should consider requiring hospital staff to either be immunized or wear a mask, similar to the practice in British Columbia, and monitor compliance. This could possibly be established in agreements between the Ministry and Local Health Integration Networks (LHINs), and LHINs and hospitals.

MINISTRY RESPONSE

The Ministry agrees that health-care worker influenza immunization is an important component of minimizing the transmission of influenza within hospitals. The Ministry strongly encourages influenza immunization for all health-care workers, as well as stringent infection control practices, and is supportive of all health-care facilities with institutional "vaccine or mask" policies in place.

Building on the work of the Ministry's Health Care Worker Influenza Immunization Task Group, the Ministry will continue to work closely with stakeholders to improve health-care worker influenza immunization rates in Ontario. The Ministry will also work with Public Health Ontario, Health Quality Ontario and other key stakeholders to study the experience of hospitals with "vaccine or mask" policies, and will examine the challenges and opportunities of establishing a provincial "vaccine or mask" policy.

Improvements to Influenza Vaccine Program Needed

Reimbursement Rates to Pharmacists Need Review

Beginning in the 2012/13 flu season, Ontario pharmacists have been allowed to administer the flu vaccine and bill the Ministry \$7.50 for each dose administered. (Before that, only pharmacies that employed nurses had been eligible to administer the flu vaccine.) Within one year, the number of pharmacies and number of doses administered had more than tripled—from about 600 pharmacies administering 250,000 doses in the 2012/13 flu season, to almost 2,000 pharmacies administering about 765,000 doses in the 2013/14 flu season. As a result, as shown in **Figure 4**, the proportion of flu vaccines administered by pharmacies has increased, with most of this increase due to fewer vaccines being administered by physicians.

In the 2013/14 fiscal year, the Ministry paid a total of \$25 million to providers for administering the flu vaccine. This amount included \$18 million paid to physicians, \$6 million paid to pharmacies and \$1 million paid to public health units. We noted that the rate at which the various health-care providers were reimbursed varied: \$5 per dose for public health units and \$7.50 per dose for pharmacies. Physicians paid on a per service basis receive \$9.60 per dose if the flu vaccine is all the patient comes in for, and \$4.50 per dose otherwise.

The Ministry had not performed an analysis to support the per-dose cost amount or the fees paid among the different health-care providers. The Ministry indicated that the reimbursement rate for pharmacies was set at \$7.50 per dose to make it financially attractive for pharmacists to administer the flu vaccine.

Questionable Billings

The Ministry has different information systems for processing payments to health-care providers who administer the flu vaccine. In particular, physicians' claims for payment are processed through the Ontario Health Insurance Plan (OHIP) system, and pharmacists' claims for payment are processed through the Health Network System.

Figure 4: Percentage of Influenza Vaccine Administered Annually, by Type of Health-care Provider, 2011/12–2013/14*

Source of data: Ministry of Health and Long-Term Care

	2011/12 (%)	2012/13 (%)	2013/14 (%)
Physicians	77	73	63
Pharmacists	0	9	25
Public health units	13	10	6
Other, including workplaces	10	8	6

* No information is available on influenza vaccines administered by nurses who are employed by family health teams.

Both the OHIP system and the Health Network System are programmed to reject a claim for payment for immunizing a person more than once in the same day. However, there are no controls to prevent payments if a claim is made for multiple flu immunizations of the same person occurring on different days within a single flu season, even though such duplicate immunizations should rarely occur for anyone over the age of 9 years. The Ministry has not electronically linked the OHIP system and the Health Network System to determine if both physicians and pharmacists were billing the Ministry for administering the flu vaccine to the same patient. As a result, the two claims payment systems had no controls to identify duplicate billings between physicians and pharmacists.

The Ministry conducted a limited, informal review of the 2012/13 and 2013/14 flu billings by pharmacists and noted a small number of duplicate billings, but no broader review was conducted. As shown in Figure 5, we identified almost 21,000 instances during the 2013/14 flu season of the Ministry paying physicians and pharmacists for administering the flu vaccine more than once to the same patient over 9 years of age. Most of these questionable payments were made through the OHIP claims system. While our analysis indicated that most physicians billed once for each patient, about 11,000 of the questionable OHIP billings involved an individual physician billing more than once for the same patient. For example, one physician billed 18 times for the same patient over six months during the 2013/14 flu season.

The Ministry did not know whether individuals had been erroneously immunized more than once or whether these were provider billing errors, and it could not readily calculate the excess amounts paid to providers for these duplicate billings. The 21,000 duplicate billings are based on all flu immunization data at the Ministry. The flu vaccine is also administered by others, such as public health units and nurses employed by family health teams, but the Ministry does not obtain any detailed patient information on these immunizations. As a result, we could not assess the extent of any additional duplicate amounts paid by the Ministry. We also found that the minimal controls over pharmacy billings had resulted in pharmacists billing for the immunization of over 300 children under 5 years of age in the 2013/14 flu season, even though, under their agreement with the Ministry, pharmacies are not permitted to administer the flu vaccine to these children.

Flu Vaccines Unaccounted For

Although the Ministry had information on the majority of the flu vaccines administered, it did not have good information on what happens to all doses of the influenza vaccine that are purchased and distributed to health-care providers. As **Figure 6** shows, a significant number of doses remain unaccounted for. Based on information available at the Ministry, we noted that for the 2013/14 flu season, there were about 961,000 such doses.

The Ministry had no information on whether these doses were administered or wasted. However, the Ministry believes that these doses were likely administered by nurses who were employees of family health teams, or possibly through other arrangements, including from long-term-care homes and Community Care Access Centres.

Figure 5: Questionable Billings by Physicians and Pharmacists for Administering the Influenza Vaccine to Persons Over 9 Years of Age, 2013/14 Flu Season

Prepared by the Office of the Auditor General of Ontario

# of times physicians billed OHIP more than once for same patient	14,700
# of times pharmacies billed Ontario's Health Network System more than once for same patient	800
# of patients for whom billings were submitted at least once on both billing systems	5,400
Total # of extra times Ministry paid for flu vaccines	20,900

Figure 6: Unaccounted-for Doses of Influenza Vaccine

Source of data: Ministry of Health and Long-Term Care

	Flu Season		
	2011/12	2012/13	2013/14
Doses purchased by the Ministry	4,558,000	4,449,000	4,625,000
Less: Doses tracked by the Ministry:			
Doses administered to patients (by physicians, pharmacists, public health units and others)	(2,655,000)	(2,781,000)	(3,080,000)
Doses wasted	(923,000)	(414,000)	(584,000)
Doses not accounted for*	980,000	1,254,000	961,000

* The Ministry has no information on whether these vaccines were administered or wasted.

RECOMMENDATION 9

Given the rapidly growing interest on the part of pharmacists to administer the influenza vaccine, the Ministry of Health and Long-Term Care (Ministry) should assess the reasonableness of the rate paid to pharmacists to administer the vaccine so as to ensure that it is not excessive and is commensurate with pharmacists' costs and experience.

To help prevent health-care providers from administering a duplicate influenza vaccine to people who have already been vaccinated and to identify erroneous duplicate billings, the Ministry should:

- review and revise its claims payment systems to reject billings from health-care providers for patients who have already received their influenza vaccine; and
- periodically compare payments made to physicians for administering the influenza vaccine to those made to pharmacists, and follow up on duplicate payments made for the same patient.

MINISTRY RESPONSE

The Ministry agrees with the importance of continually improving the Universal Influenza Immunization Program (UIIP) to optimize the prevention and control of influenza in Ontario, including improvements in both reimbursement policies and data systems. The Ministry will review the reimbursement rate paid to pharmacists to determine if future changes are required.

The Ministry will consider additional measures to ensure appropriate billing, including potential changes to its current billing systems. To strengthen the current post-payment verification process for physician and pharmacist claims, the Ministry will review the potential of this verification process to provide information on patients who are recorded as accessing multiple influenza immunizations from physicians and pharmacists, as well as assess the causes for any duplicate, incorrect or inappropriate billings, and take appropriate action as part of the Ministry's broader risk/fraud management framework. The Ministry will also further enhance data quality by developing continuing educational material for providers to reinforce the importance of using the correct codes for all immunizations. In addition, the Ministry will work to close the data gap by identifying how many influenza immunizations were administered by nurses in Family Health Teams.

Better Tracking Needed of Adverse Events Following Immunization

Adverse events following immunization include any undesirable medical occurrence that happens after a person is immunized—for example, allergic reactions, convulsions, rash, pain, and redness and swelling that lasts for at least four days. In Ontario, adverse events include medical occurrences following a vaccination that are a possible, but not a confirmed, result of the vaccine. This approach is taken to ensure that potential adverse events are not missed. For vaccines administered in the 2013 calendar year, over 640 adverse events, including about 45 considered serious or medically significant (for example, anaphylaxis that is treated in an emergency department), were reported to Ontario's public health units primarily by patients or physicians following immunization.

Although health-care providers, including physicians and pharmacists, administering vaccines in Ontario are required to inform patients about the risks and benefits of immunizations, they may not always advise patients on potential adverse events that should be reported, such as allergic reactions, versus normal reactions that need not be reported, such as having a sore arm for a few days. Without such information, patients may report only very serious adverse events, such as those requiring a hospital visit. In fact, Public Health Ontario notes that less serious adverse events are likely underreported in Ontario. In the United States, health-care providers must provide standardized information to patients on which adverse events should be reported for each vaccination. Providing such standardized information can result in more consistent and complete reporting of adverse events.

For the 2013 calendar year, we noted that two public health units in the Greater Toronto Area had disproportionately low rates of adverse event reporting, with Toronto having 21% of the provincial population but only 9% of the adverse events, and York having 8% of the province's population but only 3% of the adverse events. Public Health Ontario had made a similar observation, with respect to adverse events reported in 2012, in its *Annual Report on Vaccine Safety in Ontario*. Public Health Ontario has not investigated the reasons for these variances. However, Public Health Ontario did contact the three public health units that reported no adverse events in 2013 to obtain their reasons for underreporting. Without complete adverse event reporting, it can be more challenging to identify potential issues and prevent future adverse events.

In Australia, most adverse event rates for publicly funded vaccines are calculated based on the number of vaccine doses administered. The Ministry does not track the number of doses administered of most vaccines. Therefore, like other Canadian provinces, Ontario uses the total population to calculate its adverse event rates, which is less meaningful because not everyone in the population is immunized. Public Health Ontario indicated that Ontario's 2012 adverse event rate was 4.7 per 100,000 people, which is half the national average. However, Public Health Ontario indicated that Ontario's lower adverse event rate is likely due to the under-reporting of adverse events.

Public health units enter adverse events into the Integrated Public Health Information System (iPHIS). Public Health Ontario can review iPHIS information, but indicated that there is insufficient adverse event data to allow for any meaningful trend analysis. We reviewed adverse event data and found problems with the data accuracy.

We also noted that iPHIS does not collect information identifying the health-care provider who administered the vaccine. Without this information, potential clusters of adverse events cannot be broken down in a way that identifies the health-care provider who administered the vaccine. Such information could help to quickly identify such clusters so that other patients who may not be effectively immunized can be identified and contacted.

RECOMMENDATION 10

To enable meaningful analysis of adverse events following immunization and to help prevent future adverse events, the Ministry of Health and Long-Term Care, in conjunction with Public Health Ontario, should:

- require health-care providers who administer vaccines to give patients standardized information about which adverse events should be reported;
- collect information on health-care providers who have administered vaccines associated with adverse events; and
- follow up on any unusual trends, including areas where adverse event rates look unusually low or high.

MINISTRY RESPONSE

Vaccine safety is a top priority for the Ministry. As such, the Ministry monitors and reports adverse events following immunization (AEFI) through a surveillance process led by Public Health Ontario. This process continually reviews and assesses the ongoing safety of publicly funded vaccines in Ontario, both existing and new. As part of this process, public health units investigate all reports of AEFIs from providers and the public and report them to Public Health Ontario, which conducts provincial surveillance and analysis and reports to the federal government to support national safety surveillance and monitoring efforts.

The Ministry agrees that health-care providers play a key role in this system to inform patients about potential AEFIs and how to report them, and will review options for best supporting providers in carrying out this role, including options for providing standardized information to patients. The Ministry will also work with Public Health Ontario to review opportunities to collect information on AEFIs according to various parameters, and will follow up on any unusual trends, including areas where adverse event rates are unexpectedly low or high. However, AEFI surveillance is focused on vaccine safety issues and the Ministry uses other ways to monitor provider performance.

Better Oversight of Vaccine Wastage Needed

In the 2012/13 fiscal year, Ontario purchased 34 different types of vaccines, at a total cost of \$125 million, through the federal/provincial/territorial bulk purchasing program administered by Public Works and Government Services Canada. The Ontario Government Pharmacy provides these vaccines free of charge to all public health units as well as to health-care providers in Toronto. The public health units distribute the vaccines free of charge to healthcare providers in other areas of the province.

Vaccine wastage in Ontario is primarily due to vaccines being spoiled, either because the vaccine expired before it could be used or the vaccine was not kept at the correct temperature. The Ontario Government Pharmacy reported vaccine wastage province-wide of \$6.6 million in the 2013/14 fiscal year (up from \$4.7 million in 2012/13, primarily due to an increase in influenza vaccine wastage). Ministry policy requires public health units to conduct annual inspections at health-care providers' premises to ensure that vaccines are used and stored in a way that minimizes vaccine wastage. Healthcare providers and public health units return spoiled vaccines to the Ontario Government Pharmacy, which returns them either to the manufacturer or to a medical waste company for safe disposal.

Vaccine Order Quantities Not Always Monitored for Reasonableness

According to ministry policy, public health units are permitted to have on hand a maximum of two months' worth of vaccine inventory. This helps prevent vaccines from expiring before they can be used. However, the 2014 Immunization System Review noted that the inventory system that the Ontario Government Pharmacy uses to track vaccines purchased and distributed is not electronically linked to the inventory systems used by the public health units. As a result, the Ontario Government Pharmacy did not have timely information on the amount of vaccines on hand at the public health units. Without such information, it cannot assess the reasonableness of public health units' vaccine shipment requests. Therefore, the Ontario Government Pharmacy almost always ships public health units the amount of vaccines they order, and does not review the reasonableness of the order quantities to ensure that each constitutes no more than two months' worth of vaccine. We noted that in 2012/13, the vaccine wastage in one public health unit was 26% of total wasted doses province-wide, although this public health unit had only 10% of Ontario's population. The Ministry indicated that Panorama's vaccine inventory tracking system, which was to be implemented by the fall of 2015, would be linked to the public health units and would therefore enable better monitoring of their vaccine orders for reasonableness in the future.

Ministry policy also states that all health-care providers should receive no more than one month's worth of vaccines at a time, regardless of whether the vaccine is distributed directly from the Ontario Government Pharmacy or through their public health unit, in order to help prevent vaccines from expiring before they can be used. However, although physicians are to indicate their vaccine inventory levels when ordering, the Ontario Government Pharmacy and the public health units do not have access to their inventory records. Therefore they do the following:

• The Ontario Government Pharmacy uses a guideline to assess the reasonableness of vaccine orders shipped directly to health-care providers in the Toronto area. This guideline considers the size of the health-care providers' practice—for example, the number of doctors in a practice and the types of doctors, including whether they are pediatricians or family doctors. Orders that are in excess of a reasonable quantity may be reduced if health-care providers do not have a reasonable explanation for why the health-care providers are ordering more vaccines.

• Outside the Toronto area, health-care providers receive their vaccines from the public health units. The two non-Toronto public health units we visited use their judgment to determine whether shipments to health-care providers should be reduced—for example, if they think a provider's order is excessive or if a provider has a history of vaccines expiring before they are used.

Consequently, while assessments by the Ontario Government Pharmacy provide some assurance of the reasonableness of Toronto health-care provider vaccine order quantities, there is very little such assurance for amounts ordered by other healthcare providers.

The Ministry indicated that although Panorama's inventory module, expected to be implemented at all public health units by fall 2015, will track vaccines distributed to health-care providers, there are no plans to track the vaccine inventory levels at physicians' offices. Without such information, public health units will continue to have difficulty assessing whether physicians are ordering significantly more vaccines than necessary. Furthermore, if immunization information was more consistently entered into the registry at the time vaccinations were administered, public health units could evaluate the reasonableness of order quantities based on the number of vaccines actually administered by each physician's office and pharmacy in the previous year. This could help reduce excessive order quantities and the expiry of vaccines before they can be used by the physicians and pharmacies that ordered them.

We noted that some jurisdictions require healthcare providers to supply information that can be used to review the reasonableness of the providers' vaccine order. For example, in New York State, physicians who receive publicly funded vaccines must provide their current vaccine inventory level when submitting a vaccine order. Further, if the order seems excessive, the physician will be asked to provide information on the number of vaccines administered. Obtaining and using such information to review the reasonableness of a provider's vaccine order quantity can help reduce excess inventory and expired vaccines.

Better Storage Needed at Health-care Providers' Premises to Maintain Vaccine Potency

Ministry policy requires vaccines to be stored between 2°C and 8°C to protect their potency. Public heath units and health-care providers are responsible for ensuring that vaccines stored in their offices are kept within these temperatures. This practice is referred to as maintaining the cold chain. Ministry cold-chain data for 2013 indicated that about 380,000 vaccine doses (or under 5% of total doses distributed) were exposed to coldchain breaks at about 2,300 health-care provider sites. Thirty-nine percent of these incidents were due to power failures; 22% to human error; and 16% to refrigerator or thermometer malfunctions. The remaining 23% were classified as having had "other" causes. Public health units, which are responsible for evaluating cold-chain incidents, determined that 34% of these, or 130,000 doses costing almost \$2 million, were spoiled. To minimize cold-chain breaks, reliable refrigeration (such as that offered by refrigerators built specifically to store vaccines) and accurate thermometer readings are needed.

Since reliable refrigeration is key to the coldchain process, the Public Health Agency of Canada recommended in 2007 that bar-style fridges not be used for vaccine storage, because they were the leading cause of cold-chain breaks. As well, in 2012, the U.S. Centers for Disease Control and Prevention recommended discontinuing the use of bar-style fridges for vaccine storage. Ministry policy also prohibits public health units from using bar fridges, noting that they "are ineffective at maintaining the required temperatures." However, Ministry policy still allows health-care providers to use bar fridges. In fact, the Ministry indicated that most health-care providers actually use bar fridges. At the two public health units visited that tracked fridge type, over 50% of health-care providers in these regions used bar fridges. The use of bar-style fridges increases the risk that vaccines will not be maintained at the correct temperature and will lose their potency. In Manitoba, bar fridges are not recommended. Rather, fridges built to store vaccines (called purpose built fridges) are recommended, and full-sized fridges (such as those used in homes) are acceptable but not recommended.

An accurate fridge thermometer will detect temperature variations, and helps ensure that vaccines are kept within the required temperature range. For example, a thermometer can be used to detect temperature changes resulting from a power outage that occurs when the health-care provider's staff are not at the premises. Ministry policy allows the use of various thermometers, including the type that just record the minimum and maximum temperature a fridge has been at since the thermometer was last reset. However, such "min-max" thermometers do not indicate the length of time a fridge was at a particular temperature or the last time the thermometer was reset. As a result, the use of min-max thermometers does not provide either health-care providers or public health unit inspectors with sufficient information to evaluate whether vaccines have spoiled. If there is any indication that the vaccines *might* have been spoiled, they must be disposed of. This can lead to unspoiled vaccines being disposed of unnecessarily. One public health unit indicated that many vaccines could be saved if more health-care providers used thermometers that logged temperatures at periodic intervals.

Without more detailed information about fridge temperatures, it is difficult to ensure that all coldchain breaks are identified and that only unusable vaccines are discarded. Only two of the six public health units we contacted about cold-chain

procedures tracked the type of thermometer used by health-care providers. Their records indicated that over 90% of health-care providers used min-max thermometers, and only 2% used thermometers that provided an alert if the fridge temperature varied outside the recommended range. The 2014 Immunization System Review also identified this issue and recommended that health-care providers use automated electronic fridge-monitoring systems that would alert their public health unit, as well as the health-care providers themselves, of any cold-chain incidents.

Public Health Unit Inspection Process Needs Review

Ministry policy requires public health units to perform an annual inspection of health-care providers to determine whether they are in compliance with vaccine storage and handling requirements. This includes ensuring that providers maintain vaccines at required temperatures such that they remain potent and that providers maintain reasonable inventory levels so that vaccines do not expire before use. The public health units use Ministry checklists to complete this inspection.

The public health units inspect fridges used to store vaccines at all sites (that is, physician's offices, pharmacies, and long-term care homes) to ensure that vaccines maintain their potency by being kept at the correct temperature. Of the six public health units on which we performed audit work:

- In 2013, all had inspected at least 95% of sites that were storing vaccines. Further, at the five public health units that tracked the overall results, most providers had passed the inspection.
- Practices varied with respect to inspections. One did mostly unannounced inspections and five did announced inspections. Despite one public health unit doing unannounced inspections, three of the public health units that did only announced inspections indicated that the unannounced approach was

impractical, because health-care practitioners' staff needed to be available at the time of the inspection. The public health unit that conducted unannounced inspections indicated that the unannounced inspection approach prevents health-care providers from preparing for the inspection—for example, by defrosting the fridge or by filling in temperatures where manual record-keeping processes were incomplete.

The public health units' inspection also involves assessing whether a health-care provider has more than one month's worth of vaccine inventory on hand. Although the public health units do not have information on vaccines used by health-care providers each month, making it difficult for them to determine whether more than one month's worth of inventory is on hand, we noted that 40% of the inspection reports we reviewed had identified excessive or expired vaccines. Moreover, five of the six public health units we spoke to expressed concerns regarding excess and expired inventory at health-care providers. However, none of the six public health units tracked the total excessive or expired inventory found during inspections as this was not a requirement of the ministry-provided inspection checklist.

Of the six public health units we tested, all forwarded inspection reports to the Ministry. Even though the Ministry requires these reports to be submitted, the Ministry simply stores almost all of these reports, sometimes without opening them. The Ministry indicated that it would use the report if a public health unit contacted it about a related issue. Further, there was no requirement for public health units to report summarized inspection results highlighting issues requiring follow-up to the Ministry, to enable the Ministry to easily determine whether public health units were conducting follow-up inspections.

In the 2013 calendar year, only 5% of cold-chain breaks were identified during inspections by public health units. The rest of the cold-chain breaks were identified primarily by health-care providers. Given the time required for public health unit staff to inspect each health-care provider every year, in our view, these inspections could be focused on healthcare providers with a higher risk of problems. For example, health-care providers that fail frequently or have hired new staff responsible for cold-chain storage could be considered high risk. The 2014 Immunization System Review also suggested making inspections risk-based rather than performing an annual inspection at every health-care provider site.

Minimal Analysis of Wastage

Within Toronto, health-care providers report vaccine wastage to the Ontario Government Pharmacy. Outside Toronto, health-care providers report vaccine wastage to the public health units, which in turn report the wastage information to the Ontario Government Pharmacy. The information reported includes the quantity and type of vaccine wasted, as well as the reason for the wastage (for example, expired, or spoiled due to temperature variances). In the 2013/14 fiscal year, the Ontario Government Pharmacy reported that total vaccine wastage province-wide was \$6.6 million (\$4.7 million in 2012/13).

In our 2003 Annual Report, we noted that the reporting of vaccine wastage to the Ontario Government Pharmacy was often inaccurate, and we recommended the Ministry obtain accurate and complete information about vaccine wastage and take action to reduce wastage. At the time of our current audit, we noted that the vaccine wastage data being reported was still not complete. For example, the information tracked by the Ontario Government Pharmacy did not include unused doses in multi-dose vials or any wastage otherwise unreported by health-care providers.

According to ministry policy, vaccine wastage within each public health unit should represent no more than 5% of the vaccines distributed to that unit annually. For the 2013/14 fiscal year, the Ontario Government Pharmacy reported that total vaccine wastage province-wide was about 6% (4% in 2012/13) of the total dollar value of vaccines distributed to health-care providers. However, although the Ontario Government Pharmacy calculated the total wastage overall, it had not calculated wastage by public health unit, since it did not analyze information in this manner. Therefore, it did not know which public health units had wastage in excess of the Ministry's policy of 5%. Based on the most recent information available at the time of our audit, we noted that for seven of the public health units, vaccine wastage exceeded 10% of the doses distributed to their public health unit in 2012/13, with two having wastage exceeding 20% of the doses distributed to their public health unit. The Ministry did not know the reason for the high wastage.

According to the Ontario Government Pharmacy, in the 2012/13 fiscal year, about 65% (about \$3 million) of total vaccine wastage was due to expired vaccines and another 21% (about \$1 million) was due to cold-chain breaks. Further, another 12% (about \$600,000) had "No reason given" (the Ontario Government Pharmacy had not followed up on these). Although the Ontario Government Pharmacy tracks the location of cold-chain breaks. it does not track the locations where vaccines expire. As a result, the Ministry did not know which physicians, pharmacies, long-term-care homes and public health units had the most expired vaccines. Without this information, the Ministry is not able to follow up with health-care providers to determine the cause of their unexpectedly high wastage and how best to reduce this wastage in the future. Further, the Ministry has no assurance all wastage is reported. If immunizations are entered directly into the immunization registry by health-care providers at the time the patient is vaccinated, the Ministry will more readily be able to account for all vaccines provided to physicians, including determining when they do not report all wasted vaccines.

The six public health units we reviewed send letters to health-care providers if they suspect patients may have received a spoiled vaccine (that is, either expired or not maintained at the correct temperature). The letter reminds the health-care

provider to determine whether any patients are not immune to a disease because they received vaccines that may have lost their potency. However, the Ministry indicated that it is not the public health units' responsibility to confirm whether physicians actually check their records or inform patients that they may not have been adequately immunized; this is up to the physicians.

Public health units send out a separate letter to health-care providers noting the retail value of the vaccines that spoiled because they weren't kept at the correct temperature, but do not require repayment, even if the health-care provider has frequent cold-chain breaks. However, only one of the six public health units we reviewed sent out similar letters to inform physicians about the value of vaccines that spoil due to excess inventory, despite expired vaccines causing a significantly larger portion of vaccine wastage than cold-chain breaks. The Ministry does not have any information on the total number of letters sent by public health units, or if these letters changed provider behaviour.

Although vaccines distributed by the Ontario Government Pharmacy are 100% funded by the Ministry, no disincentives have been established for public health units or health-care providers to minimize vaccine wastage due to over-ordering and associated vaccine expiry. For example, neither public health units nor health-care providers incur any costs or penalties with respect to their vaccine wastage. The 2014 Immunization System Review also recommended holding health-care providers accountable for wastage. One public health unit we spoke to suggested charging health-care providers if they waste vaccine.

RECOMMENDATION 11

To minimize vaccine wastage and maintain vaccine potency, the Ministry of Health and Long-Term Care should:

• implement processes aimed at ensuring that the volume of vaccines ordered by and distributed at no cost to health-care providers is reasonable (for example, by monitoring information on their inventory levels through the new Panorama system);

- revise the minimum standards for the types of fridges and thermometers used by health-care providers in vaccine storage, such as by prohibiting the use of bar fridges and min-max thermometers, which are less reliable at maintaining the correct vaccine temperature or providing information about the length of time fridge temperatures were outside an acceptable range needed to maintain vaccine potency;
- in conjunction with the public health units, obtain and review information on vaccine wastage by each health-care provider, and follow up on providers with higher wastage levels; and
- review whether the process followed by public health units to inspect health-care providers' offices would be more cost-effective if it used a risk-based approach, such that providers that have higher wastage levels—whether because vaccines are not being kept at the correct temperature or because vaccines are expiring before they can be used—receive more focus, and require some inspections to be performed on an unannounced basis.

MINISTRY RESPONSE

The Ministry agrees that minimizing vaccine wastage and maintaining vaccine potency are important components of Ontario's publicly funded immunization program. As part of Ontario's cold-chain inspection process, public health units employ a customer service approach in providing education and increasing awareness regarding proper vaccine storage and handling practices. Building on the current strengths of this initiative, and as part of the Immunization Program Renewal action plan currently under development by the Ministry, the Ministry will:

- develop tools, supports and processes to further strengthen the Ministry's existing vaccine order-monitoring practices, leveraging the enhanced standardized inventory information that will be available as part of the Inventory Management component of Panorama with its alerting capability (for example, automating historical ordering and wastage reports, and instituting auto flags for intervention, such as vaccine-ordering discrepancies);
- work with stakeholders such as the Ontario Medical Association and Ontario Pharmacists

Association to consider opportunities for reducing vaccine wastage, including a review of minimum vaccine storage and handling requirements pertaining to vaccine refrigerators and min-max thermometers; and

 review opportunities to incorporate a riskbased approach within Ontario's cold-chain inspection process, with more emphasis on unannounced inspections and improved processes for identifying and working with providers experiencing higher levels of vaccine wastage.

Appendix 1—Government Players and Selected Key Responsibilities for Ontario's Immunization Program

Prepared by the Office of the Auditor General of Ontario

Organization/Entity	Key Responsibilities
Federal	
Health Canada	Approves vaccines for use
National Advisory Committee on Immunization (NACI)	 Provides scientific advice and makes recommendations on use of vaccines approved by Health Canada
Canadian Immunization Committee	Publishes national advice on immunization program implementation
Public Works and Government Services Canada	 Co-ordinates bulk purchasing program under which provinces and territories (in Ontario, the Ministry's Ontario Government Pharmacy) order their vaccines
Provincial	
Chief Medical Officer of Health	 Reports to the Legislative Assembly on risks to public health in Ontario, including vaccine-preventable diseases
	 As a senior official of the Ministry, reports to the Deputy Minister of Health and Long- Term Care on Ontario's immunization program
Ministry of Health and Long-Term	Oversees Ontario's immunization program, including developing policy
Care (Ministry)	Advises the government on which vaccines to publicly fund and for whom
Public Health Ontario	 Provides information to the Ministry and the public on, among other things, immunization coverage rates and adverse events
	 Through the Provincial Infectious Diseases Advisory Committee—Immunization (PIDAC), advises the Ministry on which vaccines should be funded and who should be vaccinated
Municipal	
36 Public Health Units	 Each, led by a local medical officer of health, administers immunization programs in its geographic area
	Each reports to its own board of health
36 Boards of Health	 Each oversees its own Public Health Unit and is comprised in whole or in part of municipal representatives

Appendix 2—Comparison of Vaccination Schedules among Canadian Provinces, 2014

Prepared by Office of the Auditor General of Ontario, from provincial immunization schedules

offers more publicly funded vaccinations than NACI recommends, although some offer fewer. All 10 provinces have similar publicly funded schedules for nine vaccina-The National Advisory Committee on Immunization (NACI) recommends routine childhood vaccinations for more than a dozen diseases and infections. No province tions: diphtheria, Hib (haemophilus influenzae type b), measles, mumps, pertussis (whooping cough), pneumococcal disease, polio, rubella and tetanus. Provincial schedules vary for the five vaccinations shown below.

	Hepatitis B	Human Papillomavirus (HPV)	Meningococcal	Rotavirus	Varicella (Chicken Pox)
NACI Recommendations	All children, regardless of age	Persons from 9-26 years old	 1st dose: Children from 12 months-5 years old Consider for children 5-11 years old 2nd dose: Persons from 12-24 years old Use a 3-dose schedule beginning at 2 months of age 	 Infants from 6 weeks-8 months 	 2 doses at least 6 weeks apart: 6 worths-12 years or 2 doses: 13-17 year- olds who have not had chicken pox
Newfoundland and Labrador	Grade 6	Grade 6 girls	 1st dose: At age 1 2nd dose: Grade 4 	Not publicly funded	One dose at age 1
Prince Edward Island	Before age 1	Grade 6 girls and boys	1st dose: At age 12nd dose: Grade 9	Before age 1	1st dose: At age 12nd dose: At age 18 months
Nova Scotia	Grade 7	Grade 7 girls	1st dose: At age 12nd dose: Grade 7	 Not publicly funded 	 1st dose: At age 1 2nd dose: At ages 4-6
New Brunswick	Before age 1	Grade 7 girls	1st dose: At age 12nd dose: Grade 9	 Not publicly funded 	1st dose: At age 12nd dose: At age 18 months
Quebec	Grade 4	Grade 4 girls	1st dose: At age 12nd dose: Grade 9	 Before age 1 	One dose at age 1
Ontario	Grade 7	Grade 8 girls	1st dose: At age 12nd dose: Grade 7	 Before age 1 	 1st dose: Before age 2 2nd dose: At ages 4-6
Manitoba	Grade 4	Grade 6 girls	1st dose: At age 12nd dose: Grade 4	 Before age 1 	 1st dose: At age 1 2nd dose: At ages 4-6
Saskatchewan	Grade 6	Grade 6 girls	1st dose: At age 12nd dose: Grade 6	 Before age 1 	 1st dose: At age 1 2nd dose: At age 18 months
Alberta	Grade 5	Grade 5 girls (and boys as of fall 2014)	 1st dose: At 2 months 2nd dose: At 4 months 3rd dose: At age 1 4th dose: Grade 9 	 Not publicly funded 	 1st dose: At age 1 2nd dose: At ages 4-6
British Columbia	Before age 1	Grade 6 girls	 1st dose: At 2 months 2nd dose: At age 1 3rd dose: Grade 6 	Before age 1	1st dose: At age 12nd dose: At age 4

Appendix 3—Vaccines Not Funded in Ontario in Accordance with Recommendations from the National Advisory Committee on Immunization (NACI)

Prepared by the Office of the Auditor General of Ontario

Shingles	NACI recommends the shingles vaccine for those aged 60 and older, but the vaccine is not publicly funded in Ontario or in any other Canadian province.
	Shingles is caused by a re-activation of the varicella zoster (chicken pox) virus. There is about a 30% chance that a person will develop shingles during his or her lifetime, usually after age 60. Although the number of cases of shingles in Ontario is not tracked, the Canadian Immunization Committee indicates that cases are increasing nationally, partly due to the aging population. Further, the Canadian Immunization Committee estimates that the Canadian hospitalization costs for shingles total over \$67 million annually.
	In 2013, the Canadian Immunization Committee indicated that the shingles vaccine is cost-effective for people aged 60 and older. Further, in 2013, PIDAC proposed publicly funding the shingles vaccine for older adults in various age groups. Notwithstanding PIDAC's proposals, the Ministry indicated that the shingles vaccine has not been publicly funded because the current vaccine must be kept in a freezer, and it is not practical to expect physicians to have freezers in their offices. A fridge-stable vaccine became available for sale in Ontario in spring 2014.
HPV	NACI recommends the HPV vaccine for everyone aged 9 through 26, but the vaccine is publicly funded in Ontario only for girls in Grade 8.
	PIDAC recommended that only girls and high-risk males be eligible for the vaccine, but did not provide an explanation for the variation from NACI's recommendation. We noted that other jurisdictions recently began publicly funding the HPV vaccine for boys in addition to girls. For example, Australia started publicly funding the HPV vaccine for boys in 2013, Prince Edward Island in the 2013/14 school year, and Alberta in the 2014/15 school year.
	A 2013 study by Public Health Ontario indicated that publicly funding the HPV vaccine for boys would be too expensive, because the health benefits and related cost savings were less for boys compared to girls. However, Public Health Ontario also noted that further research was needed to determine if immunizing boys against HPV was cost-effective overall. Two of the public-health units we visited indicated that immunizing boys against HPV should be a priority, because doing so will reduce the spread of the infection and therefore reduce related diseases.
	PIDAC also recommended conducting the HPV vaccination program in Grade 7 rather than in Grade 8, because it would be more economical, in terms of nursing time and administration costs, to give this vaccine at the same time as the other two vaccines given in Grade 7. The Ministry's HPV working group did not agree: it was concerned that a third vaccine would be too many needles for Grade 7 students. As a result, the HPV vaccine continues to be administered only in Grade 8.
Meningococcal	NACI recommends the meningococcal vaccine for adolescents, generally at age 12, while the Canadian Immunization Guide further recommends the vaccine for young adults up to 24 years of age. The vaccine is publicly funded in Ontario for Grade 7 students. The Ministry has not quantified how many people are at risk of developing this vaccine-preventable disease because they have not been vaccinated.

Pertussis (whooping cough)	NACI recommends the pertussis vaccine for all adults, but the vaccine is not publicly funded in Ontario for those aged 65 and older. The Ministry indicated that the NACI recommendation has been under review since 2011. However, the Ministry had not yet analyzed whether it would be cost-effective to increase eligibility for pertussis to all adults—for example, by considering the potential health-care costs of treating pertussis in children under 6 months old who may have acquired pertussis from an older adult.
	The Canadian Immunization Guide (published by the Public Health Agency of Canada) indicates that adults often have waning immunity for some vaccine-preventable diseases, such as pertussis. Therefore it recommends immunizing adults who have not been immunized since childhood and who are in contact with infants. Somewhat similarly, PIDAC recommended in 2011, and again in 2012, that eligibility for the pertussis vaccine be broadened to include all adults due to concerns about waning immunity.
Varicella (chicken pox)	NACI recommends two doses of the varicella vaccine for individuals between 12 months and 49 years old who have not previously had varicella (and are therefore susceptible to the disease). Due to the Ministry's position that varicella is mainly a childhood disease, as well as other ministry funding priorities, the vaccine is publicly funded in Ontario only for children born in or after the year 2000.
	Despite the fact that varicella tends to be more dangerous as people age, individuals born before 2000 who are still susceptible to varicella because they have not previously had the disease are not eligible to receive the vaccine. People may choose to pay for this vaccine, and two doses are recommended for adequate protection. The Ministry has not quantified how many people are at risk of contracting this vaccine-preventable disease because they have not been vaccinated.

Glossary of Terms

Prepared by the Office of the Auditor General of Ontario

Adverse event following immunization—An undesirable medical occurrence that happens after a person is immunized, including an occurrence that may not be directly caused by the vaccine. Adverse events include allergic reactions, convulsions, rash, pain, or redness and swelling that lasts for at least four days.

Board of health—The governing body for a public health unit. The medical officer of health of each public health unit reports to a board of health that consists primarily of members appointed by the local municipality. The boards of health are responsible for, among other things, ensuring the provision of the publicly funded vaccine-preventable diseases program within their respective public health units. The boards report primarily to their local municipality; they also report information on certain performance indicators to the Ministry, in accordance with their accountability agreements with the Ministry.

Chicken pox—Also called varicella. A disease that usually results in flu-like symptoms, fever, and a rash with blisters lasting one week before forming scabs. Chicken pox can be serious, especially in babies, susceptible adults (for example, those who have not had the disease previously) and people with weakened immune systems. Complications include bacterial skin infections and/or necrotizing fasciitis ("flesh-eating disease") and pneumonia. Following the initial illness, the virus may be reactivated later in life as shingles.

Chief Medical Officer of Health—The Chief Medical Officer of Health is responsible for dealing with risks to public health in Ontario, and reports to the Minister of Health and Long-Term Care on issues such as which vaccines should be publicly funded in Ontario and any concerns regarding immunization coverage rates across the province.

Cold chain—The process of ensuring that vaccines are continuously stored within the temperature range (2°C to 8°C) required to ensure that the vaccine remains potent.

Cold-chain break—A period of time during which a vaccine is not stored within the temperature range required to ensure that the vaccine remains potent.

Diphtheria—An upper respiratory system disease. Complications include suffocation, paralysis, heart failure, coma and death. One in 10 people who contract diphtheria die from it.

Haemophilus influenzae type b (Hib)—A type of bacteria that may result in respiratory tract infections leading to pneumonia, bronchitis, and ear, eye and sinus infections, or more serious conditions such as meningitis and bone infections. Long-term effects of meningitis can include permanent hearing loss, paralysis, seizures, brain damage and death.

Hepatitis B—A disease that can cause such symptoms as abdominal pain, nausea, vomiting and jaundice for weeks or months. A small number of people who contract hepatitis B become infected for life. The fatality rate is about 1%.

Herd immunity level—The percentage of a population that must be vaccinated to reduce or stop the spread of an infectious disease within that population.

Human papillomavirus (HPV)—An infectious disease that can result in cancers related to the cervix, vagina and vulva, anus, oral cavity (certain parts of the mouth), or oropharynx (back of the throat) in females and in cancers related to the penis, anus, oral cavity, or oropharynx in males.

Immunization Records Information System (IRIS)—The immunization registry software used by public health units to track the immunization records for most Ontario school children and some children enrolled in daycare centres. It will be replaced by a new immunization registry (one component of Panorama) that is expected to be fully implemented by March 2016.

Immunization registry—A database in which all immunizations administered are recorded and tracked; can be used to identify individuals who are due to be immunized as well as, in the event of an outbreak, those who were not immunized.

Immunization schedule—The listing of the vaccines that are publicly funded, who is eligible to receive the vaccines and the timing of when the vaccines should be administered.

Influenza (flu)—A respiratory illness that lowers the body's ability to fight other infections. It can lead to bacterial infections, such as pneumonia, and in some cases death, especially in vulnerable people, such as the elderly, children, pregnant women, and people with chronic medical conditions.

Integrated Public Health Information System (iPHIS)—The federally based system that Ontario public health units use to report all instances of reportable communicable diseases (including most vaccine-preventable diseases) and adverse events following immunization.

Measles—A disease characterized by a red, blotchy rash that begins on the face. Complications include diarrhea, pneumonia and infections of the brain. In developed countries, two to three cases per 1,000 result in death.

Medical officer of health—The person responsible for a public health unit's vaccine-preventable disease program and other public health programs. In most cases, staff at the public health unit report to the medical officer of health, who in turn reports to a board of health.

Meningococcal disease—An invasive disease that often results in meningitis and/or septicemia (life-threatening blood infection). Symptoms include fever, drowsiness, irritability, intense headache, vomiting, stiff neck and rash. Severe cases can result in delirium and coma and, if untreated, toxic shock and death.

Mumps—A disease that brings about inflammation of the salivary glands in 40% of those who contract it. Mumps can cause viral meningitis and is associated with hearing loss and inflammation of the pancreas.

Panorama—A new public health system being implemented by the Ministry that includes a new immunization registry and vaccine inventory tracking system, which are expected to be fully implemented in all Ontario public health units by March 2016. The system is expected to be expanded to include outbreak management and disease investigation capabilities. Panorama is also being implemented by a number of other Canadian provinces.

Pertussis—Also called whooping cough. A disease that is characterized by fever, vomiting and coughing attacks. Complications include pneumonia, seizures, brain damage and death. In children under the age of 1, death is estimated to occur in one out of every 200 cases.

Pneumococcal disease—A bacterial disease that can cause four serious infections: meningitis (brain infection), bacteremia (bloodstream infection), pneumonia (lung infection), and otitis media (middle-ear infection). Complications from pneumococcal infections can cause serious harm to children and older adults, including brain damage and death.

Poliomyelitis (polio)—A disease that invades the nervous system and can cause paralysis or death if the breathing muscles are affected. There is no cure for polio. Due to vaccinations, polio is considered eradicated from many parts of the world, including Canada.

Public Health Ontario (previously called the Ontario Agency for Health Protection and Promotion)—A provincial government agency that is responsible for, among other things, monitoring immunization coverage rates and adverse events following immunization.

Public health unit—Any of the 36 local organizations across Ontario that are responsible for, among other things, administering the Ministry's publicly funded immunization program in their respective geographic areas. Each public health unit is led by a local medical officer of health and governed by a board of health.

Rotavirus—The most common cause of severe gastroenteritis. Symptoms include diarrhea, nausea and vomiting. In infants and young children, it is responsible for more than 500,000 deaths each year worldwide.

Rubella—Also called German measles. A disease that results in a rash, joint pain, abnormal lymph nodes and low-grade fever. Serious complications are rare. Rubella infection during pregnancy poses a risk for serious birth defects in surviving offspring.

Shingles—Also called herpes zoster. An infection that occurs when the varicella zoster virus (which causes chicken pox) is reactivated. It often causes pain and itching on one side of the face or body, followed by a painful rash. Shingles can affect the eyes, including a loss of vision. Other symptoms can include fever, headache, chills and upset stomach.

Tetanus—Also called lock jaw. A disease that can result in painful muscle contractions and/or stiffness in the jaw, neck, arms, legs and stomach. Muscle spasms can be so intense that bones may break. Complications include breathing problems, lung infections, coma and death. Death rates are highest in infants and the elderly.

Varicella-See chicken pox.