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LESSONS LEARNED REVIEW:

PUBLIC HEALTH AGENCY OF CANADA AND
HEALTH CANADA RESPONSE TO THE 2009 H1N1 PANDEMIC

NOVEMBER 2010

The information in this report was obtained by the Public Health Agency of Canada Evaluation Services Directorate through a review of relevant material and a series of interviews. This report does not draw exhaustive or definitive conclusions on all the activities leading up to or taken by various individuals or entities during the H1N1 pandemic response. Rather, the observations in this report are meant to give senior management of the Public Health Agency of Canada and Health Canada a general overview of what worked well in response to this particular event and what needs further refinement to be better prepared for future pandemics and other national public health events.

ACKNOWLEDGEMENT

It is important to acknowledge the profound professionalism, commitment and hard work of staff across the Public Health Agency of Canada and Health Canada during the H1N1 pandemic. Their dedication to anticipating and responding to the needs of Canadians was admirable.

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EXECUTIVE SUMMARY

Introduction

The Lessons Learned Review examined the response of the Public Health Agency of Canada and Health Canada to the 2009 H1N1 influenza pandemic. The purpose of this joint Review was to gain an understanding of what worked well and areas for action. Health Portfolio management and staff will use the findings for planning and decision making in preparation for future pandemics and other types of national public health events.

The Review analyzed information from multiple sources. First, key internal documents were examined, such as assessments conducted by operational areas within the Public Health Agency of Canada and Health Canada or by various groups within the response structure, including those with provincial/territorial officials and expert advisors. Second, reviews completed by other organizations were analyzed (e.g. provinces, non-governmental organizations and other countries). Third, written feedback was solicited from external organizations engaged by the Public Health Agency of Canada and Health Canada during the H1N1 pandemic. Finally, interviews were conducted with key senior managers.

Background

Influenza pandemics have the potential to cause serious illness, death, and extensive social and economic disruption. There were three influenza pandemics in the 20th century: 1918-19, 1957-58 and 1968-69. Each pandemic differed in severity, duration and the populations most affected.

The virus responsible for the 2009 pandemic was a unique combination of influenza virus genes never before identified in either animals or people. Determined to be the cause of severe respiratory illness outbreaks in Mexico in March 2009, the virus spread to Canada within weeks. The first Canadian cases of H1N1 were confirmed by the Public Health Agency of Canada on April 26, 2009.

Influenza pandemics are difficult to predict. At the very outset of the pandemic, the Public Health Agency of Canada was instrumental in achieving a better understanding of the virus that emerged in Mexico and its impact on populations around the world. The National Microbiology Laboratory was called on for laboratory assistance and five Public Health Agency scientists helped with testing in Mexico over the course of six weeks. Due to the National Microbiology Laboratory's work, Canada was the first country to characterize the entire genomic sequence of the pandemic H1N1 influenza virus. This made a significant contribution to international scientific understanding of this novel strain.

As knowledge of the H1N1 virus evolved, information to Canadians also evolved, which, at times, contributed to uncertainty and anxiety among some Canadians.

As one key informant noted, the Health Portfolio *“dealt with constantly evolving knowledge and evidence requiring it to adjust its advice and manage the flow of information in ‘real time’ across 14 jurisdictions, each with different needs and capacities, and spread across six time zones.”*

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To date, Canada has experienced two distinct waves of H1N1. The first wave occurred in spring 2009 between April 12 and August 29, with influenza activity reaching its peak during the first three weeks of June. The second wave reached its peak in early November 2009. On January 27, 2010, the Public Health Agency of Canada announced that the second wave of the pandemic in Canada was over. Later in the year, on August 10, 2010, the World Health Organization announced that the world had entered the post-pandemic phase.

The Health Portfolio's initial response to the first wave of the pandemic had an exponential tempo. The Health Portfolio Emergency Operations Centre was activated quickly and ran 24 hours a day and seven days a week for several weeks.

Canada's second wave resulted in four to five times more hospitalizations and deaths compared with the first wave. Increased rates of hospitalization, intensive care unit admissions and mortality were found to be highest among Aboriginal people, pregnant women and individuals with at least one underlying medical condition, although the risk for Aboriginal people and pregnant women decreased considerably in the second wave compared with the first wave.

The virus is still having an impact. Some of those who experienced the most serious symptoms have reported lingering effects.

Pandemic response is a shared responsibility among municipal, provincial, territorial and federal governments, and involves a complex interface of multi-jurisdictional players, policies, plans and procedures. The Health Portfolio plays an important leadership role, as outlined below.

The Public Health Agency of Canada is the lead federal agency responsible for addressing pandemic influenza preparedness and response. Key activities include the following:

- conducting scientific research to better identify, understand and track the virus
- obtaining surveillance (or tracking) information from its federal, provincial, territorial and local partners, as well as non-governmental organizations (influenza surveillance helps to determine: when, where and which influenza viruses are circulating; their intensity, spread and impact; and if specific population groups are at higher risk for illness)
- ordering sufficient vaccine for the Canadian population, in collaboration with the provinces and territories
- stockpiling pharmaceuticals, equipment and supplies to assist the provinces and territories with surge capacity
- providing information and advice to the general public and particular groups, such as vulnerable populations, as well as issuing guidance for health professionals and other stakeholders
- providing regional coordination of federal health emergency activities
- managing international aspects of pandemic preparedness and response, including liaising with the World Health Organization and acting as the focal point for coordinating the implementation of the *International Health Regulations*
- developing and supporting the process required to update and maintain the *Canadian Pandemic Influenza Plan for the Health Sector*, in cooperation with Health Portfolio and provincial/territorial representatives.

During a pandemic, Health Canada engages and coordinates efforts among domestic and international partners in the following areas:

- developing a regulatory framework for the review, approval and release for sale of pandemic vaccines and other health products used to prevent or treat the H1N1 influenza virus
- ensuring new influenza vaccines meet standards of safety, quality and efficacy
- undertaking surveillance and risk management of post-market safety issues related to the use of health products to treat or prevent influenza, including antivirals, masks, hand sanitizers and disinfectants
- protecting public health on conveyances (e.g. aircraft and ships) and related infrastructure (e.g. airports and seaports) to reduce the spread of the pandemic into, across and out of Canada.

Health Canada is also responsible for ensuring that health services are available and accessible to on-reserve First Nation communities. This includes assistance in the development, testing and revision of pandemic plans. In collaboration with provinces and territories, the First Nations and Inuit Health Branch of Health Canada is also responsible for distributing and administering vaccines and antivirals, reporting adverse effects of immunization and treatment, as well as providing culturally appropriate information and guidance to health care workers on reserves.

Findings and recommendations

This was the first pandemic in 40 years. It tested the Health Portfolio's ability to respond to a pan-Canadian and international public health event.

What worked well?

Overall, the response of the Health Portfolio to the H1N1 pandemic is considered to have been effective. Strengths can be identified in all nine areas of pandemic readiness and response capacity. The following were identified as high-level activities that worked particularly well during H1N1. The Public Health Agency of Canada and Health Canada should continue to build on these successes.

Surveillance, science and research

- Existing networks, systems and tools facilitated the prompt exchange of science, surveillance and research information
- The Public Health Agency of Canada helped identify, understand and monitor the H1N1 virus
- Health Canada's review of the H1N1 vaccine's safety was conducted promptly
- The Public Health Agency of Canada and Health Canada were leaders in the international response to H1N1

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Collaboration with provinces and territories

- Federal and provincial/territorial governments demonstrated a high level of collaboration
- Basic mechanisms to support federal/provincial/territorial collaboration were in place
- New structures were created to respond to emerging issues

Guidance

- Guidance documents were produced for a variety of audiences
- Expert advisors were effective in assisting in the development of guidance

Stakeholder engagement

- A stakeholder engagement plan was put in place
- The Chief Public Health Officer established a Science Advisory Committee of researchers from the academic community
- There was strong collaboration with other countries, as well as international organizations

Communicating with Canadians

- Communication with the Canadian public was a key priority during the pandemic
- Key spokespeople, like the Minister of Health and the Chief Public Health Officer, were visible throughout the pandemic
- Advance planning ensured key communication products and activities were quickly implemented
- Social marketing efforts helped to change infection prevention behaviours
- There was strong and effective coordination of communication activities between federal and provincial/territorial governments

Federal response in on-reserve First Nation communities

- Many First Nation communities had pandemic plans in place
- Vaccination clinics on reserves were generally successful
- Antivirals were pre-positioned in remote and isolated communities for the second wave and personal protection equipment was purchased
- There was good cooperation among Health Canada, the Public Health Agency of Canada, Indian and Northern Affairs Canada, the provinces and First Nations leadership
- Health Canada appointed a Senior Medical Advisor to oversee the H1N1 on-reserve response

Emergency stockpile

- Advance planning ensured antivirals and emergency medical supplies were readily available

EXECUTIVE SUMMARY

Vaccine

- Advance planning for the vaccine supply ensured timely access to a safe and effective vaccine
- The Canadian rate of immunization was one of the highest in the world
- There was close collaboration with the World Health Organization and international regulatory counterparts
- Science, policy and regulatory experts worked together as a team
- Interim orders were appropriate regulatory measures to expedite access to the H1N1 vaccine, as well as to antivirals for children under one year of age

Operational management

- Key structures, resources, relationships, plans and tools were in place
- Staff showed remarkable dedication and endurance
- A financial framework for pandemic influenza had been already established
- Internal communications with staff began early and was extensive

Areas for action

Notwithstanding these strengths of the Health Portfolio response, improvements are required. Specific areas for action are identified below:

Surveillance, science and research

- Finalize agreements on sharing surveillance information across jurisdictions
- Consider options to ensure that appropriate mechanisms exist to facilitate the rapid conduct of critical research
- Refine approaches for translating scientific knowledge into information useful for planning, decision-making and communications

Collaboration with provinces and territories

- Continue to work with provincial and territorial partners to review and streamline the federal/provincial/territorial governance structure for pandemic influenza
- Clarify and communicate the roles and responsibilities of the various advisory groups within the pandemic governance structure
- Clarify decision-making processes during a pandemic and communicate them to expert or advisory groups

EXECUTIVE SUMMARY

Guidance

- Clarify the federal role in developing clinical guidance
- Formalize an expedited approval process for guidance documents
- Fill gaps in existing guidance
- Use appropriate language and formats for guidance documents

Stakeholder engagement

- Increase multi-jurisdictional coordination of information for stakeholder groups
- Enhance capacity to anticipate and respond to issues raised by all stakeholder groups
- Support development of guidance documents for health professionals
- Review Health Portfolio management of international relationships

Communicating with Canadians

- Improve consistency of information communicated to Canadians across different jurisdictions
- Review strategies to communicate uncertainty, risk and shifts in scientific knowledge in order to build public trust

Federal response in on-reserve First Nation communities

- Develop guidance on the logistical aspects of implementing pandemic plans
- Ensure timely availability of public health guidance for First Nation communities
- Respond to local issues by using regional spokespeople
- Address barriers for the movement of health professionals during a public health event

Emergency stockpile

- Review the National Emergency Stockpile System and the National Antiviral Stockpile in light of the H1N1 experience
- Consider options for prescribing and dispensing antivirals in remote and isolated communities during a pandemic
- Seek authority to donate stockpile supplies to other countries

Vaccine

- Implement an integrated surveillance system for immunization, including managing inventories, tracking vaccine uptake and monitoring adverse events
- Review the approach for federal delivery of vaccines to provinces and territories
- Establish a permanent regulatory regime for future public health events
- Effectively communicate regulatory processes and mechanisms

Operational management

- Governance during significant public health events
 - Examine the Incident Management System used in the Health Portfolio Emergency Operations Centre and adapt it for future responses
 - Develop a common understanding of the decision-making process during an emergency when public health and public policy issues intersect
 - Look for opportunities to streamline briefings and meetings involving senior management
 - Continue to distinguish roles and responsibilities among the Public Health Agency of Canada's senior executives
 - Distinguish roles and responsibilities within the Public Health Agency of Canada between the emergency management and the operations groups
- Corporate support during significant public health events
 - Put mechanisms in place to ensure responsiveness of the Public Health Agency of Canada's corporate services
 - Pay particular attention to policies, plans and procedures for human resources management

Cross-cutting recommendations

The 34 areas of action listed above can be clustered into three overarching recommendations for improvements within existing roles, responsibilities and structures. The first recommendation is specific to pandemic preparedness and response, and requires federal collaboration with the provinces and territories. The second recommendation is federally oriented and specific to emergency management. The scope of the third recommendation is limited to the Public Health Agency of Canada and Health Canada and focuses on strengthening science-based communications.

Recommendation 1 — Further strengthen federal/provincial/territorial capacity to prepare for and respond to pandemic influenza.

- Update the *Canadian Pandemic Influenza Plan for the Health Sector* with a particular focus on:
 - adaptability and scalability to different pandemic scenarios
 - efficiency and effectiveness of governance structures (i.e. roles and responsibilities of all partners, composition of committees/groups, as well as accompanying decision-making and approval processes)
 - collaborative processes to develop and strengthen guidance documents to ensure availability, accessibility and consistency of messaging
 - finalization and implementation of data-sharing agreements with provinces and territories.

Recommendation 2 — Continue to clarify, communicate and test federal emergency management roles, responsibilities and mechanisms, with particular attention to sustainability of response capacity and decision-making roles.

- Finalize the *Health Portfolio Emergency Response Policy* and update the *Health Portfolio Emergency Response Plan* with attention to:
 - decision-making roles and responsibilities and accompanying approval processes/timelines
 - activation and escalation standards commensurate with the severity of an event
 - principles and procedures for ensuring the sustainability of response with sufficient surge capacity.
- Continue to orient and train on emergency management.
- Consider a more integrated approach to lessons learned exercises.

Recommendation 3 — Improve the Health Portfolio's ability to communicate science to various audiences.

- Develop plain-language approaches to convey complex scientific findings, processes, uncertainties, risks and shifts for various audiences/purposes, including:
 - Health Portfolio staff in areas such as policy, program, communications and operations
 - decision makers/decision influencers
 - stakeholders
 - the media
 - the general public.

Next steps

Planning is a continuous process. The lessons learned from the experiences from the Severe Acute Respiratory Syndrome (SARS) outbreak and other significant events, such as the 2008 listeriosis outbreak, laid the groundwork for improvements to the Health Portfolio's pandemic response capacity. For H1N1, lessons learned from the first wave were applied to activities during the second wave. It is expected that the lessons learned from this Review will lead to an even more efficient and effective response to future pandemics and other types of national public health events.

Immediate steps should be taken by the Public Health Agency of Canada and Health Canada to implement the lessons learned highlighted in this report. Senior management should oversee the development, implementation and ongoing monitoring of a detailed action plan to respond to each of the findings and recommendations.



1. INTRODUCTION

Purpose and scope of the Lessons Learned Review

The Lessons Learned Review examined the response of the Public Health Agency of Canada and Health Canada to the 2009 H1N1 influenza pandemic. The purpose of this joint Review was to gain an understanding of what worked well and what requires action. Management and staff should use the findings and recommendations of this internal review for planning and decision-making in preparation for future pandemics and other types of national public health events.

The Review examined nine broad areas of the Health Portfolio's pandemic response:

- surveillance, science and research
- collaboration with provinces and territories
- guidance
- stakeholder engagement
- communicating with Canadians
- federal response in on-reserve First Nation communities
- emergency stockpile
- vaccine
- operational management.

This report devotes separate sections to each area above. Their order is not intended to reflect their relative importance and some sections overlap in content. For example, issues about vaccine distribution and use are discussed in section 3.3, Guidance; section 3.6, Federal response in on-reserve First Nation communities; and section 3.8, Vaccine. To avoid duplicating content, some sections direct the reader to related content elsewhere in the report.

This report:

- provides a description of the H1N1 context
- documents the response of the Public Health Agency of Canada and Health Canada to the pandemic
- identifies what worked well, as well as areas for action, within each of the nine broad areas of pandemic response listed above, culminating in three cross-cutting recommendations for improvements within existing roles, responsibilities and structures at the Public Health Agency of Canada and Health Canada.

Methodology

The Review was conducted by the Evaluation Services Directorate, a group internal to the Public Health Agency of Canada but not involved in the program areas that responded to the pandemic.

The Review analyzed information from multiple sources.

- Key internal documents including:
 - assessments of pandemic response conducted by various operational areas within the Public Health Agency of Canada and Health Canada (sometimes known as after-action reports or ‘hotwashes’)
 - assessments of the H1N1 experience carried out by various groups within the response structure, including provincial/territorial officials and expert advisors
 - a synthesis of H1N1-related public opinion research
 - an analysis of media coverage of the pandemic.
- Reviews of the H1N1 response completed by other organizations (for example provincial governments and/or their Chief Medical Officer of Health, other Canadian organizations, as well as other countries). In some instances, direct quotes from these reviews have been included in the report (sources are cited in the endnotes in the References section).
- Written feedback from domestic stakeholders engaged by the Public Health Agency of Canada and Health Canada during the H1N1 pandemic including:
 - national Aboriginal organizations
 - health professional associations
 - private sector representatives (engaged through the Private Sector Working Group on Avian and Pandemic Influenza Planning)
 - emergency response organizations
 - organized labour for the health sector.
- Interviews with key senior managers from the Public Health Agency of Canada and Health Canada. Verbatim quotes from some of these interviews have been integrated into the report to help illustrate key points and patterns that emerged from the analysis. Quotes from these interviews have not been attributed to the source.

The project was supported by two internal groups that provided advice to the project team: an Assistant Deputy Minister Project Advisory Committee and a Director General Reference Group.



2. BACKGROUND AND CONTEXT

This section provides a description of the nature of the H1N1 2009 influenza virus, its evolution and the experience in Canada in 2009-10. It also provides a broad overview of the roles and responsibilities for public health in Canada and internationally. In terms of the domestic response to pandemics (and H1N1 in particular), this section outlines roles and responsibilities across jurisdictions and mandates: municipal and provincial/territorial governments, non-governmental organizations, federal/provincial/territorial collaboration and the federal government. It also delineates the key committees, networks, plans and strategies.

H1N1 — The pandemic

Pandemic influenza

People are exposed to different strains of influenza viruses many times during their lives, allowing them to build immunity over time. Three to four times each century, for unknown reasons, a radical change takes place in the influenza A virus, causing a new strain to emerge. When this happens, people's immune systems may not provide protection against the new strain causing them to be more vulnerable to becoming ill from the virus. An influenza pandemic occurs with the appearance of a new influenza virus against which none of us has any immunity, resulting in several, simultaneous epidemics worldwide.¹

The H1N1 2009 virus

The influenza A H1N1 2009 virus was determined to be a unique combination of influenza A virus genes, never before identified in either animals or people. Initial reports referred to the virus as "swine flu" because the virus genes appeared to be a combination of genes most closely related to North American and Eurasian H1N1 swine influenza viruses. Further investigation determined that the H1N1 virus contained genetic elements from North American swine influenza, North American avian influenza, human influenza and a Eurasian swine influenza.

Because H1N1 2009 was a new strain of influenza, a large population of humans had little to no natural immunity to the virus. While similar in some ways to seasonal influenza, H1N1 2009 led to patterns of death and illness not normally seen in seasonal influenza infections. Figure 2.1 highlights the differences between the H1N1 influenza and seasonal influenza.

Although the illness caused generally mild symptoms for most people, it proved to be severe in a small minority of cases. The World Health Organization indicated that, globally, some groups of people appeared to be at higher risk of more complicated or severe illness including:

- pregnant women
- infants and children under age five (especially those younger than two years old)
- people of any age with certain chronic health conditions (including asthma or chronic lung disease, liver disease, heart disease, diabetes, severe obesity, blood disorders, kidney disease or some neurological conditions)
- people with severely compromised immune systems (for example, people taking cancer drugs or people with HIV/AIDS).²

BACKGROUND AND CONTEXT

FIGURE 2.1 Comparison between seasonal influenza and H1N1³

	SEASONAL INFLUENZA	INFLUENZA A PANDEMIC H1N1 2009
Origins of the virus	<p>Influenza A or B strains similar to previous years with minor variation.</p> <p>Many people have some immune protection from previous exposure.</p>	<p>A new virus that:</p> <ul style="list-style-type: none"> • has never before circulated in humans • is of animal origin with a unique mix of genes from swine, bird and human influenza viruses • has a genetic composition distinctly different from that of the older H1N1 virus that has been causing seasonal epidemics since 1977. <p>Exposure to seasonal influenza does not protect most people from infection.</p>
Epidemiological patterns	<p>In countries with a temperate climate, seasonal epidemics typically taper off in the spring and end before the summer.</p>	<p>Epidemiological patterns differed from seasonal epidemics of influenza. A widespread, high level of infection with the new virus occurred during the summer in the northern hemisphere in multiple countries, and was followed by even higher levels during the fall and winter months.</p>
Symptoms	<p>Seasonal influenza symptoms:</p> <ul style="list-style-type: none"> • fever greater than 38°C • cough • fatigue • muscle aches • lack of appetite • runny or stuffy nose. <p>Nausea, vomiting and diarrhea may occur and is more common in children.</p>	<p>Same as seasonal influenza. Nausea, vomiting and diarrhea may occur.</p>
Pattern of illness and death	<p>Majority (more than 90 percent) of deaths occur in frail elderly people, who often suffer one or more chronic medical conditions.</p> <p>Most cases of pneumonia are caused by secondary bacterial infections, which usually respond well to antibiotics.</p>	<p>People age 65 or older are the least likely to be infected with the virus, but those who do get sick are also at high risk of developing serious complications, just as they are from seasonal influenza.</p> <p>Unlike seasonal influenza, younger age groups, including those who were otherwise healthy, were most affected in all categories:</p> <ul style="list-style-type: none"> • those most frequently infected • those requiring hospitalization • those requiring intensive care • those dying from their infection. <p>A frequent cause of death was viral pneumonia, caused directly by the virus and difficult to treat.</p> <p>While many of those who died had underlying medical conditions associated with a higher risk, many others who died were previously in good health.</p>

Evolution of H1N1 2009

Determined to be the cause of severe respiratory illness outbreaks in Mexico in March 2009, the H1N1 2009 virus spread to the United States and Canada within weeks (see Figure 2.2). On April 25, 2009, the Director General of the World Health Organization declared the 2009 H1N1 outbreak a “*public health emergency of international concern*” in accordance with the *International Health Regulations*. The World Health Organization warned of the “*pandemic potential of the new swine flu virus which can be transmitted from human to human*” and recommended that “*all countries intensify surveillance for unusual outbreaks of influenza-like illness and severe pneumonia.*”⁴

Over the course of the next six weeks, the virus spread rapidly worldwide. When the World Health Organization raised the level of pandemic influenza alert to phase 6 on June 11, 2009, signalling the first pandemic of the 21st century, 74 countries and territories had reported laboratory-confirmed cases.⁵ By July 18, 2010, the World Health Organization reported that worldwide more than 214 countries and overseas territories or communities had reported laboratory-confirmed cases of H1N1, including over 18,000 deaths.⁶

BACKGROUND AND CONTEXT

FIGURE 2.2 Timeline: The H1N1 pandemic in Canada

MARCH	APRIL	MAY	JUNE	JULY	AUGUST
<p>18 Detection of severe respiratory infections in Mexico</p>	<p>20 Public Health Agency notifies provincial/territorial health authorities of two confirmed cases of new H1N1 influenza in California</p> <p>22 Activation of the Health Portfolio Emergency Operations Centre to level 2 (partial activation)</p> <p>23 National Microbiology Laboratory confirms specimens from Mexico are positive for H1N1 influenza</p> <p>23 Activation of the Health Portfolio Emergency Operations Centre to level 3 (partial activation)</p> <p>26 Public Health Agency reports first case of H1N1 influenza in Canada</p> <p>26 Activation of the Health Portfolio Emergency Operations Centre to level 4 (full 24/7 activation)</p> <p>29 World Health Organization raises level of pandemic influenza alert to phase 5</p> <p>29 Public Health Agency purchases 5.7 million doses of antivirals to supplement National Antiviral Stockpile</p>	<p>1 Chief Public Health Officer announces change in terminology from “swine flu” to H1N1 influenza A</p> <p>1 Public Health Agency recommends antiviral treatment of moderately ill people at high risk for influenza</p> <p>3 Public Health Agency launches pandemic planning page on website</p> <p>6 International vaccine regulatory and public health information-sharing teleconference is initiated</p>	<p>11 World Health Organization declares a global pandemic: phase 6</p>	<p>2 Minister of Health and Chief Public Health Officer participate in international meeting on global response to H1N1 flu virus in Cancun, Mexico</p> <p>28 Provinces and territories report surveillance data through FluWatch</p>	<p>6 Minister of Health announces Canada’s order of 50.4 million doses of H1N1 vaccine</p> <p>29 First wave of H1N1 pandemic officially ends in Canada</p> <p>30 Second wave of H1N1 pandemic officially begins in Canada</p>

BACKGROUND AND CONTEXT

FIGURE 2.2 Timeline: The H1N1 pandemic in Canada (cont)

SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER	JANUARY	FEBRUARY
<p>16 Chief Public Health Officer issues guidance on H1N1 2009 vaccine sequencing</p>	<p>19-25 Manufacturer begins shipment of H1N1 2009 vaccine to provinces, territories and federal agencies for pre-positioning</p> <p>21 Health Canada authorizes the sale of adjuvanted H1N1 2009 vaccine</p>	<p>12 Health Canada authorizes the sale of unadjuvanted H1N1 2009 vaccine</p>	<p>4 All FluWatch influenza indicators continue to decline</p>	<p>1 Public Health Agency and Health Canada begin to de-escalate H1N1 pandemic response</p> <p>6 Minister of Health announces five million doses of the H1N1 2009 vaccine to be sent to Mexico by the manufacturer</p> <p>27 Public Health Agency announces end of the second wave of the H1N1 pandemic</p>	<p>10 Health Portfolio Emergency Operations Centre demobilizes H1N1 response</p>

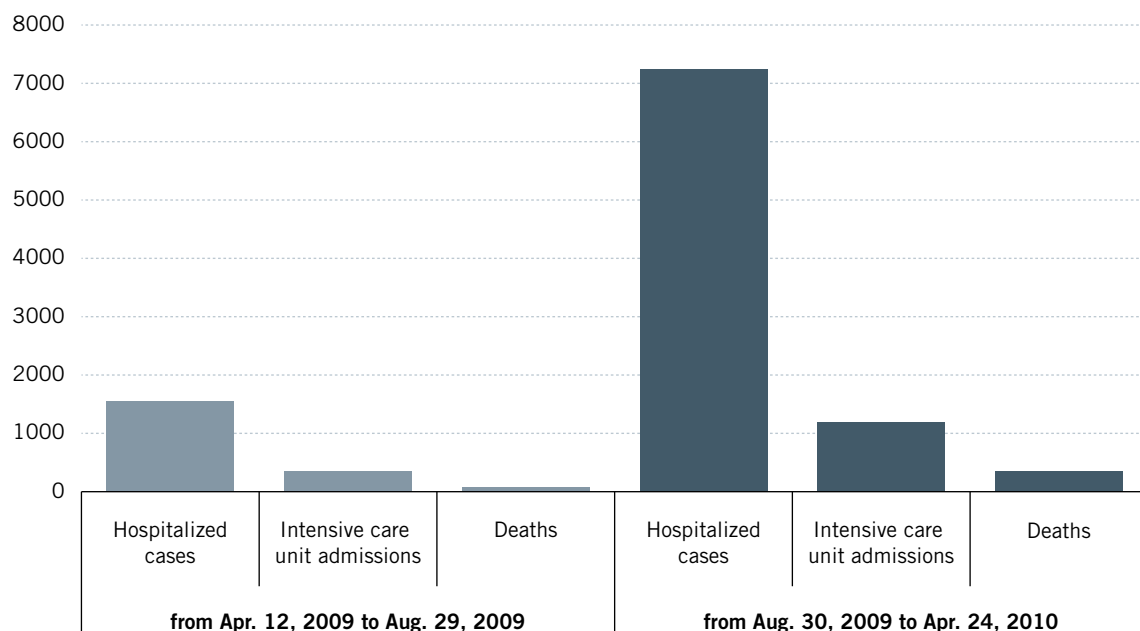
H1N1 — The Canadian experience

The first Canadian cases of H1N1 were confirmed by the Public Health Agency of Canada on April 26, 2009.⁷ Canada experienced two distinct waves of H1N1 (see Figure 2.2). The first wave occurred in the spring between April 12, 2009 and August 29, 2009. During this period, influenza activity reached its highest level during the first three weeks of June. The first wave was followed by a second wave in the fall between August 30, 2009, and January 27, 2010. Influenza activity during the second wave reached its highest level in early November 2009.⁸

At the end of the second wave, Canada reported over 40,000 laboratory-confirmed cases of H1N1.^{9, 10} This figure is a significant underestimation of the actual number of Canadian cases for several reasons. First, a large proportion of those affected did not seek medical attention because they had mild symptoms and so remained undetected. Second, the type of influenza was not determined for a large number of laboratory samples tested during the pandemic time period. Finally, beginning in early June 2009, given that treatment approaches for influenza symptoms were regularized and there were limited laboratory resources for testing, only hospitalized cases were tested in a number of provinces and territories. As a result, the number of reported laboratory-confirmed H1N1 cases cannot be compared between the first and second waves.

However, hospitalization rates, intensive care unit admissions and deaths can be compared. As seen in Figure 2.3, most of these hospitalizations, intensive care unit admissions and deaths occurred during the second wave of increased influenza activity. The second wave was substantially larger than the first and resulted in four to five times more hospitalizations and deaths compared with the first wave. All provinces and territories showed higher levels of transmission during the second wave, except Manitoba and Nunavut, which reported higher hospitalization rates in the first wave.¹¹

FIGURE 2.3 Cumulative numbers of hospitalized cases, intensive care unit admissions and deaths among pandemic H1N1 confirmed cases, Canada, April 12, 2009, to April 24, 2010¹²



Increased rate of hospitalization, intensive care unit admission and mortality were found to be highest among Aboriginal peoples, pregnant women and individuals with at least one underlying medical condition, although the risk for Aboriginal people and pregnant women decreased considerably in the second wave.

The virus is still having an impact. Some patients who spent time in the intensive care unit with the virus report lingering effects.

Roles and responsibilities for public health

Public health events such as the H1N1 pandemic involve international health authorities, as well as municipal, provincial/territorial health authorities, non-governmental organizations, the Public Health Agency of Canada, Health Canada and federal emergency response partners.

The H1N1 pandemic occurred against a backdrop of pandemic response planning at all levels of government including years of developing, refining and exercising response plans at the international, federal, provincial/territorial, regional and community levels in anticipation of an avian influenza A (H5N1) outbreak. Despite differences in planning scenarios and the actual H1N1 pandemic, many of the response plans and systems established through pandemic planning, and the roles and responsibilities defined in these plans, came into play in the response to H1N1.

International

In responding to a public health event, Canada works with its international partners through organizations such as the World Health Organization and mechanisms such as the Global Health Security Initiative. Canada also works closely with its North American partners, the United States and Mexico.

WORLD HEALTH ORGANIZATION

The World Health Organization provides leadership on global health matters and has the lead in the international public health response to pandemic influenza.

The responsibilities of the World Health Organization in a disease outbreak include:

- coordinating the international response
- declaring the level of global pandemic alert (phases 1 to 6)
- selecting the pandemic vaccine strain and making recommendations for when to begin production of a pandemic vaccine instead of a seasonal influenza vaccine
- coordinating rapid containment operations
- providing early assessments of pandemic severity on health.¹³

BACKGROUND AND CONTEXT

As a result of its experience with the Severe Acute Respiratory Syndrome (SARS) outbreak, the World Health Organization recognized the need to strengthen disease detection and reporting capabilities. It introduced the *International Health Regulations* (2005), an international agreement that came into force in June 2007 and to which Canada is a party. The Regulations provide a framework for detecting, reporting and managing international outbreaks and for strengthening international public health security.¹⁴ Each member state is required to designate or establish a national *International Health Regulations* focal point, responsible within its respective jurisdiction for the implementation of health measures under these Regulations.

Also in 2005, the World Health Organization began working with its international partners to plan for the possibility of an avian influenza outbreak. Through the *Pandemic Influenza Preparedness and Response: A WHO Guidance Document*, it sought to improve international coordination, transparency and management of risk in responding to such threats.¹⁵

The World Health Organization's Special Advisory Group of Experts was established in 1999 to provide technical guidance and support on immunization and vaccines. During the H1N1 pandemic, the Special Advisory Group of Experts activated an Ad Hoc Policy Advisory Working Group on influenza A (H1N1) vaccines. The Special Advisory Group of Experts reviewed the feasibility of influenza A (H1N1) vaccines and provided recommendations to the Director General of the World Health Organization on international guidelines and procedures on use and distribution of H1N1 vaccines.¹⁶

The World Health Organization also maintains an electronic network, the Global Outbreak Alert and Response Network, to manage and regularly communicate critical epidemiological and operational information about outbreaks to its member countries, key international health professionals, laboratories and other members of the Network.

GLOBAL HEALTH SECURITY INITIATIVE

Canada is a member of the Global Health Security Initiative, an international partnership among jurisdictions such as France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States, intended to strengthen preparedness and response globally to public health threats. During the H1N1 pandemic, participation in this partnership helped Canada acquire critical information relevant to vaccine development and authorization, target groups, vaccination strategies, the use of antiviral drugs, and risk communications strategies and approaches.

In 2001, the Global Health Security Action Group of senior officials was established by health ministers of these countries to develop and implement concrete actions to improve global health security. It would also serve as a network of rapid communication/reaction in a crisis. The Global Health Security Action Group has established a number of technical working groups, among them three groups that had an important role in the global H1N1 pandemic response: the Global Health Security Laboratory Network, the Pandemic Influenza Working Group, and the Risk Management and Communications Working Group.

Health Canada acts as the international secretariat for the Global Health Security Initiative, ensuring coordination among member countries and convening senior officials to address collaborative efforts to respond to global risks to health.

NORTH AMERICAN COLLABORATION

Canada works closely with its North American neighbours, the United States and Mexico. Among the priorities of this relationship is the protection of people from disease.

Guided by the *North American Plan for Avian and Pandemic Influenza*, Canada, Mexico and the United States work together to prepare for and manage an outbreak of avian influenza or an influenza pandemic in North America. Recognizing that the social and economic health of the three countries is closely intertwined, this *Plan* outlines a collaborative and coordinated North American approach to controlling the spread of avian influenza or a novel strain of human influenza.

The *North American Plan for Avian and Pandemic Influenza* describes joint activities to be carried out through six lines of action: health promotion and risk communications, coordination, epidemiological surveillance and laboratory practices, health care provision, strategic stockpile, and research and development, with the aim to:

- detect, contain and control an avian influenza outbreak and prevent transmission to humans
- prevent or slow the entry of a novel strain of human influenza to North America
- minimize illness and deaths
- sustain infrastructure and mitigate the impact to the economy and the functioning of society.¹⁷

Canadian public health system

Public health is a shared responsibility in Canada. All levels of the public health system (municipal, provincial/territorial and federal) collect information to detect and monitor emerging disease threats and to detect changes in disease trends. Information collected locally is shared with the province or territory and with the Public Health Agency of Canada as appropriate, and if identified in existing information-sharing agreements.

MUNICIPAL AND PROVINCIAL/TERRITORIAL ROLES

In general, a domestic infectious disease outbreak or emergency involving the health of the population is managed first at the local level by front-line public health responders and/or emergency management systems working with local health care providers. The role of local public health authorities includes monitoring and detection of health events, conducting outbreak investigations to identify the source (including laboratory testing, isolation and treatment), and following up with contacts of those affected.

Municipalities have a significant role to play in planning for and responding to a pandemic. Municipal governments are generally responsible for the first response to an emergency (e.g. police, ambulance and firefighter services). As highlighted by the Federation of Canadian Municipalities on its website,¹⁸ business continuity and response services provided by other orders of government are dependent on core municipal infrastructure, including police, firefighters, water and wastewater treatment, public transit and municipal public health services.

Provincial or territorial health authorities may become engaged in a disease outbreak or an emergency if local public health authorities request assistance or resources. If an outbreak spreads beyond local borders, has serious human health implications or exceeds local capacity, the province or territory will assume leadership in coordinating the management of the response.¹⁹ Provinces and territories have their own public health legislation, emergency management plans, standards and guidelines for responding to outbreaks, and laboratory services. The provinces and territories deliver health care services to the population as well as deliver vaccines through local health authorities.

NON-GOVERNMENTAL ORGANIZATIONS

Public health practice relies heavily on collaboration among government and non-governmental organizations, such as professional associations. These groups may be health-focused or may have primary interests in other related areas.²⁰

Non-governmental organizations play essential roles in responding to a pandemic and actively contribute in a manner consistent with their mandate. For example, various organizations may be involved in the development and dissemination of guidance documents, share information and provide advice through participation on various committees, work to ensure business continuity planning is in place, and deliver services in the community.

FEDERAL/PROVINCIAL/TERRITORIAL COLLABORATION

Conference of Deputy Ministers of Health

The federal/provincial/territorial Deputy Ministers of Health report to the Ministers of Health. During the H1N1 response, in addition to their regular face-to-face conferences, bilateral and multilateral calls were held weekly, and sometimes daily, to make decisions on key policy and other issues related to the response.

Pan-Canadian Public Health Network

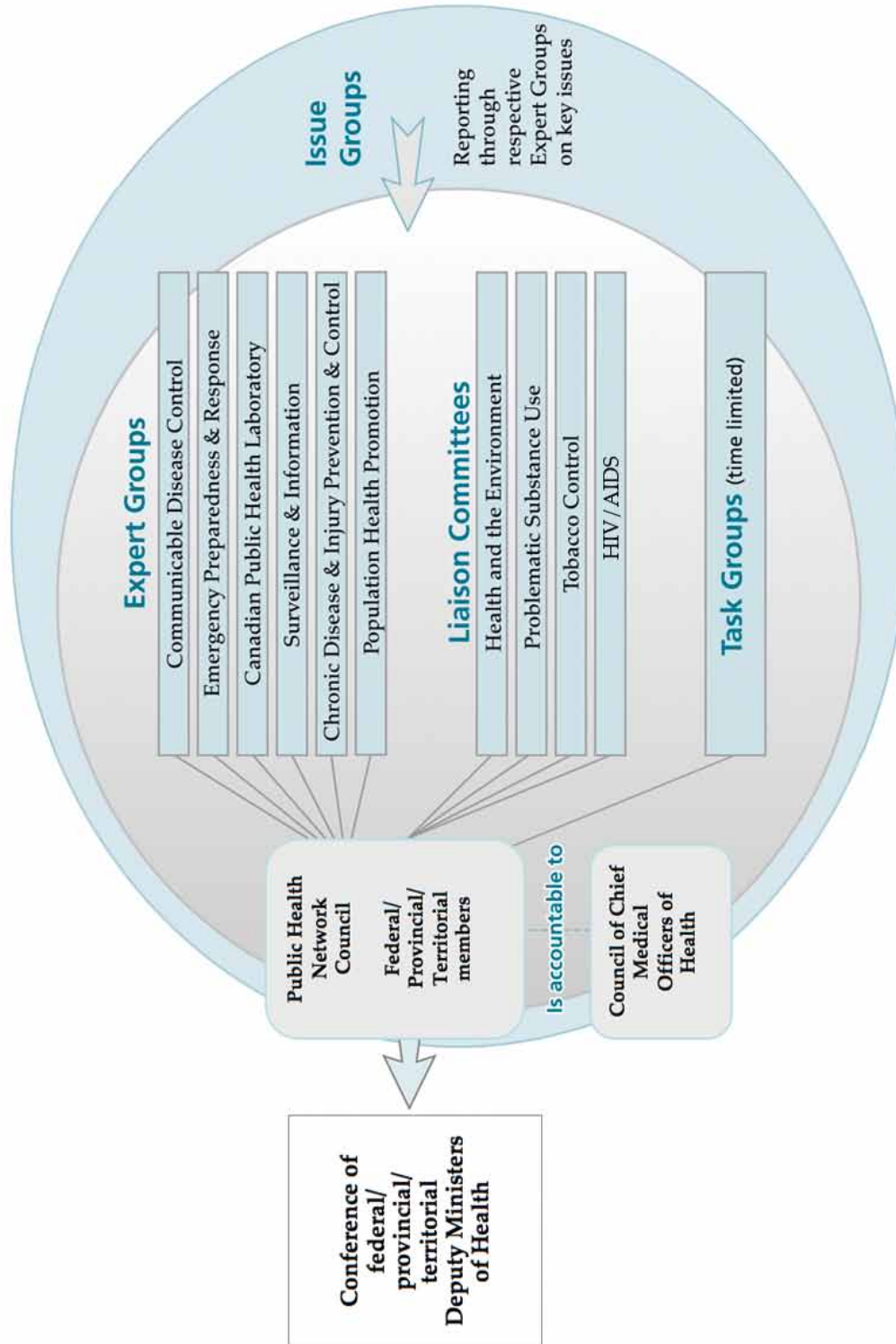
The Pan-Canadian Public Health Network was established by Canada's federal, provincial and territorial Health Ministers in 2005 (see Figure 2.4). Led by a 17-member Pan-Canadian Public Health Network Council, with representatives from each province and territory and the federal government, the Network enables different levels of government and experts to work together to improve public health in Canada. The Pan-Canadian Public Health Network takes a collaborative approach to public health that is critical at all times, but is especially important for coordination and collaboration during public health emergencies. The Public Health Agency of Canada acts as the Secretariat for the Pan-Canadian Public Health Network Council and its groups and committees.

The mandate of the Network is multifaceted, ranging from facilitating the sharing of information among all jurisdictions in Canada, to working with and providing policy and technical advice to federal/provincial/territorial Deputy Ministers of Health on public health matters, to supporting the public health challenges jurisdictions may face during emergencies and crises. The Network's link with government decision makers and other key players in the public health arena supports strong and integrated public health policy development and implementation.

The Council of Chief Medical Officers of Health is also integrated into the Network's structure: it reports through the Public Health Network Council to federal/provincial/territorial Deputy Ministers of Health. From the unique perspective of their roles and responsibilities, the Chief Medical Officers of Health contribute technical, strategic and policy advice.

BACKGROUND AND CONTEXT

FIGURE 2.4 Pan-Canadian Public Health Network composition as of March 31, 2010²¹



Canadian Pandemic Influenza Plan for the Health Sector

In 2004, through the Pan-Canadian Public Health Network, the federal and provincial/territorial governments established the *Canadian Pandemic Influenza Plan for the Health Sector*. The *Plan* is the product of extensive dialogue and collaboration with representatives from all provinces and territories; Chief Medical Officers of Health; epidemiologists; virologists; communicable disease specialists; clinical, public health and laboratory specialists; and a wide group of stakeholders including non-governmental organizations, local governments, emergency planners and bioethicists.

Updated in 2006, the *Plan* is intended to provide a broad frame for Canada's collaborative response to pandemic influenza, and guides the roles and responsibilities of the Public Health Agency of Canada, Health Canada, the provinces and territories. The goal of the *Canadian Pandemic Influenza Plan for the Health Sector* is to help minimize serious illness, death and societal disruption during and after a pandemic by assisting and facilitating a coordinated planning and response effort.

FEDERAL GOVERNMENT ROLE

The federal government coordinates the nationwide pandemic influenza response, including surveillance, international liaison and coordination of the vaccine.²²

While the Public Health Agency of Canada and Health Canada play leading roles, other federal departments and agencies play specific roles in the response to H1N1, including the following:

- Central agencies, such as the Privy Council Office, coordinate responses to issues facing the Government and the country. As Head of the Public Service of Canada, the Clerk of the Privy Council serves as the principal link between the Prime Minister and the public service.
- Public Safety Canada is responsible for exercising leadership relating to emergency management in Canada by coordinating, among government institutions and in cooperation with the provinces and other entities, emergency management activities.
- The Canadian Food Inspection Agency has the lead role in responding to animal health emergencies. It works with the provinces and territories, the swine industry and private sector veterinarians to enhance monitoring of swine herds for signs of illness and to maintain enhanced biosecurity measures on farms across the country.
- The Department of Foreign Affairs and International Trade coordinates Canada's international response.
- The Public Health Agency of Canada and Health Canada also work with the Royal Canadian Mounted Police, the Canada Border Services Agency and Citizenship and Immigration Canada to manage screening of travellers and events at the international border and points of entry.

Federal Emergency Response Plan

The *Federal Emergency Response Plan* outlines the processes and mechanisms to facilitate an integrated Government of Canada response to an emergency and to eliminate the need for departments to coordinate a wider Government of Canada response. The aim of the *Federal Emergency Response Plan* is to harmonize emergency response efforts by the federal and provincial/territorial governments, non-governmental organizations, and the private sector. In the *Plan*, Public Safety is identified as the federal coordinating department with responsibility for engaging relevant federal departments.

Assistant Deputy Ministers Emergency Management Committee

The Assistant Deputy Ministers Emergency Management Committee coordinates the federal response to an emergency and serves as a forum for the coordinated exchange of information and advice at the senior level before, during and after an emergency. During the H1N1 pandemic, the Committee put in place a subcommittee on H1N1 and, consistent with the *Federal Emergency Response Plan*, provided direction to the Government Operations Centre (managed by Public Safety Canada), as well as coordinated and recommended response options for senior decision makers.

Federal Healthcare Partnership — Pandemic Planning Working Group

The ad hoc Federal Healthcare Partnership — Pandemic Planning Working Group was created on May 11, 2009, to provide coordination between partners and federal organizations currently providing health care to federal populations. Federal partners include: Citizenship and Immigration Canada, Correctional Service Canada, the Department of National Defence, Health Canada, the Public Health Agency of Canada, the Royal Canadian Mounted Police and Veterans Affairs Canada. The Federal Healthcare Partnership Working Group was designed to answer questions posed by partners and to provide strategic guidance on issues related to H1N1, vaccination and access to the National Emergency Stockpile System and the National Antiviral Stockpile.

HEALTH PORTFOLIO

Under the *Department of Health Act*, the Minister of Health has a broad mandate to protect the people of Canada against risks to health and the spread of diseases. The Minister's duties, functions and powers in relation to health include the investigation of and research into public health matters, including the monitoring of diseases. Under the Act, both Health Canada and the Public Health Agency of Canada exercise various duties, functions and powers on behalf of the Minister.

The Minister of Health is supported by the Health Portfolio, which comprises Health Canada, the Public Health Agency of Canada, the Canadian Institutes of Health Research, the Hazardous Materials Information Review Commission, the Patented Medicine Prices Review Board and Assisted Human Reproduction Canada.

Within the Health Portfolio, the response to H1N1 was managed primarily by the Public Health Agency of Canada and Health Canada with research support from the Canadian Institutes of Health Research.

Health Portfolio Executive Group

The Health Portfolio Executive Group is the decision-making body that only convenes during an emergency or public health event, such as H1N1. The core Health Portfolio Executive Group consists of senior decision-makers from across the Health Portfolio. As needed, this group is expanded to include Directors General from the Health Portfolio to address specific event issues.

Health Portfolio Emergency Operations Centre

The Health Portfolio Emergency Operations Centre is the central command and coordination platform for emergency response for the Public Health Agency of Canada and Health Canada. It operates under an Incident Management System during emergencies. The Incident Management System is intended to be a flexible, scalable structure that can be expanded or contracted to meet the needs of specific events or emergencies. During the H1N1 pandemic, the activation level ranged from level 2 (partial activation) to level 4 (full 24/7 activation). It is based on the core functions of management, planning, logistics, finance/administration and operations, with the operations group typically customized to the event. The Incident Management System is designed to provide day-to-day operational leadership while the Health Portfolio Executive Group provides strategic leadership.

Health Portfolio Regional Offices

Regional offices within the Public Health Agency of Canada and Health Canada lead Health Portfolio emergency response activities in the regions. Activities include regional emergency preparedness committees, regional emergency coordination centres and bilateral arrangements among regional offices and various other government departments to ensure a strong inter-departmental and intergovernmental presence during public health events, such as H1N1.

Each province and territory has a Regional Federal Council at which the Regional Director for each department sits. Federal Councils play an interdepartmental communication and coordination role in each region and have done so in pandemic preparedness and response.

Health Portfolio Emergency Response Plan

The *Health Portfolio Emergency Response Plan* is structured as an “all hazards” plan for emergency response, including responding to a public health event like H1N1. It defines the scope, framework, roles and responsibilities within which the Public Health Agency of Canada and Health Canada operate to ensure an appropriate response to a range of emergencies that could affect the health and well-being of Canadians.²³

Avian and Pandemic Influenza Preparedness Program

The need for a coordinated and comprehensive plan specifically to address both avian and pandemic influenza was identified by the federal government. The 2006 Avian and Pandemic Influenza Preparedness framework comprises a suite of avian and pandemic preparedness initiatives being undertaken by the Public Health Agency of Canada, Health Canada, the Canadian Institutes of Health Research and the Canadian Food Inspection Agency. The suite of initiatives encompasses:

- vaccines and antivirals
- prevention and early warning
- emergency preparedness
- critical science and regulation
- surge capacity
- risk communications
- federal/provincial/territorial and international collaboration.

BACKGROUND AND CONTEXT

Health Canada's Role

Health Canada is responsible for the regulatory regime governing the safety of products including: food, drugs, medical devices, natural health products, consumer products, chemicals, radiation-emitting devices, cosmetics and pesticides. To carry out its legislative mandate, the department is involved in:

- scientific research, evaluation, standard setting, regulation development, policy development, data collection, surveillance, testing for safety and efficacy, and education and outreach
- health information analysis and evaluation, to enhance Canada's ability to prevent and respond to health crises
- social and natural scientific research and development of new laboratory methods and techniques to support policy research and analysis to enable decision making
- health surveillance, monitoring and exposure assessment to identify emerging issues and monitor existing ones
- measurement of Canada's regulatory effectiveness and post-market monitoring of health products and pesticides
- strengthening capacity through internal and external research and research-related activities to accurately define health risks, trends and emerging issues
- supporting effective design and delivery of health programs and services.

During a public health event like the H1N1 pandemic, Health Canada engages and coordinates efforts among domestic and international health partners in the following areas:

- developing a regulatory framework for the review, approval and release for sale of pandemic vaccines and other health products used to prevent or treat the H1N1 influenza virus
- ensuring new influenza vaccines meet the highest standards of safety, quality and efficacy
- undertaking surveillance and risk management of post-market safety issues related to use of health products used to treat or prevent H1N1 influenza, including: antivirals, masks, hand sanitizers and disinfectants
- protecting public health on conveyances (e.g. aircraft, ships) and related infrastructure (e.g. airports, seaports) to reduce the spread of the pandemic into, across and out of Canada.

In recognition of the unique status and needs of on-reserve First Nations people in Canada, Health Canada collaborates with on-reserve First Nation communities to address health barriers and disease threats, and to attain health levels comparable to other Canadians living in similar locations. There is a high degree of variability in the way routine health services are provided in First Nation communities in Canada, based on factors such as location, level of integration with provincial health services and degree to which the community manages its own services.

BACKGROUND AND CONTEXT

In preparing for and responding to the threat of an influenza pandemic, such as H1N1, in on-reserve First Nation communities, Health Canada is responsible for the following:

- ensuring that health services are available and accessible to on-reserve First Nation communities
- representing and raising awareness of the pandemic planning needs of on-reserve First Nation communities among national and regional government and non-government stakeholders
- working closely with communities to advise on and support the development, testing and periodic revision of their influenza pandemic plans, which should be incorporated into existing emergency response plans in the community
- providing on-reserve First Nation communities with the resources to plan for an influenza pandemic, which include educational materials and training opportunities
- participating, in collaboration with the provinces, in the distribution, administration, and reporting (of adverse reactions) of vaccines using existing arrangements for on-reserve First Nation communities
- participating, in collaboration with the provinces, in the management, distribution, administration and reporting (of adverse reactions) of antiviral drugs using existing arrangements in on-reserve First Nation communities
- maintaining a personal protective equipment stockpile for health care workers and support staff assisting in the delivery of health care services
- providing information and guidance, based on guidelines developed by the Public Health Agency of Canada and/or the provinces, to health care workers providing services in on-reserve First Nation communities.

Public Health Agency of Canada's role

The Public Health Agency of Canada is the lead federal agency responsible for addressing pandemic influenza preparedness and response. On behalf of the Health Portfolio, it is mandated to manage public health emergencies and the regional coordination of federal health emergency activities.

The *Public Health Agency of Canada Act* came into force in December 2006. The creation of the Public Health Agency of Canada was the culmination of numerous calls over the years for federal leadership in coordinating federal/provincial/territorial approaches to public health issues. Reports on how the 2003 Severe Acute Respiratory Syndrome (SARS) outbreak was handled, including *Learning from SARS: Renewal of Public Health in Canada* (Naylor Report), and the 2003 Standing Senate Committee on Social Affairs, Science and Technology report titled *Reforming Health Protection and Promotion in Canada: Time to Act*,²⁴ highlighted inadequacies in the public health response and the need to improve and strengthen coordination in the area of public health.

As noted in the *Canadian Pandemic Influenza Plan for the Health Sector*:

*"The Public Health Agency of Canada was created in response to growing concerns about the capacity of Canada's public health system to anticipate and respond quickly and effectively to public health threats. The Agency will provide a clear focal point for federal leadership and accountability in managing public health emergencies and improved collaboration within and among jurisdictions."*²⁵

BACKGROUND AND CONTEXT

In preparation for emergencies, and for responding to and recovering from the public health implications of pandemic influenza, the Public Health Agency of Canada plays a coordinating function in emergency planning, training and activities that engage all levels of government, as well as the voluntary and private sectors. It works with international partners, provinces and territories and other federal partners to monitor the international and domestic influenza situation and to mobilize a pan-Canadian response to disease outbreaks of national or international concern.

The Public Health Agency of Canada leads and/or undertakes the following activities:

- conducts scientific research to better identify, understand and track the influenza virus
- obtains surveillance (or tracking) information from its federal, provincial, territorial and local partners, and non-governmental organizations. Each week, this information is analyzed and interpreted, then shared with the broader public health community through FluWatch, the Public Health Agency of Canada's online information-sharing vehicle. Influenza surveillance helps to determine: when, where and which influenza viruses are circulating; their intensity, spread and impact; and whether specific population groups are at higher risk for illness
- orders sufficient vaccine for the Canadian population in collaboration with the provinces and territories and monitors vaccine safety
- actively monitors adverse events, together with Health Canada, following immunization with the H1N1 influenza vaccine in Canada (with the collaboration of the provinces and territories, the Canadian Paediatric Society and a network of researchers)
- provides access to materials from federally controlled stockpiles (e.g. antiviral medication and general emergency supplies) to assist the provinces and territories with surge capacity, as well as facilitates the procurement of additional emergency supplies to complement provincial and territorial stockpiles
- provides public health advice for the general public and certain groups such as vulnerable populations through the coordination of pan-Canadian communications
- links with national and international experts, during the management of an outbreak, to develop advice and guidance for health professionals and other stakeholders on areas such as public health measures, laboratory testing and clinical management
- supports targeted communications to national Aboriginal organizations and communities through teleconference briefings and email notifications; Health Canada has the primary role for the federal response in on-reserve First Nation communities during a pandemic
- provides regional coordination of federal health emergency activities
- manages international aspects of pandemic preparedness and response, including liaising with the World Health Organization and acting as the focal point for coordinating the implementation of the *International Health Regulations*
- develops and supports the process required to update and maintain the *Canadian Pandemic Influenza Plan for the Health Sector*, in cooperation with Health Portfolio and provincial/territorial representatives.



3. FINDINGS

3.1 SURVEILLANCE, SCIENCE AND RESEARCH

Background

The Public Health Agency of Canada and Health Canada are recognized as science-based organizations. In addition to using established science, both organizations conduct and support research to increase knowledge on a range of health topics. To understand health threats that require the intervention of the federal government, these organizations rely on their specialized staff, external experts and global/domestic surveillance systems to track the spread of new or existing infectious diseases that could have an impact on the health of Canadians. During significant public health events such as an influenza pandemic, collecting data about the behaviour of a virus and developing scientific knowledge about infection prevention and control are key factors that support decision making.²⁶

What worked well?

Through surveillance, health authorities around the world realized in mid-April 2009 that an H1N1 influenza virus had the potential to become a pandemic. The situation reported from Mexico City showed that an unrecognized source of infection was hitting groups of the local population, that symptoms were those of a severe respiratory illness, and that the contagion was spreading quickly through contact with an ill person. This information triggered a flurry of Public Health Agency of Canada and Health Canada scientific activities that involved surveillance and research at the international, national, provincial/territorial and local levels.

From that point onward, scientific activities sought to identify the virus, study its evolution for possible mutations and analyze how transmission occurred. In addition, researchers continued to work to identify the factors that made some groups more vulnerable to infection and to assess the evidence-based literature and expert opinion on the best prevention and clinical treatment approaches. The goal was to inform the government response to:

- test for the H1N1 influenza virus strain
- assess the response of the virus to known antivirals and a vaccine
- understand how the pandemic was developing
- support the development of guidance on prevention and treatment
- identify and fund areas of research.

The knowledge, expertise and experience of both the Public Health Agency of Canada and Health Canada employees proved to be essential for the international response to the pandemic.

Existing networks, systems and tools facilitated the prompt exchange of science, surveillance and research information

In the detection of disease outbreaks, the Public Health Agency of Canada plays a key role by linking information between geographically dispersed but related cases. Before the H1N1 outbreak, the Public Health Agency of Canada had worked with the provinces and territories to develop and maintain systems and tools to detect and report respiratory illnesses. For example, FluWatch, Canada's national influenza surveillance system, provided a surveillance protocol and case report form for the rapid identification and reporting of severe respiratory illnesses of unknown cause. In response to the dynamics of H1N1 and the increased rates of severe disease, the Public Health Agency of Canada was able to quickly expand FluWatch surveillance activities to include the collection of epidemiological data on H1N1 hospitalizations, intensive care unit admissions, and deaths.

In advance of the H1N1 pandemic, the Public Health Agency of Canada had also developed electronic information systems to support the investigation, monitoring and reporting of public health events across the country. For instance, the Canadian Network for Public Health Intelligence is a secure, web-based system used by local health authorities, provinces, territories and the Public Health Agency of Canada to communicate with each other, including posting public health alerts about emerging or evolving public health events. To track confirmed cases of the H1N1 influenza virus, the Public Health Agency of Canada's National Microbiology Laboratory established a national database using the Canadian Network for Public Health Intelligence platform. The Public Health Agency of Canada also used the Canadian Adverse Events Following Immunization Surveillance System. This System is supported by health care professionals who report adverse events to their provincial or territorial public health offices, which is then shared with the Public Health Agency of Canada.

During the H1N1 pandemic, the Public Health Agency of Canada monitored information from unofficial international sources, such as the media and newswires, to detect H1N1 and other health issues in other countries that could affect the health of Canadians. To support this function, the Public Health Agency of Canada maintains the Global Public Health Intelligence Network to gather preliminary reports of disease outbreaks or other public health events of concern from around the world, 24 hours a day, seven days a week and in seven languages: Arabic, simplified and traditional Chinese, English, French, Russian, and Spanish.²⁷ The Public Health Agency of Canada then works with the World Health Organization and other countries' health authorities to verify this unofficial information to assess the risk to Canada. In the spring of 2009, the Global Public Health Intelligence Network played a critical role in identifying and communicating the outbreak of H1N1 2009 while it was still an unknown respiratory disease.

The Public Health Agency of Canada worked with the provinces and territories to facilitate the most effective and efficient use of laboratory resources during the H1N1 outbreak. The National Microbiology Laboratory supported provincial laboratories through the Canadian Public Health Laboratory Network to increase Canada's readiness to detect the arrival and spread of the H1N1 pandemic influenza virus. In partnership with this Network, most provinces now have laboratories that are able to identify new strains of influenza using standardized molecular technology.

The Public Health Agency of Canada helped identify, understand and monitor the H1N1 virus

From the very beginning of the pandemic, the Public Health Agency of Canada's National Microbiology Laboratory, internationally recognized as a state-of-the-art facility, was a leader and helped guide the global response. The Laboratory was asked to assist with testing specimens from people in Mexico City who showed symptoms of a severe respiratory illness. Five Public Health Agency scientists assisted with testing in Mexico over the course of six weeks. After identifying the virus in mid-April, the National Microbiology Laboratory developed and supported the implementation of a test that allowed researchers and provincial/territorial laboratories to determine whether the strain of influenza tested was the H1N1 influenza virus. The National Microbiology Laboratory sequenced the Mexican and Canadian strains to better understand the virus and its impact on populations around the world. Due to the National Microbiology Laboratory's work, Canada was the first country to characterize the entire genomic sequence of the pandemic H1N1 influenza virus. This made a significant contribution to international scientific understanding of this novel strain.

Health Canada's review of the H1N1 vaccine's safety was conducted promptly

The review by Health Canada's Biologics and Genetic Therapies Directorate respected the highest standards for an expedited approval of a vaccine in Canada and no shortcuts were taken in the examination of the evidence available. The benefits of international collaboration were demonstrated in the vaccine review process as many discussions with international regulators were held to analyze concerns about some of the vaccine's components. More details on the vaccine review are found in section 3.8, Vaccine.

The Public Health Agency of Canada and Health Canada were leaders in the international response to H1N1

Canada's National Microbiology Laboratory played a leadership role in supporting domestic and international efforts to identify, better understand and monitor the novel H1N1 influenza virus. Canada's successful domestic response to the H1N1 pandemic was in part a result of the strong pre-established relationships with key international partners at the policy, technical and senior official levels. For example, the need for a strong liaison network between Canada, the United States and Mexico for a pandemic response was anticipated and planned before the onset of the pandemic.

During the pandemic, the Public Health Agency of Canada and Health Canada led and participated fully in international consultations and exchanges, which included senior-level participation in World Health Organization science conferences and in teleconferences and exchanges with Canada's main partners. In addition to the Global Public Health Intelligence Network,²⁸ many communication and exchange vehicles were used during that period, including:

- the World Health Organization Developing Countries' Vaccine Regulators Network, which was established in the pre-pandemic period among Health Canada and other international regulatory partners, had biweekly teleconferences during the pandemic to discuss regulatory issues and to share clinical and safety data on H1N1 vaccines in real time

- the Global Health Security Initiative, a network of countries that came together shortly after September 11, 2001 to ensure exchange and coordination of practices in confronting new risks such as pandemic influenza, facilitated Canada's ability to receive information on the epidemiology of H1N1 globally and the mitigation strategies employed by other countries, which helped inform Canada's domestic response
- a trilateral group of regulators formed between Health Canada, the United States Food and Drug Administration, and the European Medicines Agency, which coordinated clinical development and pharmacovigilance plans for the H1N1 vaccines
- the pilot exchange of public health liaison officers between the United States Department of Health and Human Services and Canada's Public Health Agency, which facilitated information sharing between the two countries.

The Public Health Agency of Canada hosted "Severe H1N1 Disease: Preventing Cases, Reducing Mortality," a September 2009 conference. Its purpose was to bring together national and international critical care and public health experts to discuss the clinical care and management of severe H1N1 disease, as well as to prepare for an expected fall pandemic wave.

The conference offered public health officials and critical care specialists an opportunity to:

- gain insights into the epidemiology of severe H1N1 disease
- discuss strategies for prevention and early recognition of severe disease
- share best practices for clinical care, disease management and resource utilization.

A key outcome was a guidance document on the epidemiology and clinical management of severe H1N1 disease to help prepare physicians, as well as intensive care and emergency health specialists, for the expected fall pandemic wave.

Areas for action

Overall, surveillance, science and research activities were effective in supporting the Public Health Agency of Canada and Health Canada in their response to the H1N1 pandemic. This Review, however, also identifies areas for action to increase readiness for a future public health event.

Effective and timely surveillance is critical to the ability of the federal government and the provinces and territories to accurately track, plan for and respond to diseases. Strengthening national surveillance capacity has been consistently recognized as a challenge for the Public Health Agency of Canada. The 2003 report by the National Advisory Committee on Severe Acute Respiratory Syndrome (SARS) and Public Health (Naylor Report) identified the need for several measures to strengthen surveillance. More recently, Chapter 5 of the *2008 May Report of the Auditor General of Canada*, entitled Surveillance of Infectious Diseases — Public Health Agency of Canada, called for a national integrated surveillance system with the capacity to effectively support both routine and emergency response efforts in the future. Since the federal Budget 2006, the Public Health Agency of Canada has received funds to develop a comprehensive national influenza and response strategy as part of the Avian and Pandemic Influenza Preparedness Program.

During the H1N1 pandemic, the Public Health Agency of Canada experienced challenges with respect to its surveillance capacity including both a lack of real time data on key epidemiological variables and epidemiological resources to review surveillance data.

At the onset of the H1N1 outbreak, the lack of a comprehensive public health surveillance system was specifically evident in First Nation communities and represented a complex challenge for the Health Portfolio. This situation resulted in an incomplete and inconsistent national picture and therefore did not support timely decision making. To respond to this issue, Health Canada developed and implemented an adhoc regional surveillance system to track H1N1 activity in First Nation communities, as well as surveillance mechanisms for reporting on vaccine uptake.

Finalize agreements on sharing surveillance information across jurisdictions

As outlined in the *Canadian Pandemic Influenza Plan for the Health Sector*, the responsibility for surveillance is shared among federal, provincial/territorial and local governments.²⁹ While it provides a framework for this type of information sharing, the *Plan* does not include the operational details essential for an efficient cross-jurisdictional surveillance system.

Provinces and territories share data with the federal government as part of routine and ongoing health surveillance activities. During the pandemic, an agreement was developed that included an annex on surveillance information sharing (epidemiologic data and laboratory data). This annex was approved by most jurisdictions. However, there are currently no commitments to share information in the event of a future pandemic.

The surveillance challenges experienced during H1N1 underline the importance of effective national reporting and data-sharing infrastructures and approaches. Integrated surveillance for immunization is discussed in section 3.8, Vaccine. Improved national coordination of surveillance activities would also allow federal and provincial stakeholders to better leverage existing capacity and expertise across public health agencies and other federal/provincial centres.

Consider options to ensure that appropriate mechanisms exist to facilitate the rapid conduct of critical research

The experiences associated with the H1N1 pandemic highlighted that existing mechanisms are not sufficiently agile to rapidly initiate strategic planning, funding and coordination of a national research response to novel and urgent public health threats, such as a pandemic influenza virus. Specifically, the Public Health Agency of Canada encountered the following challenges:

- absence of a standardized process to rapidly set research priorities during a pandemic and to critically evaluate proposals for research funding against priorities
- lack of available contingency funds to initiate rapid research projects
- lack of human resources capacity to coordinate and administer rapid research projects
- absence of a mechanism to rapidly provide funding for project proposals (in emergencies, the timelines associated with standard procurement processes, as well grants and contributions processes, are not sufficiently responsive).

It is suggested that the Public Health Agency of Canada, in collaboration with the Canadian Institutes of Health Research, consider options for the development of standardized mechanisms to facilitate the rapid conduct of critical research so that the Public Health Agency of Canada has the necessary information for decision making during a public health event. This could be considered in the context of the Public Health Agency of Canada's science and research strategic plan. The development of options should consider the following:

- standardized processes to rapidly identify research opportunities, set research priorities and critically review internal and external proposals for funding
- contingency funds to initiate rapid research projects
- human resources capacity to coordinate and administer rapid research projects
- rapid funding mechanisms.

Refine approaches for translating scientific knowledge into information useful for planning, decision-making and communications

In a crisis, the availability of scientific knowledge is critical. But it is also important that policy and communication officers, senior managers and central agencies can use that information for planning and decision making, as well as for communication with stakeholders and Canadians. Enhancing the Health Portfolio's capacity to convey complex scientific information is essential. More details on this topic are provided in section 4, Summary and recommendations (see Recommendation 3).

3.2 COLLABORATION WITH PROVINCES AND TERRITORIES

Background

The Public Health Agency of Canada and Health Canada primarily collaborate with their provincial/territorial partners on public health and pandemic preparedness through the Pan-Canadian Public Health Network. The Public Health Network, established in 2005 and made up of academics, scientists, federal public servants, senior officials in provinces and territories, as well as members of non-governmental organizations, aims to address the need for a coordinated approach to public health in Canada. It is a key intergovernmental mechanism for jurisdictions to work together on public health issues, including planning for and responding to pandemics. The Network also provides policy and technical advice to the Conference of Deputy Ministers of Health on public health matters.

Through the Public Health Network, the federal, provincial and territorial governments developed the *Canadian Pandemic Influenza Plan for the Health Sector*, a broad framework for Canada's collaborative response to pandemic influenza and guidance for the federal Health Portfolio and other governments.

What worked well?

Federal and provincial/territorial governments demonstrated a high level of collaboration

Public Health Agency of Canada and Health Canada staff, as well as senior officials in the provinces and territories, generally agreed that there was a high level of federal and provincial/territorial collaboration during the H1N1 pandemic.

At the multilateral meeting of federal/provincial/territorial clerks and Cabinet secretaries on January 20 and 21, 2010, jurisdictions agreed that collaboration was strong among their governments. All parties made concerted efforts to work together to minimize the effect of H1N1 on the Canadian population; at the same time, ministers and officials from across the country, both within their governments and in their public communications, demonstrated a solidarity that ensured an effective and transparent response. Daily teleconferences of the Conference of Deputy Ministers of Health, organized primarily through Health Canada and Manitoba (the provincial/territorial co-chair for H1N1 during the first and second waves), ensured senior-level collaboration and appropriate information sharing at the right level among all parties throughout the H1N1 pandemic.

In her report on how Ontario fared during the H1N1 pandemic, Ontario's Chief Medical Officer of Health described it this way: *"Here in Canada, the Federal-Provincial-Territorial response, while not without the kind of challenges you would expect in any undertaking this complex and important, was always driven by an absolute commitment to getting it right on behalf of Canadians."*³⁰

Basic mechanisms to support federal/provincial/territorial collaboration were in place

The Pandemic Influenza Committee was established in 2001 under a federal/provincial/territorial working agreement. Members of the Pandemic Influenza Committee included provincial and territorial public health experts, other public health and emergency response experts, an ethicist, and Public Health Agency officials. When the Pan-Canadian Public Health Network Council was established in 2005, the Pandemic Influenza Committee was integrated into this Network as an issue group under the Communicable Disease Control Expert Group.

The Pandemic Influenza Committee mandate was established in 2006 to provide technical and science-based recommendations, liaison capacity and expert opinion to support the health and safety mandates of all orders of government related to the health sector preparation for, and response to, an influenza pandemic. The Pandemic Influenza Committee provided the same services in response to novel influenza viruses with pandemic potential and aimed to ensure federal, provincial/territorial collaboration in the development of the *Canadian Pandemic Influenza Plan for the Health Sector*.

In December 2007, the Public Health Network Council and the Council of Chief Medical Officers of Health agreed to establish a central coordinating body for pandemic influenza planning to improve the overall management of pandemic-related activities, increase operating efficiency and reduce the strain on federal, provincial and territorial staff resources involved in multiple Public Health Network groups. The Pandemic Preparedness Oversight Committee was established to leverage funds and address federal and provincial/territorial policy issues. This committee became the Pandemic Coordination Committee in June 2009 and the Pandemic Influenza Committee was disbanded.

The *Canadian Pandemic Influenza Plan for the Health Sector* proved to be an invaluable tool in providing a baseline and structure for the overall H1N1 response. The *Plan*, however, was a national framework document that had been developed in anticipation of what would be needed to respond to a pandemic situation. While an overarching federal/provincial/territorial structure for managing pandemic influenza had been put in place within the *Canadian Pandemic Influenza Plan for the Health Sector*, the federal/provincial/territorial governance structure evolved over the course of the pandemic to enable timely decision making on emerging issues. In August 2009, the Conference of Federal/Provincial/Territorial Deputy Ministers of Health approved a time-limited federal/provincial/territorial H1N1 health emergency management response and organization structure with various functional areas co-led by representatives from the provinces, the territories and the federal Health Portfolio.

New structures were created to respond to emerging issues

During the pandemic, federal, provincial and territorial Ministers and Deputy Ministers of Health needed to have more regular contact to share information and make decisions on emerging policy and operational issues related to the H1N1 response as mentioned above. A new time-limited federal/provincial/territorial emergency management structure was established to support Deputy Ministers and their overall management responsibilities during the H1N1 pandemic (see Figure 3.2.1). This governance structure allowed for collaboration in several core response functions including: planning, operations, logistics, communications and health services. A Deputy Minister of Health was assigned for each of these functional groups and was responsible for regular

reporting to all federal/provincial/territorial Deputy Ministers of Health on emerging issues. To support this H1N1 governance structure, several new time-limited federal/provincial/territorial task groups were established, including the following:

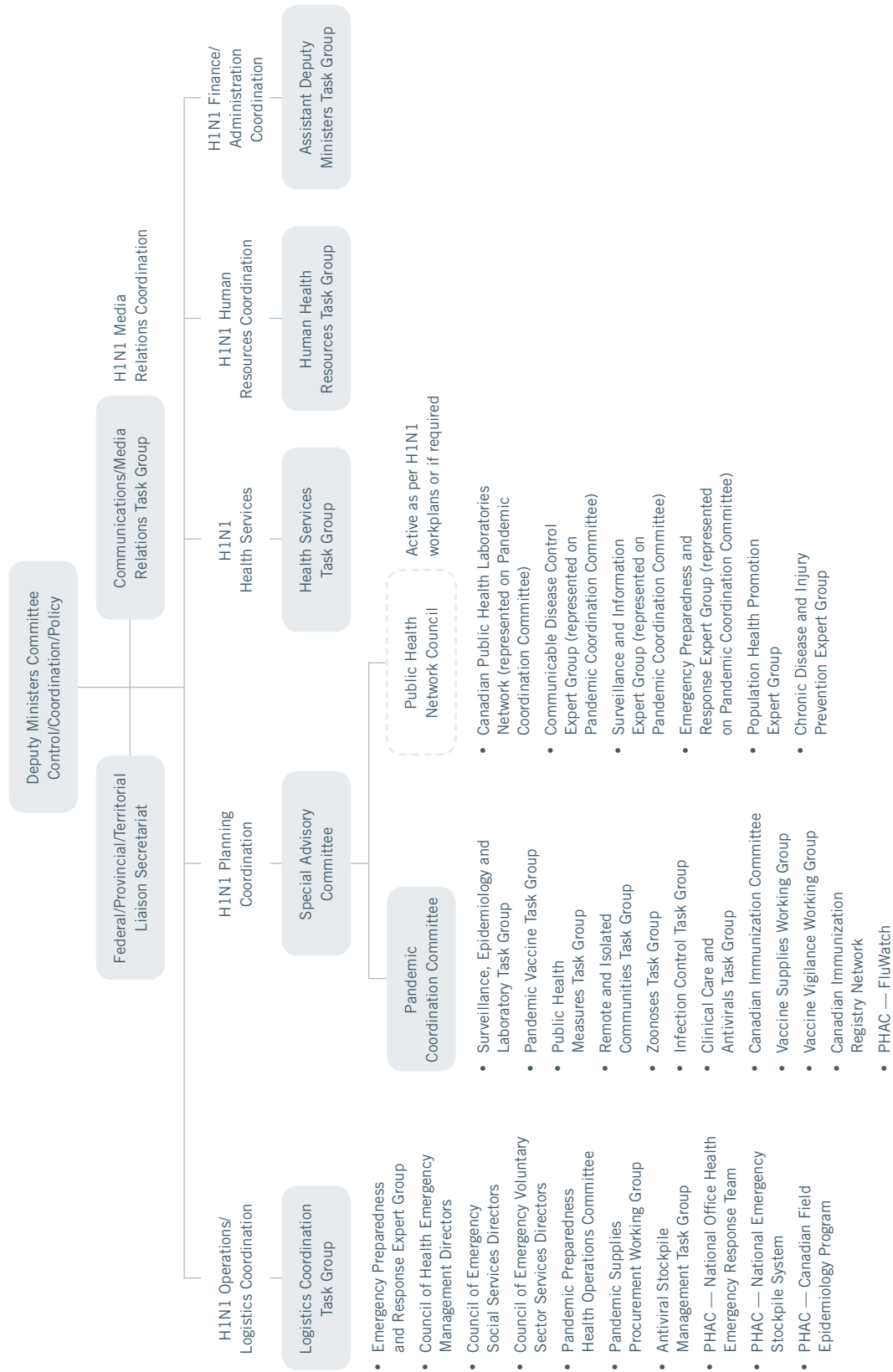
- **Special Advisory Committee on H1N1:** was established in April 2009 to provide a national coordinated response and ensure rapid, evidence-based decisions. This group comprised federal, provincial and territorial members of both the Pan-Canadian Public Health Network Council and the Council of Chief Medical Officers of Health. Reporting to the Deputy Ministers of Health, the Special Advisory Committee provided advice related to technical and operational issues in public health such as clinical care guidelines for pregnant women and antivirals.
- **Logistics Coordination Task Group:** examined logistics coordination and support that could benefit from a pan-Canadian approach. The Task Group provided advice on issues such as: the maintenance of essential facilities; surge capacity; mutual aid between jurisdictions; stockpiles for equipment and supplies (e.g. antivirals); procurement; and operational communications and information sharing (e.g. linkages with the emergency voluntary sector).
- **Communications and Media Relations Task Group:** used a federal/provincial/territorial communications governance structure to respond to the H1N1 influenza pandemic. Reporting to both the Special Advisory Committee and the federal/provincial/territorial Deputy Ministers of Health, this group facilitated enhanced information sharing and coordinated public responses on emerging issues during the H1N1 pandemic. It also shared social marketing products and communication tools to be used and tailored by all jurisdictions (e.g. public communications on the H1N1 and seasonal influenza vaccines).
- **Human Health Resources Task Group:** provided advice to the Deputy Ministers of Health on specific health human resources policy issues during the H1N1 pandemic. For example, this group provided advice on: the use of respiratory protection; the supply of safety officers; facilitating temporary staff transfers; the right to refuse unsafe work; labour legislation provisions; and cross-jurisdictional methods to encourage the vaccination of health care workers.
- **Health Services Task Group:** focused on broader health system issues related to clinical and acute care (e.g. intensive care capacity, best practices concerning access and triage) and coordinating broad health services issues during the H1N1 pandemic (e.g. identification of health system surveillance issues).
- **Federal/Provincial/Territorial Liaison Secretariat:** provided ongoing support to Deputy Ministers by identifying emerging issues, managing agendas and coordinating activities across the various federal, provincial and territorial H1N1 committees through the use of a federal/provincial/territorial H1N1 workplan.

In addition, certain groups were established to support the Special Advisory Committee:

- The **Pandemic Coordination Committee** was formed as an interim committee to manage all pandemic H1N1 national-level priority activities in preparation for the second wave. Discussions between members took place daily for an extended period (primarily by teleconference), allowing for input and information sharing.
- The following time-limited **task groups** supported the Pandemic Coordination Committee. The task groups were created where no existing group or expertise could be identified within the existing Public Health Network structure. Composed of technical and scientific experts from across Canada, members were responsible for developing strategic documents, guidance or reports. The composition of the membership of the task groups provided expertise to respond to information and decision-making needs. Some individuals served on more than one task group. This cross-membership between task groups helped facilitate information sharing and collaboration. These task groups covered the following areas:
 - Surveillance, Epidemiology and Laboratory
 - Pandemic Vaccines
 - Public Health Measures
 - Remote and Isolated Communities
 - Zoonoses
 - Infection Control
 - Clinical Care and Antivirals
- Pre-existing **Public Health Network groups** were leveraged for strategic or expert advice in the development of guidance or recommendations. Members were academics, scientists, public servants and members of non-governmental organizations from across Canada. The following existing Public Health Network groups provided guidance during the H1N1 pandemic:
 - Canadian Public Health Laboratories Network (represented on Pandemic Coordination Committee)
 - Communicable Disease Control Expert Group (represented on Pandemic Coordination Committee)
 - Surveillance and Information Expert Group (represented on Pandemic Coordination Committee)
 - Emergency Preparedness and Response Expert Group (represented on Pandemic Coordination Committee)
 - Population Health Promotion Expert Group
 - Chronic Disease and Injury Prevention Expert Group.

Figure 3.2.1 shows the relationship between the groups established for the H1N1 response as they had evolved by December 2009.

FIGURE 3.2.1 Federal/provincial/territorial H1N1 health emergency management response and organization as of December 21, 2009 (time limited for H1N1 response only)



Areas for action

While it is generally agreed that federal/provincial/territorial collaboration worked well, concerns were raised by provincial and territorial Deputy Ministers of Health and stakeholders regarding the timeliness of key actions. A few examples are provided below regarding vaccine supply and clinical guidance.

In her report on how Ontario fared during the H1N1 pandemic, Ontario's Chief Medical Officer of Health stated,

We also were affected, and not always in a positive way, by decisions made elsewhere that had a huge impact on us. For example, the contract between the federal government and [GlaxoSmithKline] required a minimum order to be placed, which resulted in Ontario receiving more than it required. The scientific information to support the use of the products was not available until we actually received the product, meaning that the required professional and public education process needed to occur over a matter of days.³¹

According to the report from the Canadian Medical Association, the College of Family Physicians of Canada and the National Specialty Society for Community Medicine,

Although the Pandemic Influenza Committee and the Special Federal/Provincial/Territorial Advisory Committee on H1N1 Influenza strove for consensus at the national level, individual provinces and territories were under no obligation to implement the guidance agreed to at the federal/provincial/territorial level. Consultative and collaborative processes at the federal/provincial/territorial level created delays in decision making and directly interfered with the capacity of front-line professionals to respond to the urgent health needs of their patients. This led to a sense of confusion in the media and a loss of trust among the public and health professionals regarding Canada's capacity to respond to pH1N1.³²

Lack of timeliness was deemed by some to be directly related to the complexity of the federal/provincial/territorial governance structures and the intensity of their activities. Efficiency and transparency were also concerns. In preparing for any future response, the following governance issues should be considered.

Continue to work with provincial and territorial partners to review and streamline the federal/provincial/territorial governance structure for pandemic influenza

While new committees and task groups were important in dealing with specific H1N1-related issues, the sheer number of meetings and accompanying work added to the complexity of activities associated with the response. One interviewee noted, *"Overall I think we really have to look at the need for all of those committees and working groups and what purpose they were serving and how much duplication there was."*

At their January 2010 meeting, federal/provincial/territorial Deputy Ministers of Health agreed that improvements to the governance structure should be continued, with the understanding that any structures would need to be flexible enough to adapt to different types of urgent situations that could affect the health sector and be in place immediately, while respecting jurisdictional responsibilities and authorities.

Clarify and communicate the roles and responsibilities of the various advisory groups within the pandemic governance structure

Responding to H1N1 meant that old structures were reviewed and new committees formed to ensure the appropriate members were at the table for advice or decision making. Establishing new structures in the midst of the pandemic, however, led to further confusion about roles and responsibilities. For example, the introduction of the Pandemic Coordination Committee as a new entity in the governance structure to respond to H1N1 created even further confusion with respect to roles and responsibilities. Existing committee and task groups that were, at the time, fulfilling similar responsibilities, felt undermined when the Pandemic Coordination Committee was formed.

There appeared to be a lack of clarity about roles and responsibilities within and between many task groups and committees, creating confusion and unnecessary effort. For example, there was confusion in the role of the new Pandemic Vaccine Task Group compared with that of the existing National Advisory Committee on Immunization, which had an established mandate, authority and reporting relationship, as well as with the already-established Canadian Immunization Committee. The various actors needed clear direction on the role of a pandemic vaccine expert group in relation to the regulatory body in assessing the manufactured vaccine product. Generally, the creation of the task groups made it unclear how pre-H1N1 committees fit into the overall response to H1N1. Therefore, the expertise residing in the pre-H1N1 or existing structures may not have been used as efficiently as possible.

As part of the federal, provincial and territorial work on pandemic preparedness, a Memorandum of Understanding for Roles and Responsibilities in a Pandemic had been in development prior to H1N1. During the H1N1 pandemic, the federal Minister of Health and most provincial and territorial Ministers of Health agreed in principle to an annex of the Memorandum of Understanding on information sharing, but narrowed its scope to the H1N1 pandemic only. It is worth noting that the Office of the Auditor General has recommended for more than a decade that a formal information-sharing agreement between the federal government and the provinces and territories be developed.

Clarify decision-making processes during a pandemic and communicate them to expert or advisory groups

Communication between decision makers and task groups was often perceived as time consuming and cumbersome. This may have been exacerbated by the solicitation of approvals from various committees.

The decision-making process did not always appear to be transparent for some because communication from decision makers to task groups was not always clear. In addition, repeat and/or additional consultations for decision-making purposes were problematic for timely approvals. This also affected the time allotted to decision makers, who were not provided with documents in adequate time for thorough reviews. The same was true of consultations needed within provinces and territories.

3.3 GUIDANCE

Background

From the beginning of the H1N1 pandemic in April 2009, the Health Portfolio recognized the need to provide guidance on responding to the pandemic in several different settings.

What worked well?

Guidance documents were produced for a variety of audiences

In response to the requests of stakeholders, including national associations for health professionals, between April and December 2009 the Health Portfolio facilitated the development of approximately 50 guidance documents. These documents addressed:

- clinical care (e.g. vaccine, infection prevention and control, treatment and clinical care, remote and isolated communities, continuing medical education)
- laboratories
- public and event organizers
- schools, daycares, post-secondary institutions and camps
- surveillance
- managing H1N1 influenza virus in various settings.

In addition to the guidance documents developed by the Public Health Agency of Canada and Health Canada, the Canadian Food Inspection Agency developed guidance information for veterinarians and swine producers, as well as information on the H1N1 influenza virus and food safety for the general public.

As guidelines became available over the course of the pandemic period, they were distributed through provincial/territorial health authorities and made available on the Public Health Agency of Canada and Health Canada websites.

A more detailed breakdown is provided in Figure 3.3.1 at the end of this section.³³

Expert advisors were effective in assisting in the development of guidance

As part of H1N1 planning and coordination, the Pandemic Coordination Committee was convened and Pan-Canadian Public Health Network expert groups were engaged (with subject-specific subgroups) to oversee the development of guidelines (see section 3.2, Collaboration with provinces and territories, for further details on the Committee's structure). These groups provided technical expertise and advice to help draft high-level guidance.

The multidisciplinary composition of the Public Health Network expert groups enabled experts from across the country to share information on a host of issues including surveillance, epidemiology, microbiology, infection prevention and control, quarantine, and clinical management. This part of the guidance development process was considered to be effective since the expert groups were able to:

- provide timely technical assistance
- expedite and facilitate information sharing within the group and with the Public Health Agency of Canada
- issue recommendations.

Group members themselves felt that they were most successful at making recommendations on infection prevention and control.

Areas for action

Clarify the federal role in developing clinical guidance

Some gaps were identified such as the need for clinical guidelines for front-line health professionals. Some provinces and territories appear to have high expectations of public health leadership from the Public Health Agency of Canada, specifically regarding the provision of guidance documents, including clinical guidance to front-line workers. The Public Health Agency of Canada assumed this role: “[We were] asked for leadership and we provided it through our structures ... there was no one else to do it. We were facilitators.” Another interviewee indicated,

There is no structure in Canada that is geared to address the clinician’s requirements and the emergency wards. Because we were dealing with provinces and territories and the provinces and territories have the health system, they identified [it] fairly early on as a gap at the same time that we were getting calls from the obstetricians, the emergency rooms and the other clinicians on “So what do they do?” [In response,] we added a clinicians’ group that did the guidelines.

The Public Health Agency of Canada established a guideline development and approval process. An expert advisory group of clinicians developed the guidelines and facilitated the process. Expertise was drawn from groups such as the Royal College of Physicians and Surgeons of Canada and the Society of Obstetricians and Gynaecologists of Canada.

During the pandemic, multiple levels of government provided similar, but not identical advice. These differences led to confusion about whose advice to follow. While the Public Health Agency of Canada’s advice was based on the best scientific evidence available at the time, the application of this advice varied across the country due to differences in provincial legislation and policies. During the second wave, the federal and provincial/territorial governments collaborated on positions on masks and gloves and tried to take a collective decision so that all were approaching the issue in the same way.

Clinically relevant and trustworthy information should be provided on a timely basis, even if levels of certainty are fluctuating. In their report *Lessons from the Frontlines: A Collaborative Report on H1N1*, the Canadian Medical Association, the College of Family Physicians of Canada and the Canadian National Specialty Society for Community Medicine called for a harmonized national response to the development of clinical practice guidelines.

Formalize an expedited approval process for guidance documents

The Public Health Agency of Canada becomes involved in a support or leadership role to coordinate a response when an outbreak involves more than one province or territory. Formal expedited processes for approving public health guidelines do not exist. This created some significant problems during the H1N1 pandemic. One interviewee indicated, *“Using the processes, which are not appropriate particularly in an emergency, of back and forth, with lots of people and building consensus and a month or three later or six months later you finally get agreement; it’s not appropriate.”*

The approval process took time. This was in part due to the need to engage a host of different levels of authority in the consultation and approval process. For example, guidelines circulated for approval among the expert advisory groups, provincial/territorial Ministers of Health and Chief Medical Officers of Health in each province and territory. At the federal level, in addition to senior levels of management within the Public Health Agency of Canada and Health Canada, the Privy Council Office and the Prime Minister’s Office also provided input to the guidance documents. While these discussions on wording and the value of evidence generated took time, it was observed that the guidance and recommendations generally remained stable and were reissued less often than those of other national jurisdictions.

Various factors had an impact on the development and dissemination of guidelines. Because the federal government communicates with Canadians in both official languages, documents need to be translated. Future planning should carefully account for the timelines required for this part of the process. Another factor was the decision to release documents in batches. This meant that guidelines ready for release were held back until others were completed. Again, future planning should take this into account.

Comparisons were made between the United States Centers for Disease Control and Prevention and Canada’s Public Health Agency. The Centers for Disease Control do not have official language requirements and may do more limited consultation, while the Public Health Agency of Canada must consult with multiple stakeholders, as well as effectively plan for the timely translation of its guidance documents. Several key informants noted that the earlier availability of the Centers’ materials led some stakeholders to take the United States guidance instead of waiting for Canadian guidance to be approved. *“Maybe at the end of the day you have to agree to disagree. We don’t have time to go in circles. People get frustrated, lose energy. Events overtake us — by the time school guidelines come out, everyone is already making decisions.”*

The fact that guidance documents were often slow to be completed and made available on the web limited the ability of expert advisors to share draft documents and agree on key messages, resulting in inconsistent messaging and duplication of work. One interviewee suggested,

There was confusion jurisdictionally around who are the priority groups, who should come forward. Another example, based on unpublished research, was that some provinces decided not to go forward with the seasonal flu campaign. That decision was not communicated in a coordinated way.

There seems to be agreement that federal, provincial and territorial authorities and health care professionals should work together in the interpandemic period to develop a pan-Canadian strategy to be used during health emergencies, with particular consideration of the following processes:

- development: establish mechanisms to undertake timely development and communication of clinical management guidelines for clinicians during a public health emergency
- approval: define who needs to be involved and specify roles and responsibilities for each level of authority
- language translation and release: plan for translation and determine when it is appropriate to release guidance documents.

Fill gaps in existing guidance

REVIEW GUIDELINES AND ADDRESS AREAS NOT CURRENTLY COVERED

Research indicates that some issues were not addressed in the guidance material and there was not always sufficient evidence to make informed decisions. For example, timely, national-level data on the health of pregnant women, their fetuses and newborns was not available in an ongoing and systematic way. Other areas include protocols for monitoring drug resistance during a pandemic and for determining the appropriate treatment dose and duration for a novel virus.

While Health Canada currently receives adverse drug reaction reports from health care providers, further discussions are required regarding the unique needs of monitoring the extensive use of antivirals during a pandemic.

RESEARCH THE NEEDS AND RESOURCES REQUIRED FOR PANDEMIC RESPONSE IN REMOTE AND ISOLATED COMMUNITIES AND DEVELOP GUIDANCE

The H1N1 experience highlighted the importance of having preparedness and response activities tailored for remote and isolated communities. By virtue of being isolated, these populations have special public health needs, requiring an approach that is different from that of the general public.³⁴

While a number of guidance documents were generated for remote and isolated communities (see Figure 3.3.1), more research may be required on the needs of persons residing in remote and isolated communities during a mass immunization to provide the necessary evidence for developing mitigation strategies. Existing national guidelines on antivirals, surveillance and public health measures may not fully address the particular needs of these populations, including their limited access to health care workers, physicians and supplies.

Use appropriate language and formats for guidance documents

Finally, some stakeholders mentioned that language used in guidance was not appropriate for lay people or even those working in front-line health care positions. Some stakeholders described guidelines as ‘confusing’ and that what was needed were ‘plain-language’ documents that were easy to access and understand. Guidance documents were also noted to be difficult to follow because of the use of acronyms, abbreviations and complex tables. Further consultations with front-line health professionals may be warranted when producing health-related guidelines. There should also be continuing attention to formats or media used to ensure accessibility and cultural appropriateness for all Canadians.

FIGURE 3.3.1 Overview of the Public Health Agency of Canada and Health Canada H1N1 influenza virus guidance

CLINICAL GUIDELINES

General

- Pandemic H1N1: Fast Facts for Front-line Clinicians

Vaccine

- Use of Pandemic Influenza A (H1N1) 2009 Inactivated Monovalent Vaccine
 - Addendum — Guidance for Use of Panvax™ H1N1 Vaccine (Unadjuvanted)
- Recommendations for pH1N1 Vaccine in Pregnancy
- Guidance on H1N1 Vaccine Sequencing
- Questions and Answers on Influenza A (H1N1) 2009 Pandemic Vaccine Arepanrix™ H1N1

Infection Prevention and Control

- Infection Prevention and Control Measures for Occupational Health Management for all Health Care Settings
 - Cleaning
 - Additional Infection and Prevention Control Guidance
- Infection Prevention and Control Measures for Health Care Workers in Long-term Care Facilities
- Infection Prevention and Control Measures for Health Care Workers Providing Care of Service in the Home
- Infection Prevention and Control Measures for Health Care Workers in Acute Care Facilities
 - Appendix B: Visitors/Accommodation
- Infection Prevention and Control Measures for Pre-hospital Care
- Additional Infection Prevention and Control Guidance for Pregnant Women, Newborns, and the Postpartum Period
- Requirements for Efficacy Claims for Hard Surface Disinfectants

Treatment and Clinical Care

- Clinical Recommendations for Patients Presenting with Respiratory Symptoms During the 2009-2010 Influenza Season
- Clinical Guidance for the Management of Influenza-like Illness in the Context of Pandemic H1N1 Influenza Virus in Adult Intensive Care Units
- Clinical Management Considerations: Timing and Mode of Delivery of Pregnant Women Requiring Hospitalization for H1N1 Influenza-like Illness
- Use of Antivirals to Treat H1N1 Flu Virus (Human Swine Flu)
 - The Management of the National Antiviral Stockpile: Options Report
- Clinical Guidance for Pregnant and Breastfeeding Women with Influenza-like Illness in the Context of the Pandemic H1N1 2009 Virus
- Important Notice: Expiry of the Interim Order That Permitted the Sale of Oseltamivir (Tamiflu®) for Use in Children Under One Year of Age in the Context of Pandemic H1N1 2009
- Information Update: Potential Medication Errors with Liquid Tamiflu®
- Guidance for Ambulatory Care of Influenza-like Illness in the Context of H1N1 Influenza Virus
- Guidance for the Management of Pandemic H1N1 2009 Outbreaks in Closed Facilities

Remote and Isolated Communities

- Guidance for Remote and Isolated Communities in the Context of the Pandemic (H1N1) 2009 Outbreak
- Looking After Someone at Home with H1N1 Flu Virus in a Remote or Isolated Community
- Guidance for Clinical Management of Patients with Influenza-like Illness in the Context of Pandemic (H1N1) 2009 in Remote and Isolated Communities
- Guidance for the Preparedness and Management of Influenza-like Illness, Including Pandemic (H1N1) 2009, in Residential Facilities in Remote and Isolated Communities
- Mass Immunization Clinics in Remote and Isolated Communities
- Hand Hygiene Recommendations for Remote and Isolated Community Settings
- Considerations for Definitions of “Remote” and “Isolated” in the Context of Pandemic (H1N1) 2009
- Guidance for Health Services Planning in Remote and Isolated Communities in the Context of Pandemic (H1N1) 2009

Continuing Medical Education

- Infectious Disease Outbreaks: Tools and Strategies for Front-line Clinicians
- A Practical Guide to the H1N1 Vaccine

LABORATORIES

- Interim Guidance for Laboratory Testing for Detection and Characterization of Pandemic H1N1 (2009)
- Novel H1N1 Flu Virus (Human Swine Flu): Guidelines — Biosafety Advisor

PUBLIC AND EVENT ORGANIZERS

- How to Look After Someone at Home with H1N1 Flu Virus
- Individual and Community-based Measures to Help Prevent Transmission of Influenza-like Illness, Including the Pandemic (H1N1) 2009 Influenza Virus, Related to Mass Gatherings

SCHOOLS, DAYCARES, POST-SECONDARY INSTITUTIONS AND CAMPS

- Public Health Guidance for Post Secondary and Boarding Schools Regarding the Prevention and Management of Influenza-like Illness Including the Pandemic (H1N1) 2009 Influenza Virus
- Public Health Guidance for Child Care Programs and Schools (K to Grade 12) Regarding the Prevention and Management of Influenza-like Illness Including the Pandemic (H1N1) 2009 Influenza Virus
- Prevention and Management of Cases of Influenza-like Illness, Including the Pandemic (H1N1) 2009 Influenza Virus, in Summer and Other Children’s Camp Settings

SURVEILLANCE

- Surveillance Protocol for Severe Respiratory Illness — Surveillance for Influenza in Hospitalized Adults 2009-2010
- Adverse Events Following Immunization Reporting Form
- Health Canada: Reporting Adverse Reactions to Antiviral Drugs During an Influenza Pandemic — Guidelines for Health Professionals and Consumers
- Case Definitions for National Surveillance H1N1 Flu Virus (Human Swine Flu)
- H1N1 Flu Virus (Human Swine Flu) Case Report Form for Initial 100 Canadian Cases

MANAGING H1N1 FLU VIRUS IN VARIOUS SETTINGS

- Public Health Guidance for the Prevention and Management of Influenza-like Illness, Including the Pandemic (H1N1) 2009 Influenza Virus, Related to Communal Living Settings
- Recommended Disinfection Procedures for Conveyance (Aircraft, Passenger Trains, Ferries, Buses and Cruise Ships) and Terminal (Airport, Cruise Ship, Bus, Ferry and Train) Operators and Their Staff
- Recommended Safe Work Practices for Flight Catering Operators and Their Staff
- Prevention and Management of Influenza-like Illness, Including the Pandemic (H1N1) 2009 Influenza Virus, on Conveyances including Airplanes, Trains, Ferries and Buses
- Prevention and Management of Influenza-like Illness, Including the Pandemic (H1N1) 2009 Influenza Virus, on Cruise Ships
- Guidance for the Management of Pandemic H1N1 2009 Outbreaks in Closed Facilities

3.4 STAKEHOLDER ENGAGEMENT

Background

What may come this fall is something that could test all of us, possibly to a limit we've never experienced... Whatever may come, I stress that we'll best meet the challenges and serve Canadians by cooperating.

— The Honourable Leona Aglukkaq, Minister of Health, August 2009³⁵

From the start of the H1N1 outbreak, the federal Minister and Deputy Minister of Health and the Chief Public Health Officer were committed to an inclusive pandemic response. In addition to collaborating with other countries and international organizations, other federal government departments (covered in section 3.9, Operational management) and provincial/territorial governments (covered in section 3.2, Collaboration with provinces and territories), the Health Portfolio engaged:

- national Aboriginal organizations
- health professional associations
- private sector representatives
- emergency response organizations
- organizations representing at-risk populations
- organized labour for the health sector
- academic researchers and institutions.

What worked well?

A stakeholder engagement plan was put in place

There was a clear understanding within the Public Health Agency of Canada and Health Canada that involvement of all stakeholders was crucial to the successful mitigation of the effects of any pandemic. H1N1 stakeholder engagement was guided by two plans. A Public Health Agency *H1N1 Strategic Relations Interim Strategy*, approved by the Health Portfolio Executive Group in May 2009, outlined a strategic approach to engaging national organizations in the response and establishing mechanisms to share information to respond to emerging issues and concerns. A comprehensive *H1N1 Influenza Virus Strategic Relations Plan (Domestic)* was approved by the Health Portfolio Executive Group in September 2009. This second plan expanded on the types of mechanisms to be used and the breadth of stakeholder organizations to be engaged. The primary goal of both plans was to build on existing relationships and to engage and communicate in a proactive and timely manner.

A variety of engagement mechanisms were developed by the Public Health Agency of Canada and Health Canada during the H1N1 response, including:

- single-window points of contact (i.e. generic email addresses)
- regular electronic notification of new documentation on the FightFlu.ca website (e.g. approximately 20 email notifications distributed to over 100 stakeholder organizations)
- teleconferences led by Public Health Agency officials every four to six weeks to provide updates, respond to questions, and hear issues and needs
- bilateral and multilateral meetings
- collaborative work (e.g. joint projects to develop guidance)
- task groups.

Engaging key national organizations in the H1N1 response was an opportunity for the Public Health Agency of Canada and Health Canada to communicate directly with stakeholders to provide information on the virus. This engagement also enabled the Health Portfolio to draw more fully on the expertise of major national organizations to inform the development of H1N1-related policy and advice.

Keeping jurisdictional issues in mind, the Public Health Agency of Canada and Health Canada should continue to build on existing stakeholder relationships and mechanisms for engagement established before and during the H1N1 pandemic for pandemic planning and response.

HEALTH PROFESSIONAL ASSOCIATIONS

The Public Health Agency of Canada held regular technical teleconference briefings with national health professional associations to provide information on the virus and respond to issues that organizations raised on behalf of their members and front-line clinicians. This engagement enabled the Public Health Agency of Canada to draw more fully on the expertise of health professionals to inform the development of H1N1-related guidance and advice as the pandemic evolved (discussed in more detail in section 3.3, Guidance). Bilateral and multilateral meetings were held on an as-needed basis to respond to emerging issues.

NATIONAL ABORIGINAL ORGANIZATIONS

The Public Health Agency of Canada, in collaboration with the First Nations and Inuit Health Branch at Health Canada, held technical teleconference briefings with 11 national Aboriginal organizations (Aboriginal Nurses Association of Canada, Assembly of First Nations, Congress of Aboriginal Peoples, Indigenous Physicians Association of Canada, Inuit Tapiriit Kanatami, Métis National Council, National Aboriginal Health Organization, National Association of Friendship Centres, National Collaborating Centre for Aboriginal Health, Native Women's Association of Canada, and Pauktutit Inuit Women of Canada). Other bilateral meetings and specific briefings were held. The objective was to provide key information, answer questions and address concerns to better enable these organizations to support their communities during the H1N1 response.

PRIVATE SECTOR

The Public Health Agency of Canada participated in the Conference Board of Canada's Pandemic Preparedness Workshop held in Ottawa in June 2009. As stated in the workshop report, a pandemic is also an economic and business continuity crisis.³⁶ As such, it needs engagement with, and leadership from, the business community as well as from pandemic specialists.

Existing mechanisms of engagement were also adapted to support the H1N1 response. The Private Sector Working Group on Avian and Pandemic Influenza Planning (co-chaired by the Public Health Agency of Canada, Public Safety Canada and the Canadian Council of Grocery Distributors) supported information sharing during the H1N1 pandemic through the engagement of 90 private sector organizations from 10 critical infrastructure sectors (energy, information and communication technology, transportation, government, health care, manufacturing, finance, safety, water and food). The Working Group's mandate is to promote a shared approach to pandemic influenza planning and preparedness through increased awareness and partnerships with private sector organizations and associations.

COLLABORATIVE ENDEAVOURS

Joint efforts between the Health Portfolio and stakeholders were undertaken to address specific aspects of the H1N1 response and the needs of particular communities.

Examples include the following:

- The Public Health Agency of Canada worked in partnership with health professional associations such as the Canadian Paediatric Society, the Society of Obstetricians and Gynaecologists of Canada, the Canadian Medical Association, the Canadian Public Health Association, the National Specialty Society for Community Medicine and the College of Family Physicians of Canada, to support the development of technical guidance for front-line health care providers (see also section 3.3, Guidance).
- The federal/provincial/territorial H1N1 Remote and Isolated Communities Task Group was co-chaired by Health Canada (First Nations and Inuit Health Branch) and the Chief Medical Officer of Health from Alberta, with participation by national Aboriginal organizations. It produced guidance to address the unique challenges facing remote and isolated communities, many of which are Aboriginal.
- Collaborative work was undertaken between human health partners (Public Health Agency of Canada, Health Canada, provincial/territorial health) and animal health partners (Canadian Food Inspection Agency, provincial agriculture ministries and other experts) to develop a variety of surveillance, guideline and risk management documents to address health issues at the human-animal interface.

The Chief Public Health Officer established a Science Advisory Committee of researchers from the academic community

Members of Canada's influenza research academic community were engaged through the Chief Public Health Officer's H1N1 Flu Virus Science Advisory Committee. This Committee was created at the outset of the H1N1 pandemic to provide science and research advice. During the height of the H1N1 pandemic, the Committee held weekly teleconferences, with a total of 24 teleconference meetings held between May 2009 and February 2010.

Specific areas on which advice was sought included:

- public health response
- vaccine development
- development and implementation of rapid point of care diagnostics
- antiviral treatment
- clinical care
- surveillance and epidemiology
- influenza pandemic forecasting and modelling.

Committee members, including Public Health Agency officials, indicated that this forum was valuable and the information shared and discussed was timely.

There was strong collaboration with other countries, as well as international organizations

On the international front, the federal Minister and Deputy Minister of Health, as well as the Chief Public Health Officer, were highly committed to engaging in direct communication with key bilateral and multilateral international partners to address high-priority issues and to promote ongoing collaboration with key international partners. The Public Health Agency of Canada and Health Canada program areas and technical experts already had strong relationships with counterparts internationally, and they continue to sustain them.

Building on lessons learned in the first wave, a Public Health Agency H1N1 flu virus international engagement strategy was developed and approved by senior management in early fall 2009. This strategy identified opportunities to further focus international engagement during the second wave of the pandemic.

Early in the H1N1 pandemic, the leveraging of previously established international relationships and communication protocols proved vital.

- Many bilateral relationships were critical to the Canadian response. For example, Canada collaborated with Australia on unadjuvanted vaccine. To facilitate and improve information sharing, Canada worked closely with Mexico from the onset of the pandemic. Canada also had a liaison network with the United States Department of Health and Human Services prior to and throughout the pandemic.

- Trilateral linkages between the United States, Mexico and Canada had been fostered through the development of the *North American Plan for Avian and Pandemic Influenza* and were critical to the response in these countries. In the early stages of the response to H1N1, there were daily calls between the United States, Canada and Mexico.
- In keeping with the *International Health Regulations*, Public Health Agency of Canada and Health Canada officials at all levels continued to work closely with their counterparts at the World Health Organization and the Pan-American Health Organization on the global response to the pandemic. While at times there were challenges with inconsistent communication to the public (given the complexities of working in a multisource environment), the level of cooperation and engagement was consistently high.
- Building on Canada's ongoing involvement in the Global Health Security Initiative international partnership, including participation in the Global Health Security Action Group, the Canadian H1N1 response was strongly supported by access to rapid communication with, and reaction from, other international partners (particularly France, Germany, Italy, Japan, Mexico, the United Kingdom and the United States). This involvement included two ministerial meetings in 2010, which facilitated information sharing and collaboration during the H1N1 pandemic response.

These international links provided a valuable means of rapid information exchange throughout the response to the H1N1 pandemic. For example, the existence of an international network of national vaccine regulatory authorities to exchange information helped to support the expeditious review, authorization and post-market monitoring of H1N1 vaccines in Canada.

Areas for action

Increase multi-jurisdictional coordination of information for stakeholder groups

Recognizing that within a federation each province/territory makes decisions within their own jurisdiction, coordination of messaging to stakeholder groups can be complex. During the H1N1 pandemic, consistency and timeliness of information to stakeholders was challenging. Stakeholder groups received information from provincial/territorial governments, as well as from the Health Portfolio. The information from these different sources was sometimes inconsistent and, at times, conflicting. In addition, although many stakeholder groups indicated that information they received was helpful, concerns were raised about its timeliness (e.g. online tools such as FightFlu.ca). Moving forward, Health Portfolio communication and engagement strategies should clearly define jurisdictional roles and responsibilities to help support improved consistency and timeliness of information to stakeholder groups.

Enhance capacity to anticipate and respond to issues raised by all stakeholder groups

There was insufficient organizational capacity within the Public Health Agency of Canada, particularly during the first wave, to respond to the significant increase in requirements for information from a variety of stakeholders. This shortfall included the capacity to address both the volume of written correspondence received by the Chief Public Health Officer and others through letters and email, and the need for oral briefings to various groups.

The response was sometimes perceived by stakeholders as reactive and token. Some stakeholders indicated that, *“In the first wave, we were uninvolved and felt marginalized. By the second wave, good outreach had resulted in much better communication, but unfortunately it was considered by some members to be ‘too little, too late’.”* Issues brought forward by stakeholders need to be meaningfully addressed in a more timely fashion.

With respect to national Aboriginal organizations in particular, stakeholders indicated that information could have been timelier and more culturally appropriate. It was suggested by stakeholders that more preplanning was required, including the need to have information and mechanisms ready to directly and quickly engage and communicate with national Aboriginal organizations.

During the interpandemic period, the Public Health Agency of Canada and Health Canada should review their pandemic strategic relations plans in light of the H1N1 experience. In particular, they should examine the tools, mechanisms and human resources required to ensure they are in a strong position to work proactively with all stakeholders, respond to stakeholder issues and avoid delays.

Support development of guidance documents for health professionals

As stated in section 3.3, Guidance, there was an increased demand for guidance documents for various stakeholders during the H1N1 pandemic, with particularly high demand among health professionals. The Public Health Agency of Canada and external health professional associations addressed this demand on an ad hoc basis and produced various guidance documents and educational tools.

While front-line health care workers indicated that they appreciated the clinical guidance received, they indicated that at times the flow of information to them was neither timely nor met their needs. Stakeholders have indicated that the process for the development and approval of clinical guidance documents:

- took too long
- needed to better incorporate flexibility of evolving and emerging information
- should have involved a broader base of organizations
- did not give enough consideration to the level of the language in the documentation (i.e. it was sometimes too technical, too detailed or unclear).

Although ad hoc structures were created for H1N1, the Public Health Agency of Canada, in collaboration with federal and provincial/territorial partners, should consider establishing a communications and engagement strategy specifically for health professionals, including established processes for the development of guidance and tools.

It has been suggested that the Public Health Agency of Canada should lead a discussion (with its federal, provincial and territorial partners, other levels of government and health professional organizations) on how best to create sources of direct clinical advice for health professionals during a pandemic. As suggested in the United Kingdom's independent review on influenza pandemic, this role may be more appropriately hosted by one or more of the professional bodies.³⁷

Review Health Portfolio management of international relationships

During the H1N1 pandemic, there was a significant increase in the volume of international engagement for Health Portfolio senior management and other staff on both technical science and strategic policy issues. Because of the nature of this event, calls were often convened by other bilateral and multilateral organizations on short notice across different time zones, and without clear knowledge of the expertise required. It was difficult to identify and brief the appropriate Health Portfolio representatives to ensure mutually beneficial discussions.

During the interpandemic period, the Health Portfolio should review its international engagement strategy in light of the H1N1 experience. It should review the designation of senior management representatives and alternates to ensure consistent representation, contributions and efficient use of time. To maintain consistent communication and information sharing across all bilateral and multilateral relationships, it should reconfirm and communicate broadly the role of an international liaison focal point internal to the Health Portfolio during a pandemic. Internal protocols or mechanisms could be put in place to track meetings called through both formal and informal channels.

3.5 COMMUNICATING WITH CANADIANS

Background

The *Canadian Pandemic Influenza Plan for the Health Sector* stresses that public communication efforts during an influenza pandemic are required to prepare Canadians to take appropriate action and to build and maintain their confidence in the government response during a pandemic. The Communications Annex (Annex K) was developed in partnership by federal, provincial and territorial governments, providing the framework for coordinated public communications across all involved organizations during a pandemic.

Pandemic influenza communications planning for the health sector is based on a strategic risk communications approach, which aims to ensure:

- open communication about pandemic influenza risks and control options
- transparency in the decisions made during the pandemic planning process
- an understanding of the gaps and efforts made to fill them when facts are uncertain or unknown.

The Public Health Agency of Canada was responsible for H1N1 communication activities for the general population with support from Health Canada, which was itself responsible for communication activities with First Nations people living on a reserve in conjunction with First Nations leadership.

In April 2009, the Government of Canada launched a public awareness campaign, led by the Public Health Agency of Canada, to inform Canadians about the H1N1 influenza virus. A key method of communicating with Canadians was through the Public Health Agency of Canada's multimedia, multiphased Citizen Readiness Social Marketing Campaign.

The campaign, implemented in stages over nine months, included marketing and advertising tactics focusing on infection prevention behaviours, personal preparedness and a call to action for Canadians to get vaccinated. The major focus of the campaign was television, print, radio, in-transit and online advertising that encouraged Canadians to get the information they needed to make decisions to protect themselves from the H1N1 influenza virus on the Public Health Agency of Canada's FightFlu.ca website. A number of marketing tactics reinforced the phased messaging: distribution of a direct mail brochure to 10 million Canadian households to promote the Public Health Agency H1N1 Preparedness Guide, distribution of 1.7 million H1N1 Preparedness Guides via 1 800 O-CANADA and Canada Post outlets, and the H1N1 pages of the Public Health Agency website.

Despite these communication activities, it is important to recognize that the federal government is not the only source of information for Canadians during a public health event. More than ever before, Canadians are living in a multisource environment where information is no longer simply from local, national and international governments or academic sources transmitted through traditional media such as television and radio, but also from social media, where anyone can post information regardless of their expertise or the use of rigorous research.

Media coverage of H1N1 was extensive and, at times, overwhelming. In October 2009, a survey found over three-quarters of Canadians (78 percent) believed the media hyped and exaggerated the threat of H1N1, representing a 10-point increase from perceptions in July.³⁸ Correspondingly, just over half of Canadians (53 percent) surveyed in the same month (October 2009) felt the general public's level of concern was exaggerated while close to four in ten (37 percent) felt the level of concern was consistent with the risks.³⁹

In public health messaging during an event, there can be a delicate balance between providing information on one hand, and raising concerns or fears unnecessarily on the other. This dynamic needs to be further balanced with the public's growing appetite and expectation for more information.

What worked well?

Communication with the Canadian public was a key priority during the pandemic

Federal Health Portfolio communication efforts began to roll out on April 24, 2009. A news conference was held two days prior to the first confirmed case of H1N1 in Canada. This was a few days after the first samples had been received from Mexico to determine the cause of the illness that had been spreading there. These news conferences continued throughout the pandemic; almost 50 were held between April 24 and December 15, 2009.

These activities respond directly to one of the key recommendations derived from the independent review of the government's activities during the listeriosis outbreak in the summer of 2008.⁴⁰ At that time, the government was criticized for a fragmented and untimely communications approach.⁴¹ During the H1N1 pandemic, however, the Public Health Agency of Canada was the lead organization responsible for communicating with Canadians. Media channels, perceived as primary sources of information for Canadians, were used.⁴² Having consistent news briefings also worked to establish a collaborative relationship with the media during this time, and maximized communication through traditional media.

The Public Health Agency of Canada's communications and marketing activities all contained a primary call to action to drive Canadians to its FightFlu.ca website, where they could find the information needed to protect themselves from the H1N1 influenza virus. Research on these marketing activities indicates that Canadians took steps to prevent the spread of influenza, including handwashing or coughing into one's arm instead of one's hand. The Public Health Agency of Canada's H1N1 web content received 6.4 million visits, had over 20 million pages of content viewed, and had more than 200,000 H1N1 information products downloaded.

Health alert notices also played an important role in the early stages of the Public Health Agency of Canada's response. Four million health alert notices were distributed to travellers at 24 Canadian airports between April 27 and May 18, 2009. Infection prevention behaviour information was displayed on screens in Canada's international airports during the first wave of H1N1. Posters outlining quarantine measures and infection prevention practices were also distributed in these locations.

Key spokespeople, like the Minister of Health and the Chief Public Health Officer, were visible throughout the pandemic

An additional key recommendation of the independent listeriosis review was the identification of a primary spokesperson during public health emergencies to demonstrate consistent federal public health leadership. Media analysis indicates that the Chief Public Health Officer and the Minister of Health received a very high number of media mentions on a wide range of issues concerning H1N1. They were positioned as credible, authoritative and effective communicators throughout the pandemic period.

Advance planning ensured key communication products and activities were quickly implemented

The Public Health Agency of Canada's Risk Communications Strategy for Pandemic Influenza, developed in 2006, guided the overall planning for the communications and social marketing response during the H1N1 pandemic. Without key activities, such as media training and creative development for the advertising campaign, it would have been very difficult to launch a multiphase, multifaceted campaign. During the H1N1 pandemic, the campaign contributed to informing Canadians and encouraging them to adopt appropriate infection prevention behaviours. As part of this strategy, advance work with national and international partners formed important links that were useful during the H1N1 response.

Social marketing efforts helped to change infection prevention behaviours

As mentioned, the Public Health Agency of Canada implemented a number of social marketing/ advertising tactics during the pandemic aimed at encouraging behaviour change among Canadians. The Citizen Readiness Social Marketing Campaign's first phase promoted infection prevention behaviours including: frequent handwashing, coughing into one's arm not hand, staying home if sick. These messages were later complemented with personal preparedness and immunization information. Research conducted shows that Public Health Agency marketing and advertising efforts helped to increase infection prevention behaviours by Canadians. For example, of those members of the public asked if they had seen the Public Health Agency of Canada's infection prevention ads that ran in the fall of 2009, almost half (46 percent) reported taking action as a result, of which roughly six in 10 (59 percent) stated (without prompting) that they started to wash their hands more often.⁴³

Basic infection prevention information (handwashing, coughing into one's arm not hand, staying home when sick) are appropriate for overall infection prevention in both pandemic and non-pandemic situations to reduce the risk of common infectious diseases such as the seasonal influenza. Infection prevention messages should be continued on an annual basis, aligning with annual influenza season.

There was strong and effective coordination of communication activities between federal and provincial/territorial governments

Consistent messaging to Canadians across federal and provincial/territorial jurisdictions was needed to maintain public confidence in the response to the H1N1 influenza virus. While there were instances where this consistency was not always achieved (as will be described below), the federal, provincial and territorial governments coordinated their approaches, communications and marketing tools, tactics and messaging.

Federal, provincial and territorial heads of communications met daily to share information and intelligence on emerging issues, concerns and announcements, and to coordinate outreach and public education efforts. Collaboration was facilitated through two subgroups: the Communications subgroup and the Social Marketing subgroup, with representatives from the provinces and territories and the Government of Canada. The Communications subgroup focused its efforts on issues management and media relations, including the creation of common speaking points and media lines on various issues for use by all jurisdictions. The Social Marketing subgroup focused on ensuring Canadians received consistent public awareness and marketing information (including television, print, radio, in-transit and online advertising) across jurisdictions.

This collaboration was highlighted when a television ad on infection prevention behaviours (creative produced by the Ontario government) was broadcast nationally (media paid for by the federal government) on behalf of the federal, provincial and territorial governments. This effort allowed smaller jurisdictions that did not have budgets for television advertising to benefit from the ad.

Areas for action

Conflusion (the aggregation of streaming together of multiple confusing items, as in a confluence of confusion) is what the public is feeling in response to the seemingly endless stream of contradictory news about H1N1 influenza.⁴⁴

— André Picard, *The Globe and Mail*, October 9, 2009

Improve consistency of information communicated to Canadians across different jurisdictions

As previously mentioned, there was a strong effort to coordinate information to Canadians across different jurisdictions. However, there were cases where contradictory or slightly different messages were communicated based on federal, provincial or territorial policy decisions. This caused some confusion among citizens. One example of confusion was the varying approach across jurisdictions to the seasonal influenza vaccination during the second wave of H1N1, where some provinces and territories chose not to move ahead with the seasonal vaccine.

The media reported on the discrepancies between messages during H1N1. Australia faced a similar challenge and reported that “the complexity of Australia’s federation, requiring coordination of one national and eight state and territory governments” may have been a contributing factor for inconsistent messaging across the country.

Differences in the timing, scope and severity of the H1N1 pandemic across jurisdictions — as well as varying response measures, public health capacity and governance structures — limit the extent to which best practices in risk communications can be consistently applied. It is expected that messaging based on individual or jurisdictional policies, communication channels and responsibilities may result in variation. However, this does create confusion among the general public and should be minimized wherever possible.

Review strategies to communicate uncertainty, risks and shifts in scientific knowledge in order to build public trust

While prevention campaigns appeared to have an impact on the general population, the Health Portfolio needs to reconsider how to communicate uncertainty, risk or shifts in scientific knowledge to the Canadian public. Some of these issues are not unique to Canada's response to H1N1. One of the recommendations coming out of the experience with H1N1 in the United Kingdom was to portray pandemics as accurately as possible, including the levels of risk, as well as to ensure greater transparency of scientific findings when communicating to stakeholders and the general public.⁴⁵

Examples of lessons from other jurisdictions:

- **United Kingdom**

The communication of only the 'reasonable worst-case' planning assumptions meant that there was an obvious gap between what the government was saying and what was observable on the ground, namely that the disease was mild in most cases and that mortality levels were low. This gap could have risked damaging the government's credibility and undermining public trust in the response.⁴⁶

- **Switzerland**

In order to raise public awareness, it was decided to adopt a communication strategy based on a worst case scenario. In line with the World Health Organization's reports on the escalation of the pandemic (phase 2/3/4/5/6), this strategy was justifiably the right choice. But due to the lack of coordination between the various stakeholders, within a relatively short time the messages became confused. The delay in the delivery of the vaccine and the extensive academic discussions which took place about "which vaccine for whom?" were at the heart of this confusion. To complicate matters even further, the escalation phase then turned into a de-escalation phase; clear, credible communication became close to impossible.⁴⁷

- **Australia**

Communication has been inconsistent partly because different parts of Australia have gone through the pandemic at different times and officials have been faced with the challenge of adjusting the response to cope with an infection that has not been as dangerous as the worst case scenario expectations that underpinned planning.⁴⁸

As with these jurisdictions, communicating risk, uncertainty and the scientific process affected the Public Health Agency's and Health Canada's overall response to H1N1. A recommendation on the development of strategies for communicating these issues to a diverse audience (including the general population, stakeholders and internal groups such as decision makers and decision influencers, with specific reference to central agencies) is discussed in more detail in section 4, Summary and recommendations.

Issues relating to the appropriateness of language and formatting for guidance documents are discussed in section 3.3, Guidance. In addition, specific communication activities are presented in section 3.2, Collaboration with provinces and territories. For particular communication activities with on-reserve First Nation communities, see section 3.6, Federal response in on-reserve First Nation communities.

3.6 FEDERAL RESPONSE IN ON-RESERVE FIRST NATION COMMUNITIES

Background

Health Canada's First Nations and Inuit Health Branch, in collaboration with the provinces, provides health care services to on-reserve First Nation communities through direct service delivery or funding through contribution agreements to First Nation organizations for delivering health care services. The First Nations and Inuit Health Branch provides basic primary care services in nursing stations in remote and isolated on-reserve First Nation communities.

During a pandemic, the First Nations and Inuit Health Branch provides health services to on-reserve First Nation communities. This includes providing assistance in the development, testing and revision of pandemic plans. In collaboration with provinces, First Nations and Inuit Health Branch is also responsible for the distribution and administration of vaccines and antivirals, reporting of adverse effects of immunization and treatment, and providing culturally appropriate information and guidance to health care workers on reserves.

While conditions are improving, First Nations people living on a reserve may experience inadequate housing and a higher risk for chronic diseases such as diabetes and tuberculosis.⁴⁹ A September 2009 study revealed that, while a quarter of First Nations people living on a reserve knew of at least one confirmed case of H1N1, other health conditions such as diabetes, cancer, smoking, alcohol and drug use were of greater concern.⁵⁰ Some other factors affecting pandemic response efforts in remote and isolated communities include: the distance required to travel to hospitals for acute care, high rates of pregnancy and in a few communities, limited access to running water. These remote communities tend to experience more difficulty overall in gaining timely access to a full complement of health services.

The public perception of the Health Portfolio's response in First Nation communities during the pandemic was shaped by the media coverage of three key events:

1. Early in the pandemic, in the spring of 2009, there was a high incidence of infections, serious cases and deaths among Aboriginal people in Manitoba.
2. In the summer of 2009, extensive national media coverage emphasized that federal government officials spent days debating whether to send alcohol-based hand sanitizers to First Nation communities over concerns about high alcohol content in the products.
3. In the fall of 2009, there was a significant negative reaction to the shipment of large numbers of body bags to some reserves.

While initially there were difficulties in Health Canada's response, many practices, changes and activities that were instituted during late spring and early summer 2009 improved the response in the fall. For example, after the shipment of large numbers of body bags to some reserves in the fall 2009, Health Canada implemented a number of changes to prevent a similar situation from recurring. Current procurement processes now have centralized control measures that set maximum quantities and flag unusual orders. In addition, regional staff review ordering patterns and supply levels when conducting regular site visits.

In general, First Nations people were able to take precautions against H1N1. By September 2009, almost seven in 10 (68 percent) First Nations people living on a reserve stated that they had already taken steps to protect themselves against the illness, most frequently citing handwashing as the most effective way to protect against H1N1.⁵¹

What worked well?

H1N1 was present in some First Nation communities early in the pandemic (May 2009). The experiences from the first wave helped to shape many preparedness and response decision-making processes and activities for the second wave. The nature of the pandemic in First Nation communities meant that there was no real distinction between the first and second waves but rather a continuous need for Health Canada's response throughout. Therefore, change and adaptation were required while the response continued.

Many First Nation communities had pandemic plans in place

Pandemic planning efforts have been funded since 2006 in on-reserve First Nation communities. It was estimated that 80 percent of communities had pandemic plans in place at the beginning of the pandemic. As of fall 2009, 98 percent of communities had pandemic plans, and 87 percent had 'tabletop-tested' at least one component of their plans such as their mass immunization plans.

During the H1N1 pandemic, Health Canada officials continued to offer advice on the establishment of and/or details relating to pandemic plans, such as twinning with similar communities. In the future, Health Canada could consider looking at all pandemic plans to consider adaptability and scalability to different pandemic scenarios.

Vaccination clinics on reserves were generally successful

The vaccination clinics that took place in fall 2009 in on-reserve First Nation communities were generally successful. Overall uptake was 64 percent, some 20 percent higher than in the rest of the Canadian population.

Given the ongoing shortages of health care professionals and the increased demands on the health care system, community health resources were sometimes overwhelmed. This resulted in a limited capacity to implement community mass immunization plans. In three regions, additional nurses, physicians and pharmacists were provided by Health Canada. Other communities received surge capacity resources through their provincial health system. Again, lessons about processes and activities learned during this time should be incorporated into future pandemic planning.

Antivirals were pre-positioned in remote and isolated communities for the second wave and personal protection equipment was purchased

Health Canada's Non-Insured Health Benefits program incorporated antiviral drugs into their standard formulary. Concurrently, Health Canada and the provinces worked together during the spring and summer of 2009 to ensure that antivirals were stockpiled in, or near, isolated or remote communities. This activity was crucial, especially for those First Nations people living on reserves. Ready access to antivirals can reduce the likelihood of serious illness. During the H1N1 pandemic, this strategy may have reduced the need for some First Nations people to be transported to tertiary care facilities for acute primary care services. This practice should be taken into account in future pandemic planning efforts.

In May 2009, in response to the H1N1 virus, Health Canada supplemented the routine personal protective equipment supplies already available by pre-positioning its modest stockpile of personal protective equipment supplies, housed at the Drug Distribution Centre in Edmonton, in many on-reserve First Nation community nursing stations and other health facilities.

First Nations and Inuit Health Branch purchased additional personal protective supplies to meet the immediate and longer-term needs of health care workers in on-reserve First Nation communities. These supplies were stored in two separate distribution centres to ensure rapid distribution of supplies to communities. Communities could order supplies monthly based on the instructions highlighted in the H1N1 personal protective equipment procedure.

There was good cooperation among Health Canada, the Public Health Agency of Canada, Indian and Northern Affairs Canada, the provinces and First Nations leadership

A number of activities took place in the summer and fall of 2009 that demonstrated cooperation between all parties. The Remote and Isolated Communities Task Group of the Pandemic Coordination Committee was established to build on and adapt existing national guidelines to “*better ensure an effective and coordinated federal/provincial/territorial influenza pandemic response in remote and isolated communities, in the context of the H1N1 outbreak.*” Membership included a total of 25 representatives from the Assembly of First Nations, provincial/territorial governments, the Council of Emergency Social Services Directors, the Council of Health Emergency Management Directors and the federal government.⁵² This provided a framework for concentrated and coordinated response to H1N1 and established relationships for future consultations of this nature.

In addition, other activities such as the signing of a Communications Protocol in September 2009 between Health Canada, Indian and Northern Affairs Canada, and the Assembly of First Nations aimed to improve coordination of communication activities (including communications regarding access to water and transportation for public health purposes). As part of this activity, a virtual summit on H1N1 in First Nation communities was held, which helped further outline infection control practices for First Nations.^{53, 54}

Moreover, communication activities used established contacts to distribute information to First Nation communities. Notices and posters were sent to co-ops, Band Council offices, Northern stores, and friendship centres. Once posted and distributed, important health information was provided to leaders at 1,400 Aboriginal health organizations such as community health groups, healing lodges, health access centres, addiction centres and nursing stations.⁵⁵

Provincial public health counterparts provided continuing support to Health Canada's First Nation and Inuit Health regions, as well as First Nation communities, whether it was the completion and testing of First Nation pandemic plans, the timely pre-positioning of antivirals or the efficient distribution of the vaccines for the mass immunization clinics.

Finally, national Aboriginal organizations representing the interests of First Nations, Inuit and Métis people across Canada were a key component of the Public Health Agency of Canada's strategic relations plans, to which the First Nations and Inuit Health Branch contributed. Even though roles and responsibilities for regular communication with these groups needed to be clarified, collaborating with national Aboriginal organizations played an integral role in the stakeholder engagement strategy throughout the H1N1 pandemic.

Health Canada appointed a Senior Medical Advisor to oversee the H1N1 on-reserve response

A number of operational changes were made during the summer of 2009 to streamline the H1N1 response. A specific H1N1 operational team was created, and roles and responsibilities were clarified. This allowed for an improved response during the second wave. In addition, a Senior Medical Advisor was appointed to lead the response with on-reserve First Nation communities (with reporting authority) while the Assistant Deputy Minister of the First Nations and Inuit Health Branch continued as the financial authority. This appointment provided a credible medical authority for discussions both within the federal government as well as with First Nation communities. The Senior Medical Advisor also enhanced media relations and communication to Canadians regarding the federal government's response to First Nations on-reserve.

Areas for action

As a result of H1N1, the level of preparedness on-reserve has significantly increased. However, important work remains to help prepare First Nation communities for any future pandemics or other public health emergencies.

Develop guidance on the logistical aspects of implementing pandemic plans

Health Canada officials noted that, while pandemic plans were put in place, there appeared to be confusion about some logistical aspects of the plans during the response that may need further consideration. Guidance is needed about timing to activate plans, such as when and under what circumstances a community should begin certain activities. As First Nation communities are diverse and spread across the country, this guidance should be specific enough to allow communities to activate their plan at the time most appropriate for them.

Ensure timely availability of public health guidance for First Nation communities

According to a survey of First Nation communities in September 2009, there was confusion about certain infection control practices. A majority of those living on a reserve believed that hand sanitizers were more effective in protecting against H1N1 than handwashing with regular soap and water. In addition, there appeared to be confusion about the seasonal vaccine as protection against H1N1.⁵⁶

Clear guidance on the use of alcohol-based hand sanitizers as an effective means of infection control was not available until after a very public incident about the delay in the supply of requested hand sanitizers in Manitoba in the summer of 2009. In addition, stakeholders requested guidance regarding the use of masks, gowns and pain medication, as well as on the risks and benefits of vaccines to help people make informed decisions. Finally, a coordinated approach across all jurisdictions for guidance regarding antivirals was required very early on in the pandemic. To minimize confusion and ensure that proper public health measures are instituted, quick production and dissemination of clinical care and infection prevention and control guidelines for health care workers and community members is essential, so that they can be disseminated to staff.

Respond to local issues by using regional spokespeople

To provide consistent federal messages to the media, the Minister of Health, the Chief Public Health Officer and the Health Canada Senior Medical Advisor were primary spokespeople. However, Health Canada officials mentioned the difficulties associated with the lack of regional Health Canada spokespeople to respond to local issues during the pandemic. Further consideration should be given to the use of regional Health Canada spokespeople during a pandemic to allow qualified and trained regional staff, with specific knowledge regarding local conditions, as well as established relationships, to publicly address issues arising from their jurisdiction.

Address barriers for the movement of health professionals during a public health event

To assist regions and First Nation communities in the delivery of mass vaccination clinics, First Nations and Inuit Health Branch provided surge capacity staff to communities in Saskatchewan, Manitoba and Ontario. However, almost all of the vaccination volunteers were licensed in Ontario and thus needed interjurisdictional licenses. To address this issue during the H1N1 pandemic, agreements were made with the provincial governments of Saskatchewan and Manitoba whereby they would recognize Ontario licenses for vaccination only and for a limited period. A special service in Human Resources expedited these agreements and special arrangements to assist in travel were established. Recognizing that surge capacity for mass vaccination clinics will be needed in future pandemic situations, barriers to the movement of health professionals across jurisdictions should be minimized to enable a quick and effective response to a public health event.

Challenges relating to surveillance are addressed in section 3.1, Science, surveillance and research. In addition, Health Canada officials working in this area raised a number of operational management issues, such as roles and responsibilities and surge capacity that are covered in section 3.9, Operational management.

3.7 EMERGENCY STOCKPILE

Background

NATIONAL EMERGENCY STOCKPILE SYSTEM

The National Emergency Stockpile System is a federally owned stockpile of emergency pharmaceuticals, medical supplies and equipment managed by the Public Health Agency of Canada. Medical supplies and equipment range from beds and blankets to advanced pediatric ventilators. Pharmaceuticals include antibiotics and antivirals. Antivirals are drugs used for the prevention and early treatment of influenza. If taken shortly after getting sick, they can reduce influenza symptoms, shorten the length of illness and potentially reduce the serious complications of influenza. Antivirals work by reducing the ability of the virus to reproduce but do not provide immunity against the virus. The H1N1 influenza virus can be treated with two different antivirals, Oseltamivir (Tamiflu®) and Zanamivir (Relenza®).

The National Emergency Stockpile System inventory is stored in 10 federal warehouses and approximately 1,300 additional pre-positioned supply centres across Canada. These pre-positioned sites, which operate under the combined management of the provincial/territorial and federal governments, are intended to respond within 24 hours to a provincial/territorial request. The National Emergency Stockpile System includes a federal stockpile of 24.2 million doses of antiviral drugs owned and managed by the Public Health Agency of Canada to provide surge capacity to provinces and territories during a pandemic.

The National Emergency Stockpile System increased its holdings of antiviral drugs, personal protective equipment and ventilators during the H1N1 pandemic. The provinces and territories accessed the System for the following items:

- 135 adult ventilators
- 198,800 masks
- 24,320 capsules of pediatric antivirals.

NATIONAL ANTIVIRAL STOCKPILE

In collaboration with provincial and territorial governments, the federal government created the National Antiviral Stockpile in the fall of 2004. The National Antiviral Stockpile is a federal/provincial/territorial government-controlled supply of antiviral drugs: enough to treat 17.5 percent of the Canadian population. The National Antiviral Stockpile is held in provincial/territorial warehouses; the provinces and territories are responsible for the implementation of the national antiviral strategy and distribution of antiviral drugs from the National Antiviral Stockpile in their jurisdictions. Antivirals in this stockpile are used for early treatment in an emergency, targeting those who are deemed to be most at risk of serious morbidity and mortality. It was agreed that antivirals would be distributed on a per capita basis to the provinces and territories, each of which would have responsibility for care and control under the terms of a national agreement for use. As of May 2009, the stockpile consisted of 48.7 million doses of adult Oseltamivir capsules, two million pediatric Oseltamivir capsules and five million doses of Zanamivir.⁵⁷ Some provinces and territories chose to purchase additional quantities. The release of antivirals from the National Antiviral Stockpile is determined by provinces and territories on an individual basis. During the H1N1 pandemic, provinces and territories released 4.4 million doses of antiviral drugs from the National Antiviral Stockpile.

Canada's antiviral stockpiles are regularly reassessed by federal and provincial/territorial governments for:

- size
- composition (type of antiviral) and relative proportion of the stockpile in line with new science
- technologies and formulations
- changing resistance rates
- disease epidemiology
- changing populations.

In addition, all drugs have a shelf life or an amount of time specified by the manufacturer during which the drug is documented to be stable and potent. This necessitates the development of a stockpile management approach that allows for the regular replacement of inventory.⁵⁸

Health Canada regulates and authorizes the sale of health products, including antivirals, sanitizers/disinfectants, ventilators and masks, contained in the stockpiles. During the H1N1 pandemic, for example, Health Canada provided regulatory authorization of antivirals (e.g. Tamiflu® for children under one year of age) and the Special Access Program authorizations for unlicensed health products (i.e. intravenous Relenza®, Peramivir). It also developed guidance, along with the Public Health Agency of Canada, on the use of disinfectants such as bleach and hand sanitizers with health claims, and provided guidance and regulated health claims supporting various masks and ventilators.

What worked well?

Advance planning ensured antivirals and emergency medical supplies were readily available

Several interviewees agreed, *“It was more of ‘When do we decide when we want to draw on that, if we need to?’ I think those were sort of the pluses from the standpoint of the wave one response.”*

During the H1N1 pandemic, the Public Health Agency of Canada was the federal lead for stockpiling and distributing supplies from the National Emergency Stockpile System to the provinces and territories, as well as for facilitating the procurement of additional emergency supplies to complement provincial/territorial stockpiles, and, to the extent possible, for coordinating federal and provincial/territorial planning and response activities.

Advance planning in anticipation of a pandemic influenza led to decisions to procure additional antivirals and other health supplies, including sanitizers/disinfectants, ventilators and masks for the National Emergency Stockpile System/National Antiviral Stockpile. One interviewee indicated, *“We stockpiled gloves and masks, as well as medications, antivirals, antibiotics. We made the decision to purchase ventilators very fast at the beginning — a good decision because we didn't know the severity in what was to come in the winter.”*

Federal Budget 2006 allocated \$600 million for general pandemic planning and preparedness activities. Among the range of health sector activities supported by these funds was the purchase of antivirals.

The Public Health Agency of Canada, with the provinces and territories, developed guidelines for the distribution of antivirals from the National Emergency Stockpile System in the event of a depleted National Antiviral Stockpile. The guidelines were approved September 11, 2009, by the Special Advisory Committee. The Public Health Agency of Canada also developed guidelines for the distribution of ventilators, which was approved by federal, provincial and territorial Deputy Ministers on October 29, 2009. Under a loan agreement, two provinces requested that their allocation be pre-positioned early in the second wave.

This planning paid off. Canada was able to mobilize quickly in response to the H1N1 threat. Having a stockpile of antiviral and medical supplies available ahead of time enabled the provinces and territories to distribute the antivirals and supplies more quickly.

Areas for action

Review the National Emergency Stockpile System and the National Antiviral Stockpile in light of the H1N1 experience

Following the H1N1 response, three primary areas for further discussion and decision emerged:

INVENTORY REPLACEMENT STRATEGY FOR BOTH STOCKPILES

As a result of usage during the H1N1 pandemic, stocks (including antivirals and other supplies) were reduced. A replacement strategy is currently under development.

EXPIRING STOCKPILES AND RENEWAL OF BOTH STOCKPILES

Antiviral stockpiles are nearing the end of their shelf life (antivirals have a shelf-life of five to seven years). A staggered purchasing and maintenance plan could be explored for antivirals in both the National Emergency Stockpile System and the National Antiviral Stockpile, which will ensure that a scalable and 'evergreen' stockpile of antivirals is available, level out commitments from year to year, and maximize the ability to adjust stock as new developments arise.

EQUITABLE REGIONAL DISTRIBUTION (BY POPULATION OR BY NEED)

In collaboration with the provinces and territories, the Public Health Agency of Canada is in the process of determining an equitable allocation strategy for antiviral distribution of the National Emergency Stockpile System as their respective National Antiviral Stockpile stocks are depleted.

The Public Health Agency of Canada also identified the stockpile content, function, lifecycle and distribution processes as areas for action in a 2006 review of the National Emergency Stockpile System.

Consider options for prescribing and dispensing antivirals in remote and isolated communities during a pandemic

A discussion emerged during the H1N1 emergency about allowing community health workers, paramedics or other officials within remote and isolated communities to dispense antivirals to influenza-stricken residents during an outbreak, specifically in cases where no doctor or registered nurse is available.

It has been suggested that “every single day they [an infected person] don’t get Oseltamivir places their health at greater risk.”⁵⁹ Opposing views to this approach suggest:

- there is a risk of people mistakenly receiving antivirals when they have not been properly diagnosed and should actually be treated for another condition
- it is outside prescribing authority
- it implies people in remote and isolated communities are being provided a different standard of care.

Consideration should be given to national and international best practices for prescribing and dispensing antivirals. For example, during the H1N1 pandemic, one Canadian jurisdiction, with support from its provincial medical association, instituted a temporary fee item to allow physicians to consult patients with suspected H1N1 symptoms over the phone and to prescribe antivirals by phone. Other countries, for example the United Kingdom, have a program that allows people to contact call centres, describe their symptoms and get a prescription, which a family member or friend can pick up.

A potential solution would be to have antivirals pre-positioned within remote and isolated communities and have them distributed by a responsible local official who is in telephone contact with physicians. A contributor to the *Canadian Medical Association Journal* suggested, “You hand it out if people meet the symptoms and in the interim, you can start to transport them out for assessment. God knows, I don’t think you should be waiting a week to get treatment.”⁶⁰

Health Canada is considering several options with provinces and territories, such as flying doctors into outbreak sites or adjusting prescribing practices to allow for prescribing of antivirals in remote and isolated communities where access to licensed prescribers may be of concern.

Seek authority to donate stockpile supplies to other countries

Currently, since the mandate of the National Emergency Stockpile System does not allow the Public Health Agency of Canada to use stockpile supplies for the purpose of international assistance, it cannot donate or loan products for this purpose unless they are declared surplus. There is sufficient statutory authority to make international donations of federally owned vaccine that is surplus to Canada’s needs, as long as the donations comply with statutory and contractual requirements. Consequently, if the Public Health Agency of Canada wants to provide international assistance, prior to the stockpile being declared surplus, it could consider seeking financial and program authorities to expand the current mandate of the National Emergency Stockpile System. If the Public Health Agency of Canada were to secure such authorities, it should follow the practice of the World Health Organization and enter into agreements with recipients setting out the terms and conditions governing the donation, whether the recipient is an international organization or another country. Further, the Public Health Agency procurement policies would need to ensure that there are no impediments to the international donation.

3.8 VACCINE

Background

Canadians receive many vaccines throughout their lifetime, many while at an early age. As noted by one interviewee, *“Aside from food, there’s probably nothing that affects the population more than vaccines. Everybody gets them: they’re given to healthy people; our kids get eight or nine vaccines before they’re one year old.”*

Within Canada, there is a division of responsibility for activities regarding vaccines.

Health Canada

Canada, like many other jurisdictions worldwide, exercises tight regulatory oversight over vaccines. All vaccines intended for human use are subject to the provisions of the *Food and Drugs Act* and the *Food and Drug Regulations*. Prior to market authorization of a new vaccine, manufacturers must file a submission with scientific and clinical evidence that demonstrates that the vaccine’s health benefits outweigh its risks and that the vaccine is efficacious and of suitable quality.

The Biologics and Genetic Therapies Directorate in the Health Products and Food Branch, as administrators of Health Canada’s vaccine regulatory program, is the focal point for activities related to the review and authorization of adjuvanted and unadjuvanted pandemic vaccines.

Since a pandemic influenza vaccine is by nature untested, the efficacy, safety and quality of the vaccine has to be established in real time. For the 2009-10 H1N1 pandemic, the development of the pandemic H1N1 vaccine could not begin until the pandemic strain was identified in spring 2009. Since the vaccine was needed almost immediately after being manufactured, there was limited time for traditional clinical trials required to authorize the vaccine under the existing regulatory framework.

The Biologics and Genetic Therapies Directorate planned for an expedited review process for a pandemic vaccine, with a “rolling” submission approach, where data would be reviewed as it became available, and with a greater emphasis on post-market commitments.

The Health Products and Food Branch reviewers assessed the risks and benefits of the vaccine, in the context of the H1N1 pandemic outbreak. While the review was expedited, early planning and extensive international collaboration on data, including clinical trial results, ensured that the safety and effectiveness of the vaccine was not compromised.

In addition to regulatory activities, Health Canada also undertook surveillance and risk management of post-market safety issues related to the use of antivirals; developed global standards for vaccine authorization, in line with the *International Health Regulations* that support World Health Organization global licensing efforts; monitored and enforced the removal of fraudulent health claims over the Internet; and issued alerts for products with health claims regarding H1N1.

Public Health Agency of Canada

The Public Health Agency of Canada has four key activities related to pandemic vaccine:

- managing a contract with a domestic manufacturer to develop a vaccine
- arranging a contract with Public Works and Government Services Canada for the purchase of sufficient vaccine for Canadians on behalf of the provinces and territories (the Government of Canada's contract with the vaccine manufacturer specifies priority access to pandemic vaccine produced at its Canadian plant)
- issuing guidance for vaccine use as well as guidance for vaccine safety surveillance
- monitoring adverse events following immunization with the H1N1 influenza vaccine in Canada in collaboration with Health Canada, the provinces and territories, the Canadian Paediatric Society, and a network of researchers.

Provinces and territories

The provinces and territories are responsible for the overall delivery of health care services to the population, as well as the delivery of the vaccine and immunization program through local health authorities.

First Nation communities across Canada offer immunization as a component of their mandatory communicable disease control programming. The distribution of the H1N1 vaccine demonstrated that First Nation communities have well-established processes for obtaining vaccine, storing and handling vaccine safely, and implementing immunization programs. First Nation communities in Canada implement immunization programs based on the guidance set by the provinces and territories, which develop their policies based on the expert recommendations made by the National Advisory Committee on Immunization. Health professionals in First Nation communities also report adverse events following immunization to their respective provinces, which then send them to the Public Health Agency of Canada for analysis.

What worked well?

Advance planning for the vaccine supply ensured timely access to a safe and effective vaccine

The Public Health Agency of Canada and Health Canada have focused significant attention over the past 10 years on timely access to a safe and effective vaccine in the event of a pandemic influenza outbreak.

CONTRACT IN PLACE WITH A DOMESTIC SUPPLIER TO ENSURE ENOUGH VACCINE WOULD BE AVAILABLE TO IMMUNIZE ALL CANADIANS

Canada was one of the first countries in the world to contract with a manufacturer domestically to assure a state of readiness in case of an influenza pandemic and to ensure access to enough vaccine for all Canadians as early and as quickly as possible at the time of a pandemic. Over the past few years, Canada has made significant investments to increase the vaccine production capacity of the domestic vaccine manufacturer.

Canada ordered approximately 50.4 million doses of adjuvanted and unadjuvanted H1N1 vaccine for the Canadian population, enough to immunize all Canadians who needed and wanted protection against the H1N1 influenza virus. An adjuvanted vaccine is a vaccine that includes a substance that boosts an individual's immune system and increases the response to a vaccine. An unadjuvanted vaccine has no 'booster' element. Adjuvanted vaccines are included in common vaccines such as tetanus and hepatitis B. The adjuvant in Canada's H1N1 influenza vaccine is made up of natural ingredients such as water, squalene oil and vitamin E. Guidelines were established to distribute adjuvanted vaccines, deemed equally efficient and safe by international standards, to the majority of the population. Unadjuvanted vaccines were acquired for pregnant women.⁶¹ As such, vaccines considered safe and effective were available to all Canadians.

MECHANISMS WERE IN PLACE TO QUICKLY REVIEW AND AUTHORIZE H1N1 VACCINE FOR SALE IN CANADA

The regulatory challenge for a pandemic influenza vaccine is to have mechanisms in place that can be used to review and authorize a safe and efficacious vaccine for use in Canada, within the shortest time frame possible, and to verify the vaccine in use is the most effective.

Health Canada worked closely with the manufacturer in advance of the pandemic to identify safety information and data on vaccine components or a 'mock' vaccine. This process, initiated in 2005, paid off during the H1N1 influenza pandemic. Once the pandemic was declared, Health Canada had limited time to review and authorize the vaccine and the experience with the mock vaccine made it possible to do this quickly. As of December 13, 2009, approximately 23.7 million doses of adjuvanted and 1.3 million doses of unadjuvanted vaccine had been delivered to the provinces and territories.

The Canadian rate of immunization was one of the highest in the world

Immunization with a safe and effective pandemic vaccine is the cornerstone of the health response to pandemic influenza in Canada. The mass immunization campaign for H1N1 was the largest ever held. Although rates of vaccine uptake varied across the country, Canada had one of the highest vaccination rates in the world, estimated by the Health Portfolio at between 40 and 45 percent.⁶² As one interviewee noted, *"We were one of the few countries in the world that had a vaccine out and in people's arms before end of December."*

There was close collaboration with the World Health Organization and international regulatory counterparts

The close collaborative relationship was emphasized by one interviewee who indicated, *"As part of our regulatory responsibilities, we worked really, really closely with our international partners and, in this particular case, it was very, very closely. It was on a real-time basis with the international community."*

Both the Public Health Agency of Canada and Health Canada have well-established linkages with international organizations including the European Medicines Agency, the medical group in the European Union, and the United States Food and Drug Administration. Between 2006 and 2007, for example, three international workshops were held with the Food and Drug Administration and the World Health Organization to establish the data required to develop, test and approve a pandemic vaccine worldwide. The workshops identified many regulatory and policy challenges that fed into Canada's pandemic vaccine planning.

Throughout the H1N1 pandemic, the international community of regulators continued to meet on a regular basis, either in-person or by conference call, sometimes daily or, at a minimum, three times weekly. A critical meeting of international heads of regulatory bodies was held in early October 2009, just prior to the approval of the vaccine later that month.

Following the H1N1 response, Canada has continued its role as a leader in international collaboration. As recently as July 2010, Health Canada organized a workshop with the United States Food and Drug Administration and the World Health Organization to identify lessons from potency testing of pandemic vaccine, and to:

- exchange knowledge and experience in vaccine release and immunization around the world throughout the 2009 influenza pandemic
- formulate plans to address gaps in our knowledge on the use of alternative approaches to assess the potency of influenza vaccines
- identify possible ways to incorporate such assays into influenza vaccine regulation.⁶³

Science, policy and regulatory experts worked together as a team

The H1N1 vaccine experience was a good example of how science and regulation are intertwined and benefit from teamwork. Both scientific and regulatory processes had to be adjusted to address the uniqueness of the H1N1 pandemic situation without compromising product safety or effectiveness. Science, policy and regulatory expertise at the Public Health Agency of Canada and Health Canada continue to work together on the pandemic vaccine file.

Interim orders were appropriate regulatory measures to expedite access to the H1N1 vaccine, as well as to antivirals for children under one year of age

Under section 30.1(1) of the *Food and Drugs Act*, “The Minister may make an interim order that contains any provision that may be contained in a regulation made under this Act if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.”

Interim orders deal with matters that would normally be covered under regulation; in this case, the proposed *Extraordinary Use New Drugs Regulations* were published in the *Canada Gazette Part I* but are not yet law.

The Minister of Health made three interim orders during the H1N1 pandemic to:

- allow the sale of Tamiflu® for expanded use as a prophylaxis or treatment of infection caused by the novel H1N1 influenza A virus in children under one year of age
- authorize the sale of the vaccine manufacturer’s H1N1 influenza A pandemic vaccines (adjuvanted and unadjuvanted)
- authorize a small amount of unadjuvanted vaccine for early distribution from other sources prior to the authorization of the larger supply from the domestic vaccine manufacturer.

Interim orders provided the flexibility to authorize a vaccine based on limited clinical data, imposed post-market commitments and allowed for pre-positioning of the vaccine across the country before its authorization. Pre-positioning of the vaccine facilitated earlier start-up of immunization programs in some provinces and territories.

Areas for action

Overall the timelines were met and a safe vaccine was made available. However, as one interviewee explained:

“What we were not prepared for was for the pandemic to occur when it did. We thought we would have more time, because we were all looking at the H5N1 epidemiology, and that’s what we were watching. So it caught us off guard in that it occurred when it did, that it started where it started in the world, that the strain was what it was. So not everything we would have liked to have had in place was in place. But we had identified some backup mechanisms, because part of preparedness was realizing you never knew when a pandemic was going to occur.”

The following four areas have been identified as key points for improvement.

Implement an integrated surveillance system for immunization, including managing inventories, tracking vaccine uptake and monitoring adverse events

During the H1N1 pandemic, it was not possible to fully track vaccine uptake/immunization coverage, such as who got the vaccine, how much was used and how much was wasted. For instance, some provinces and territories experienced delays in data entry and processing, as well as in forwarding uptake data to the Public Health Agency of Canada. In some provinces and territories, vaccines administered by physicians were not captured by the jurisdiction. Both these factors are believed to have contributed to lower-than-expected reported H1N1 vaccine coverage. Consequently, data on H1N1 vaccine uptake across the country are estimates and may not accurately represent national uptake. Tracking unexpected adverse reactions in real time was also challenging in terms of timely information sharing across the Health Portfolio and with partners.

In response to lessons learned from the Severe Acute Respiratory Syndrome (SARS) outbreak, an integrated public health surveillance system was proposed.⁶⁴ The ability for public health professionals to work together to efficiently manage individual cases, outbreaks, notifications, immunizations and vaccine inventories across the country was identified as a particular need. Public health professionals would benefit from the ability to forecast and record immunization information including information on consent and adverse reactions.⁶⁵ In support, efforts continue for establishing electronic health records.⁶⁶

For more details on other aspects of vaccine surveillance, see section 3.1, Surveillance, science and research.

Review the approach for federal delivery of vaccines to provinces and territories

SOLE PANDEMIC VACCINE SUPPLIER

The Government of Canada's contract with a sole pandemic vaccine supplier results from the fact that, at the time of the open tendering and awarding of the contract in 2001, there was only one manufacturer interested in establishing sufficient domestic capacity to manufacture enough vaccine to inoculate the entire population in the event of an influenza pandemic.

PRIORITY GROUPS (SEQUENCING)

Several factors influenced the timing of the production of the H1N1 pandemic influenza vaccine and contributed to delays in its production and, therefore, to an initial delay in H1N1 vaccine distribution. While Canada has domestic production capacity to manufacture pandemic and seasonal influenza vaccines, vaccine manufacturing does not allow for them to be produced simultaneously. Similarly, adjuvanted and unadjuvanted vaccine cannot be produced simultaneously.

In the early stages of the H1N1 pandemic, it was unknown whether the pandemic H1N1 influenza virus would be the only strain of influenza circulating in the fall of 2009. Therefore, in accordance with the World Health Organization recommendation that vaccine manufacturers complete their seasonal influenza vaccination production before starting its H1N1 influenza vaccine production, the Government of Canada instructed its manufacturer to complete the 2009-10 seasonal influenza vaccine production. Immediately upon completion of the seasonal influenza vaccine production, the manufacturer began pandemic vaccine production. Filling adjuvanted vaccine began on September 4, 2009. However, production of the adjuvanted vaccine was briefly interrupted to fill unadjuvanted vaccine for pregnant women in early October, in keeping with the recommendation of the World Health Organization's Strategic Advisory Group of Experts that pregnant women receive the unadjuvanted H1N1 influenza vaccine, if available.

Finite production capacity, the completion of seasonal influenza vaccine production, and the switch to production of unadjuvanted H1N1 vaccine, contributed to a limited supply of pandemic vaccine for several weeks at the beginning of the campaign. It was anticipated that Canada's pandemic vaccine order would be made available in batches over weeks during the pandemic and would necessitate some prioritization within the population as initial doses of the vaccine became available. Pandemic vaccine prioritization was based on a framework that considered scientific evidence, ethical considerations, program issues and additional policy considerations. In keeping with the *Canadian Pandemic Influenza Plan for the Health Sector* goal of minimizing serious illness and overall deaths, it was determined that those who would benefit most from immunization would be the first to receive the pandemic H1N1 (2009) influenza vaccine once it became available.

There was close federal collaboration with the provinces and territories on prioritization through the Pandemic Vaccine Task Group, including specific guidance on vaccine sequencing. However, the implementation of sequencing recommendations varied across the country at the outset. This resulted in confusion among some Canadians about the different priority groups for immunization.

While there was some initial inconsistency in implementing the vaccine sequencing guidelines, some aspects of this issue were effective. For example, there have been positive comments about the priority given to remote and isolated areas with respect to H1N1 preparations and vaccine distribution. From a northern perspective, federal/provincial/territorial coordination and cooperation was considered strong. Having a shipment of vaccine sent to one locale was useful, notwithstanding the related challenge of then distributing supplies to 30 communities. This may be an indication of the significant work which was done by the Remote and Isolated Communities Task Group.

BATCHING/PACKAGING OF VACCINE

Doses of the vaccine were delivered to provinces and territories in batches as the vaccine became available. At times, the quantity of vaccine delivered to the provinces and territories was insufficient. In British Columbia's report on the response to the H1N1 pandemic, the Provincial Health Officer says that "*going forward, we plan to work with the federal government to see if there are ways of securing larger quantities of vaccine sooner for future pandemics.*"⁶⁷

Packaging was also an issue.

*The vaccine was received in large boxes of 500 doses, which was much too big for most small health care providers and physicians to receive, leading to delays while they were re-packaged. And we couldn't start repackaging until Health Canada had approved us to do so which subsequently led to a complex and time consuming process to ensure safety and quality assurance. The day-to-day uncertainties related to our vaccine supply were another example, as were recommendations related to the choice of flu vaccine to be used in pregnant women. I would put it this way, with an eye to improving things for next time: the level of collaboration was unprecedented, but the coordination and communication that characterized our national response needs work.*⁶⁸

Provinces and territories were allowed to stock the vaccine in their centres before it was approved for use, an unusual practice since distribution is normally not allowed until the product is approved for sale. This was done to reduce the time lag due to the repackaging necessary for shipping smaller quantities of vaccine to smaller centres. Two issues emerged due to this strategy:

- It is unlikely that the Public Health Agency of Canada or provincial and territorial officials anticipated the amount of time needed to repackage the vaccine shipment.
- Most provinces and territories do not have the establishment licences that cover the repackaging activity. The provincial centres without licences authorizing this repackaging activity were required to provide assurances that the vaccine would be handled in a controlled environment that would not affect its quality (i.e. using a refrigerated facility).

COMMUNICATION ABOUT TYPES OF VACCINES

There was also confusion about the types of vaccines offered. Five different types of vaccines were available during the immunization period (adjuvanted H1N1 vaccine, Canadian unadjuvanted H1N1 vaccine, Australian unadjuvanted H1N1 vaccine, and two seasonal influenza vaccines). This range of vaccine options complicated the process in terms of volume of documentation required, staff education and stockpiles.

Establish a permanent regulatory regime for future public health events

Given the need for timeliness in pandemic response, regulatory capacity must be sufficient so as not to delay delivery of safe and effective vaccine. The 2009 H1N1 influenza pandemic brought unprecedented attention to the regulatory requirements for the release and marketing authorization of pandemic influenza vaccines.

Rather than relying on interim regulatory measures, a permanent regulatory regime should be established for future public health events. Work had been under way for the past three years to identify particular regulatory challenges related to releasing vaccines during an emergency.

Two draft regulatory amendments were in development that recommended new frameworks for authorizing the sale of a vaccine without the use of an interim order:

- Proposed amendments respecting the sale of Extraordinary Use New Drugs; these proposed regulations detail the criteria that a new drug would have to meet before the manufacturer could file an Extraordinary Use New Drug submission. The regulatory framework outlines requirements for submissions, labelling, plans for post-market safety and efficacy data acquisition and annual reporting. However, the *Extraordinary Use New Drugs Regulations* had not been published in the *Canada Gazette Part I* by the onset of the 2009 H1N1 pandemic.
- Proposed amendments respecting the block release of drugs to address public health emergencies continue to be developed, and, therefore, were not law at the onset of the 2009 H1N1 pandemic.

Effectively communicate regulatory processes and mechanisms

It is important that Health Portfolio staff at all levels understand the approval process for vaccines and the role of each of the key players in terms of communicating with the manufacturer (i.e. Health Canada's role as the regulator and the Public Health Agency of Canada's role in negotiating the contract).

Some interviewees suggested that, *"When we got into this situation of pandemic, we realized that basically there was no knowledge ... this is not unique to Canada ... the Australians ... from the therapeutic drugs administration ... said [their] biggest challenge was explaining to [their] own Minister what [they] do and that you can't make a vaccine in a couple of hours."*

3.9 OPERATIONAL MANAGEMENT

Background

Previous sections have addressed what worked well and areas for action across eight specific areas of response activity. This ninth section addresses the overall operational management of the response by the Public Health Agency of Canada and Health Canada, more specifically, issues of governance, emergency management and corporate services during the pandemic.

What worked well?

Key structures, resources, relationships, plans and tools were in place

Critical building blocks for the response had been worked out prior to the pandemic, including the creation of the Public Health Agency of Canada, the appointment of a Chief Public Health Officer of Canada, the existence of the National Microbiology Laboratory, and the development of the *Canadian Pandemic Influenza Plan for the Health Sector*, the *Federal Emergency Response Plan*, the *Health Portfolio Emergency Response Plan* and a Health Portfolio Emergency Operations Centre. Networks and tools such as FluWatch, the Global Public Health Intelligence Network, the Canadian Network for Public Health Intelligence, the Canadian Adverse Events Following Immunization Surveillance System, and the Canadian Public Health Laboratory Network were also up and running (as described in section 3.1, Surveillance, science and research). On the international front, the *International Health Regulations* and the *North American Plan for Avian and Pandemic Influenza* also helped lay the foundation for the Health Portfolio response to the H1N1 pandemic. A more recent addition, the Avian and Pandemic Influenza Preparedness Program, an interdepartmental federal initiative coordinated by the Public Health Agency of Canada, was also instrumental in preparedness (as described later in this section).

Staff showed remarkable dedication and endurance

It is important to acknowledge the enormous commitment, hard work and professionalism of staff across the Public Health Agency of Canada and Health Canada. For those directly involved, this often meant extremely long hours that included evenings, nights and weekends, dealing with the challenges of adjusting to extended hours, as well as balancing work with personal and family responsibilities and obligations. Unfortunately, in some cases, this resulted in fatigue, high levels of stress, burnout and staff departures. For those not directly involved in the response, it may have meant frustration at the inability to get attention for their important files. As one interviewee noted:

“I don’t think we were prepared for how fast this took over our lives. But I think what took everybody by surprise — and not only our group — but what took everybody by surprise was the fact a pandemic was declared so quickly, that it had started in North America, and that Canada knew that it had something novel, from coast to coast — in other words from the west coast to the east coast — that happened overnight. (...) in the course of — and my memory may be a bit off on this — but in the course of six hours, we had gone from confirming that novel influenza existed in the (...) East coast — to within six hours later of being confirmed that it had hit the West coast.”

— Interviewee

The Health Portfolio's initial response to the first wave of the pandemic had an exponential tempo. The Health Portfolio Emergency Operations Centre was activated quickly and ran 24 hours a day and seven days a week for about three weeks. To provide a sense of the intensity and length of effort for just one area of the Public Health Agency of Canada that was involved in the response, Figure 3.9.1 displays the activation levels of the Emergency Operations Centre, and the accompanying hours of operation, over the 237 days of activation from April 22, 2009, to February 10, 2010.

FIGURE 3.9.1 Description of H1N1 activation levels in the Emergency Operations Centre (EOC)

H1N1 ACTIVATION 2009-10												
	22-Apr	23-Apr	26-Apr	15-May	29-May	22-Jun	29-Oct	10-Feb	Total			
Activation Level	Activation Level 2	Activation Level 3	Activation Level 4	Activation Level 3	Activation Level 3	Activation Level 2	Activation Level 2	Demobilization of H1N1 Response				
Number of Days at Activation Level	1	3	20	15	16	93 (Managed by Taskforce)	69		237			
Hours of Operation	Monday-Friday with on-call	08:00-16:00 Rotation 1: 08:00-16:00 Rotation 2: 16:00-00:00	Command Staff Rotation 1: 07:00-19:00 Rotation 2: 19:00-07:00	24 hours/day & 7 days/week	08:00-20:00	08:00-17:00	08:00-20:00	08:00-20:00 with on-call. May 16 th -18 th inclusive, the EOC was staffed from 09:00-17:00 EDT with continued 24/7 on-call coverage in all functional areas.	Monday-Friday with on-call			
Rotations	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.	No. of Rotations Hrs.				
	1 8.5	2 8.5	2 11.5	3 8	1 13.5	1 8.5						
Identified IMS Function	48											
FTEs/Day	96											
Person Days	288											
Person Hours	2,448											
	Day one staff complement unknown		1,120		240		8,303		10,276		18,768	
			12,880		1,920		8,303		10,276		59,627	
			56		12		41		13		32	
			28		4		41		37		32	
			56		12		41		37		32	
			1,120		240		615		592		2,208	
			12,880		1,920		8,303		5,032		18,768	
			12,880		1,920		8,303		10,276		59,627	

This effort represents just one piece of the response. It does not include: the Communications, Policy and Operations Groups within the Incident Management System; the Human Resources Directorate; members of the Health Portfolio Executive Group; technical experts in the Centre for Immunization and Respiratory Infectious Diseases; staff at the National Microbiology Laboratory; the work done by the Public Health Agency of Canada's Regional Operations in regional coordination centres across Canada; or any of the Health Canada efforts.

A financial framework for pandemic influenza had already been established

Federal Budget 2006 provided \$1 billion over five years to improve Canada's general preparedness to respond to the threat of pandemic influenza. This included \$600 million for the Avian and Pandemic Influenza Preparedness Program, and \$400 million for a Pandemic Contingency for the Public Health Agency of Canada, Health Canada and the Canadian Food Inspection Agency to address short-term pressures associated with the elevated risk of pandemic influenza. The existence of this contingency allowed the Health Portfolio to access needed resources to implement additional activities in response to the pandemic. Contingency resources for 2009-10 and 2010-11 were accessed for the first and second waves of the pandemic.

Although the policy framework for access and use of the contingency was helpful in guiding the principles and triggers for accessing resources, the process for accessing the contingency was viewed by some as cumbersome and lengthy. Options should be examined to streamline access to the contingency reserve.

Internal communications with staff began early and was extensive

During the H1N1 pandemic, internal communications played a large role in keeping Health Canada and the Public Health Agency of Canada's employees informed of current events and expectations regarding health issues and work priorities. Communication activities with employees began on April 24, 2009, and continued well into 2010. For instance, Public Health Agency employees were sent messages from the Chief Public Health Officer and the Associate Deputy Minister in a variety of formats and an employee toolkit was developed to provide information on the response, and its implications and opportunities for employees.

Areas for action

Governance during significant public health events

Given the involvement of so many organizations during the pandemic, coordination of decision making and information sharing was complex, challenging and time consuming. It will be helpful for future response efforts to continue to clarify structures, roles and responsibilities, as well as decision-making and approval processes at various levels.

Examine the Incident Management System used in the Health Portfolio Emergency Operations Centre and adapt it for future responses

The H1N1 response was the first time the Health Portfolio's Incident Management System was fully implemented by the Health Portfolio Emergency Operations Centre, which is managed by the Public Health Agency of Canada (see Figure 3.9.2). The Incident Management Structure is a key component of the System. Clarity of roles and responsibilities, accompanied by clear operating procedures, is critical. Special attention should be paid to further clarifying the division of operational roles and responsibilities across all aspects of emergency response between the Public Health Agency of Canada and Health Canada. Similarly, during a public health event, the respective roles of the Health Portfolio Emergency Operations Centre and the Government Operations Centre, managed by Public Safety Canada, need to be reviewed and formalized. It will be important to ensure a shared understanding of how the Incident Management System used during a significant public health event relates to ordinary business-as-usual governance structures and business processes.

Develop a common understanding of the decision-making process during an emergency when public health and public policy issues intersect

Not surprisingly, at times throughout the pandemic, some of the public health decisions that were required had public policy implications. Sequencing guidelines is one example where public health and public policy issues intersected. Going forward, it will be important to ensure that there is a shared understanding between federal/provincial/territorial Ministers, the Public Health Agency of Canada and Health Canada, as well as central agencies, of decision making roles, processes and timelines in emergency situations.

Look for opportunities to streamline briefings and meetings involving senior management

During the pandemic response, senior managers were immersed in a myriad of briefings and meetings for various existing and new structures (known internally as the Executive Business Cycle). In some cases, the number of briefings and meetings was higher than expected.

For instance, from May 1 to December 24, 2009 (171 calendar days), eight of the Public Health Agency senior managers very involved in the response attended a total of 1,030 meetings and briefings. The situation was similar for Health Canada senior managers. Four types of pandemic-specific meetings required the most involvement of senior managers:

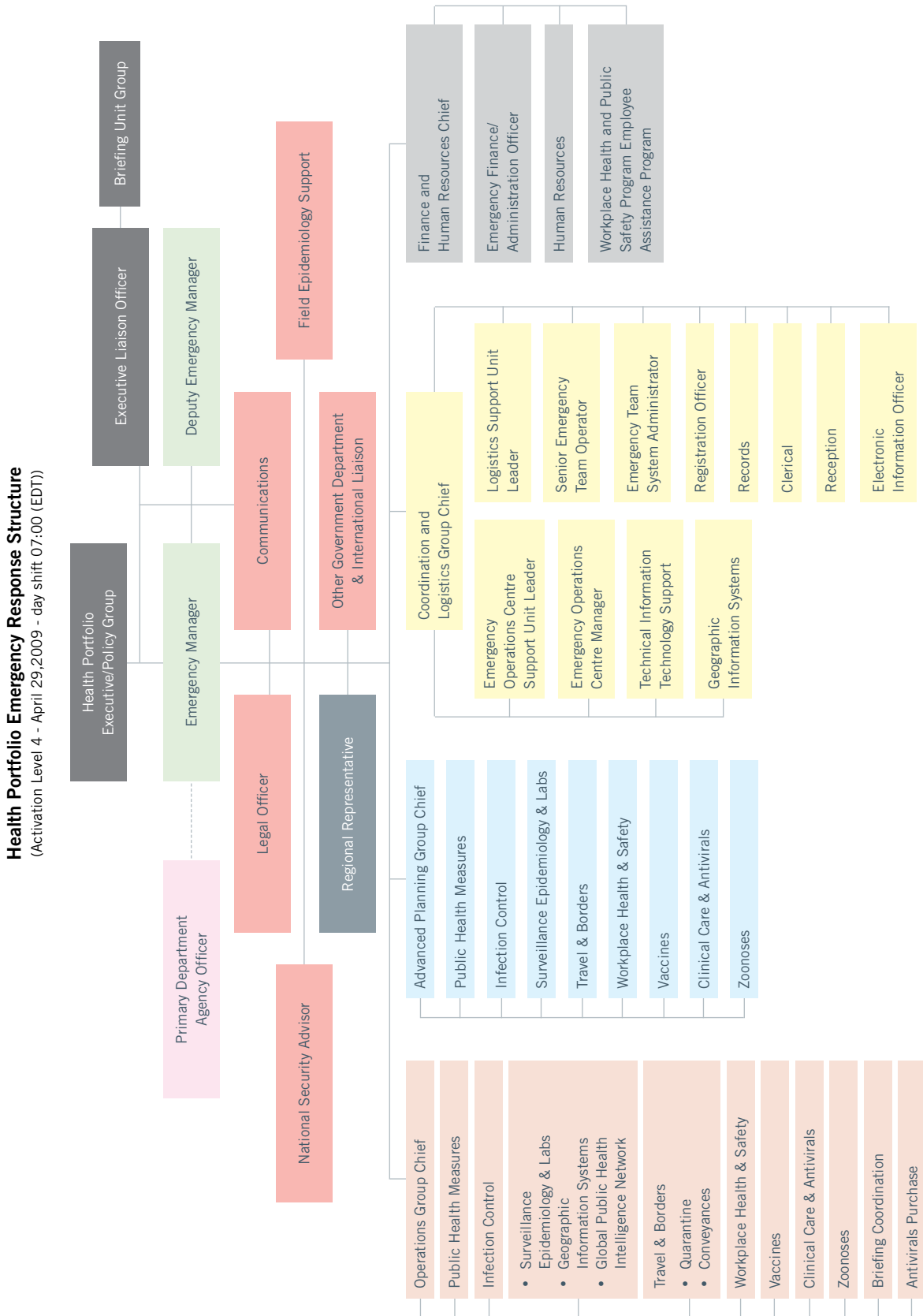
- Health Portfolio Executive Group (141 meetings)
- Minister of Health's Office (94 briefings)
- Federal/provincial/territorial Special Advisory Committee (74 meetings)
- "Four Corners," which included the Public Health Agency of Canada and Health Canada senior managers, the Minister of Health's Office, the Privy Council Office, the Prime Minister's Office, Public Safety Canada and the Minister of Public Safety's Office (71 meetings).

It is important to note that significant infrastructure is required to manage and maintain the Executive Business Cycle (e.g. scheduling, preparation of agendas and records of decision, development of briefing materials). The daily schedule was packed and the timing between meetings/calls was often very tight. There seemed to be good systems in place for agendas and records of meeting discussions and decisions; however, there is room to improve on being clear up front on the precise purpose of the meeting and specific agenda topics of the various teleconferences and meetings. This effort will assist in determining which senior manager or technical expert is best suited, and required, to attend. Attempts should continue to be made to reduce the burden of calls and meetings on senior managers, to the extent possible.

Senior managers still needed to attend regular meetings that were not pandemic-specific. One example is “Daily Update”, which is an ongoing forum for Public Health Agency senior management discussion and decision making concerning issues that pose significant risk to the health of Canadians, or other risks to the Minister, the Public Health Agency of Canada or its employees. There were 153 Daily Update meetings during the same time period.

The number of meetings and briefings peaked during the height of vaccine discussions in October 2009.

FIGURE 3.9.2 Example of the Incident Management System



In addition, Health Portfolio senior managers prepared H1N1 briefings for the House of Commons Standing Committee on Health and participated on calls with Committee members. The Committee held a total of 13 meetings under the topic of “H1N1 Preparedness and Response” between August 12 and November 25, 2009. The meetings started with two ministerial appearances in the summer of 2009 (the House of Commons was on summer recess). Canada’s Chief Public Health Officer appeared as a witness on both occasions. Most of the meetings were used as general briefings for Committee members. Senior officials from the Public Health Agency of Canada and Health Canada would typically appear for one hour, give an overview of activities of the last week, and then answer questions from members. In total, Public Health Agency officials appeared on nine occasions.

There were also 27 briefings with Opposition critics. Members of Parliament also visited the Health Portfolio Emergency Operations Centre.

Based on the H1N1 experience, as well as other recent significant public health events (such as the 2008 listeriosis outbreak), the Public Health Agency of Canada and Health Canada should prepare for intense briefing requirements. In the future, consideration should also be given to possible streamlining and simplification of the briefing process. In addition, a liaison function should be put in place to ensure that a senior advisor is assigned to each senior manager at all key meetings to ensure post-meeting information sharing and briefing, as well as follow-up on action items arising out of meetings. The consistency and continuity of this kind of support to senior managers is essential.

Continue to distinguish roles and responsibilities among the Public Health Agency of Canada’s senior executives

The independent investigator into the 2008 listeriosis outbreak recommended that an Associate Deputy Minister position be created at the Public Health Agency of Canada to act as the second-in-command and assume a Chief Operating Officer role “*to allow the Chief Public Health Officer to focus on his executive duties and responsibilities as the lead health professional of the Government of Canada in relation to public health.*”⁶⁹ An Associate Deputy Minister was assigned to the Public Health Agency of Canada in September 2009 and this helped to support the response to the second wave.

An event like the H1N1 pandemic demands, to some extent, the time and attention of all senior managers: Chief Public Health Officer (Deputy Head), Associate Deputy Minister (sometimes referred to the Executive Vice-President and Chief Operating Officer), Senior Assistant Deputy Minister of the Programs Sector (to whom the Assistant Deputy Minister of Infectious Disease Prevention and Control reports), and Assistant Deputy Minister of Emergency Management and Corporate Affairs (staffed as of June 2010). With these positions in place, it continues to be important that stakeholders and staff clearly understand the roles of the members of the senior executive group during significant public health events.

In addition, further clarity is needed on the respective roles of the Director General of the Centre for Emergency Preparedness and Response and the Director General of the Centre for Immunization and Respiratory Infectious Diseases during a pandemic. This leads into the next point.

Distinguish roles and responsibilities within the Public Health Agency of Canada between the emergency management and the operations groups

Roles and responsibilities were sometimes blurred among various functions within the Public Health Agency of Canada, such as emergency management and the operational group (in this case, immunization and respiratory diseases). Given the requirement for timely and informed decisions, the operational group often provided key input into the decision-making process; however, this involvement had the potential to cause the perception of encroachment on the roles and responsibilities of emergency management and to affect working relationships and staff morale. Therefore, clear roles and responsibilities should be assigned with an explicit delineation between the emergency management and operational/program parts of the pandemic response. A formal decision-making process should be followed at all times.

Corporate support during significant public health events

Put mechanisms in place to ensure responsiveness of the Public Health Agency of Canada's corporate services

Some pandemic response activities were affected by a lack of sufficient capacity in a variety of internal corporate services such as human resources, procurement, accommodations, facilities management, personnel security screening, information management/information technology, executive correspondence, and janitorial and catering services. Work should be done to improve the responsiveness of corporate support at times when the Public Health Agency of Canada is called on to address significant public health events.

Pay particular attention to policies, plans and procedures for human resources management

As employees are at the heart of the response to any public health event, a standardized, yet flexible, model for managing human resources during emergencies is critical. This effort includes rapid and sustainable capacity management (identifying, mobilizing and demobilizing staff). The *Health Portfolio Emergency Response Plan* outlines some human resources management responsibilities, including:

- providing advice on staffing, hours worked, leave, standby, deployment, overtime, childcare entitlements, management of stress and right to refuse dangerous work during an emergency
- hiring casual or temporary staff as required
- tracking time of personnel involved
- processing claims for compensation
- arranging for Employee Assistance Program services
- arranging for employee crisis intervention and counselling, as needed.

The Public Health Agency of Canada's Human Resources Directorate, which had experienced many changes prior to the onset of the pandemic, was understaffed. When the need to significantly increase Public Health Agency capacity became apparent during the pandemic, the Human Resources Directorate was not initially able to provide services such as staffing support in a timely fashion.

Through the course of the pandemic, the Public Health Agency of Canada's Human Resources Directorate capacity did improve and provided important supports to the response, including:

- making sure that the working conditions of Public Health Agency employees were respected and that deployed employees were covered with the necessary protection and insurance
- consulting with union representatives and collective bargaining agents
- negotiating agreements with the Public Service Commission for expedited hiring processes.

These Human Resources Directorate contributions were essential and should be considered in the planning of human resources management for future pandemic responses.

The Public Health Agency of Canada is currently implementing an overarching People Management Framework that includes an emphasis on emergency/event human resources management. A number of important areas should be considered, including:

- sources for surge capacity, including within the Health Portfolio
- succession planning (including senior executives, as well as medical and technical experts)
- identification of essential, critical and key positions
- tracking of financial expenditures (for preparedness or response activities)
- shift work capacity
- consultation with unions
- employee assistance programming
- insurance providers.



4. SUMMARY AND RECOMMENDATIONS

Summary of what worked well

It is important to acknowledge up front that Public Health Agency of Canada and Health Canada staff worked extremely hard during the pandemic. They demonstrated profound professionalism and commitment. Their dedication to anticipating and responding to the needs of Canadians was admirable.

Overall, the response of the Health Portfolio to the H1N1 pandemic is considered to have been effective. Critical federal building blocks for the response had been established prior to the pandemic, including the creation of the Public Health Agency of Canada, the appointment of a Chief Public Health Officer, the existence of the National Microbiology Laboratory, the establishment of a Pandemic Contingency reserve, as well as development of the *Federal Emergency Response Plan*, the *Health Portfolio Emergency Response Plan* and a Health Portfolio Emergency Operations Centre. Key situational awareness tools such as the Global Public Health Intelligence Network were also up and running. Mechanisms for provincial/territorial collaboration were also in place, such as the Conference of Deputy Ministers of Health, the Pan-Canadian Public Health Network, the Council of Chief Medical Officers of Health, the Canadian Public Health Laboratory Network, and the *Canadian Pandemic Influenza Plan for the Health Sector*. Collaboration with other countries was aided by relationships and plans already in place, such as the *North American Plan for Avian and Pandemic Influenza*.

In addition to these key structures, resources, relationships, plans and tools already in place, many important successes were identified in all aspects of the Health Portfolio's pandemic response.

On the science side, pandemic influenza is difficult to predict. Responses must be tailored as knowledge evolves about the characteristics of the virus. At the very outset of the pandemic, the Public Health Agency of Canada was instrumental in achieving a better understanding of the virus that emerged in Mexico and its impact on populations around the world. The National Microbiology Laboratory was called on for laboratory assistance during the early stages of the pandemic and five Public Health Agency scientists assisted with testing in Mexico over the course of six weeks. Due to the National Microbiology Laboratory's work, Canada was the first country to characterize the entire genomic sequence of the pandemic H1N1 influenza virus. This made a significant contribution to international scientific understanding of this novel strain.

In terms of regulation, Health Canada expedited the approval of the H1N1 vaccine, working closely with the manufacturer in advance of the pandemic to identify safety information and data. Science, policy and regulatory experts adjusted scientific and regulatory processes to address the uniqueness of the H1N1 pandemic situation. Although processes were expedited, no shortcuts were taken that would compromise the safety of Canadians.

As key players on the international scene, Health Canada and the Public Health Agency of Canada held ongoing exchanges with Canada's main partners including the United States and Mexico. Throughout the H1N1 pandemic, there was also close collaboration with the World Health Organization, the Pan American Health Organization, the Global Health Security Initiative and other international organizations.

SUMMARY AND RECOMMENDATIONS

The Health Portfolio worked closely with provinces and territories and established a response structure for managing the H1N1 pandemic, building on existing mechanisms and adding new structures to respond to emerging issues as understanding of the pandemic, and the required response, evolved. For the most part, federal and provincial/territorial governments created a transparent, cooperative working environment. A significant collaborative activity was the development of guidance documents on various topics for various audiences (e.g. clinicians, surveillance specialists, laboratory scientists, public event organizers, schools, daycares, post-secondary institutions and camps).

Great benefits were derived from advance pandemic planning. Establishing a 10-year contract with a domestic manufacturer in 2001 helped to ensure timely access to a safe and effective vaccine during the pandemic. Canada's immunization rate was the second highest in the world, with almost half of our population vaccinated. Having the National Emergency Stockpile System and National Antiviral Stockpile in place enabled the provinces and territories to distribute antivirals and medical supplies quickly.

In terms of addressing the needs of on-reserve First Nation communities, many communities had pandemic plans in place and vaccination clinics on reserves resulted in high rates of immunization. Following some initial challenges, there was good cooperation among Health Canada, the provinces and First Nations leadership.

The Public Health Agency of Canada and Health Canada also understood the importance of timely, clear communication with the Canadian public during the pandemic. Key spokespeople, like the Minister of Health and the Chief Public Health Officer, were visible throughout the pandemic. Coordinated communication activities were encouraged among federal and provincial/territorial governments. Infection control practices instilled during this time generated the added benefit of reducing the impact of all infectious diseases.

The involvement of all stakeholders was crucial. Information about the pandemic was provided using a variety of engagement mechanisms with health professional associations, national Aboriginal organizations, the private sector, emergency response organizations, organizations representing at-risk populations and organized labour. Members of Canada's influenza academic research community were engaged through a Science Advisory Committee.

Cross-cutting recommendations for action required

Notwithstanding these strengths of the Health Portfolio response, lessons were learned and improvements are required. This Review identified 34 areas for action across the nine elements of pandemic response examined. The areas of action can be clustered into three overarching recommendations for improvements (see Figure 4.1). The first recommendation is specific to pandemic preparedness and response capacity; it demands federal and provincial/territorial collaboration. The second recommendation is federally oriented and deals with emergency management. The scope of the third recommendation is limited to the Public Health Agency of Canada and Health Canada, and focuses on strengthening science-based communications.

Pandemic preparedness and response capacity

The federal government, along with provincial/territorial partners, has made significant investments in building pandemic preparedness and response capacity over many years. In 2006, after extensive dialogue and collaboration, the federal, provincial and territorial governments approved the *Canadian Pandemic Influenza Plan for the Health Sector*. The *Plan* provides a broad, national-level framework for a collaborative response to pandemic influenza in Canada and aims to establish the roles and responsibilities of the Public Health Agency of Canada, Health Canada, the provinces and territories during a pandemic.

There is no doubt that this advance planning paid off, allowing a collaborative approach for the response to H1N1. However, challenges arose when implementing the national *Plan*. The *Plan* should be updated to address these challenges.

When assessing the *Plan* in light of H1N1, it is apparent that it was based on, minimally, a moderately severe scenario where *“in the absence of a pandemic vaccine and antivirals, it is estimated that between 15 and 35 percent of Canadians could become ill, 34,000 to 138,000 individuals may need to be hospitalized, and between 11,000 and 58,000 deaths could occur.”*⁷⁰ This scenario did not reflect what happened on the ground during the H1N1 pandemic. Federal/provincial/territorial partners need to examine the foundation of the *Plan* to ensure that all potential scenarios have been considered, including one potential scenario where the virus spreads quickly but the levels of morbidity and mortality are below moderately severe. Therefore, activities and responsibilities for all partners can be adjusted accordingly.

Success hinges on confidence in the *Plan* itself and the process used to develop it. Consultations with all relevant parties should be an integral component of this review. Within the federal sphere, this includes corporate support services within the Health Portfolio as well as staff in central agencies.

Clearer governance structures and decision-making processes should be communicated to advisory groups. Governance structures should be agreed to and in place so they can be implemented immediately in any future pandemic. This would provide clarity in roles and responsibilities and a more streamlined decision-making and approvals process.

Some provinces and territories appear to have high expectations of public health leadership for the Public Health Agency of Canada, specifically regarding the provision of guidance documents, including clinical guidance to front-line workers. Collaborating with all partners that have a role in the development of guidance is crucial for these documents to be available when needed by their target audiences in a format that is accessible, understandable and available. Enhanced collaboration will also lead to a reduction in varying messaging, often deemed confusing to Canadians and specific stakeholders, such as front-line health care workers.

Another very important consideration is the finalization and implementation of data-sharing agreements with provinces and territories. It is also important to clarify, in advance of a communicable disease emergency, roles and responsibilities at all levels of government pertaining to services provided to First Nations people living on a reserve.

RECOMMENDATION 1

Further strengthen federal/provincial/territorial capacity to prepare for and respond to pandemic influenza.

- Update the *Canadian Pandemic Influenza Plan for the Health Sector* with a particular focus on:
 - adaptability and scalability to different pandemic scenarios
 - efficiency and effectiveness of governance structures (i.e. roles and responsibilities of all partners, composition of committees/groups, as well as accompanying decision-making and approval processes)
 - collaborative processes to develop and strengthen guidance documents to ensure availability, accessibility and consistency of messaging
 - finalization and implementation of data-sharing agreements with provinces and territories.

Emergency management

Under the *Emergency Management Act* (2007), section 6(1), all Ministers accountable to Parliament for a government institution are responsible for identifying the risks that are within or related to their area of responsibility, including those linked to critical infrastructure, and to do the following in accordance with the policies, programs and other measures established by the Minister of Public Safety:

- prepare emergency management plans
- maintain, test and implement those plans
- conduct exercises and training in relation to those plans.

The Health Portfolio prepared a *Health Portfolio Emergency Response Plan* that describes the high-level roles and responsibilities of the Public Health Agency of Canada and Health Canada. A draft of this *Plan* was revised and approved in the midst of the pandemic in September 2009 (although certain annexes still require completion). The Health Portfolio should update the *Plan*, taking into account lessons learned from the entire H1N1 experience, as well as recent guidance on emergency management planning from Public Safety Canada.

The Health Portfolio did prepare a draft *Health Portfolio Emergency Response Policy* in 2007, which identifies the emergency response roles and responsibilities of organizational units and regions within the Public Health Agency of Canada and Health Canada. The *Policy* has not yet been finalized and approved.

It should be noted that a Public Health Agency lessons learned review in December 2008 following the listeriosis outbreak also recommended that the *Health Portfolio Emergency Response Plan* and related *Policy* be finalized and approved.⁷¹

SUMMARY AND RECOMMENDATIONS

The *Health Portfolio Emergency Response Plan* needs to reflect the reality of the governance and operational management structures. More specifically, it should ensure the linkages are clear between Health Portfolio management of a public health event and Public Safety Canada's government-wide emergency coordination. Furthermore, it should include a description of the roles and responsibilities of the Minister's Office, central agencies and members of Parliament, and attempt to anticipate their briefing requirements.

The *Health Portfolio Emergency Response Policy* should describe the specific roles of strategic policy, communications, operational/program groups and regional offices, as well as outline the type of support expected from corporate services. The sustainability of emergency response services and business continuity are dependent on the support of corporate services.

More work should also be done in the *Health Portfolio Emergency Response Plan* on activation and escalation standards to ensure that they are commensurate with the severity of an event.

Once the science of the H1N1 virus emerged, the implications for the Health Portfolio's human resources demands became increasingly clear and "*the response morphed into a marathon, rather than a sprint.*" It is critical that the *Health Portfolio Emergency Response Plan* contain principles and procedures for ensuring the sustainability of response with sufficient surge capacity.

Regular orientation and training on the *Emergency Response Plan* and related *Policy* should take place with Health Portfolio employees, as well as staff from the Minister's Office and central agencies (as appropriate), to ensure a shared understanding of structures, roles and responsibilities, and decision-making and approval processes.

One type of required training is emergency simulations. The Health Portfolio has never experienced a "no notice" test and should consider the feasibility of an unanticipated simulation to test for preparedness and to practise various types of response scenarios. These types of simulations, however, are resource intensive and logistically challenging. Therefore, the Health Portfolio should continue to leverage real-life events as training opportunities. 'Tabletop' exercises with Health Portfolio management, as well as staff from the Minister's Office and central agencies, should also be considered.

Finally, the Health Portfolio should consider a more integrated approach to lessons learned exercises as noted in the June 2010 Public Health Agency of Canada's *Audit Report on Emergency Preparedness and Response*.⁷² There was a great deal of disciplined reflection by many organizational units throughout and following the H1N1 experience. This was in the form of after-action/after-event reports, 'hotwashes', post mortems, and other types of formal and informal studies and assessments. Organizational units should be commended for this important work. However, it would be beneficial to have mechanisms in place for:

- taking a more standardized approach to completing these reviews
- sharing reviews across organizational units
- synthesizing patterns of lessons learned to brief senior management and to ensure that lessons learned are also applied at a corporate level
- monitoring the implementation of recommended improvements
- archiving all reviews in a central repository so they are easily accessible for future reference.

RECOMMENDATION 2

Continue to clarify, communicate and test federal emergency management roles, responsibilities and mechanisms, with particular attention to sustainability of response capacity and decision-making roles.

- Finalize the *Health Portfolio Emergency Response Policy* and update the *Health Portfolio Emergency Response Plan* with attention to:
 - decision-making roles and responsibilities and accompanying approval processes/timelines
 - activation and escalation standards commensurate with the severity of an event
 - principles and procedures for ensuring the sustainability of response with sufficient surge capacity.
- Continue to orient and train on emergency management.
- Consider a more integrated approach to lessons learned exercises.

Communicating science

The Public Health Agency of Canada and Health Canada are both organizations whose business is based on scientific knowledge. In a period of health crisis such as a pandemic, scientific knowledge should be the key factor in decision making. But communicating science-based suggestions to decision makers and then the science-based decisions to a variety of audiences (such as other federal government departments and central agencies, provinces and territories, stakeholders, the Canadian public, as well as the media) is a challenge that requires preparation prior to activating and escalating a pandemic response.

COMMUNICATING UNCERTAINTY

The Public Health Agency of Canada and Health Canada need to work on how to describe uncertainty, clearly state options and provide justification for decisions taken. As science-based organizations, there are a number of times when communication will have to focus on not knowing the response but at the same time instilling confidence in the general population that the government is capable of responding.

People think you don't know what you are doing and you're changing your mind when in fact you knew full well at the start that the data will dictate, in the end, what the recommendations are ... (it's) having people sensitized to that certain level of uncertainty and risk' — maintaining confidence while in the face of uncertainty.

COMMUNICATING RISK

The Science Advisory Committee believes that the pandemic's risk may have been overstated and suggests that, in the future, science and research may want to focus more on firmly determining a pandemic's virulence before communicating it to the public. However, it is important to state that any future pandemic will take place in a multisource environment and therefore a wait-and-see approach may not be the best one to take with the general public. They will get their information from another government source, be it within Canada or externally — such as the United States or from the World Health Organization — or from social media sources, which may not provide accurate information or assessments of the situation.

Instead, there is a need to plan for different scales of pandemic response, dependent on the severity of the virus but recognizing that, even when there is a lower risk of morbidity and mortality with certain strains of a pandemic influenza, there will always be tragic cases that may move public opinion and therefore must be accounted for in a low-risk pandemic situation. As one interviewee said, *“If you were more brutal in your assessment of who was at risk, more Canadians would have seen themselves NOT at risk.”*

The majority of communication activities targeted the general population with guidance for specific populations coming later in the process. While a broad communications strategy is essential in keeping Canadians informed, a more targeted approach may also be necessary to ensure higher-risk populations receive timely and specific information necessary to respond to the pandemic. This approach should examine both message and mode of transmission (social media as well as traditional sources of information such as television, print or from trusted sources such as health professionals).

COMMUNICATING SHIFTS IN SCIENTIFIC KNOWLEDGE

The Public Health Agency of Canada needs to continue to be mindful that decisions may change as the science evolves. As discussed earlier, initial communications were based on a different type of virus. As the science evolved, communications were adjusted. One senior manager stated:

You could give them your best educated — more than a guess — prognosis, but that science was shifting as the pandemic was unfolding and, if science shifted, that didn't mean there had been a mistake at the front end. They saw a change in the context as either a mistake or a failure to predict. As distinct from a molecular — literally — shift.

The problem of communicating uncertainty, risk and shifts in scientific thinking is not limited to the Canadian public or other external stakeholders. It is also problematic when communicating findings, evidence and processes to decision makers and decision influencers (such as central agencies within the federal government) to ensure approval of messages to be communicated to the general public.

Making health science and the uncertainty linked to the basic scientific process easy to understand for the general public should be an important task for both organizations. Audience-specific learning tools should be available and disseminated prior to any emergency to accelerate decision making and to ensure that the rationale behind decisions about public health measures is understood.

RECOMMENDATION 3

Improve the Health Portfolio's ability to communicate science to various audiences.

- Develop plain-language approaches to convey complex scientific findings, processes, uncertainties, risks and shifts for various audiences/purposes, including:
 - Health Portfolio staff, in areas such as policy, program, communications and operations
 - decision makers/decision influencers (senior management and central agencies)
 - stakeholders (health professional associations, national Aboriginal organizations, private sector, front-line health care workers, Federal Healthcare Partnership, emergency response organizations, organizations representing at-risk populations, organized labour for the health sector, academic researchers and institutions)
 - the media
 - the general public.
-

Next steps

Planning is a continuous process. The lessons learned from the experiences with the Severe Acute Respiratory Syndrome (SARS) outbreak and other public health significant events, such as the 2008 listeriosis outbreak, laid the groundwork for improvements in the Health Portfolio's pandemic response capacity. For H1N1, lessons learned from the first wave were applied to activities during the second wave. It is expected that the lessons learned from this Review will lead to an even more efficient and effective response to future pandemics and other significant public health events.

Immediate steps should be taken by the Public Health Agency of Canada and Health Canada to respond to the findings and recommendations in this report. Senior management should oversee the development, implementation and ongoing monitoring of a detailed action plan.

SUMMARY AND RECOMMENDATIONS

FIGURE 4.1 Areas for action and cross-cutting recommendations

CROSS-CUTTING RECOMMENDATIONS			
- 1 - Further strengthen federal/ provincial/territorial capacity to prepare for and respond to pandemic influenza	- 2 - Continue to clarify, communicate and test federal emergency management roles, responsibilities and mechanisms, with particular attention to sustainability of response capacity and decision-making roles	- 3 - Improve the Health Portfolio's ability to communicate science to various audiences	
AREAS FOR ACTION (n=34)	RECOMMENDATION		
	1	2	3
1. Surveillance, science and research			
1.a Finalize agreements on sharing surveillance information across jurisdictions	✓		
1.b Consider options to ensure that appropriate mechanisms exist to facilitate the rapid conduct of critical research		✓	
1.c Refine approaches for translating scientific knowledge into information useful for planning, decision-making, and communications			✓
2. Collaboration with provinces and territories			
2.a Continue to work with provincial and territorial partners to review and streamline the federal/provincial/territorial governance structure for pandemic influenza	✓		
2.b Clarify and communicate the roles and responsibilities of the various advisory groups within the pandemic governance structure	✓		
2.c Clarify decision-making processes during a pandemic and communicate them to expert or advisory groups	✓		
3. Guidance			
3.a Clarify the federal role in developing clinical guidance	✓		
3.b Formalize an expedited approval process for guidance documents	✓		
3.c Fill gaps in existing guidance	✓		
3.d Use appropriate language and formats for guidance documents			✓
4. Stakeholder engagement			
4.a Increase multi-jurisdictional coordination of information for stakeholder groups	✓		
4.b Enhance capacity to anticipate and respond to issues raised by all stakeholder groups	✓		
4.c Support development of guidance documents for health professionals	✓		
4.d Review Health Portfolio management of international relationships	✓		
5. Communicating with Canadians			
5.a Improve consistency of information communicated to Canadians across different jurisdictions	✓		
5.b Review strategies to communicate uncertainty, risks and shifts in scientific knowledge in order to build public trust			✓

SUMMARY AND RECOMMENDATIONS

FIGURE 4.1 Areas for action and cross-cutting recommendations (con't)

AREAS FOR ACTION (n=34)		RECOMMENDATION		
		1	2	3
6. Federal response in on-reserve First Nation communities				
6.a	Develop guidance on the logistical aspects of implementing pandemic plans	✓		
6.b	Ensure timely availability of public health guidance for First Nation communities	✓		
6.c	Respond to local issues by using regional spokespeople	✓		
6.d	Address barriers for the movement of health professionals during a public health event	✓		
7. Emergency stockpile				
7.a	Review the National Emergency Stockpile System and the National Antiviral Stockpile in light of the H1N1 experience	✓		
7.b	Consider options for prescribing and dispensing antivirals in remote and isolated communities during a pandemic	✓		
7.c	Seek authority to donate stockpile supplies to other countries	✓		
8. Vaccine				
8.a	Implement an integrated surveillance system for immunization, including managing inventories, tracking vaccine uptake and monitoring adverse events	✓		
8.b	Review the approach for federal delivery of vaccines to provinces and territories	✓		
8.c	Establish a permanent regulatory regime for future public health events	✓		
8.d	Effectively communicate regulatory processes and mechanisms			✓
9. Operational management				
<i>Governance during significant public health events</i>				
9.a	Examine the Incident Management System used in the Health Portfolio Emergency Operations Centre and adapt it for future responses		✓	
9.b	Develop a common understanding of the decision making process during an emergency when public health and public policy issues intersect		✓	
9.c	Look for opportunities to streamline briefings and meetings involving senior management		✓	
9.d	Continue to distinguish roles and responsibilities among the Public Health Agency of Canada's senior executives		✓	
9.e	Distinguish roles and responsibilities within the Public Health Agency of Canada between the emergency management and the operations groups		✓	
<i>Corporate support during significant public health events</i>				
9.f	Put mechanisms in place to ensure responsiveness of the Public Health Agency of Canada's corporate services		✓	
9.g	Pay particular attention to policies, plans and procedures for human resources management		✓	

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