

Chapter 1

Section 1.04

Ministry of Health and Long-Term Care

Immunization

Follow-Up on VFM Section 3.04, 2014 Annual Report

RECOMMENDATION STATUS OVERVIEW					
	# of Actions Recommended	Status of Actions Recommended			
		Fully Implemented	In Process of Being Implemented	Little or No Progress	Will Not Be Implemented
Recommendation 1	1			1.0*	
Recommendation 2	2		1.0	1.0	
Recommendation 3	1			1.0*	
Recommendation 4	4		1.5	2.5*	
Recommendation 5	1			1.0	
Recommendation 6	3		2.0	1.0	
Recommendation 7	1			1.0*	
Recommendation 8	1		1.0		
Recommendation 9	3			2.0	1
Recommendation 10	3	1	1.0	1.0	
Recommendation 11	4		3.0	1.0	
Total	24	1	9.5	12.5	1
%	100	4	40	52	4

* Targeted implementation in 2020

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.

Ontario's publicly funded immunization schedule includes vaccines that protect against 17 infectious diseases. Eligible people in Ontario

can be immunized against these infectious diseases at no cost. Most vaccines are administered by family physicians, but other health-care providers also administer certain vaccines, such as public health nurses administering the Hepatitis B vaccine in middle schools and pharmacists administering the influenza vaccine.

The Ministry of Health and Long-Term Care (Ministry) has overall responsibility for Ontario's immunization program, including advising the government on which vaccines to publicly fund and

the eligibility criteria for each one. The federal government is responsible for approving new vaccines prior to their use.

We estimated that operational funding for Ontario's immunization program was about \$260 million in the 2015/16 fiscal year (\$250 million in 2013/14 fiscal year). However, because the Ministry does not routinely track the total costs of the immunization program, it does not know whether the program is being delivered cost effectively. Information on children's immunization rates still relies on parents reporting information to public health units, often years after their child is vaccinated, as opposed to health-care providers reporting the information when they administer the vaccines. Consequently, immunization coverage information is not reliable.

Other significant issues we noted in our 2014 audit included the following:

- There was minimal provincial co-ordination of the immunization programs delivered by the 36 municipally governed public health units in Ontario. Public health units act independently and are not responsible to Ontario's Chief Medical Officer of Health. Moreover, the Ministry had not determined the most effective model for delivering Ontario's immunization program.
- Ministry funding to the public health units varied significantly, from \$2 per person in one public health unit area to \$16 per person in another. The Ministry had not analyzed the reasons for these variations to determine if such cost discrepancies are justified.
- Ontario was implementing a new system called Panorama, which was to include a vaccination registry, at an estimated cost that had escalated by over \$85 million and was expected to exceed \$160 million. Only vaccinations previously entered in the old immunization tracking system and those given to middle-school students were contained in Panorama. Vaccines given to infants were not recorded at the time of immunization and therefore Panorama did not provide the data needed to identify areas of the province with low immunization coverage rates.
- Ontario's child immunization rates were below federal targets and, in most cases, below the level of immunization coverage necessary to prevent the transmission of disease. One public health unit reported that outbreaks would occur if its measles immunization coverage rate decreased by as little as 10% from its current immunization rate.
- The Ministry lacks information on immunization coverage in licensed daycares. Parents choosing a daycare for a child who is not able to be vaccinated cannot readily access public information on the percentage of children who are not immunized in each daycare. In one situation, we noted that 31% of children in a daycare were not immunized against measles.
- We found questionable flu immunization billings in 2013/14, including about 21,000 instances where the Ministry paid physicians and pharmacists for administering the flu vaccine more than once to the same person. As well, the Ministry did not have information on how many, of almost one million doses of the flu vaccine that it purchased, had actually been administered.
- The majority of the public health units we reviewed expressed concerns regarding excess and expired inventory at health-care providers. There is no cost to public health units or health-care providers who order more of the publicly funded vaccines than they use, and the Ministry has no system to consistently identify unreasonable orders. Health-care providers and public health units reported \$3 million in vaccines expiring before use for the 2012/13 fiscal year.
- There was no process in place to ensure that new adult immigrants are immunized before or soon after arriving in Ontario. This makes them more susceptible to acquiring a vaccine-

preventable disease, which may spread to other unimmunized Ontarians.

Our recommendations included that the Ministry review the immunization program delivery structure and consider alternative options; develop processes to enable physicians and other health-care providers to electronically update the immunization registry each time they provide a vaccine to both children and adults; establish provincial immunization coverage targets and monitor whether they are being achieved; 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 rates; publicly report immunization rates by daycare and school; and implement processes aimed at ensuring that the volume of vaccines ordered by health-care providers is reasonable.

Status of Actions Taken on Recommendations

In December 2015, the Ministry finalized a strategy to overhaul its immunization program by 2020. The 2020 strategy indicates the Ministry will address most of the recommendations made in our 2014 audit by that time, including reforming the governance and funding structure and reviewing the number and size of public health units; recording immunizations in a central database (Panorama) at the time of vaccination; developing immunization target coverage rates; and tracking actual rates of vaccination.

As such, and according to other information received from the Ministry, most of our recommendations are in the preliminary stages of being addressed. For example, the Ministry has initiated working groups and engaged consultants to oversee the redevelopment of immunization performance measures for public health units, and is implementing software that will allow physicians to record immunizations in a central electronic database

(Panorama). Also, legislation requiring parents to attend a course if they opt to not vaccinate their school-aged children due to religious or conscience reasons only received first reading in May 2016. With the prorogation of the Legislature, however, this bill would have to be re-introduced and subsequently passed in order for these new requirements to apply to parents seeking exemptions from immunization.

As of the beginning of 2016, all public health units were inputting all middle-school immunizations, and any infant immunizations they had administered, directly into Panorama. However, no new immunizations had been directly entered by family physicians. Therefore, paper records, or the “yellow cards,” continue to be used predominantly for recording immunizations. The Ministry’s estimated date for establishing an electronic interface with Panorama that will allow each physician to input vaccination records and to be able to query immunization records is the summer of 2017.

The Ministry added HPV immunization for boys in Grade 7 and shingles immunization for seniors aged 65 to 70 to the publicly funded schedule in 2016, as a result of re-evaluation of a long-term cost benefit analysis, and the shingles vaccine now being available in a fridge-stable form, respectively.

Overall, few of the recommendations we made in our *2014 Annual Report* have been implemented. While it is understandable that systemic changes such as establishing access to the Panorama system in doctors’ offices could require some lead time, in our view, six years to implement some of the recommendations (between our 2014 audit and the 2020 strategy’s end time) is excessive. The Ministry indicated it will not implement our recommendation to disallow duplicate billings by health care providers that administer the flu vaccine. Also, the Ministry has made little progress toward some of our recommendations relating to the following: publicly reporting immunization rates at daycares; identifying schools with low immunization rates; providing immunizations to all immigrants before they enter Ontario; and improving on the collection

of information on pharmacists and public health unit staff who have administered vaccines associated with adverse events.

Complex Program Delivery Structure

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.

Status: Little or no progress made.

Details

The Ministry's 2020 strategy includes a plan to conduct a prospective review of how immunization services are delivered, with the goal of increasing immunization rates. The Ministry also facilitated a meeting of stakeholders in spring 2016 to discuss how immunizations are delivered in Ontario.

The Ministry indicated that it has not considered structural changes to the delivery of immunization services, such as the potential merging of neighbouring health units serving small populations. The Ministry informed us that since health units deliver about a dozen services other than immunization, a decision to merge would require a broader review of the public health system. The Ministry indicated that as part of its Patients First commitment, it plans to appoint an Expert Panel on Public Health, with the mandate of providing advice on structural, organizational and governance changes to public health. The Ministry plans to implement changes to the public health system in the future, which will be informed by the findings of this panel.

In regard to funding, the Ministry completed an internal review in 2013 of the funding methodology for public health units, which recommended using a formula where socio-economic characteristics of the local population, geography and health risks would determine appropriate funding levels. In

2015, the Ministry used this formula to proportionately allocate 2% additional funding to eight health units based on their socio-economic profiles. The Ministry has indicated that it will apply the funding formula on a year-by-year basis with some flexibility to address local needs. At the time of our follow-up, the Ministry had finalized its public health unit funding for 2016, which included application of the funding formula.

Cost and Reliability Concerns with New Information System

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.

Status: In the process of being implemented by the summer of 2017.

Details

Vaccines administered by physicians represent the majority of vaccinations received over a person's lifetime. As a part of its 2020 strategy, the Ministry intends to record and track all immunizations in Panorama, including those given to infants by physicians.

The only data currently contained in Panorama has been either transferred from the old immunization tracking system or entered by public health units. At the time of our follow-up, the Ministry was in the process of developing a software tool

for physicians to use to record vaccinations in Panorama at the time they are administered. The Ministry commissioned an external consultant to develop the software tool in the summer of 2015. The Ministry plans for physicians to be able to input vaccinations in Panorama by the summer of 2017, at which time they will also be able to query patients' immunization records.

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.

Status: Little or no progress made.

Details

In March 2015, Cabinet approved the removal of modules on outbreak management and investigations of vaccine-preventable diseases from the scope of the Panorama system's implementation. The Ministry had already internally decided to remove these two modules at the time of our 2014 audit. Without them, the management and investigation of disease outbreaks will continue to be performed through the old system. The Ministry has indicated that the old system will support these functions for another three to five years. It plans to begin a preliminary assessment of other technological options for performing outbreak management and investigation functions in the spring of 2017, which may include actually implementing the two modules of Panorama that were previously removed, continuing with the existing system, or acquiring a different software tool. The Ministry also plans to complete a review of lessons learned from British Columbia's implementation of these two Panorama modules. At the time of our follow-up, the Ministry had not conducted an analysis of the costs and benefits of implementing the two modules.

Better Tracking of Immunization Coverage Rates Needed

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.

Status: Little or no progress made.

Details

The Ministry retained a consultant to prepare a performance management and measurement framework in 2015, but this framework did not include any targeted coverage rates. The Ministry plans to continue to informally use the national immunization targets established by the Public Health Agency of Canada. The Ministry indicated that it might adopt these rates more formally after the Public Health Agency of Canada completes a review of coverage targets, which the Ministry will participate in. This review began in the summer of 2016.

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

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;

Status: In the process of being implemented by December 2017.

Details

The Ministry has not developed an overall piece of legislation to address immunization requirements for both daycares and schools. However, in August 2015 the *Day Nurseries Act* was replaced by the *Child Care and Early Years Act*, and an amendment to it came into effect in August 2016 requiring parents of children in daycare to complete a Ministry-issued form and to swear before a commissioner for taking affidavits (e.g., lawyer, justice of the peace) that an immunization conflicts with their religious or conscience convictions. This is the same requirement and process for seeking non-medical exemptions for students attending school under the *Immunization of School Pupils Act*. While an overall piece of legislation was not introduced, the exemptions process has been harmonized by amending the *Child Care and Early Years Act*.

Regarding the harmonization of processes to suspend children who are not immunized, the regulations under the *Child Care and Early Years Act* give the Ministry of Education the authority to require daycares to comply with recommendations made by a public health unit regarding any matter that may affect the health or well-being of a child in daycare. The Ministry indicated that it plans to develop a process through which public health units can request the Ministry of Education to require daycares to obtain from parents of children in their care either a record of completed immunizations or an exemption form. The daycare may then suspend unimmunized children if their parents do not provide this information. The Ministry plans to implement this process when it finalizes updates to the Ontario Public Health Standards by the end of 2017.

Public health units continue to have authority and established processes for suspending unimmunized school students without exemptions.

- 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;

Status: In the process of being implemented for children in school when the bill amending the *Immunization of School Pupils Act* is passed; little or no progress made for children in daycare.

Details

In May 2016, the Ministry proposed an amendment to the *Immunization of School Pupils Act* that would require parents of school pupils who wish to exempt their children from immunization for religious or conscience reasons to attend a course on the risks of not vaccinating their child. Since the Legislature was prorogued at the time of our follow-up, the bill amending the Act could not be passed. Consequently, the Ministry could not estimate whether it will become mandatory for children attending school in the 2017-2018 school year, or a later year. The Ministry had yet to finalize the format and content of the course, and whether to make it available online or in-person only.

The Ministry has not finalized whether to require parents of children in daycares seeking a non-medical exemption from vaccinations to attend the proposed educational course on the risks of not vaccinating. The requirement currently only applies to parents of school children.

- 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

Status: Little or no progress made.

Details

In February 2015, the Ministry sent a letter to all public health units asking them to identify and report back any instances of their non-compliance with public health standards on vaccine-preventable diseases, along with a plan to achieve compliance. One of these standards is the requirement of public health units to monitor coverage rates, but the Ministry's letter did not specifically ask public health units to report on whether they have evaluated immunization rates at schools and daycares in their region, identified any with low coverage rates, and taken relevant action to address them. Of the 19 public health units that reported non-compliance, only one explicitly reported having identified schools with low immunization rates for measles. The others did not report whether they had performed a review to identify such schools.

To strengthen the requirement for public health units to identify and address areas with low immunization coverage rates, the Ministry indicated that it will update Ontario's public health standards, and plans to do so by the end of 2017, and strengthen the requirements for public health units to perform such reviews.

- *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.*

Status: Little or no progress made.

Details

The Ministry informed us that it plans to expand public reporting by publishing immunization coverage rates on a local basis, for example, by public health unit, school or school-board level, as part of its 2020 strategy. The Ministry indicated that it plans to begin publicly reporting immunization rates by school in March 2019 as part of the rollout of Panorama.

Because public health units are not currently required to receive children's immunization records before they are enrolled in school, the information necessary to determine and report immunization coverage rates at daycares is not currently available. The Ministry informed us that it plans to begin, in March 2019, to evaluate the feasibility of reporting immunization rates by daycare after it implements this requirement for schools. This will be made possible if a proposed amendment to the *Immunization of School Pupils Act* is passed to require physicians to report immunization information directly to public health units. If this occurs, the immunization status of children would be available at the time when they start attending daycare.

Process Needed to Better Deal with Vaccine-Preventable Disease Entering Canada

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.

Status: Little or no progress made.

Details

Although Ontario has not introduced new policies to address the immunization of immigrants, new policies were introduced regarding the Syrian refugee situation. In January 2016, the Ministry, in conjunction with Public Health Ontario, provided tailored education material to both Syrian refugees and primary-care physicians highlighting the importance of their immunization. This was aimed at ensuring refugees were immunized as soon as possible once they reached Ontario. The Ministry

introduced this measure because refugees are considered higher risk than other immigrants as they are susceptible to more illnesses due to exhaustion and other stresses and the lack of organized immunization services in refugee camps. However, this program is not able to stop illnesses from entering the province.

The federal government has expressed its intention to offer and fund immunizations for all refugees prior to entering Canada, as a part of the “Immigration Medical Exam,” starting in April 2017. This physical examination is performed before refugees depart for Canada and also includes a urine test and chest X-ray. While the Ministry has informed us that it is advocating for further expansion of this initiative to all newcomers, at the time of our follow-up the Ministry was still in the early stages of its discussions with the federal government and had not yet identified a timeline for implementing this requirement.

Improvements Needed to Promotion of Immunization

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 stakeholders 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;*

Status: In the process of being implemented by the end of 2018.

Details

The Ministry has developed and, in September 2016, distributed accessible clinical and technical information about five vaccines for physicians to use, and a series of fact sheets that provide simple terms and explanations about vaccines for

patients. These include practical steps parents can take before, during and after a vaccine, such as being alert for common soreness and swelling or symptoms of a rare adverse event following immunization. The Ministry has also developed information on ten vaccine-preventable diseases, and included these on its website, called the Immunization Well-Child Toolkit. Physicians can also provide this information to parents and patients.

- *determine whether the bonus payments currently made to certain physicians are resulting in improved immunization rates in a cost-effective manner;*

Status: Little or no progress made.

Details

Immunization bonuses were introduced in the late 1990s through contract negotiations with the Ontario Medical Association (the body that negotiates payment contracts for all Ontario doctors) prior to our audit. The Ministry has determined that there is little evidence suggesting that bonus payments, whereby family physicians receive up to \$2,200 for immunizing 95% of the children in their practice, have resulted in improved immunization rates. Any future change to the immunization bonus program would be subject to the Ministry’s negotiations with the Ontario Medical Association.

- *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.*

Status: In the process of being implemented by December 2017.

Details

In the summer of 2015, the Ministry surveyed public health units to better understand their needs for ministry-produced educational materials. Public health units indicated that they produce their own educational materials about half of the time

because often the ministry-produced materials are too generic (for example, local clinic information is not included), or they are received too late to be useful. However, public health units also indicated that because their communications teams are often small, the Ministry and Public Health Ontario could help by providing insight on the most effective communication approaches. As part of updating Ontario's Public Health Standards, the Ministry will begin reviewing a draft of a more formal protocol in December 2016, which is to outline what educational materials are best developed centrally and provided in a generic form, and which materials are best developed by individual health units. The Ministry expects to finalize the protocol by the end of 2017.

Regarding vaccine hesitancy materials, as noted in the previous section, the Ministry developed the Immunization Well-Child Toolkit in 2015, which includes a number of educational materials and fact sheets that both physicians and public health units can provide to parents and patients who are vaccine-hesitant.

Cost-Benefit Analysis Needed of Some Federally Recommended 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.

Status: Little or no progress made.

Details

As was the case at the time of our audit, prior to adding a vaccine to Ontario's publicly funded immunizations, the Ministry consults various scientific studies produced at the national and provincial

levels. Based on a review of this evidence, the Ministry makes a decision. Since our 2014 audit, the Ministry has added two vaccines recommended by the National Advisory Committee on Immunization to Ontario's publicly funded schedule and used a similar process to that followed at the time of our audit. The Ministry still has not adopted a consistent process for examining the costs and benefits of publicly funded vaccines in Ontario.

At the time of our follow-up, Public Health Ontario's analysis indicated that the shingles (Herpes Zoster) vaccine was particularly cost-effective for people aged between 65 and 70. The Ministry did not previously provide it to these people because, unlike other vaccines, the shingles vaccine at the time was required to be stored frozen until it was administered. The shingles vaccine can now be refrigerated similar to other vaccines. Consequently, in September 2016, the Ministry made the shingles vaccine available to Ontario seniors between the ages of 65 and 70 free of charge. This decision results in some of the people in the recommended age group receiving the vaccine, but not all because the Ministry did not provide the vaccine to seniors between 60 and 65 years of age, even though the analysis indicated it was cost-effective for this age group as well.

In the case of HPV, the Ministry re-examined studies conducted in 2012 and determined HPV immunization for boys to be cost-beneficial. HPV vaccines for boys are to be given in grade 7 starting in the 2016–17 school year.

Previously, these two vaccines accounted for the major differences between nationally recommended immunizations and the ones publicly funded in Ontario. However, the decisions to approve these two vaccines were based on different decision models, and not a consistent process for evaluating costs and benefits: one was based on practical considerations regarding storage conditions; and the other on a re-examination of a comparison between the cost of the vaccine against the number of healthy years a patient is expected to gain as a result of the vaccine.

Better Oversight of Influenza Immunization Program Needed

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.

Status: In the process of being implemented by summer of 2017.

Details

In October 2015, Public Health Ontario completed a review of strategies used in Canadian and U.S. hospitals to prevent and control hospital-acquired influenza, including a review of “vaccinate or mask” policies. It concluded that these policies were effective in increasing flu immunization rates among hospital staff. However, Public Health Ontario also noted that available evidence on the effectiveness of hospital staff immunization in reducing flu transmission in hospitals was limited and further research on the topic is necessary. The Ministry anticipates further information on this to become available when a study that is currently underway across several Toronto hospitals is completed in the summer of 2017.

Staff at one Ontario hospital challenged that hospital’s “vaccinate or mask” policy and in September 2015, after contentious discussions and sometimes conflicting testimony from medical experts, an arbitrator struck down the policy as an unreasonable condition of employment. The Ministry informed us that this decision applies to only this hospital and it would continue to encourage all health-care workers to be immunized against the flu. The Ministry also informed us that the arbitrator’s decision would have no impact on the deliberations of an executive steering committee

that was tasked in spring of 2015 with providing a recommendation on whether to implement a “vaccinate or mask” policy throughout the province. At the time of our follow-up, the steering committee had not made a recommendation but was planning to do so by the end of 2016. The Ministry indicated it would make a decision on the “vaccinate or mask” policy by the spring of 2017.

Improvements to Influenza Vaccine Program Needed

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.

Status: Little or no progress made.

Details

In the fall of 2015, the Ministry compared the fees payable to Ontario pharmacists for administering the flu shot to those paid to pharmacists in other provinces. This comparison indicated that the \$7.50 Ontario fee was lower than those paid in most other provinces. However, during our 2014 audit we noted that the Ministry had not performed an analysis of the relative costs and experience of the different health-care providers that were administering the flu vaccine to determine the reasonableness of the amount paid to pharmacists. At the time of our follow-up, the Ministry indicated that it would conduct further analysis of the reasonableness of the fee.

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*

Status: Will not be implemented. Though consideration should be given to the minority of patients who require two doses of the flu vaccines, we continue to recommend that the claims payment system be updated to reject billings for patients who have already received an influenza vaccine.

Details

In May 2015, the Ministry implemented changes to its billing system, which now disallows payments for flu vaccinations outside of the flu season (which is September to May), and payments for a third immunization for the same person within a flu season. The Ministry indicated that payments for duplicate immunizations continue to be allowed since some patients, such as those with a compromised immune system, may require two doses within one season. We noted in our 2014 audit that only a minority of patients legitimately requires two vaccine shots to create immunity against the flu. However, the Ministry does not intend to revise its claim system to reject duplicate payments because the Ministry has concluded that duplicate physician billings for the flu vaccine occur too infrequently to warrant such measures.

- *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.*

Status: Little or no progress made.

Details

The Ministry informed us that while it had not yet done so at the time of our follow-up, it planned to review billing data to identify any inappropriate billing patterns for the 2014/15 and 2015/16 flu seasons, and conduct a manual review of health-care providers to determine if the services they provided were appropriate. This review is to be completed by March 2017. During the 2015/16

flu season around 870,000 flu vaccinations were administered by pharmacists. No comparison of pharmacists' and physicians' flu-vaccination billings were made for the 2014/15 or the 2015/16 flu season to identify duplicates because the Ministry had not linked the two billing systems. The Ministry indicated that it planned to compare the billings for the 2015/16 flu season by March 2017.

Better Tracking Needed of Adverse Events Following Immunization

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;*

Status: Fully implemented

Details

In spring 2016, the Ministry and Public Health Ontario developed a fact sheet with information for parents on how to identify a reaction that could indicate an adverse event following immunization, such as worsening swelling at the injection area or rash. The fact sheet suggests an adult patient or a child's parent call the health-care provider who administered the vaccine to report the adverse event. Starting in the summer of 2016, as part of physician office inspections to ensure compliance with vaccine storage requirements, public health units began providing copies of the fact sheets to physicians and educating them on the importance of distributing the fact sheets to patients at the time of vaccination. The Ministry plans to survey physicians in the summer of 2017 to evaluate the effectiveness of this approach. Although the

Ministry has not implemented a strict requirement for health-care providers administering a vaccine to provide the fact sheet to parents, it has developed a fact sheet and is encouraging its use.

- *collect information on health-care providers who have administered vaccines associated with adverse events; and*

Status: Little or no progress made.

Details

In April 2015, in response to our recommendation, Public Health Ontario updated the requirements on the information that public health units were required to collect regarding adverse events following immunization, making it mandatory for public health units to input the name of the physician who administered the vaccine. Having this information available makes it possible to identify physicians with unusually high adverse event rates. However, while Public Health Ontario collects the names of the other health-care providers that administer the flu vaccine, such as pharmacists and public health unit nurses, it does not enter them into its database. The Ministry is planning to require that the identity of pharmacists start to be collected by requiring that this information be entered in the database. The Ministry is considering whether to also require public health unit nurse identities to be entered in the database.

- *follow up on any unusual trends, including areas where adverse event rates look unusually low or high.*

Status: In the process of being implemented by December 2017.

Details

In the spring of 2014, following our field work, for cases where it determined that reported adverse event rates were unusually low, Public Health Ontario began contacting public health units' Medical Officers of Health to discuss strategies on how to ensure adverse events do not go unreported. Beginning with its November 2015 report on vac-

cine safety, Public Health Ontario published the rates of reported adverse events following immunization per 100,000 of the population for each public health unit. These rates ranged from less than 1 per 100,000 population to over 27 per 100,000. For the 2017 calendar year, the Ministry plans to implement a performance indicator capturing the adverse event reporting rates for Meningococcal, HPV and Hepatitis B immunizations that health units administer to middle school students. These will be included in the Ministry's agreements with public health units and consequently any unusually high or low reported rates will be identified for follow-up.

Better Oversight of Vaccine Wastage Needed

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);*

Status: In the process of being implemented by the summer of 2017.

Details

Starting in November 2015, all 36 public health units started using the inventory module of Panorama, which means that the Ministry is now able to review and assess vaccine inventory in public health units as well as the quantities distributed to physicians' offices by the health units. Also in 2015, the Ministry updated the standard form used by physicians to order new vaccines; the form now requires physicians to include the number of vaccines they currently have on hand. This information can help the Ministry ensure that physicians'

offices do not order unreasonably large amounts of vaccines (that is, more than a month's worth). The Ministry indicated that public health units can now use Panorama to generate reports showing the monthly vaccine orders of each physician. They can therefore estimate the amount of vaccines a physician would use in a month and assess the reasonableness of vaccine orders. More accurate information on vaccine inventory levels at physicians' offices will become available when vaccinations are entered into Panorama as they are administered, which is not scheduled to occur until the summer of 2017.

- *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;*

Status: Little or no progress made.

Details

At the time of our follow-up, physicians were still permitted to use bar fridges and min/max thermometers. The Ministry plans to update the Public Health Standards in December 2017, which is to include requirements for storing publicly funded vaccines. The Ministry informed us that it plans to include a requirement for physicians who use bar fridges to store vaccines, to use data-logging thermometer to assess whether vaccines could have been spoiled by temperatures outside the acceptable range. While this measure would not reduce the risk of exposing vaccines to temperatures outside the safety range, which has been attributed to small generic bar fridges, it could at least provide data on the duration of exposure to more accurately assess whether a vaccine's potency has been affected.

- *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*
Status: In the process of being implemented by spring 2017.

Details

Prior to June 2016, the agreements between the Ministry and public health units did not hold the public health units accountable for vaccine wastage occurring at physicians' offices. In June 2016, the Ministry introduced a performance indicator that required public health units to monitor and minimize vaccine wastage in physicians' offices for one of the more common vaccines, the measles, mumps and rubella vaccine. The Ministry indicated that it plans to analyze the data forwarded from public health units in January 2017 from this new indicator and follow up with public health units in the spring of 2017. The Ministry also plans to follow up with public health units in spring 2017 regarding the wastage they have identified at physicians' offices.

- *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.*

Status: In the process of being implemented by March 2018.

Details

Since May 2016, the Ministry has required public health units to conduct unannounced inspections of physician offices with either prior instances of high wastage of vaccines or inappropriate vaccine storage practices. In such cases, the public health units are also to provide education on appropriate

inventory management practices, reducing vaccine orders, encouraging stock rotation and minimizing vaccine stock at the provider's office. At the time of our follow-up, the Ministry indicated that it was planning to develop an evaluation framework to assess whether the current process would be more cost-effective if it used a more risk-based approach, such as sometimes waiving the requirement for an annual visit if the physician in question had low wastage in the past. The Ministry planned to complete this assessment by March 2018.