



Canada's pandemic vaccine strategy

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Abstract

The Public Health Agency of Canada has a mandate to prepare and respond to public health events, including influenza pandemics. Pandemic preparedness requires a multifaceted approach with collaboration from all levels of government. The *Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector* (CPIP) is a guidance document that outlines key health sector preparedness activities designed to ensure Canada is ready to respond to the next influenza pandemic.

This article, the first in a series, outlines Canada's pandemic influenza vaccine strategy as described in the CPIP annex on vaccines. The strategy encompasses all elements of a vaccine program including prioritization of the initial vaccine distribution, securing a pandemic vaccine supply, regulatory approval of a pandemic vaccine, vaccine safety, distribution and storage of the vaccine, allocation and vaccine uptake.

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Introduction

Influenza pandemics are recurring but unpredictable events that arise when a novel influenza A virus spreads widely and causes a worldwide event. Planning for a prolonged and widespread health emergency with an unpredictable impact is challenging but essential. The Public Health Agency of Canada (PHAC) has a mandate to prepare for and respond to public health events through leadership, partnership and action. In an influenza or other pandemic, PHAC leads the health sector preparedness and response at the national level, collaborates with international partners and represents Canada on global health security initiatives.

Pandemic preparedness necessitates a multifaceted approach with collaboration from all levels of government (local, provincial/territorial, federal). Key components of health sector preparedness include disease surveillance, laboratory testing and research, health care service and public health guidance, communications and medical countermeasures to mitigate transmission and reduce burden of illness through the use of antivirals and vaccines.

The 2009 H1N1 pandemic (pH1N1) provided the first test of Canada's pandemic preparedness planning and led to unprecedented collaboration among all levels of government and successful stakeholder engagement. Leveraging existing laboratory networks, such as the Canadian Public Health Laboratory Network, and surveillance systems, such as the national influenza surveillance system FluWatch, proved invaluable.

Health planners learned a lot from the 2009 pH1N1 (1). Two key lessons that informed subsequent planning considerations were to ensure that:

- triggers for activation and deactivation of specific response elements are well defined; and
- pandemic plans allow for scalability and flexibility.

These reflect the fact that the impact and timing of pandemic virus activity can vary by region and that there can be unique considerations for each jurisdiction (e.g., province, territory and federal government). Finally, there is a need to clearly articulate the roles and responsibilities of federal, provincial and territorial (FPT) governments in the event of any public health emergency.

National pandemic planning for the health sector

The *Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector* (CPIP) is an FPT guidance document that outlines how the jurisdictions can work together to ensure a coordinated and consistent health sector approach to pandemic preparedness (2). The body of the CPIP describes the overarching principles, concepts and shared objectives that are critical to effective pandemic preparedness and response. This is followed by the annexes that provide technical operational plans on specific issues such as surveillance, public health measures and the vaccine strategy.

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The CPIP is an evergreen document that is routinely reviewed and updated as new information and best practices emerge. This article marks the beginning of a series providing an update on the different sections of the CPIP by summarizing Canada's pandemic influenza vaccine strategy as outlined in the CPIP's Vaccine Annex (3).

Canada's pandemic vaccine strategy

Immunization of susceptible individuals is the most effective method of preventing disease transmission and death from influenza. A safe and effective vaccine is the cornerstone of pandemic preparedness and response. Canada's pandemic influenza vaccine strategy is built upon the strength of the seasonal influenza programs; however, there are unique differences to consider during a pandemic.

Pandemic vaccine prioritization framework

Initial supplies of a new pandemic vaccine are unlikely to be sufficient to immediately supply everyone living in Canada. To address this situation in an equitable manner, national recommendations for the prioritized use of the vaccine will be developed by the National Advisory Committee on Immunization (NACI) using the *Pandemic Vaccine Prioritization Framework* until sufficient vaccine is available for all Canadians (approximately one month after initial lots are available) (4).

NACI is an expert advisory body to the PHAC, responsible for making recommendations on all vaccines used in Canada (5). This includes the seasonal and pandemic influenza vaccines, through NACI's Influenza Working Group. The NACI guidance on the use of the pandemic vaccine will be updated as required. For example, initial recommendations may change as the specific epidemiology of a pandemic becomes clear.

At the outset of a pandemic, the prioritization framework provides a systematic way of looking at all the relevant scientific evidence while taking into account ethical, logistical and other considerations. The recommendations will categorize risk and age groups into various priority groupings, using the most effective strategies to address national pandemic goals. The framework was successfully used to develop sequencing guidelines for the rollout of the vaccine during pH1N1. The determined priority groups included people under 65 years with chronic conditions, pregnant women, children between six months and five years of age, people in remote and isolated settings, health care workers involved in the pandemic response or providing essential services, household contacts and care providers of people at high risk who could not be immunized, and other high-risk populations (6).

Vaccine supply

Domestic production of the influenza vaccine is essential to guarantee that Canada has access to an adequate supply as the availability of offshore-manufactured vaccine may be limited during a pandemic because of trade and travel embargoes, as well as increased demand. Canada was one of the first countries to implement a long-term pandemic vaccine contract with a vaccine manufacturer in 2001. The first opportunity to benefit from this came during pH1N1 in 2009 and the result

was sufficient vaccine for all Canadians who wanted to be immunized. Since then, Canada has put in place another 10-year contract (which began in 2011). The contract stipulates that the manufacturer fulfill their commitment to Canada before selling the vaccine to other countries, ensuring an adequate supply for every person residing in Canada. To ensure capacity for manufacturing the vaccine, the current contract includes access to a share of Canada's seasonal influenza vaccine market.

Vaccine regulation

All vaccines intended for use in Canada are subject to the provisions of the *Food and Drugs Act* (7) and the *Food and Drug Regulations* (8). Before authorizing a new vaccine, Health Canada evaluates the scientific and clinical evidence submitted by the manufacturer. The process used to authorize approved seasonal influenza vaccines each year is a modification of the full process for a new vaccine because seasonal vaccines involve only a change in the influenza strain(s) used. Months before the flu season begins, manufacturers send updated information to regulatory authorities on the strains anticipated in the upcoming season. Health Canada then expedites a review of the data and authorizes the new seasonal vaccine.

Standard regulatory processes cannot be used in a pandemic because the production of a pandemic vaccine cannot begin until the virus strain has been identified. For a vaccine to be useful in mitigating the pandemic impact, it will be needed almost immediately after it is manufactured. So what can be done to pass regulatory review with limited time and data?

Regulatory approval of a pandemic vaccine can occur in three ways. First, similar to seasonal vaccine, a prototype pandemic vaccine can undergo prior market authorization based on surrogate immunogenicity data as this would be followed by subsequent authorization of the strain change. Second, the Extraordinary Use New Drugs (EUND) regulations, enacted in 2011 after pH1N1, may be used (9). These regulations allow Health Canada to expedite authorization of a pandemic vaccine based on animal data supplemented by any available human data as long as a complete "quality package" (information on manufacturing the vaccine) is available and a rigorous postmarket surveillance plan is in place. Finally, if the EUND regulations do not apply (because the quality package is incomplete, for example), an Interim Order, based on a state of public health emergency, may be issued by the federal Minister of Health. Such an Interim Order can suspend certain requirements of the *Food and Drugs Act* and *Food and Drug Regulations Act* allowing the issuance of a time-limited authorization with additional sponsor obligations, such as timely submission of missing quality and clinical data as well as postmarketing information.

Vaccine safety

The scale of the pandemic vaccination campaign and the EUND regulatory pathway warrants careful attention to vaccine safety to minimize risk and maximize the benefits of the vaccine. Pandemic vaccine safety is built upon the infrastructure and systems already in place for monitoring routine vaccines. Postmarket surveillance of adverse events following immunization (AEFI) is undertaken by PHAC and Health Canada with provincial and territorial partners and other key stakeholders. Despite the fact that



premarket regulatory application provides a significant amount of information, postmarket surveillance is critical to capture reports of serious and unexpected AEFIs. This information is then used to investigate the relevant vaccine and to enable regulatory action as needed. However, a vaccine released under EUND would have little or no postmarket data and existing surveillance activities undertaken by PHAC, Health Canada and provincial and territorial partners would require considerable scaling up.

In a pandemic, it is critical that AEFI information be quickly passed on to the federal Health Portfolio (e.g., Health Canada and PHAC), where reports can be aggregated and analyzed. A vaccine safety signal from an AEFI report could include an increase in frequency or severity of events known to be caused by influenza vaccine (e.g. allergic reactions) or a previously unknown adverse event (e.g. narcolepsy). Signals need to be quickly investigated so that the cause can be assessed and action taken as appropriate. Possible actions include updates to the product monograph, revisions to vaccine recommendations, changes to administration practices and quarantine or recall of a vaccine lot by Health Canada. Key needs for such enhanced safety monitoring and case report assessment include protocols for rapid field investigations, analytical capacity and knowledge of background rates of potential adverse events to compare observations with expectations.

Vaccine allocation, distribution and storage

An allocation plan (i.e. the amount of vaccine each province and territory receives) will be developed by the Vaccine Supply Working Group, an FPT forum to coordinate vaccine procurement and vaccination programs. Similar to pH1N1, distribution to the provinces and territories will be done on a per capita basis at the outset, beginning with the first lots available and continuing throughout the vaccine production cycle.

As with all vaccines, proper storage and handling guidelines must be followed. For example, the cold chain must be maintained throughout the distribution process. Detailed information is provided in the [National Vaccine Storage and Handling Guidelines for Immunization Providers](#) (10).

Vaccine uptake

To assist with the prompt distribution of pandemic vaccine, it is important to establish the most efficient use of care providers to administer the vaccine and to have a common infrastructure to capture surveillance data. Most provinces and territories have some type of a hybrid delivery model (with pharmacists, public health nurses and physicians administering vaccine) for seasonal influenza. In addition, each province and territory maintains its own information system, using electronic databases and/or paper-based systems, to track vaccination coverage. This incompatibility across systems has made tracking seasonal influenza vaccine challenging and may result in missing information. At the national level, PHAC monitors seasonal influenza vaccine uptake through the National Seasonal Influenza Immunization Coverage Survey and the Canadian Community Health Survey, but this has a significant lag time and would not be timely in a pandemic situation. In the event of a pandemic, interoperable information systems that allow multiple providers to access and enter vaccine records are needed to provide accurate and timely estimates of vaccine coverage. To close the

gap in vaccination coverage and uptake monitoring, work is underway to develop provincial and territorial registries for both seasonal and pandemic influenza surveillance.

Discussion

Canada's pandemic influenza vaccine strategy is built on the strength of the seasonal influenza programs and informed by the lessons learned during pH1N1. Since pH1N1, Canada's pandemic vaccine strategy has been enhanced through a new pandemic vaccine contract with a domestic vaccine manufacturer; new regulatory processes that allow for expedited regulatory approvals; enhanced vaccine safety surveillance; and the ongoing efforts to develop vaccine registries.

Canada's vaccine strategy is always subject to change as a result of new developments. For example, plant-based vaccines are a new technology that may obtain market authorization as a prototype vaccine during the life of the current pandemic vaccine contract. Planners must take into account this possibility and the potential impact and cost these new technologies may have over time. Other new research developments may also signal the need to revise the strategy.

Conclusion

The pandemic influenza vaccine strategy is one element of Canada's pandemic preparedness strategy. It represents a continuing commitment on behalf of all FPT governments to work collaboratively and ensure Canada is ready to respond in the event of an influenza pandemic. Canada was well prepared for pH1N1 and, as a result of the lessons learned from the response, it is even better prepared now.

Conflict of interest

None.

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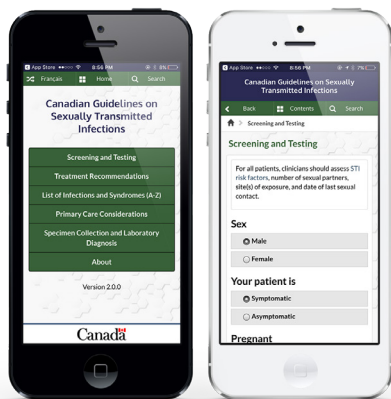


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