How new vaccines are introduced into programs & why programs differ across Canada

BC Centre for Disease Control
An agency of the Provincial Health Services Authority

Western Canada Immunization Forum

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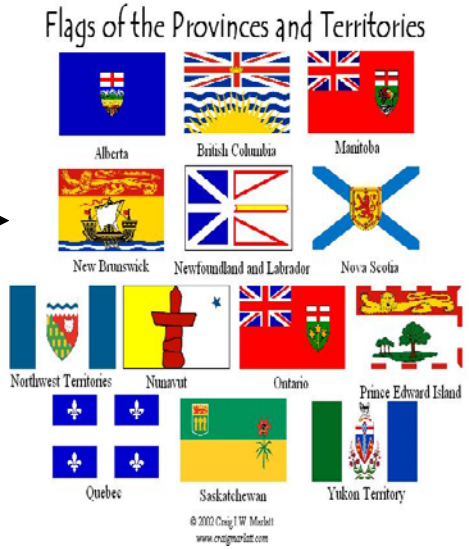
Conflicts of interest: I have no affiliation (financial or otherwise) with a commercial or other industry interest

Immunization program cycle

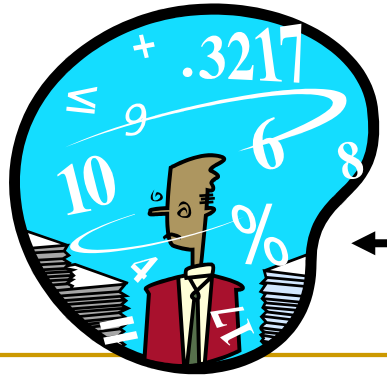
Manufacturer

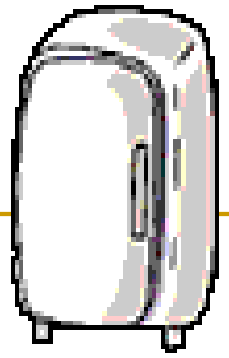
Health Canada and
Public Health Agency of Canada



Program planning and implementation

Program evaluation





Public Health Agency of Canada:

Recommendations for use of the vaccines- NACI

Surveillance of VPDs

Canada's commitments to international disease reduction and elimination goals

Public Health Agency of Canada
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National Advisory Committee on Immunization (NACI)

About NACI

NACI is a national advisory committee of experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and public health. The Committee reports to the Assistant Deputy Minister of Infectious Disease Prevention and Control, and works with staff of the Centre for Immunization and Respiratory Infectious Diseases of the Public Health Agency of Canada to provide ongoing and timely medical, scientific and public health advice.

NACI makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable diseases for whom vaccination should be targeted. NACI knowledge syntheses, analyses and recommendations on vaccine use in Canada are included in published literature reviews, statements and updates. NACI recommendations are also published in the Canadian Immunization Guide.

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Health is a provincial/ territorial responsibility under the British North America Act of 1867

Pace of introduction of new vaccines

Pre-2000

- DPT-Polio/Hib
- MMR
- Hepatitis B

In 2000-2010

- Varicella
- Meningococcal C conjugate
- Pneumococcal conjugate 7
- aP as TdaP
- Policy: infant influenza, PCV schedule, mumps 2nd dose, DPTP/Hib/HBV
- HPV
- Pneumococcal conjugate 13

‘Analytic framework’

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Vaccine 23 (2005) 2468–2474

Vaccine

www.elsevier.com/locate/vaccine

An analytical framework for immunization programs in Canada

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[d] *Institut national de santé publique du Québec, Canada*

Analytic Framework Components

Burden of illness	▪Disease (infectious agent, mode of transmission, etc.) ▪Epidemiology in Canada, risk groups
Vaccine characteristics	▪Efficacy, effectiveness (short and long term) ▪Safety: short-term, long term
Immunization strategies	▪Schedules ▪Age group/ risk group ▪Modes of delivery (physician, public health, school-based)
Cost effectiveness	▪Vaccine related ▪Disease related ▪Perspective (health care system, societal, individual)
Acceptability and feasibility	▪Public ▪Health care professionals ▪Political
Ability to evaluate program	▪Vaccine effectiveness ▪Adverse events ▪Vaccine coverage ▪Disease
Research questions	▪Fundamental ▪Intervention ▪Program delivery
Other considerations	▪Equity, ethics, legal, political
Overall recommendation	▪Should the vaccine be publicly funded and if so, for whom?

Ref: Erickson L, deWals P, Farand L. Vaccine 2005(23): 2468-74

By 2010…

Budgetary realities:

- End of federal financial investment in vaccines
- Several potential future vaccine programs in the pipeline e.g., rotavirus, MCV4, 2nd dose varicella, hepatitis A, newer influenza vaccines
- Desire by ministry to receive advice to allow for forecast demand

Implications for decision making process:

Develop and adopt a priorization approach in BC

2011 through today:

- Rotavirus, MMRV, Varicella 2nd dose, HAV
- Influenza: adjuvanted, LAIV, QIV and QLAIV
- Meningococcal conjugate quadrivalent
- HPV9: high risk male, school age male
- Approved: high dose influenza, zoster, menB, PCV13 adult indications
- Future: New influenza vaccines, HBV, C. diff, GAS, GBS, Staph aureus, Lyme, RSV, travel (Zika, Chik.)

Provincial decision-making structure

Ministry of Health/ Gov. BC

↑

Communicable Disease Policy Advisory Committee

↑

BC Immunization Subcommittee

Dr. Perry Kendall
Provincial Health Officer

Provincial decision-making structure

Ministry of Health/ Gov. BC

↑

Communicable Disease Policy Advisory Committee

↑

BC Immunization Subcommittee

Dr. Bonnie Henry
Provincial Health Officer

Effective January 31st

Summary of recommended new vaccines for public funding in British Columbia

Vaccine	PCV 13 catch-up for 3+4 year olds	HPV catch-up for females 18-26 years old	Varicella 2nd dose ★	Hepatitis A for FN: routine infant, VIHA K entry permissive for <19 ★	Zoster	Rotavirus ★
Burden of Illness	3 to 9 cases per year in past 4 years of PCV13 types in children aged 2-4	Sufficient burden for cervical cancer and dysplastic lesions	Low at this time including outbreaks; likely to increase in coming decade especially in adolescents	Low overall and declining, periodic outbreaks especially in First Nations communities	Sufficient burden after age 60 to warrant consideration; incidence rises after 50 yo	High incidence but low severe outcomes
Vaccine Characteristics	High immunogenicity and protection expected based on experience with PCV7	Excellent efficacy; high safety profile	High immunogenicity after 2nd dose; acceptable safety	Highly immunogenic and effective; high safety profile	Moderate efficacy; acceptable safety	Excellent efficacy, effectiveness; acceptable safety
Immunization Strategies	Physician and PHN immunization of children 2 years to 59 months, 1 dose	Adolescent and early adulthood prior to infection with oncogenic HPV strains	Routine immunization at 1 of three milestones: 18 month, K, grade 6	Infant or adolescent	Physician, public health and pharmacist immunizers	Physicians and public health
Cost Effectiveness	Cost per QALY gained US for 16-35 mos $25,052; 16-59 mos $73,564	Published literature suggests cost / QALY for age group including 26 up to $150K; BC analysis ICER for 18-26 is $60-70K/QALY; better if genital warts protection included.	Yes especially for K or grade school: CER per QALY gained $106K, $41K and $28K for 12 month, 4-6 years and grade 4, respectively.	CEA results range from <$20K to >$100K per QALY; likely cost effective in infants Cost effectiveness lower in adolescence because of acquisition of hepatitis A	Yes; $33,000 per QALY for 65 yo; less than $75,000 per QALY for 75+ (Canadian)	At current pricing of Rotarix this program is now cost effective in at least two Canadian CEAs with health care system perspective only i.e., not societal
Acceptability	Likely yes as prevents 'bacterial meningitis'; uptake may be low as other vaccines not given until end of this age group	Likely higher than for school girl program but coverage rates may be low because of distributed delivery system	Yes; consider potential for use of MMRV for 2nd dose (18 mos or 4-6 years)	Likely yes; issue of 'stigmatization' but outbreak experience is supportive and less of an issue if not given in school	YES: for patients YES: for limited providers willing to handle frozen formulation	Yes, for both parents, infants and providers; orally administered
Feasibility	Uptake may be relatively low compared to routine infant schedule. Targeted reminder campaign such as personal mailing recommended for optimal uptake.	Yes but require multiple providers and settings including physicians, pharmacy, student health services; targeting those with lower probability of prior infection not feasible	Yes; see cell above	Yes, with consideration of schedule of infant injections especially for infants (6 mo+ 18 months) and catch-up on VIHA for K entry because of repeat outbreaks. Under 19 program will likely have low uptake.	Freezer stable formulation would require investment in cold chain infrastructure; Pharmacare consideration but subject to 'Fair' Pharmacare i.e., means based co-funding	Yes; series completion will be higher with 2-dose series as cannot give after 8 mos; MSP billing code required
Ability to Evaluate Program	Yes, reportable disease readily diagnosed with isolates from normally sterile site	Coverage assessment requires survey; effectiveness can be evaluated using specifically designed and funded study initiatives and linked data bases; capture of vaccination data into registry requires additional effort	Impact on burden with administrative data bases	Yes; reportable disease but often asymptomatic in infants and young children. Impact on disease burden may not be seen for some years.	Impact on burden with administrative data bases; coverage by survey and net doses distributed	Not in current system; sentinel surveillance required
Research Questions	Whether other non vaccine preventable serotypes will emerge over time	Effectiveness, duration of protection, factors influencing uptake	Impact on varicella and shingles incidence longer term; duration of protection	Whether targeted program will result in disease reduction overall	Duration of protection	Serotype specific incidence; whether use in infants will shift burden to older ages

Task group summary to CD Policy Committee July 12 2011

Key issues select past or future vaccines

Vaccine	NACI recommendation	Likely target population for BC program	Key issues were/ will be:
HPV for males	Recommended	Grade 6, in line with the 'core' program for girls	Health economic analysis, primary goals of the program and how to achieve objectives, equity
Meningococcal quadrivalent conjugate vaccine	Children based on epidemiology in the province	Preadolescents/ adolescents	Very low incidence which drives economic analysis, but Y in 15-24 yo
Pneumococcal 13-valent conjugate vaccine	No routine recommendation for older adults	As per NACI	Incremental benefit of PCV13 over PPV23, additional cost
Zoster (shingles)	Likely permissive for 50+ and recommended for 60-65+	Likely starting at age 60 or 65	Cost and health economic analysis

Other types of factors: freezer stability (varicella, zoster); low incidence (menB); fair evidence and hard to target population (PCV13 high risk adults)

Child and adolescent immunization schedule BC 2018

Age	Vaccine(s)
2 mo	DPT-Polio/Hepatitis B/ Hib, PCV13, MenC, rotavirus
4 mo	DPT-Polio/Hepatitis B/ Hib, PCV13, rotavirus
6 mo	DPT-Polio/Hepatitis B/ Hib Influenza (2 doses, to 23 mos only) Hepatitis A (aboriginal)
12 mo	MMR, MenC, PCV13, Varicella
18 mo	DPT-Polio/Hib, Hepatitis A (aboriginal)
4-6 years/ Kindergarten	DPT-Polio, MMR+Varicella
Grade 6	HPV girls and boys
14-16 years/ Grade 9	Tdap, Men4C

Against 16 diseases, given from 2 months through 14 years of age

See www.bccdc.ca Immunization Manual

Canadian Paediatric Society position statement for harmonized provincial territorial schedules posits the following:

- Canada's children and youth are at potential risk for VPDs because of disharmony of P/T schedules
- Differing schedules confuse parents and health care providers
- Patchwork of vaccine schedules creates access inequities and added safety (reliability) issues in our system.

CPS position statement ID 2011-01

Is harmonization a concept in the NIS?

- 'Harmonization' is not mentioned in the NIS
- NIS recognizes that PTs look to NACI for guidance and will often use the NACI recommended schedule in their jurisdiction
- NIS goals were:
  - Equitable access to recommended vaccines
  - More efficient use of public health human and other resources
  - Timely introduction of new immunization programs across Canada
  - Commitment to international health initiatives
- Intersectoral collaboration on immunization issues

NIS = National Immunization Strategy, Final Report 2003

What is harmonization in immunization?

- Is it:
  - Same diseases targeted by vaccination
  - Same ‘schedule’ of vaccination by age or grade, interval and number of doses
  - Same vaccines
  - Same strategies and implementation models
  - Use of the same information systems and processes for recording information
  - Same processes for following up underimmunized children

Can harmonization be achieved in Canada?

- Federal government levers to ‘make’ P/Ts all do the same thing:
  - legislation
  - funding
  - guidelines/ moral suasion

Differences are inevitable in the Canadian system in which the federal government neither legislates nor funds uniformity, but issues guidelines.

Keelan J et al. CJPH 99(5) 2008

Is lack of harmonization a problem?

- Are preventable diseases occurring in children and adults because of:
  - lack of a vaccine program?
  - variable schedules?
- Would a harmonized schedule simplify the management of a newly arrived child without an immunization record?
  - CIG 2006: Immunization of Children and Adults with Inadequate Immunization Records
  - MOST IMPORTANT=electronic immunization registries that source data from multiple immunization service providers and can exchange records across jurisdictional boundaries

Examples of differences in BC

- We have programs some other P/Ts do not:
  - hepatitis A for aboriginal children/ youth
  - hepatitis B infant program
    - Rationale: epidemiologic differences
- We don't/ didn't have programs some other P/Ts did:
  - meningococcal quadrivalent conjugate adolescent
  - Tdap routine adult booster dose
  - high dose influenza (MB, ON)
    - Rationale: very low incremental benefit, high number needed to vaccinate, low value for money

Benefits of differences

- Allows for comparative evaluation:

For example: reduced dose schedules

- MenC Conjugate vaccine
- PCV7 and 13
- HPV for girls

Bettinger J et al. Vaccine 2012; Eggertson L CMAJ 2007; Dobson S et al. 26th International HPV Conference http://hpv2010.org/main/; Smolen K Vaccine 2012

SUMMARY

- Current system requires decision making at the P/T level; program decisions are based on:
  - Epidemiologic risk
  - Interpretation of available scientific data
  - Value for money, ‘political’ considerations
- Harmonization will not solve the problem of multiple providers and inadequate immunization records
- Complete harmonization cannot be achieved in the current Canadian model