COMMENTARY

Influenza Pandemic Planning and Performance in Canada, 2009

Alan P. Kendal, PhD,[1] Noni E. MacDonald, MD[2]

ABSTRACT

This commentary evaluates Canadian actions following identification of pH1N1 influenza virus in 2009. We also report on some international issues affecting vaccine manufacture, and compare pH1N1 influenza vaccination programs in several industrialized countries.

WHO's pandemic declaration was the trigger for Canada to take the following steps: 1) implement its sole source pandemic vaccine supply contract, 2) use an alternate, internationally-developed approach to authorize emergency use of adjuvant-containing vaccine not yet fully approved in Canada, 3) release stocks of antiviral, and 4) develop many health-related policies, through committees other than those normally used outside a pandemic. We note key successes and challenges in these steps, and suggest responses to two priority issues: first, improve planning for surges in demand for the clinical services that represent the main way in which severe disease impact was reduced, and second, establish from the outset of Public Health planning that immunization programs will phase use of vaccine in different target groups, as done elsewhere, reflecting realistic vaccine delivery rates and the likely early occurrence of the main epidemic wave.

Key words: Influenza pandemic; vaccines, health care delivery; disaster planning; antivirals; rural health

La traduction du résumé se trouve à la fin de l'article.

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This report covers key steps taken in Canada after pandemic H1N1 influenza (pH1N1) 2009 virus emerged, and describes vaccination programs in some other industrialized nations. We summarize Canadian successes and challenges, and propose solutions to two priorities.

US experts identified pH1N1 virus in April 2009 from cases in late March,[1] and retroactively linked it to community outbreaks in Mexico earlier in March.[2] Most Canadian cases that soon followed were mild, but clusters of severe cases occurred in several remote Aboriginal communities. Hospitalizations of younger people rather than the elderly occurred – unusual for influenza – and characterized this pandemic.[3-6] Those born prior to 1957 were largely spared because the pH1N1 2009 virus was more related to earlier, rather than recent, H1N1 strains.[7]

The World Health Organization's (WHO) declaration of a pandemic in mid-2009[8] stimulated countries to act. Canada's response was guided by the 2004 Canadian Pandemic Influenza Plan for the Health Sector.[9] All provinces and territories had jurisdictional pandemic plans, the completeness of which varied.

International aspects related to the Canadian response

When evaluating "lessons learned" from human cases of avian influenza in Hong Kong in 1997, influenza experts proposed that WHO facilitate agreements to expedite international detection of potential new pandemic strains.[10] International Health Regulations of 2005 now require such surveillance and reporting to WHO.[11] But, as noted above, identification of the first known cases of pH1N1 virus was delayed, potentially slowing vaccination efforts by a few weeks.

WHO's pandemic declaration legally triggered European authorization of pandemic influenza vaccines (including some with adjuvant, like Focetria™ and Pandemrix™) in September 2009, before full approval.[12,13] In October 2009, Canada similarly authorized Arepanrix™,[14] a Canadian-made vaccine like Pandemrix™. Regulatory agencies allowed this in the belief that *"the actual numbers of cases that require hospitalisation and deaths in the pandemic period is expected to be higher than the numbers seen in recent years for seasonal influenza"*.[12]

However, WHO guidelines in 2009 did not stipulate the need for evidence of severity with regard to a pandemic declaration.[15] Such inconsistency between criteria to declare a pandemic and criteria to authorize pandemic vaccine is undesirable. Various people have questioned the processes for issuing the pandemic declaration and recommendations for advance stockpiling of antiviral, as well as the precautionary purchases of large amounts of pandemic vaccines in 2009.[16] Had WHO maintained the language in its earlier guide that required *"evidence of severe impact in at least one population group"* before declaring a pandemic,[17] and had it achieved consensus that pH1N1 severity matched the assumption about impact

Author Affiliations

1. Adjunct Professor of Epidemiology, Rollins School of Public Health, Emory University, Atlanta, GA
2. Professor of Paediatrics, IWK Health Centre, Dalhousie University, Halifax, NS

Correspondence: Dr. Alan P. Kendal, 710-188 Douglas Street, Victoria, BC V8V 2P1, Tel/Fax: 250-383-2944, E-mail: kendal2@shaw.ca

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Table 1. Variation in pH1N1 Influenza Vaccination Programs in Selected Industrialized Countries

Vaccine Use	Australia	Canada	England	France	Sweden	US
Types and targets						
Adjuvant - egg grown	NO	All groups	All except egg allergy	>9 yrs, if no special vaccine risk	All groups	NO
Adjuvant-free - egg grown	All groups	Option in pregnancy	NO	Pregnancy, <10 yrs, transplants	NO	All, but some age restricted
Adjuvant-free, cell-culture	NO	NO	Egg allergy	Egg allergy	NO	NO
Live attenuated option	NO	NO	NO	NO	NO	2-49 yrs, x pregnant or high risk
Phases planned	YES	NO, but used (see comment 2)	YES	YES	YES	YES
Phase 1						
Front-line health staff	& social workers	YES	& social workers	& social workers	YES	YES
Pregnant women	YES	YES	YES, see comment 2	YES; <3 mo only if other risk	YES	YES
Children	Health risk, >9 yrs	All 6 mo to 4 yrs	Health risk, >6 mo	Caregivers of <3 yr. old	Health risk, >9 yrs	Health risk, & 6 mo to 4 yrs
Adults	Health risk	Health risk	Health risk	NO	Health risk	NO
Seniors	Health risk	NO	Health risk	NO	Health risk	NO
Aboriginal	YES	YES	NO	NO	NO	NO
Phase 2	Add 6 mo to 9 yrs	Add any who ask	Add healthy >6 mo to 5 yrs	Add all >6 mo to 18 yrs	Add all >6 mo to 18 yrs	Add all 5 yrs to <19 yrs Add Health risk 19-64 yrs
Later additions	Add any who ask			Add all >18 yrs	Add all >18 yrs	
Main vaccination sites						
GPs and specialists	Most vaccine	Not in first phase	Most vaccine	From Jan 2010	Most vaccine	Not in first phase
Public health clinics or new community sites		Most vaccine		Most vaccine		Most vaccine in 1st phase
Retail pharmacy & food stores					Shopping centres in phase 3	YES, when supply increased
Schools					YES	YES, especially with live vaccine
Notification of eligibility	Media	Media	From GP	Mailed voucher from government	Media	Media
Appointments	Some sites	Mainly not	Yes, at GPs	For target group, time window	Mainly not	Mainly not
Vaccine use, January 2010						
Approx. overall coverage (* = doses supplied as % population)	30%*	40%, see comment 3	20%*, see comment 3	10%*, see comment 2	>60%, see comment 2	25%
High priority coverage	Denominator unknown	Not known	45%; see comment 3	Denominator unknown	Not known	35%
Comments	1: See ref. 18	1: See text and refs. 23-25, 30, 43-45	1: See refs. 19,28	1: See ref. 27	1: See ref. 26	1: See refs. 21,29
	2: 2010 seasonal vaccine with pH1N1 will be free to extended high-risk groups	2: Vaccine for all planned; but priorities needed at first	2: Cell-grown vaccine optional on request in pregnancy	2: About 7 million, priority vaccinated by March	2: Data reported early January	2: Coverage varied 3X by jurisdiction
		3: Doses administered not reported nationally; range from 28% to about 55% reported in 3 locations referenced above	3: About 13 million doses distributed and 4 million in priority groups vaccinated by mid-January; estimate assumes all these were in Phase 1 priority group of 9 million			

Note: Data on programs and vaccine use were from refs. listed in comment 1, and personal communication from persons listed in the text and in acknowledgements. Local variations occurred and most programs included household caregivers/contacts of some high-priority groups.

used by vaccine regulators, there would be less concern about the scale of vaccine orders.[16]

WHO recommendations for pH1N1 2009 vaccine defined the virus strain composition. Each country determines its vaccination programs, and these varied considerably among industrialized countries (refs. 18-22, and Table 1).

By late January 2010, Canada and Sweden had offered vaccine universally and had enough doses to meet demand, largely because only a single dose proved necessary for most people. Canada has not published national vaccine uptake data. Final rates are about 28% to 55% where reported.[23-25] Sweden's coverage, as determined from a combination of vaccination and distribution reports, was

about 60% by January 2010.[26] Elsewhere, only specific priority groups were vaccinated, including at least some children and younger adults (including pregnant women), and health care workers. Vaccination rates, based on distribution for their total populations, were therefore lower at about 7-25% by the end of January 2010 (refs. 27-29, and personal communication (Dr. Greg Tannock, Burnet Institute, Melbourne, Australia, January and April 2010)). Coverage rates averaged 35% for target groups in the US.[29] Data were lacking on safety of adjuvant in pregnancy,[12] and Canada initiated production of a small supply of adjuvant-free vaccine. Delayed production necessitated importation of such vaccine, mainly from Australia.[30]

Global assessment of actual supply and use rates for different types of pH1N1 2009 vaccines would help future planning.

Planning and implementing Canada's response

Committees

Canada's Public Health response was led by the Public Health Agency of Canada (PHAC) through a Special Advisory Committee (SAC) for pH1N1 virus; SAC was comprised of Chief Medical Officers of Health from all provinces and territories. This committee reviewed and approved policies, including ones missing from the Pandemic Plan. Separate PHAC expert groups or consultants supported deliberations over pandemic issues such as vaccines, antiviral use, surveillance, infection control and communications. PHAC posted public documents approved by SAC, and other information from PHAC, on a website.[31]

The experts faced many challenges, including determining the amount of time patients should wait before returning to normal activities in the community. Lacking hard data on infectious periods, their interim precautionary recommendations in May and June 2009 were that patients should stay at home for 7 days after illness onset (documents archived). This could be problematic, especially for children feeling well after a few days. Updated advice in August 2009 was more practical; specifically, for most low-risk settings, patients should stay home until they are symptom-free and able to fully participate in daily activities.[32] Guidance for hospitals with regard to patient visitations appeared only in February 2010,[33] when pH1N1 activity had all but disappeared in Canada.

Work done by the committees to fill gaps existing before the pH1N1 pandemic will improve Canada's Influenza Pandemic Plan. Involving those Canadians most affected by the pH1N1 official guidance documents in evaluating the strengths and weaknesses of the recommendations therein should be of assistance to those revising the Plan.

Using ad hoc pandemic advisory groups in a future pandemic may not be the best use of Canada's limited number of experts. They could be overwhelmed by adding ever-increasing tasks to existing heavy professional responsibilities, and by fragmenting tasks that need integration. We noted the problem especially in how vaccination policies were developed in 2009. Although a Pandemic Task Group was responsible for drafting pandemic vaccine recommendations, the National Advisory Committee on Immunization (NACI) retained responsibility to make seasonal influenza vaccine recommendations.

The benefit of a separate process for pandemic vaccine recommendations is unclear and it complicated coordination with use of seasonal vaccine.[34] NACI is experienced in assessing influenza vaccine safety and performance, and in making recommendations even when scientific uncertainties exist. Canadian physicians and nurses normally receive and implement NACI's recommendations, which they appear to trust. Why not continue to use NACI to make integrated influenza vaccine recommendations in a pandemic, building on this committee's role? Other existing committees of professional societies and official advisory groups might be more efficient at preparing updated policy drafts in other complex areas, such as infection control practices.

Whatever committee system evolves, Canada currently does not involve active clinicians and administrators with primary responsibility for clinical health care delivery within the core national pandemic policy committee. Such experts would help ensure that clinical needs are fully considered, which was not the case in 2009 (see below).

Determining Disease Impact

PHAC determined impact by collating timely surveillance reports, and collecting standardized data about early cases, from all provinces and territories. They also collected an important subset of data about severe cases for analysis. However, the provinces and territories have not yet agreed collectively how to rapidly establish coordinated multi-jurisdictional field studies in an emergency, with quick data-sharing between different jurisdictions and unified analysis. Consequently, the attack rate with pH1N1 virus across Canada is not known, and we are only left with speculation about the causes for severity in remote Aboriginal populations.[35,36]

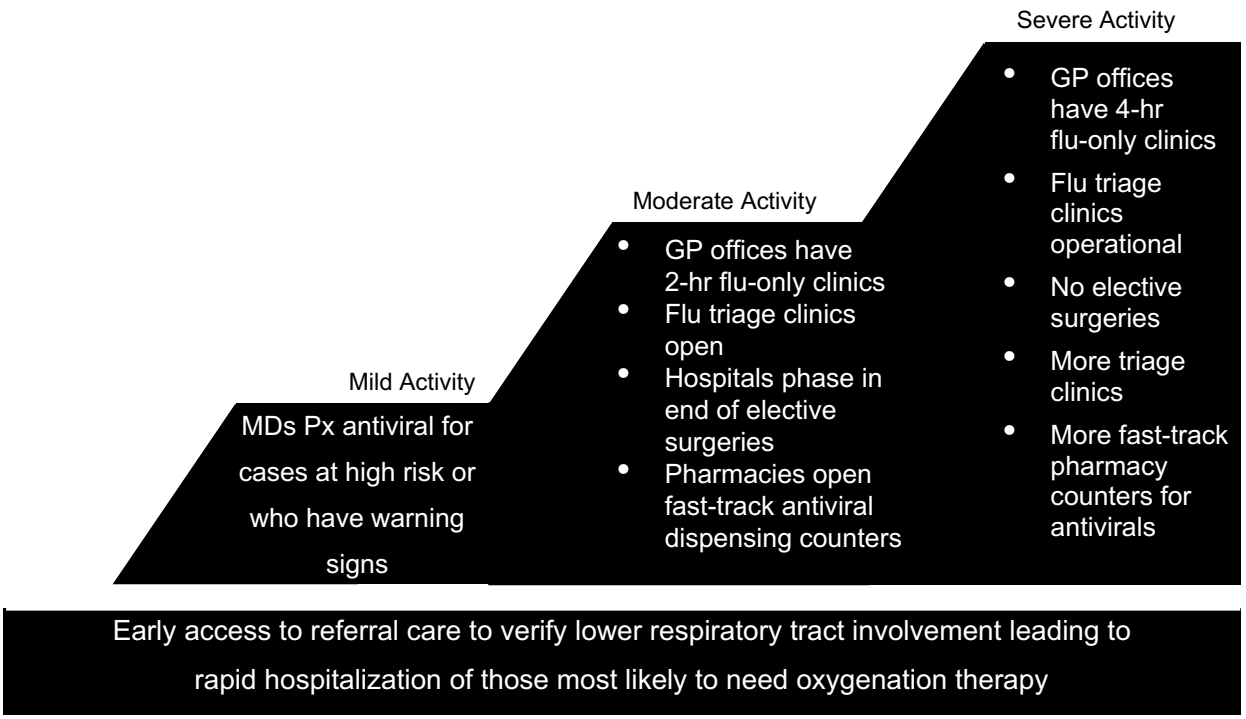
Clinical Care

Because vaccine was not initially available, clinical care was the main way to reduce the severity of cases in 2009. Intensive Care Units (ICUs) were the safety net for the most serious illness. Unfortunately, the National Pandemic Plan lacked many operational specifics about clinical care, and did not address the additional resources for increased use of clinical services and supplies, other than governmental stockpiling of antivirals.

Thus, while the national plan recognized that many patients with lung dysfunction might need treatment, improving the national ventilator supply was not addressed early on. Similarly, the Plan states: *"primary assessment should also include monitoring of oxygen saturation (e.g., pulse oximetry, arterial blood gases) whenever possible both at presentation, and routinely during subsequent care"* (Annex G, 3.2.1, ref. 9). But no funds were allocated to support purchase of extra pulse oximetry equipment. Many patients with uncomplicated illness went to Emergency Rooms instead of consulting their family physician, seeking antiviral or other treatment.[37] Unlike in the United Kingdom,[38] no national policies existed expediting access to antivirals.

In areas with high virus activity, ICUs came close to capacity, partially because of late diagnosis or antiviral treatment of patients to prevent severe disease.[35] Some health authorities opened triage sites and decreased the burden on emergency departments and physicians' offices (as suggested in the Canadian Pandemic Plan). Each jurisdiction had to develop their own approaches. Federal plans did not include costs of surges in consultations with physicians, pharmacy dispensing fees for the "free" antiviral supply, and extra hospital or triage clinics.

Figure 1. Scalable model scheme to identify and treat people with high-risk conditions or impaired respiratory function in a severe pandemic



Several key antiviral issues were not anticipated. Therefore, special authorization was needed for dispensing oseltamivir for <1 yr olds, a known high-risk age group.[39] Furthermore, the stockpile largely comprised adult doses, not paediatric capsules or liquid preparations. Health authorities gave out details of a cumbersome procedure to prepare paediatric suspensions at the approved dosages for infants <12 months, for older children when paediatric capsules were lacking, or for children refusing capsules.[40] Policies for access to antiviral in remote locations were also lacking. After reports of severe impact in remote Aboriginal communities, the latter became high-priority locations for use of early antiviral treatment. However, physicians to authorize antiviral use are usually scarce in isolated areas. Before the main pandemic wave occurred, BC developed a regulation and decision tool authorizing trained registered nurses to dispense oseltamivir in remote areas.[41]

Pandemic impact varies over time and geographic area. Had the elderly been susceptible to the pH1N1 virus, its impact would have been much greater. Thus, scalable models for increasing care in a pandemic are needed. Figure 1 provides a hypothetical model scheme, something lacking in the National Plan.

Vaccination

Officials in many countries – including Australia, Sweden, the UK and the US (Table 1) – anticipated limited vaccine supply by the time of the main pandemic wave and prioritized vaccine use. The United Kingdom's Chief Health Officer advised on July 1, 2009 that, *"as not all vaccine will be available immediately, there will inevitably be a need to prioritize the vaccination activity",*[42] and listed priorities shortly after.

Canada waited until mid-September 2009 before listing groups who might benefit most from vaccination, but still deferred recommending prioritization.[43] When Canada's first vaccine supplies became available in late October 2009, the second H1N1 wave was in progress.[22,25] The supply reached about 2 million doses per week (corresponding to about 6% of the total population), inadequate to noticeably dampen an epidemic in progress. Nevertheless, consistent with national policy, vaccine was initially offered universally in many jurisdictions, e.g., Ontario.[44] Some other jurisdictions prioritized use of the limited supply, e.g., NL,[45] – something which most provinces subsequently had to do for several weeks.

Other countries' plans for phased vaccine use (Table 1) appeared well suited to the low impact of pH1N1 2009 virus in older adults, the need for first vaccine use where it would do most good (assuming pandemic waves would occur early in winter), and the limited rate of vaccine supply.

By the end of the vaccination campaign, which was stimulated by media coverage of deaths in otherwise healthy children and

Table 2. Principles for Success in Pandemic Influenza Vaccination Program

Vaccine supply security: Consider more than one vaccine in case of manufacturing problems

Vaccine logistics: Seek vaccines with standard handling needs, e.g., good shelf life after opening

Goals: Set timelines to reach priority targets that match realistic rate of vaccine supply

Reaching families: Use trusted parts of health care system by involving family doctors

Reaching adults: Make vaccine available at after-working-hours sites (pharmacies, food store sites)

Reaching workers: Enable workers to access vaccine without using sick leave

Build trust: Present risk/benefit balance ethically, including unknowns, in consistent messages

Resources: Fund extra immunization/safety monitoring staff, and logistical costs (not just vaccine)

Table 3A. Successes in Canada's Planning for pH1N1 2009 Influenza Virus

Planning: Core aspects of Canada's National Plan set policy and helped procure vaccine
Virus detection: Modern diagnostic testing and enhanced surveillance were rapidly put in place
Remote communities: Lessons from early remote outbreaks improved interventions elsewhere
Behavioural changes: Handwashing and coughing "etiquette" appeared widely accepted
Clinical response: Skilled intensive care staff directly saved lives
Antiviral use: Oseltamivir available from the stockpile, and use in <1 yr olds quickly authorized
Vaccine supply: Advance work enabled authorization of adjuvant vaccine before epidemic peak
Vaccine utilization: Record immunization coverage in a short timeframe in many locations
Vaccine safety: Expanded rapid checks of vaccine adverse events, including in adults
Research: Important data quickly obtained from ICUs, and other research projects implemented

Table 3B. Challenges in Canada's Responses to pH1N1 2009 Influenza Virus

Policy development: Not reliably timely or practical enough for national health care emergency
Resources: Minimal federal support to meet surge in demand for clinical health care
Aboriginal communities: Lack of advance preparations for multiple severe disease outbreaks
Data on impact: No process for rapid national study in multiple jurisdictions
Antiviral use: Unprepared for large need for children, or ensuring early access in remote areas
Vaccination: Ambitious objectives did not conform to realities of supply and demand
Vaccine safety: Limited vaccine uptake data, needed to strengthen community adverse event analysis
Risk management: No independent analysis of Canada's plans as global data evolved

adults,[25] several locations achieved their highest-ever influenza vaccine coverage of about 40-60%.[23,24] This was not a universal finding, and Toronto's coverage of 28% was no better than usual.[25] Lack of a system to record the numbers and ages of people vaccinated in most locations prevents accurate national assessment of vaccine coverage. This can also reduce statistical confidence of some reported rates of severe adverse events.[46]

In Table 2, we suggest some lessons that may improve future distribution and use of pandemic vaccine. Lower-than-expected stability of Arepandrix™ vaccine[47] supports the idea that a second vaccine source is desirable, as the possibility of manufacturing problems can never be excluded. The ideal that at least some pandemic vaccine should be accessible in a timely manner to all countries also needs consideration.

Lessons learned and priorities for the future

Many notable successes occurred during the pH1N1 2009 pandemic (Table 3A). These include the apparent effectiveness of PHAC's campaign to improve personal hygienic practice of hand-washing, evidenced by the proliferation and use of hand sanitizers in the country; and a joint Federal-Provincial-First Nations effort to improve pH1N1 virus prevention and treatment in BC, which improved health care access for Aboriginal people.[48] Key challenges mentioned in this commentary are summarized in Table 3B. We have added reassessing risks and responses as knowledge of the pandemic grows, an especially important issue for multinational organizations.[16]

We suggest two key priorities for Canada to resolve, as they had such a dramatic impact on national response:

Priority 1: Better preparedness for surges in clinical services.

Cause of challenge in 2009: Limited stakeholder role for clinical health care representatives in core policy-setting groups.

Solution: Designate a "National Pandemic Health Care Committee" to plan emergency responses, including surging demand for both clinical and public health care services, and to ensure funding for increased staff and supply needs of both sectors.

Priority 2: Match vaccination policy with rate of supply.

Cause of challenge in 2009: Processes in the National Pandemic Plan did not result in properly estimated weekly vaccine supply, did not clearly state attainable disease prevention objectives for vaccination, or efficiently integrate seasonal and pandemic vaccinations.

Solution: Utilize National Advisory Committee on Immunization, with extra resources as needed, to assess risk and make recommendations about pandemic vaccination policies. Phase vaccine recommendations to maximize benefit of available vaccine, including consideration of school vaccination programs to reduce community spread.

CONCLUSIONS

Canada achieved many successes in 2009, but must not be complacent.[49] Lessons learned from any pandemic threat include the need to update risk-assessment and risk-management processes,[10] currently an important topic in terms of international guidance.[16] The specific questions to address in Canada when updating influenza pandemic preparedness plans include:

- What international steps will ensure urgent, modern diagnosis of disease outbreaks?
- Did Canadians find health policies in 2009 to be timely and effective for societal needs?
- How can Canada meet large surges in demand for primary and emergency clinical care?
- How can medical supplies, vaccines and antiviral be available quickly with low waste?
- Can jurisdictions agree on how to rapidly run joint field studies with centralized analysis?

Responses at the local level (e.g., Toronto[25]), as well as in places with generally similar approaches to health care delivery to those of Canada, should be reviewed, as we have done on a small scale concerning vaccinations. The UK government has already received a full, independent review of the response in 2009.[38] This is very relevant to Canada, especially as the UK now has 4 National Health Authorities with devolved responsibilities, like Canadian provinces in many ways.[38] The sooner Canada has its own independent

reviews, the sooner it can use the information to enhance Canadian preparedness.

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RÉSUMÉ

Ce commentaire évalue la réponse canadienne lors de l'apparition de la grippe pandémique H1N1 en 2009. On y trouve un compte rendu de quelques enjeux internationaux ayant influencé la fabrication du vaccin ainsi qu'une comparaison des programmes de vaccination contre la grippe pandémique H1N1 dans plusieurs pays industrialisés.

Au Canada, la déclaration de l'Organisation mondiale de la santé (OMS) confirmant une pandémie a été l'élément déclencheur pour amorcer les mesures suivantes : 1) Mettre en œuvre le contrat à fournisseur unique pour l'approvisionnement du vaccin pandémique; 2) Utiliser une approche de rechange, élaborée à l'international, pour autoriser l'utilisation urgente d'un vaccin avec adjuvant qui n'était pas encore complètement homologué au Canada; 3) Rendre disponible les médicaments antiviraux; et 4) Faire élaborer de nombreuses politiques en matière de santé par des comités différents de ceux habituellement utilisés lorsqu'il n'y a pas de pandémie.

Les auteurs décrivent les principaux succès et obstacles liés à ces mesures, et proposent des réponses à deux enjeux prioritaires : 1) Améliorer la planification des poussées soudaines de la demande de services cliniques, qui ont été la principale mesure permettant de diminuer les répercussions graves de la maladie; et 2) Décider, dès le début de la planification en santé publique, que les programmes de vaccination feront une utilisation échelonnée du vaccin pour différents groupes désignés. Cette mesure, utilisée ailleurs, tient compte des débits réalistes d'administration des vaccins et de la probabilité d'une apparition précoce de la principale vague épidémique.

Mots clés : pandémie d'influenza; vaccins, prestation des soins de santé; plan catastrophe; antiviraux; santé en zone rurale

Coming Events • Activités à venir

Nursing Leadership: So What? Now What?
2011 Nursing Leadership Conference
13-15 February 2011 — Montréal, QC
Contact:
www.cna-aiic.ca

Harm Reduction Canada 2011: A National Conference
Revisioning – Reconstructing – Refocusing
23-25 February 2011 — Ottawa, ON
Sponsored by CAST Canada
Contact: Tel: 705-749-6145
gt@cast-canada.ca — www.cast-canada.ca

The 5th National Community Health Nurses Conference
5e Conférence nationale des infirmières et infirmiers en santé communautaire
The Time is Now: Influence, Impacts, Outcomes
Le moment est arrivé : influence, effets, résultats
16-18 May/mai 2011 — Halifax, NS
Contact/contacter :
http://chnc.ca/

Public Health in Canada: Innovative Partnerships for Action
La santé publique au Canada : des partenariats novateurs en action
Canadian Public Health Association 2011 Annual Conference
Conférence annuelle 2011 de l'Association canadienne de santé publique
19-22 June/juin 2011 — Montreal, QC
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International Epidemiology Association
7-11 August 2011 — Edinburgh, Scotland
Contact:
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