Analysis of H1N1 Vaccine Policy In The Maritime Provinces

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H1N1…a Pandemic?

- A pandemic is a worldwide epidemic of a disease
- It does not necessarily mean mass fatalities
- Pandemic refers to how far across the globe the disease has spread, rather than its severity
- June 11, 2009, Dr. Margaret Chan

  "The world is now at the start of the 2009 influenza pandemic"

Canadian Pandemic Influenza Plan (CPIP)

- Pandemic contingency planning activities in Canada began in 1983
- latest plan, first published in February 2004
- one of several national emergency response plans
- intended to provide guidance and support planning at the P/T, regional, local and facility level
- Primary Goal: to minimize serious illness and overall deaths,
- Secondary Goal: to minimize societal disruption among Canadians as a result of an influenza pandemic

Vaccine Sequencing Recommendations
Those Who Will Benefit Most

- **Persons with chronic conditions (NACI list) under the age of 65**
  - ***Rationale**: at higher risk of complications; 65+ less affected to date, Canadian modeling suggests immunizing this group decreases population morbidity and mortality more than immunizing children (i.e. groups with highest attack rate)*
- **Pregnant women**
  - ***Rationale**: at highest risk of severe disease, and to potentially protect their infants*[1]
- **Children 6 months to less than 5 years of age**
  - ***Rationale:** Children 6-23 months of age are at particular risk of severe disease and hospitalisation and are the primary focus of this group. Children aged 2 years to less than 5 years of age were included within this group because: they are at higher risk of severe disease and hospitalisation than older children, and from a targeting perspective for operationalizing vaccine delivery the single category of 6 months to less than 5 years effectively captures all "pre-school" aged children.*

http://www.phac-aspc.gc.ca/alert-alerte/h1n1/vacc/vacc-eng.php

Vaccine Sequencing Recommendations
Those Who Will Benefit Most

- **Persons residing in remote and isolated settings or communities**
  - ***Rationale**: limited access to medical care, potential for development of mass immunity and prevention of infection, logistically easier to target whole community; equity, high concentration of persons with chronic conditions, observed morbidity/mortality in some remote Aboriginal communities*
- **Health care workers HCW (all health care system workers involved with the pandemic response or delivery of essential health services*)**
  - ***Rationale**: prevent HCW spread to vulnerable patients, prevent outbreaks, protect HCW (reciprocity) and protect essential health infrastructure. All health care workers involved with the pandemic response or delivery of essential health services: Those who provide direct patient care as well as those who support the provision of health care services*
    - *Includes full-time staff, part-time staff, students, regular visitors and volunteers i.e. all persons carrying out the health care function*
    - *Settings include acute care, chronic care, ambulatory/community care, emergency medical services, laboratory, public health departments, pharmacies etc.*
    - *Includes Canadian Blood Services/Héma Québec and vaccine manufacturers*
- **Household contacts and care providers of:**
  - **Infants <6 months of age**
  - **Persons who are immunocompromised**
  - ***Rationale**: indirect protection for persons at high risk who cannot be immunized or may not respond to vaccine*

Vaccine Sequencing Recommendations
Others Who Will Benefit From Immunization

- **Children 5 to 18 (inclusive) years of age**
  - ***Rationale**: high attack rates experienced by this age bracket would suggest they be considered a priority within this phase of immunization to possibly reduce transmission of the virus, children identified as a priority in public consultations*
- **First responders (police, firefighters)**
  - ***Rationale**: frequently attend emergency health situations with Emergency Medical Services (EMS)*
- **Poultry and Swine Workers**
  - ***Rationale**: to prevent opportunities for viral reassortment*
- **Adults 19 to 64 (inclusive) years of age**
  - ***Rationale**: increased risk of severe H1N1 disease*
- **Adults 65 years of age and over**
  - ***Rationale**: low attack rates, potential for reduced response to vaccine*

SOGC Recommendations for Vaccine

- **For pregnant women over 20 weeks gestation**
  - Get vaccinated against H1N1 as soon as a vaccine (adjuvanted or non-adjuvanted) is available.
- **For pregnant women under 20 weeks gestation**
  - If you are healthy, wait to receive the non-adjuvanted H1N1 vaccine
  - If you have a chronic health condition get vaccinated against H1N1 as soon as a vaccine (adjuvanted or non-adjuvanted) is available.
  - If you reside in an area where H1N1 flu rates are high or increasing, get vaccinated against H1N1 as soon as a vaccine (adjuvanted or non-adjuvanted) is available.
- PHAC guidelines differed, with a greater focus on non-adjuvanted vaccine for all pregnant women, unless there is a pressing need for immediate vaccination

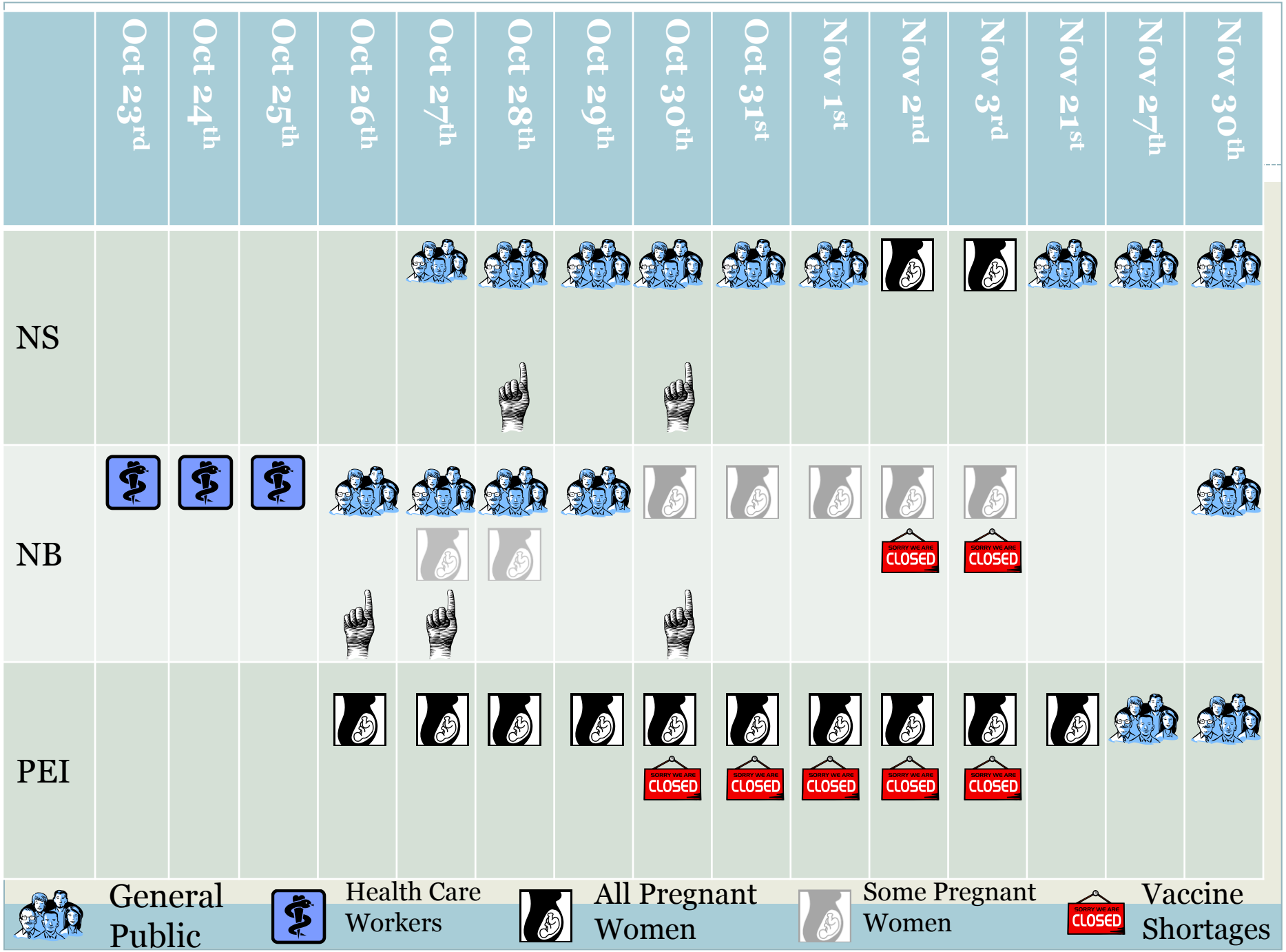
Adjuvant vs. non-Adjuvanted

- An adjuvant is a substance that helps stimulate the body's immune response
- The GSK (used in Canada) adjuvanted H1N1 vaccine is made of squalene (naturally occurring oil), water and vitamin E.
- Generally, flu vaccines in Canada do not contain an adjuvant
- Similar adjuvants have been used in other vaccines, particularly in Europe
- WHO reports both types of vaccine are safe

Adjuvanted vs. non-Adjuvanted

Considerations for Pregnant Women	Adjuvant H1N1 Vaccine	Non-Adjuvant H1N1 Vaccine
Amount of viral inoculate required to protect an individual	Lower dose (4 times less viral material than the non-adjuvanted vaccine)	Higher dose (4 times more viral material than the adjuvanted vaccine
Number of doses required to achieve immunity	1	1
Cross-protection against mutations of the virus	Possible	None

http://www.sogc.org/h1n1/H1N1AdjuvantVsNonAdjuvantVaccineENGFinal.pdf


Oct 23rd
Oct 24th
Oct 25th
Oct 26th
Oct 27th
Oct 28th
Oct 29th
Oct 30th
Oct 31st
Nov 1st
Nov 2nd
Nov 3rd
Nov 21st
Nov 27th
Nov 30th
NS
NB
PEI
SORRY WE ARE CLOSED
General Public
Health Care Workers
All Pregnant Women
Some Pregnant Women
Vaccine Shortages

General Comparison of three provinces

- NB and NS initially opened to general public, then asked people to follow priority groups sequencing, then mandated same
- NS more conservative with groups eligible to receive vaccine, many concerned as children were “left out”
- NB and PEI eventually had to close clinics
- Public concern in all three provinces cited examples from the two other maritime provinces
- No clear best plan

Canadian Pandemic Influenza Plan (CPIP) Ethical Framework

- The ethical principles guiding the CPIP framework are
  - Promote and protect public health
  - Ensure equity and distributive justice
  - Respect the inherent dignity of all persons
  - Use the least restrictive means
  - Optimize the risk benefit ratio
  - Work with transparency and accountability

Promote and protect public health

- Swift response to promote public health
  - Vaccine administration occurred in less time than predicted in CPIP documents
- Potential disadvantage for those not able to access a computer
  - Most accurate and up to date information available online
- In NS, Chief Health Officer addressed public directly through news outlets explaining rationale for priority groups
  - Often media reports were unclear or not specific, with the majority of quotes provided by lay public, resulting in heightened fear from the public

Ensure equity and distributive justice

- Although provinces and territories were responsible for determining who was eligible for vaccine, administration at different levels led to increased confusion and perceived delays
  - Differences between three provinces with very similar populations
  - Within individual provinces, variation between Health Authority administration of vaccine delivery resulted in confusion
- Given difference between provincial delivery dates and recommendations, cross border travel occurred
  - Those who live nearer borders had earlier access to vaccine by travelling to nearby provinces with more lenient or earlier vaccine administration

Ensure equity and distributive justice

- Clear rationale available for those chosen as priority group provided at national level
  - Confusion resulted as three different provinces interpreted these differently
- Challenges within the maritime provinces where one province chose to only immunize those who were greater than 20 weeks pregnant
  - Potential for prejudice against those not planning on continuing their pregnancy
  - Greatest risk was in second and third trimester of pregnancy

Respect the inherent dignity of all persons

- Rationale for administering vaccine to pregnant women clearly communicated the personal benefit to pregnant women in addition to potential harms
  - Avoided pregnant women being seen solely as a medium by which to vaccinate neonates
- Lack of rationale behind availability to First Nations populations resulted racist public outcry
  - Greater than 50% of some populations less than 20 years of age
  - Higher incidence of pregnancy within this population

Use the least restrictive means

- In NS, special clinics for pregnant women at IWK were helpful, alleviated the concerns of public with respect to waiting out in cold
  - Only ran for two days
- In general clinics were held in regionalized areas, to promote equal access
  - Constrains of personnel available to administer vaccines
  - Some regions overlooked, i.e. pregnant women in Yarmouth at a disadvantage
- The sequencing plan for administration of the vaccine often meant pregnant women would have to queue several times if they were caring for children or others in different at risk groups

Optimize the risk benefit ratio

- Great deal of confusion re: adjuvanted vs. non-adjuvanted vaccine
  - PHAC and SOGC moved very quickly to alleviate the concerns though publications on their websites
    - Unfortunately, the information they presented was not consistent
    - Improved communication could have occurred with media, as rationales for choices of vaccine were clearly articulated

Work with transparency and accountability

- Once again, PHAC and SOGC communicated quickly via their website
  - There were subtle differences between the recommendations these two organizations presented resulting in increased confusion
  - Unfortunately local media tended to focus on regional news and less on these sources of accurate information
  - Information provided was very technical, resulting in confusion for some

Work with transparency and accountability

- Chief Medical Officers could have more effectively communicated rationale for adjuvanted vs. non-adjuvanted vaccine
  - Similar to PHAC and SOGC, the inconsistency of the message presented resulted in confusion and public doubt
- A great deal of variability between clinics
  - How stringently recommendations were adhered to
    - In some clinics, those living with pregnant women immunized, not so in others

Summary

- Overall, pregnant populations well served by the vaccine sequencing strategies
  - They were, however, at risk of being confused by the inconsistencies seen in the “early days” of vaccine administration
- Given small sizes within provinces, a united front with respect to strategies might have alleviated “cross-border travel”
- Despite appearance of no clear direction by lay public, implementation closely followed plan outline previously by CPIP
  - Caveat being the initial plan to open immunization clinics to the general public and backtracking with respect to which vaccine was “best” for pregnant women