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7. Antivirals and Vaccines

Production facilities have to be ready to manufacture vaccines and drugs; others should be stockpiled and distributed around the country.

John M. Barry, The Great Influenza

Antivirals (anti-influenza drugs) can be used to treat and prevent influenza, and will be an important disease management strategy during an influenza pandemic – particularly during the early wave(s) when vaccine is not available. The effectiveness of antivirals against the pandemic strain is unknown, but, when used to treat seasonal influenza, they have been shown to reduce the length of time people are ill, symptoms and hospitalizations.

Ontario is working with the federal government to develop an antiviral stockpile that will be large enough to treat 25% of the population, as recommended by the World Health Organization. This represents the proportion of the population who will be sick enough to need antiviral treatment. Although antivirals can be used both for treatment and prophylaxis (prevention), Ontario will use its supply primarily for treating people who are ill.

Vaccines is the most effective means to prevent disease and death from influenza during a pandemic; however, it will take six months after the pandemic strain is identified to develop a vaccine so it will likely not be available for the first wave. This complex process cannot begin until the pandemic begins and the new virus has been identified. This means that a vaccine will probably not be available when the first wave of the pandemic strikes Canada.

The effectiveness of the vaccine (once developed) against the pandemic strain is unknown, but vaccines for seasonal influenza usually prevent illness in 70 to 90% of healthy adults.

Canada is one of the few countries in the world prepared to have a vaccine manufacturer develop and supply a pandemic influenza vaccine as soon as a new strain is identified. Under a 10-year contract signed in 2001 between the Government of Canada and ID Biomedical (now GlaxoSmithKline Biologicals), the company will be able to produce enough vaccine for all Canadians in the event of an influenza pandemic. There is a global effort to develop prototype pandemic vaccines, including H5N1 vaccines, as part of pandemic preparedness.

7.1 Objectives

Antivirals

1. To ensure the security of the supply of antivirals allotted to the PCCHU from the MOHTLC.
2. To store, distribute, allocate and administer antivirals efficiently and appropriately.

3. To monitor the safety and effectiveness of antivirals as well as any development of resistance to antivirals.

Vaccine

1. To ensure the security of vaccine supply allotted to the PCCHU from the MOHLTC.
2. To store, distribute, allocate and administer vaccine supplies efficiently and appropriately.
3. To monitor the safety and effectiveness of vaccine programs.

7.2 Antivirals

7.2.a Antiviral Supply

The federal government is responsible for approving and licensing antivirals. At the current time, two antivirals are licensed for use in Canada for prophylaxis and treatment of influenza A infections: amantadine and oseltamivir (Tamiflu®), a neuraminidase inhibitor (neuraminidase inhibitors are much more expensive than amantadine). When administered within two days (48 hours) of the onset of illness, neuraminidase inhibitors (e.g., oseltamivir) are effective in reducing length of illness, hospitalization and influenza complications. Resistance to amantadine is now well established and can develop when the drug is used for treatment during annual influenza season. Another antiviral, zanamivir (Relenza™) is licensed for treatment only – and is the recommended treatment for pregnant and lactating women. A fourth antiviral, rimantadine is not currently licensed in Canada.

Because of amantadine's side effect profile and individual dosing requirement, oseltamivir (Tamiflu®) is the drug of choice for most people during a pandemic. Clinicians may consider other drugs, based on their clinical expertise and judgment. Federal, provincial and territorial governments have established a national stockpile of antivirals for use in the event of an influenza pandemic. Additional supplies are being acquired, including antiviral solution for young children and other people who cannot swallow capsules. Governments intend to increase the stockpile to 55 million doses—enough to treat the estimated number of Canadians who will require medical attention during a pandemic.

Ontario has committed to maintaining a stockpile large enough to treat up to 25% of the population, and has placed orders to purchase more antivirals (in addition to its share of the national stockpile). The stockpile will consist primarily of oseltamivir, but the MOHLTC is also purchasing a supply of zanamivir to diversify the stockpile and provide appropriate treatment for pregnant and lactating women.

7.2.b Antiviral Storage and Distribution

To be effective, antivirals must be started within 48 hours of the onset of symptoms; and the earlier they are started, the more effective they are. To provide timely treatment, Ontario must have an effective distribution system for antivirals. The PCCHU will implement the MOHLTC guidelines for distribution of antivirals.

The Ministry of Health and Long-Term Care (MOHLTC) will partner with the Ontario Pharmacists' Association (OPA) to develop a strategy to release antiviral medications from the provincial stockpile. The goal of this strategy is to ensure that antivirals are readily available to those who need them for treatment. Pharmacists and pharmacies play a key role in this strategy.

Pre-determined quantities of antiviral medications from the provincial stockpile will be distributed to pharmacies in Ontario. Once received, these drugs will be stored securely in accordance with industry best practice, separately from the commercial supply.

Antiviral medications from the provincial stockpile are to be made available at no charge to individuals that have a prescription, when prescribed in accordance with ministry guidelines.

Prescriptions for antiviral medications related to non-recommended uses (such as pre-exposure prophylaxis) will be dispensed as directed by the MOHLTC. During the H1N1 pandemic, they were dispensed only from commercial supplies and followed standard prescription billing processes (i.e., payment must be received from the client or an insurer if applicable).

Pharmacists will use the Health Network System (HNS) to track antivirals dispensed from the provincial stockpile. The drug will be provided to the pharmacy at no cost; therefore, no drug cost will be included in the HNS claim. An audit process may apply to prescribers and pharmacists to safeguard against non-recommended use of provincial supplies.

Pharmacy staff should ensure that appropriate infection prevention and control and occupational health and safety measures are in place.

For more information on this strategy, visit the OPA's H1N1 website at www.opatoday.com/H1N1FluVirus.asp or refer to MOHLTC guidance document for the distribution of antivirals during an H1N1 pandemic at http://www.health.gov.on.ca/en/ccom/flu/h1n1/pro/docs/pharmacies_guidance.pdf or the PHAC at http://www.phac-aspc.gc.ca/alert-alerte/h1n1/index-eng.php

7.2.c Use of Antivirals

Currently there is no evidence that putting large groups of otherwise healthy individuals on antivirals in order to prevent influenza (i.e., prophylaxis) will slow or stop the spread of a pandemic; however,
prophylaxis with antivirals may play a key role in maintaining critical services (i.e., preventing infection in and providing reassurance to people caring for individuals with influenza as well as workers in critical industries) until a vaccine becomes available.

They are in the process of developing a provincial policy on the use of antivirals for prophylaxis based on the national policy and in accordance with the ethical framework for decision-making. This will help ensure a consistent approach to using antivirals for prophylaxis across all provinces and territories, which will lead to stronger public confidence and morale.

With regard to antivirals for treatment, the MOHTLC is committed to providing treatment for individuals who become ill during an influenza pandemic and will maintain an antiviral stockpile large enough to treat 25% of the population.

7.2.d Monitoring Adverse Effects

Based on national recommendations, the MOHLTC will develop a mechanism to monitor adverse effects from antivirals as well as the development of antiviral resistance.

The PCCHU and/or Pharmacists will monitor and track:

- Antiviral distribution and uptake
- The development of antiviral resistance in the pandemic strain; and
- Adverse reactions to antiviral drugs used.

7.3 Vaccine

7.3.a Immunization Strategies and Vaccine Sequencing

As directed by the MOHLTC, the PCCHU offers free seasonal influenza immunization to anyone in the Peterborough County and City over the age of six months with no contraindications to influenza immunization since the fall of 2000. The program, known as the Universal Influenza Immunization Program (UIIP), provides approximately five to six million doses of trivalent influenza vaccine a year to residents of Ontario.

The PCCHU will continue to actively promote annual universal influenza immunization, particularly with groups identified by the National Advisory Committee on Immunization (NACI) as being at high

risk of complications from influenza. Annual influenza immunization will reduce the morbidity, mortality and demands on the health care system from seasonal influenza strains.

The PCCHU will also promote pneumococcal vaccination of NACI "high-risk" groups during the interpandemic period to reduce the incidence and severity of secondary bacterial pneumonia in people with influenza.

7.3.b Vaccine Supply

The federal government is responsible for vaccine procurement and supply, including developing the domestic infrastructure, maintaining a standby supply of fertilized hens' eggs ready to convert into vaccines, phasing in new technologies, and ensuring security of supply (i.e., via a pandemic contract). In case of a pandemic, the domestic supplier (IDBiomedical) guarantees to manufacture eight million (+/- 10%) monovalent doses, per month, for a period of four months. This will start within four to five months after the receipt of the pandemic seed strain for Canada.

In October 2001, Ontario signed a Memorandum of Understanding to participate in the Canadian influenza vaccine procurement and supply process. That agreement runs until March 2011. To immunize the entire province, Ontario would require 24 million monovalent doses (based on two doses per person, over approximately four months).

7.3.c Access to Vaccine

Each year, the National Advisory Committee on Immunization (NACI) makes recommendations (published in the Canada Communicable Disease Report) on priority groups for influenza immunization (i.e., persons who are most at risk for influenza, those who could spread influenza to persons at greatest risk). In the event of a pandemic, the Pandemic Influenza Committee, which includes representation from NACI, will make recommendations to federal/ provincial/ territorial governments on priority groups for immunization based on the epidemiology of the pandemic strain.
Ontario's goal is to obtain enough vaccine for the entire population but, during the early stages of a pandemic, vaccine will be in short supply. In this situation, the province will follow the national recommendations for priority groups for influenza immunization, adapting them as required to meet provincial needs. It will also use the ethical framework to guide the decision-making process.

The PCCHU will distribute vaccine to residents of the City and County as directed by the MOHLTC. This may include vaccine sequencing. Vaccine sequencing refers to the Government of Canada advice to provinces and territories on which groups and populations would benefit most from vaccination so that the timing and location of immunization clinics could be targeted appropriately.

Refer to the PHAC guidance document on H1N1 vaccine sequencing at http://www.phac-aspc.gc.ca/alert-alerte/h1n1/faq/faq_rg_h1n1-fvv-eng.php ; the PHAC Pandemic Vaccine Prioritization Framework at http://www.phac-aspc.gc.ca/cpip-pclcpi/vf/index-eng.php or the PHAC guidance document on vaccine sequencing at http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/vacc-eng.php

7.3.d Distribution and Administration

Ontario has a vaccine distribution system in place to support its Universal Influenza Immunization Program. In the current system, vaccine is shipped directly to the PCCHU. The PCCHU then distributes the vaccine to physician offices, workplace clinics, and a variety of other settings where immunization services are provided. The same distribution mechanism may be applied during a pandemic. However, distribution is dependent on how the vaccine is packaged and the shelf-life of the vial once it is open. If the vaccine is packaged in small quantities, it may be easy to distribute to primary care practitioners. If it is only available in large quantities, it may be distributed to family health teams or to those who can hold large clinics.

Refer to the MOHLTC Health Unit Allotment for H1N1 vaccine at http://www.health.gov.on.ca/en/ccom/flu/h1n1/public/allocation.aspx , or PHAC Vaccine Allotment by province at http://www.atlantique.phac.gc.ca/alert-alerte/h1n1/vacc/vacc-archive/dist-archive-eng.php

7.3.e Monitoring Adverse Events

The federal government maintains an adverse event following immunization (AEFI) surveillance system through the CIDPC. In Ontario, adverse events associated with influenza vaccination are reportable under the Health Protection and Promotion Act. The PCCHU enters all vaccine adverse events in the Integrated Public Health Information System (iPHIS). The information is electronically transmitted to the MOHLTC.