Report of the National Immunization Strategy Task Group (NIS-TG) to the Communicable and Infectious Disease Steering Committee (CIDSC) of the Pan-Canadian Public Health Network (PHN)

FUTURE DIRECTIONS FOR IMMUNIZATION IN CANADA

TECHNICAL REPORT

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I. INTRODUCTION

Purpose and Use of This Report

This Technical Report sets out the analysis and conclusions of the National Immunization Strategy Task Group (NIS-TG) review of the National Immunization Strategy (NIS), focusing on strengths, weaknesses, gaps and opportunities that might be addressed to focus and guide the future of immunization in Canada. It provides supporting analysis and rationale for the recommendations set out in the NIS-TG's corresponding Executive Report. (For convenient cross-reference, the recommendations in the Executive Report are set out in exactly the same order as the analysis sections of this Technical Report.)

This Technical Report and the accompanying Executive Report are submitted to the Communicable and Infectious Disease Steering Committee (CIDSC) of the Pan-Canadian Public Health Network (PHN), for its consideration, including use of the reports in any follow-up presentations and discussions with the PHN and beyond, as warranted.

Possible responses to, and uses of, the ideas and recommendations set out in these reports include:

- strategic, policy, organizational and/or operational decisions with respect to PHN's interests in, responsibilities for, and activities related to immunization and its positioning within the broader sphere of public health management
- engagement and consultation among stakeholders on possible future directions and priorities on immunization programming and disease prevention in Canada
- consideration by various jurisdictions, authorities and stakeholders with respect to potential new directions and improvements in their respective immunization efforts, both unilaterally and in collaboration with each other

Responsibility for Immunization in Canada

In Canada, all 14 federal, provincial and territorial (F/P/T) jurisdictions have substantial roles, authorities and activities in immunization. This involves not only all health departments, agencies and ministries, but numerous other public authorities and public/private partnerships at various levels that are involved in diverse aspects of immunization program planning, implementation, evaluation and support, including vaccine development, assessment, regulation, guidance and promotion.

While each jurisdiction and each respective agency/authority has a distinct mandate and a unique operating context, the activities of these diverse bodies are characterized heavily by complementarity and collaboration. This F/P/T cooperation and interaction is a pragmatic response to a number of realities:

- Infectious diseases respect neither jurisdictional nor geographic boundaries, and to be effective immunization needs to be reasonably complete and consistent across regions.
- Success in dealing with vaccine-preventable diseases calls for specialized expertise and resources that often can be found only collectively and not within a single jurisdiction or agency.
- Full exploration and understanding of the needs for, alternative approaches to, and benefits of immunization programs—vital for evidence-based decision making—often requires evaluation

and research involving large and diverse populations. This is possible only with studies and innovation efforts that engage several—and ideally all—P/T populations.

- Significant mutual benefit can be gained through the sharing of insights, experiences and best practices amongst diverse parties, and through collaboration that leverages external resources and yields efficiencies and economies of scale.

The following chart illustrates the complex mosaic of Canada's collaborative immunization landscape:

Key Federal and Provincial/Territorial Responsibilities in Immunization		
Activity	**Federal** (PHAC unless otherwise noted)	**Provincial/Territorial**
Overarching Direction and Coordination	• International commitments, cooperation, regulations and reporting: United Nations, Pan American Health Organization, World Health Organization • National goals and standards • Pan-Canadian Public Health Network	• Input to international commitments and national goals • Provincial/local goals/targets • Reporting on compliance and progress • Pan-Canadian Public Health Network
Vaccine Guidance	• Technical guidance: National Advisory Committee on Immunization • *Canadian Immunization Guide* • Committee to Advise on Travel Medicine and Tropical Health • Public and professional education • Professional immunization competencies	• Programming guidance: Canadian Immunization Committee (F/P/T) immunization program design and guidance • Professional training • Technical guidance: vaccine review bodies
Immunization Schedules and Programs	• Immunization arrangements and interests related to "federal" populations: First Nations and Inuit Health Branch, Correctional Service of Canada, RCMP, Department of National Defence, Citizen and Immigration Canada, Veterans Affairs Canada, Aboriginal Affairs and Northern Development Canada	• Immunization program planning, design, delivery and evaluation for mainstream populations and targeted at-risk groups • Policy development by P/T governments, arm's length agencies, or a combination of both
Program Evaluation and Research	• Research support: PCIRN (PHAC/CIHR Influenza Research Network); Canadian Institutes of Health Research (CIHR) grants and contributions • Data analysis and exchange	• Program evaluation and research led by P/T public health • *Ad hoc* investigator-driven research, with external funding (e.g., CIHR)
Surveillance	• National systems and surveys: Public Health Agency of Canada, Health Canada and Statistics Canada • Registry standards and networks • National monitoring and coordination	• Design and maintenance of immunization registries • Disease and safety surveillance • Program monitoring
Outbreak and Adverse Event Response	• National monitoring and coordination	• P/T and local response and intervention
Public and Professional Education and Engagement	• National leadership, advocacy and messaging • Promotional campaigns, tools and materials • Core competence guides and tools • Professional education tools	• Public and professional engagement • Immunization campaigns and information services • Professional training, education and guidance
Security of Vaccine Supply	• Bulk F/P/T vaccine procurement: Public Works and Government Services Canada • Facilitation of P/T allocations	• Bulk vaccine procurement, and inventory management • Cooperation with colleague P/Ts on

	• National coordination of response to vaccine shortages and safety issues	allocations and responses to shortages and recalls
Vaccine Innovation and Development	• Regulatory approval for use: Health Canada • Research and development; industry liaison: National Research Council, CIHR, Industry Canada	• Input to articulation of public health needs and priorities for vaccines and vaccine technologies • Specific collaborations and centres—e.g., Vaccine and Infectious Disease Organization International Vaccine Centre (VIDO-Intervac) and other biotech institutions
No-Fault Injury Compensation	• No program in place	• Québec program only

Early Calls for a Pan-Canadian Immunization Strategy

F/P/T Deputy Ministers of Health 1999

The need for a pan-Canadian approach to immunization was originally identified by the F/P/T Deputy Ministers of Health in 1999. At their June 17−18 Conference, the Deputy Ministers heard from their F/P/T Advisory Committee on Population Health setting out a proposal entitled *National Strategies for Immunization: Protecting Canadians from Vaccine Preventable Diseases*.

At that time, Deputy Ministers were informed that the control of infectious diseases in Canada was incomplete and that vaccine-preventable diseases continued to occur. The following points were raised with the Deputy Ministers at the time:

- Pertussis occurs at unacceptable rates, and infants die of this preventable disease.
- Influenza hospitalizes and kills thousands of people each year, partly because vaccine coverage of high-risk groups may be as little 30% and seldom exceeds 80%.
- Pneumococcal infection is estimated to cause more than 50,000 potentially life-threatening illnesses and up to 4,000 deaths in Canada each year, yet vaccine coverage in high risk groups has been as low as 1% to 5%.
- The occurrence of avian (chicken) influenza in Hong Kong in December 1997 drew attention to the potential for an influenza pandemic similar to those that occurred in 1918−1919, 1957 and 1968.

F/P/T Deputy Ministers of Health:

- Confirmed a commitment to achieving an optimal level of immunization for Canadians and complete coverage of all children with vaccines included in their respective P/T immunization schedules.
- Supported development of a plan to ensure that vaccines are available and delivered in a coordinated and cost-effective manner across the country, as well as a review of targets and measures recommended to date.
- Endorsed a strategic approach to vaccine procurement to enhance stability of price and security of supply, including improvements to the F/P/T Bulk Procurement Program (BPP), as well as other innovative measures.

- Support the development of P/T immunization registries in all jurisdictions as a high priority.

These early calls and commitments for a more comprehensive and cohesive Canadian approach to immunization programming were subsequently reinforced through several prominent reports and commissions, and continually echoed by key stakeholder groups and organizations.

Romanow 2002

In November 2002, the Commission on the Future of Health Care in Canada, chaired by Roy Romanow, issued its report *Building on Values: The Future of Health Care in Canada.* Among many observations, the Romanow report noted that immunization is one of the most effective illness prevention strategies, and that Canada's immunization rates for most infectious diseases compare favourably with other Organisation for Economic Co-operation and Development (OECD) countries. However, the report noted that in recent years the cost of new vaccines and lack of accurate information on their effectiveness and safety have worried public health specialists. Observing that Canadian immunization programs were dated and had been in place for many years he concluded that Canada was not well prepared to face new and emerging problems due to globalization and the evolution of infectious diseases. In addition, the Romanow report expressed concerns that in some regions of the country immunization rates have deteriorated as a result of public fear of vaccines as well as lack of attention by health care professionals.

The Romanow report recognized that the National Advisory Committee on Immunization (NACI) had facilitated discussion about these issues with the provinces, territories and federal government, but even the specialists who participate in this committee admitted that the time had come to move to another stage in which some form of *joint planning* is done, in addition to sharing information. Proposed specific measures included:

- establishment of an immunization registry
- harmonization of immunization schedules
- identification of national standards in terms of coverage
- vaccine safety monitoring
- national procurement and evaluation policies
- national information and awareness campaigns
- engagement of a national agency to be responsible for developing guidelines and purchasing vaccines as part of a new national immunization strategy

Senate Committee 2002

In October 2002 the Standing Senate Committee on Social Affairs, Science and Technology, chaired by Senator Michael Kirby, issued a final report *The Health of Canadians—The Federal Role*. The report argued for greater attention to *non-medical* determinants of health, which have far greater impact on the health of the population than health care. However, it also noted the challenges associated with the fact that the very positive outcomes from promotion, prevention, protection and population health activities are generally visible only over the longer term, and thus are less newsworthy, hence less likely to capture the attention of the general public and less attractive politically.

The report noted that the death rate from infectious diseases in Canada has increased since 1980, and that infectious diseases account for $2.6 billion annually in economic burden. Seven infectious disease trends threaten Canadians:

- Many infectious diseases, such as AIDS and hepatitis C, persist.

- There are new and emerging infectious disease threats, including mad cow disease and *E. coli*, as well as West Nile Virus.
- Global travel and migration can quickly introduce new diseases into the population.
- Environmental changes, such as global warming, deforestation, and tainted water, may increase the spread of infections.
- Behavioural changes, particularly high-risk sexual practices and drug use, can foster the spread of HIV and other infectious diseases.
- Public resistance to immunization could cause a resurgence in polio and measles, for example.
- Anti-microbial resistance in infectious organisms may reduce the effectiveness of traditional curative measures, such as antibiotics.

The report concluded that programs and policies with respect to public health, health protection and health and wellness promotion are critical to enhancing the health of Canadians, and that a coordinated and integrated approach is needed in which the federal government can and should play a leadership role. It recommended that the federal government ensure strong leadership and provide additional funding to sustain, better coordinate and integrate the public health infrastructure in Canada as well as relevant health promotion efforts, supported by $200 million in additional federal funding annually.

Naylor 2003

The 2003 *Report of the National Advisory Committee on SARS and Public Health* ("the Naylor report") (Committee chaired by Dr. David Naylor, Dean of Medicine at the University of Toronto) made specific observations on the state of immunization in Canada, as part of its review of lessons learned from the Severe Acute Respiratory Syndrome (SARS) outbreak. The Naylor report noted substantial diversity in the publicly funded program and legislation pertaining to immunization and vaccination. As one example, it observed that not all children in Canada have received two doses of measles vaccine because some P/Ts could not afford to institute "catch-up" programs in 1996−1997. The Naylor report noted that, although the benefits of adolescent hepatitis B immunization were recognized a decade previously, Canada took seven years to reach national coverage because of variable uptake across P/T jurisdictions. The report recommended the devotion of $100 million annually to support a National Immunization Strategy, complemented by a further $100 million for infectious disease control.

Senate Committee 2003

Following up on its 2002 report, and responding to the Naylor report, the Standing Senate Committee on Social Affairs, Science and Technology issued a report entitled *Reforming Health Protection and Promotion in Canada: Time to Act*. The report strongly supported the Naylor recommendation to develop a national immunization program, noting that immunization is a central activity of health protection and promotion and a very cost-effective illness prevention measure, protecting millions of children and adults from contracting debilitating, disabling and sometimes fatal infectious diseases. It asserted that a national immunization program requires strong federal leadership, along with workable F/P/T collaboration. The report recognized that there would be those who would say that, since immunization is a provincial/territorial responsibility, any immunization program should be the exclusive responsibility of those jurisdictions. However, the Senate Committee "passionately" disagreed with that position, arguing that: infectious diseases do not respect provincial or national boundaries; although new vaccines are not cheap, a national program of vaccine purchase will dramatically reduce the cost per unit; and vaccines are most cost-effective when they are delivered through large-scale programs.

The Committee reiterated the Naylor report recommendation that the federal government should invest $100 million annually for the realization of a National Immunization Program, whereby the federal government would purchase agreed-upon new vaccines to meet provincial and territorial needs, support a consolidated information system to track vaccinations and immunization coverage, and track vaccine-associated adverse events through increased funding for surveillance and a mandatory reporting requirement, and provide funding for research on possible long-term adverse effects of vaccines.

Stakeholder Groups

The pursuit of a more comprehensive, cohesive and well-coordinated nation-wide approach to immunization has also consistently been advocated by stakeholders.

The **Canadian Public Health Association** (CPHA) Invitational Round Table Series report *Setting the Stage for Advancements in Immunization in Canada* (October 5, 2009) identified several areas of priority concern that need to be addressed to enhance "Canada's readiness for new developments in immunization, and optimize the health benefits to all Canadians that will arise from future vaccine developments":

- establishment of a national, comprehensive, automated national immunization registry
- harmonization of vaccine delivery and equitable access
- sustainable funding and service delivery across jurisdictions
- more efficient and accessible administration of vaccines
- more cost-effective management and deployment of vaccine resources
- better alignment of timelines and committees involved in vaccine reviews and guidance
- closer partnerships and communication between industry, government and public health stakeholders, in particular in supporting vaccine development and immunization uptake
- better education and promotion, including addressing of vaccine hesitancy and anti-science lobbies
- strengthening of the National Immunization Strategy

The **Canadian Paediatric Society** (CPS) report *Are We Doing Enough: A status report on Canadian public policy and child and youth health—2012 Edition* highlighted the importance of the early years (before the age of 6) in child development on longer term health, emotional well-being and life success. Among several key factors, the report focused specifically on publicly funded immunization programs, noting that "immunization is one of the most cost-effective and successful public health efforts of the past century." The CPS report noted that, in addition to the slate of vaccines that have been part of the routine immunization schedule for a number of years, the CPS, along with NACI, recommended that children and youth receive immunization against rotavirus, varicella (chickenpox), adolescent pertussis (whooping cough), influenza and certain forms of meningitis (meningococcal and pneumococcal infections), and that human papillomavirus (HPV) vaccine should be provided at no charge. The CPS observed that, while most P/Ts offer these vaccines, not all are administering them according to the schedule recommended by the CPS and NACI. In the report, the CPS recommended that the Government of Canada "ensure sustainable funding for full implementation of the National Immunization Strategy, including a national registry and a harmonized immunization schedule."

The 2012 report echoes a more detailed CPS position statement in 2011, *A harmonized schedule for Canada: A call to action*, which noted that Canada stands in contrast to other industrialized countries

where single, harmonized countrywide immunization schedules are "de rigeur," and instead has a "confusing system" that results in inequitable protection across the country and presents particular coverage challenges and risks to the many Canadians who move inter-provincially each year (400,000 in 2007−2008). This compounds the problems arising from the fact that Canadians have no consistent and complete source of information about the availability of existing programs or the launch of new ones. The CPS position paper notes that, where the variations amongst jurisdictions vary widely by age, such as with hepatitis B vaccines, the risk of missed vaccines for those who move from one province to another is higher. It also notes that a harmonized schedule would yield several notable benefits: greater economies of scale and greater security of supply through larger bulk purchases of vaccines; more simplified and accessible public and professional educational information across the country; efficient and coordinated introduction of new programs using the same schedule; and equitable protection against vaccine-preventable diseases. The CPS argues that, while provinces and territories have the right to determine their own vaccine schedules, this "does not impede them from implementing a national harmonized schedule."

The **Canadian Nurses Association** (CNA) November 2012 position statement on influenza immunization of registered nurses recognized that influenza is a serious illness that affects certain populations disproportionately, with vulnerable populations such as infants, seniors, pregnant women and those with chronic illnesses being at higher risk of experiencing complications from influenza. The CNA notes that, in a given year, between 2,000 and 8,000 Canadians die of influenza and its complications, and that, depending on the severity of the influenza season, there may be up to 20,000 hospitalizations annually related to influenza. The position statement indicated that the CNA supports annual influenza immunization as "the most effective method of preventing influenza and its complications," with special focus warranted for three priority groups: those at high risk of influenza-related complications, those capable of spreading influenza to individuals who are at high risk of influenza-related complications, and those who provide essential community services. The CNA supports "removing barriers that would make influenza immunization universally accessible." Dealing with the more specific issue of immunization for front-line health workers, the CNA also advocates that all registered nurses (with the exception of those for whom immunization is contraindicated) should receive the influenza vaccine annually to protect themselves, their families and those in their care.

The **Canadian Coalition for Public Health in the 21st Century** (CCPH21) is a national network of non-profit organizations, professional associations, health charities and academic researchers who share the common goal to improve and sustain the health of Canadians. Formed in May 2003, CCPH21 now includes 30 member organizations. Its mandate advocates for public policy to ensure that adequate public health functions are in place and information is made available to protect and promote health, and prevent disease and injury. The Coalition aims to help all stakeholders work together for the future of public health by generating ideas and potential policy directions for discussion among both the public and decision makers. CCPH21 has called for more federal investments in research granting councils which would help bolster vaccine program evaluation and research in Canada. In January 2012, CCPH21 wrote to the Council of the Federation (P/T Premiers) proposing that future F/P/T health agreements should include significant investments "upstream" in health functions, including disease prevention and pandemic preparedness and response, to improve the health of Canadians and ease pressures on health systems.

Canada's vaccine industry and related academic researchers/centres and biotechnology firms are interested in ensuring that Canada enjoys a more secure supply of vaccines for F/P/T programs, and that the country meets evolving public health needs for innovative vaccines and vaccine technologies. BIOTECanada is the national industry association with nearly 250 members across Canada, reflecting diverse interests in Canada's health, industrial and biotechnology sectors. Its Vaccine Industry Committee (VIC) is comprised of the leading vaccine manufacturers serving the Canadian market and early-stage

Canadian companies developing advanced vaccine technologies. The Committee works to ensure a secure supply of vaccines for Canada, advocates for equitable access to vaccines for all Canadians, and promotes the value of immunization as one of the most cost-effective health interventions available. VIC is active in the promotion and development of public policies focused on:

- promoting the value of vaccines and the importance of the industry
- ensuring adequate and timely funding mechanisms for new vaccines
- improving Canada's procurement and safety of supply policies to ensure availability of vaccines
- implementation of the National Immunization Strategy
- ensuring that Canada has an internationally competitive system for vaccine licensing
- improving the transparency and recommendation timelines of national advisory committees
- obtaining a satisfactory bar coding system with acceptable timelines

Canadian consumers generally understand and accept the importance and benefits of immunization, but there are a number of areas of concern. For example, a September 2011 Ekos Research Associates Inc. *Survey of Parents on Key Issues Related to Immunization* revealed that only 6% of parents surveyed felt that their knowledge about childhood vaccines was relatively limited. Nine in ten parents indicated that they believe that childhood vaccines in general are effective and important for their child's health. However, only one quarter felt that the seasonal flu vaccine was highly important. About 65% of parents rated childhood vaccines as highly safe, and a further 30% as moderately safe. However, one half of parents indicated concern that newer vaccines are not as safe as older vaccines and four in ten parents indicated they are more concerned about the safety of vaccines now than five years ago. One third of parents feel that children today receive too many vaccines. Among parents who said that their child had missed an immunization, 28% felt that vaccines are unnecessary, arguing instead that the human body is fully capable of caring for itself. Sixteen percent of these parents do not believe in vaccine use, either for philosophical reasons or as a consequence of religious beliefs, and a similar proportion has concerns about the safety of vaccines. A conclusion of the survey is that there is a small but significant group of parents who "do not have enough information, are confused, or generally have doubts about the need, safety and effectiveness of immunization for their children."

The National Immunization Strategy

In 2003, the Federal/Provincial/Territorial Conference of Deputy Ministers of Health approved a National Immunization Strategy (NIS) that provides a framework for inter-jurisdictional collaboration to improve the relevance, effectiveness and efficiency of immunization programming in Canada. At the time of its creation, the NIS was specifically designed to address a number of challenges to immunization which all jurisdictions were facing, including: escalating vaccine prices; concern regarding the security of supply of vaccines; and public complacency toward immunization, and concern regarding vaccine safety.

NIS Objectives and Scope

Supported by an initial federal investment of $45 million over five years (now $5.6 million per year ongoing), and complemented by substantial P/T investments of financial resources, expertise and in-kind support, the NIS is a collaborative F/P/T initiative. It provides a vehicle for jurisdictions to pursue opportunities of mutual interest and benefit and to create consistent, equitable approaches to immunization planning, purchasing, delivery and education.

Emphasizing initiatives that maximize economies of scale, complementarity of effort and sharing of best practices, the NIS has focused most heavily on:

- collaboration on information sharing, strengthening of professional competencies, surveillance, and adverse event reporting/response
- a cooperative bulk purchasing program for vaccines in common use
- cooperation with vaccine reviews and guidance documents
- work on more complete and mutually compatible vaccine registries

Broader Immunization Efforts of Interest to the NIS

While not formally included under the aegis of the NIS, a number of major federal programs and initiatives are of interest to, and benefit from, the leadership and outputs of the NIS, including:

- Health Canada's responsibilities for vaccine regulation and approval
- federal purchase of vaccines for administration to First Nations and Inuit, inmates, service personnel, RCMP, veterans and others ($4.5– $5.0 million per year)
- federal contributions from the Public Health Agency of Canada (PHAC) and Canadian Institutes of Health Research (CIHR) to PCIRN (PHAC/CIHR Influenza Research Network) for influenza-specific research ($10.8 million 2009−2012; $1.4 million per year ongoing)
- National Research Council (NRC) and Industry Canada vaccine-related innovation and development activities
- other federal departments and agencies with certain immunization activities and interests, including Citizenship and Immigration, Veterans Affairs, Aboriginal Affairs and Northern Development Canada, and the Patented Medicine Prices Review Board

The federal government also established two consecutive one-time federal trust funds of $300 million each for the introduction of new immunization programs by provinces and territories. The first three-year trust fund (2004−2007) introduced meningococcal C conjugate, pneumococcal conjugate, varicella, and adolescent pertussis, while the second (2007−2010) introduced HPV. The federal investments were matched by substantial P/T funding at a ratio of roughly 4:1.

Ongoing P/T immunization programs account for the majority of immunization activities and investments in Canada, including bulk purchase of vaccines ($250−$300 million per year), plus storage and handling, vaccine administration, development and maintenance of immunization registries, participation in surveillance systems, conduct of program evaluation and research, and design and delivery of public and professional education, awareness and engagement initiatives. In round numbers, direct P/T expenditures on vaccine purchases for immunization programs average $900 per child for full immunization coverage from birth to age 18.

Review of the NIS

NIS Task Group

In April 2011, the Public Health Network Council (PHNC) confirmed that a review of the National Immunization Strategy, and its renewal, including addressing emerging vaccine technologies, is a CIDSC priority. In June 2011, the CIDSC approved the creation of a new, time-limited National Immunization Strategy Task Group to undertake a review of the NIS and report to CIDSC with conclusions and recommendations for the future of immunization in Canada.

The Federal Co-Chair of the Task Group was Dr. John Spika, Director General of the Centre for Immunization and Respiratory Infectious Diseases (CIRID), Public Health Agency of Canada, and the P/T Co-Chair was Dr. Martin Lavoie, Deputy Chief Medical Officer of Health, Alberta.

In addition to the Co-Chairs, the NIS-TG was composed of members, appointed by the CIDSC, who have knowledge of immunization practice and multidisciplinary expertise in public health relating to immunization in terms of policy, programming, research and evaluation, and the international context. Other experts were invited as guests when required to provide complementary expert perspectives. (See *Annex 3: NIS-TG Membership*.) While the NIS-TG included experts from different regions of Canada, the group was composed as an expert advisory group and *not* as any form of representative body responsible for soliciting views of the jurisdictions, which is a broader responsibility of the PHN overall.

Focus of the NIS Review

As set out in its initial work plan, approved by CIDSC in September 2011, the output of the NIS-TG review consists of a report with recommendations for NIS renewal to the CIDSC, addressing priority elements of immunization programming where: valuable ongoing work warrants reaffirmation; there are critical gaps that need to be addressed; and/or there are opportunities to make appreciable improvements in areas of mutual interest and benefit, especially within existing authorities and resources. Reflecting this mandate, the companion NIS-TG reports (this Technical Report with detailed analysis, and the accompanying Executive Report with conclusions and recommendations) address issues and opportunities under the following themes:

- Overarching Direction and Coordination
- Common Vaccine Guidance
- Coordinated Immunization Schedules and Programs
- Program Evaluation and Research
- Surveillance
- Outbreak and Adverse Event Response
- Public and Professional Education and Engagement
- Security of Vaccine Supply
- Vaccine Innovation and Development
- No-Fault Injury Compensation

The work of the NIS-TG consisted of the following:

- convening of teleconferences of the entire NIS-TG every few weeks (see *Annex 4: NIS-TG Meetings and Teleconferences*)
- conduct of four one or two-day face-to-face working sessions of the full NIS-TG
- several NIS-TG sub-groups, each consisting of two to three NIS-TG members, with each sub-group focusing on one of the above priority areas for improvement
- participation, as required, by the NIS-TG and its sub-groups of additional officials and experts to provide input and serve as sounding boards
- ongoing support by a small secretariat of policy and program analysts providing research, analytical and logistical support

II. IMMUNIZATION IN CONTEXT

The Global Importance of Immunization

Immunization is a powerful public health tool that is widely recognized as an effective means to reduce the burden of disease. With the exception of clean, safe drinking water, no treatment has rivalled immunization in reducing mortality rates. The World Health Organization (WHO) refers to immunization as a "major life-saver" and estimates that between 2 and 3 million deaths from diphtheria, tetanus, pertussis (whooping cough), and measles are prevented annually as a result of immunization. Hepatitis B vaccination prevents an additional 600,000 deaths worldwide from liver cirrhosis and liver cancer annually.

Along with enormous improvements in sanitation and hygiene, immunization is also credited with the significant increase in life expectancy observed in the past century. As such, immunization is considered one of the great public health success stories. Indeed, the widespread establishment of immunization programs over the past 30 years has led to remarkable achievements:

- Smallpox was eradicated in 1977.
- The worldwide incidence of poliomyelitis has dropped by more than 99% since 1988.
- Indigenously transmitted cases of measles have been eliminated in the Western Hemisphere and measles mortality decreased by an estimated 68% globally from 2000 to 2006.
- Neonatal tetanus mortality has been reduced by about three quarters, with estimated deaths decreasing from 800,000 in the 1980s to less than 200,000 in recent years.

Reduction of Vaccine-Preventable Diseases in Canada

In Canada, over the past 50 years, immunization has contributed to reducing more deaths from certain types of infectious diseases than any other health intervention. Through innovative tools, education and training, as well as strategies to remain vigilant in immunization delivery, more than 30 common infectious diseases that were once a major cause of morbidity and mortality in Canada, particularly amongst children, are now preventable with vaccines.

Vaccines are responsible for the control of many infectious diseases that were once common in Canada, including polio, measles, diphtheria, pertussis, rubella, mumps, tetanus and *haemophilus influenzae* type b (Hib). However, the viruses and bacteria that cause vaccine-preventable disease still exist in Canada and/or in other countries and can be transmitted to people who are not protected by immunization. If immunization programs were stopped, diseases that are now rarely seen in Canada because they are controlled through vaccination would reappear, resulting in epidemics of diseases causing sickness and death.

Young children are particularly susceptible to vaccine-preventable diseases because their immune systems are not mature enough to fight infection. While newborns are immune to many diseases because they have received maternal antibodies, this immunity disappears during the first year of life. Timely immunization of infants is necessary to protect young children from vaccine-preventable diseases.

Prevention of infection by immunization is a lifelong process; adults require immunization to remain protected against vaccine-preventable diseases. In addition, immunization of adults is protective for young children and others at increased risk of vaccine-preventable diseases.

Vaccines protect not only the individuals who receive them but others in the general population. These include children who are too young to be vaccinated but are susceptible to disease (such as young infants prior to receipt of a complete series of pertussis-containing vaccine), those who cannot be vaccinated for medical reasons (e.g., certain immunosuppressed people who should not receive live vaccines), and those who do not adequately respond to vaccination. If a significantly large proportion of the population is successfully vaccinated these vulnerable populations enjoy "herd immunity," since the risk of exposure is greatly reduced.

Given the importance of immunization of the mainstream population and the associated herd immunity effects for those who cannot be vaccinated successfully, immunization is thus a collective activity that can protect an entire group of people, whether directly or indirectly. Indeed, high immunization rates in one region, jurisdiction or country benefit other regions, jurisdictions and countries, particularly since infectious diseases can travel so easily across borders given global trade, migration and travel, and general inter-connectedness both domestically and internationally. Similarly, high immunization rates in one generation benefit the next generation to follow.

Canada's Immunization Programs

The charts below show the incidence (reported new cases) of selected vaccine-preventable diseases from time periods before and after the introduction of immunization programs.

The first chart compares the incidence of nine vaccine-preventable diseases from selected eras as far back as the 1920s to the most recent five-year period, 2006−2010. For each of the nine selected vaccine-preventable diseases, the chart shows:

- when the vaccine was authorized and/or introduced
- when immunization programs were implemented
- when notifiable disease reporting was undertaken
- the average annual incidence (reported new cases) per 100,000 population over the selected five-year pre-vaccine era, compared to the average annual incidence per 100,000 population in the era 2006−2010
- the peak number of annual cases in each of the pre-vaccine and 2006−2010 eras

The second chart provides indicators of the reduction of four selected vaccine-preventable diseases following the initiation of vaccine programs under the above-mentioned 2004 Immunization Trust Fund.

Reduction in Incidence of Selected Vaccine-Preventable Diseases in Canada, Pre-Vaccine Era Compared with 2006–2010 Era					
Disease	**Vaccine Introduction and Disease Reporting**	**Pre-Vaccine Era***		**2006–2010****	
		Five-Year Average Annual Incidence per 100,000	**Peak Annual Number of Cases**	**Five-Year Average Annual Incidence per 100,000**	**Peak Annual Number of Cases**
Diphtheria	Diphtheria toxoid introduced 1926 Routine infant immunization since 1930 National notifiable diseases reporting began 1924	84.2 (1925–1929)	9,010 (1925–1929)	0.005	4
***Haemophilus influenzae* type b (Hib) (children < 5 years)**	Vaccine introduced 1986 Current Hib conjugate vaccines introduced 1991–1992 National notifiable disease reporting of invasive Hib disease began 1986	22.7 (1986–1990)	526 (1986–1990)	0.60	18
Measles	Live vaccine authorized 1963 Universal infant immunization program implemented 1983 Two-dose MMR (measles, mumps, rubella) schedule introduced 1996–1997 No notifiable diseases reporting 1959–1968	369.1 (1950–1954)	61,370 (1950–1954)	0.17	102
Mumps	Vaccine authorized 1969 Universal infant immunization program implemented 1983 Two-dose MMR schedule introduced 1996–1997 No notifiable diseases reporting 1960–1985	248.9 (1950–1954)	43,671 (1950–1954)	1.74	1,110
Pertussis (whooping cough)	Whole cell pertussis vaccine authorized 1943 Acellular pertussis vaccine replaced whole cell 1997–1998 Adolescent acellular vaccine formulation authorized 1999	156.0 (1938–1942)	19,878 (1938–1942)	4.96	2,346
Poliomyelitis	Inactivated polio vaccine (IPV) introduced 1955 Oral polio vaccine authorized 1962 and used in Canada until 1997 IPV used exclusively from 1998	17.3 (1950–1954)	1,584 (1950–1954)	0	0
Rubella	Rubella vaccine introduced 1969 Universal infant immunization program implemented 1983 Two-dose MMR schedule introduced 1996–1997	105.4 (1950–1954)	37,917 (1950–1954)	0.02	12
Congenital rubella syndrome (CRS)	National notifiable diseases reporting of CRS began 1979	2.4*** (1979–1983)	29 (1979–1983)	0.00***	0

* Five years preceding vaccine introduction.
**Provisional numbers for measles, rubella and CRS from the Canadian Measles and Rubella Surveillance System (CMRSS). All other data from the PAHO Annual Vaccine Preventable Diseases Data Request.
***Per 100,000 live births.
Sources: National Advisory Committee on Immunization. *Canadian Immunization Guide, Seventh Edition, 2006*. Ottawa: Public Health Agency of Canada, 2006. And Immunization Monitoring Program ACTive (IMPACT).

Reduction in Selected Vaccine-Preventable Diseases in Canada Since Creation of the 2004 Immunization Trust Fund		
Vaccine	**Disease**	**Reduction**
Varicella	Chickenpox	76% reduction in hospitalizations of children under age 15, between 2003 and 2009
Conjugated meningococcal serogroup C	Invasive meningococcal disease group C	75% reduction in incidence among children under age 5 between period 1995−2004 and period 2005−2007
Adolescent acellular pertussis	Whooping cough	64% reduction in incidence among children/youth 10−19 years of age between period 1995−2004 and period 2005−2007
Conjugated pneumococcal	Pediatric invasive pneumococcal disease associated with conjugated pneumococcal vaccine	80% reduction in incidence since 2004

Source: Immunization Monitoring Program ACTive (IMPACT).

Cost-Benefits of Immunization

Vaccine-preventable diseases result in significant costs to individuals, the health care system and society, including costs associated with visits to health care providers, hospitalizations and premature deaths. Parents may lose time from work to care for sick children and sick children may miss school. Serious illness from vaccine-preventable diseases can affect long-term work productivity and public and personal care costs.

Vaccines can be one of the most *cost-effective* public health interventions, measured in terms of the value of benefits gained per unit cost, and the relative benefits of investing in immunization versus other health interventions. For instance, the WHO estimates that while smallpox eradication cost some $US300 million, it generated over $US27 billion in cost savings over a 20-year period. In the United States, cost-benefit analyses indicate that every dollar invested in a vaccine dose saves $US2−$US27 in health expenses.

The table below shows some government health and safety programs, along with estimates of costs per life year saved. Costs represent the net annual costs of the program (i.e., minus any downstream savings). Each benefit is expressed in life years, or the additional years of life people can expect to enjoy as a result of the program. The ratio of cost over life year saved showcases the net annual costs associated with a given health intervention for one additional year of life a person is expected to enjoy as a result of that intervention. It is a measure of cost-benefits that is widely used by the WHO and public health decision makers.

In some cases the establishment of publicly funded vaccination programs results in both health improvements and net *cost savings*, i.e., additional life years are being generated, with net public savings. In other cases, health benefits are achieved at a net public cost. For instance, as detailed in the table below, the publicly funded varicella vaccine for children program costs society (government) $16,000 for each additional year of life gained, and hepatitis B screening in pregnancy and vaccination of children of carriers costs only $164 for each additional year of life gained.

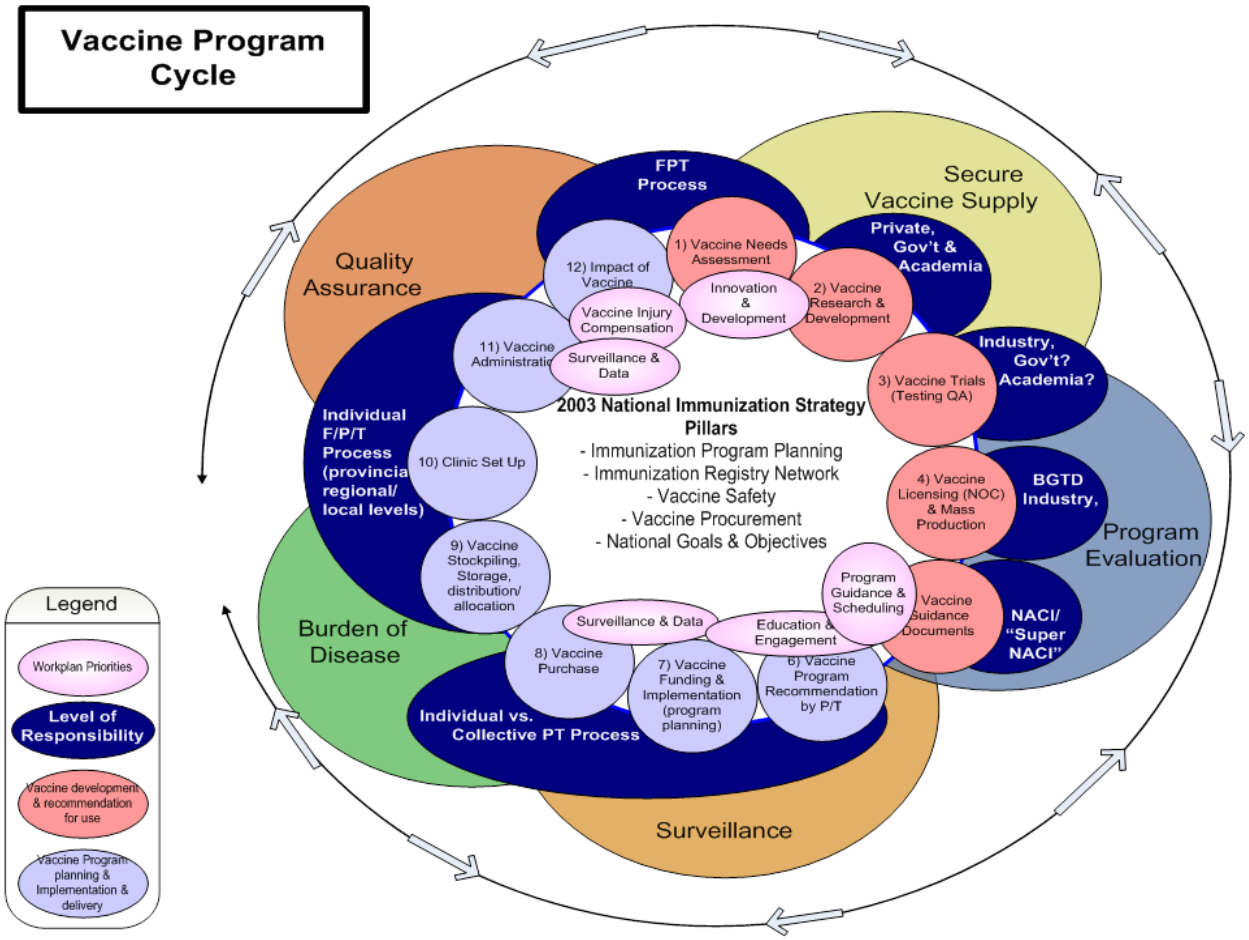
Immunization also improves longevity and quality of life, and eases pressures on the health care system. It helps to alleviate wait times by preventing associated outpatient visits, antibiotic use, hospitalizations and long-term disabilities. In addition, it offers economic benefits by impacting on areas other than health, such as education, labour and productivity, and early childhood development. It can also help to mitigate impacts of social disadvantage on health, and improve equity in health care service provision.

Public Program Costs per Life Year Saved for Selected Vaccine Programs and Other Public Health Interventions	
Public Health Intervention	**Public Program Costs per Life Year Saved**
Vaccines	
Measles, mumps, rubella for children	Less than $0 (net $16 *saved* per $1 spent)
Diphtheria, pertussis, tetanus for children	Less than $0 (net $6 *saved* per $1 spent)
Influenza for adults 65 years of age and older	Less than $0 (net $45 *saved* per $1 spent)
Pneumococcal polysaccharide for adults 65 years of age and older	Less than $0 (net $8 *saved* per $1 spent)
Hepatitis B screening in pregnancy and vaccination of children of carriers	$164
Varicella vaccine for children	$16,000
Pneumococcal conjugate vaccine for children	$125,000
Other Interventions	
Mandatory seat belt law	$69
Chlorination of drinking water	$3,100
Smoking cessation counselling	$1,000–10,000
Bicycle helmet law	$39,000
Annual screening for cervical cancer	$40,000
Driver and passenger air bags/manual lap belts (vs. airbag for driver only and belts)	$61,000
Smoke detectors in homes	$210,000
Low cholesterol diet for men 20 years of age and older	$360,000
Crossing control arm for school buses	$410,000
Radiation emission standard for nuclear power plants	$100,000,000

Source: National Advisory Committee on Immunization. *Canadian Immunization Guide, Seventh Edition, 2006*. Ottawa: Public Health Agency of Canada, 2006.

III. OVERVIEW ASSESSMENT OF IMMUNIZATION IN CANADA

The issue is how to strengthen, renew and reframe/reposition the National Immunization Strategy (NIS) as a relevant, effective and sustainable F/P/T mechanism to promote, facilitate and coordinate collaborative immunization initiatives of mutual interest and benefit. This entails building on the strengths of the NIS, while focusing on improvements and the filling of gaps at all critical stages in the vaccine immunization program cycle, as illustrated in the highly conceptual schematic immediately below.



Given the mutually complementary—and frequently overlapping—roles, responsibilities and interests in immunization amongst the 14 jurisdictions in Canada, as noted in the previous chapter, success is highly dependent upon a highly collaborative and mutually respectful F/P/T approach to the planning, design, delivery, monitoring, evaluation and continual improvement of the National Immunization Strategy. It is against these general values and aspirations that the NIS-TG assessed the NIS and suggested the potential future directions for immunization in Canada that are set out in the accompanying Executive Report.

SITUATION

NIS Contributions and Successes to Date

As detailed in the subsequent chapters of this report, the NIS has been instrumental in helping F/P/T authorities achieve several notable successes in their immunization programming:

- ***Review and Guidance***
  - facilitation of vaccine introduction through expert review and guidance (e.g., NACI, CIC)
  - some knowledge translation to support evidence-based decisions (e.g., *Canadian Immunization Guide; Canadian Immunization Conference*)
- ***Uptake and Coverage***
  - strengthening of core competencies for program design and delivery (e.g., guides and tools)
- ***Safety and Public Confidence***
  - improvements to adverse event reporting (e.g., pandemic H1N1 vaccine)
  - some capacity to coordinate response to safety and supply issues (e.g., Quadracel)
- ***Security of Supply***
  - lower prices (10%−75% below U.S.) (e.g., helped through F/P/T bulk procurement)
  - more reliable supply through better use of multiple suppliers and industry engagement (e.g., flu vaccine)
  - emerging ability to trace and share stocks (including substitutes) in response to shortages (e.g., pilot bar coding)
- ***Federal/Provincial/Territorial Collaboration***
  - F/P/T collaboration on initiatives in areas of mutual interest and benefit (e.g., PHN, working groups and advisory committees, joint initiatives, sharing of best practices)

ASSESSMENT

Gaps and Shortcomings in Immunization Programming

Despite the above-noted NIS successes, critical challenges remain and there are appreciable gaps and shortcomings in immunization programming in Canada. This is due in part to the very decentralized approach taken by Canada's 14 jurisdictions (federal, provincial and territorial). As noted further below, among 11 high-income federated OECD countries, Canada's patchwork of different immunization programs stands as the most decentralized, compounding an array of continuing issues and challenges in immunization planning, delivery and support:

- inconsistent and incomplete articulation of immunization goals and targets to inspire and guide F/P/T collaboration in areas of mutual interest and benefit, and absence of strong and consistent oversight and direction for the coordination of F/P/T efforts within the framework of the NIS
- unnecessary duplication of F/P/T vaccine guidance processes that represent inefficient use of limited federal and P/T time, effort and resources

- delays in the development and release of National Advisory Committee on Immunization (NACI) and Canadian Immunization Committee (CIC) statements and recommendations
- absence of common guidance on vaccines being adopted for use by jurisdictions, resulting in confusing and contradictory messages that undermine public confidence and sense of security
- a confusing and inconsistent patchwork of different schedules for many vaccines from one province or territory to another, resulting in gaps and inequitable protection across the country, and the risk of missed or unnecessarily duplicated vaccinations for the several hundred thousand Canadians who move inter-provincially each year
- delays (up to seven years) for the introduction of new vaccines by all P/Ts across Canada, resulting in critical gaps in coverage and protection for many Canadians
- loss of opportunity for early consideration of plans and guidance for program evaluation, research, surveillance, messaging, risk mitigation and security of supply measures
- incomplete information on immunization coverage (registries) contributing to serious challenges in identifying and targeting key vulnerabilities and high-priority populations at risk
- inadequate surveillance of evolving risks, leading to delays and vulnerabilities in protecting Canadians
- inadequate, unclear and poorly coordinated mechanisms and protocols to ensure timely and effective response to outbreaks, vaccine safety issues and other events of concern
- threats to the reliable, timely and efficient supply and deployment of vaccines, resulting in gaps in coverage
- inadequate innovation in vaccine development to address longer term evolving public health needs and priorities
- absence of programs in all but one jurisdiction to provide fair, expedient and appropriate compensation for rare, unavoidable injuries for which litigation is either not appropriate or not practical

The results are:

- inadequate levels of immunization coverage for protection against critical diseases of national concern
- inequitable access to vaccines across jurisdictions and amongst different population groups
- public confusion over the necessity, utility and safety of certain vaccines
- unnecessary duplication and inefficiencies in F/P/T immunization processes and programming
- excessive levels of vaccine-preventable diseases that impose avoidable burdens on health systems and families and undermine Canada's productivity and competitiveness through avoidable school and work absentees

Of particular concern is that Canada has experienced several vaccine-preventable disease outbreaks, including nine notable measles outbreaks since 2006, a B.C. mumps outbreak in 2011 and recent pertussis outbreaks in Aboriginal communities. These highlight the challenges Canada faces in delivering on its international commitments for disease reduction and elimination.

Unless the key gaps are addressed through enhanced F/P/T collaboration under the NIS, further ground will likely be lost and there will be untapped potential for greater savings and public health improvements for mutual F/P/T benefit.

Building on Success—Addressing Outstanding Gaps and Opportunities

The NIS-TG concludes that an ongoing and renewed NIS can continue to serve an important role in leading, facilitating and coordinating collaborative F/P/T initiatives of mutual interest and benefit. The NIS-TG's *recommendations* for future direction for immunization in Canada, set out in the accompanying Executive Report, seek to enhance immunization programming in Canada by addressing the key gaps and responding to the evolving needs and opportunities identified in detail in this Technical Report, most notably:

- **OVERARCHING DIRECTION AND COORDINATION:** establishment of suitable mechanisms and responsibility for the close and continuous oversight, direction and coordination of F/P/T initiatives under the aegis of the NIS, including the articulation of immunization goals to focus and inspire F/P/T collaboration in areas of mutual interest and benefit
- **COMMON VACCINE GUIDANCE:** establishment of a common guidance process for vaccines being considered for use by F/P/T jurisdictions, to provide more timely guidance, minimize duplication in F/P/T guidance processes, and support more consistent and complementary strategies, approaches and messages that facilitate equitable protection and reinforce public confidence and sense of security
- **COORDINATED IMMUNIZATION SCHEDULES AND PROGRAMS:** more consistent, timely and well-coordinated adoption of schedules and implementation of programs for the introduction of new vaccines across Canada, to: avoid gaps in coverage; ensure equitable and effective protection for all Canadians; and facilitate efficient and cost-effective program delivery
- **PROGRAM EVALUATION AND RESEARCH:** more comprehensive, timely and reliable program evaluation, research and other data to support evidence-based decisions on program design, implementation and continuous improvement
- **SURVEILLANCE:** completion and improved alignment of immunization registries to provide accurate, complete and timely information on coverage so as to identify and target key vulnerabilities, complemented by strengthening of surveillance of vaccine-preventable diseases, risk factors, adverse events following immunization, and other public health and safety triggers
- **OUTBREAK AND ADVERSE EVENT RESPONSE:** establishment of new and enhanced protocols and procedures to trigger and coordinate the investigation, assessment and response to vaccine-preventable disease outbreaks, adverse events following immunization, and other health and safety risk factors and triggers, to ensure timely and effective protection of Canadians
- **PUBLIC AND PROFESSIONAL EDUCATION AND ENGAGEMENT:** enhancement of collaborative efforts and the sharing of best practices in public and professional education and engagement to promote and support increased immunization coverage and address vaccine hesitancy and public confidence
- **SECURITY OF VACCINE SUPPLY:** enhancement of measures to ensure more reliable, timely and efficient supply and deployment of vaccines, including response to vaccine shortages, recalls and quality or safety issues
- **VACCINE INNOVATION AND DEVELOPMENT:** encouragement and facilitation of innovation in vaccine development to address longer term evolving public health needs and priorities

- **NO-FAULT INJURY COMPENSATION:** encouragement of no-fault vaccine injury compensation programs to provide fair, expeditious and appropriate compensation for those rare, unavoidable injuries for which civil litigation is either not applicable or not practical

Prospective Benefits

While the benefits of the NIS-TG review and its recommendations set out in the Executive Report will be a direct function of whether and how the recommendations are adopted, the overall intent of the recommendations is to identify opportunities to strengthen F/P/T collaboration in key areas of mutual interest and benefit:

- eliminate/reduce duplication of processes and mechanisms
- maximize pooling and strategic use of scarce expertise and resources
- emphasize complementarity

With such enhanced collaboration focused on mutual objectives and shared priorities, implementation of the recommendations of the NIS-TG report will help achieve the following:

- greater and more equitable health protection for Canadians, especially high-risk and hard-to-reach populations
- reduction in vaccine-preventable diseases
- reduced burdens on health systems and on individuals and families
- savings on vaccine program implementation
- more reliable security of vaccine supply and more timely and effective response to shortages and recalls
- more focused, well-targeted and cost-effective vaccine program design and implementation
- delivery on domestic and international commitments for disease reduction/elimination, enhancing F/P/T credibility as effective leaders and reliable partners in disease prevention
- innovation in Canada's vaccine industry and research community for public health, industrial and economic benefits
- mutually respectful and effective F/P/T relationships, with reciprocal benefits for broader intergovernmental cooperation on public health initiatives in general

IV. DETAILED ASSESSMENT OF IMMUNIZATION PROGRAMMING ELEMENTS

A. Overarching Direction and Coordination

SITUATION

International Commitments and Goals

UN World Summit for Children

In 1990, Canada, along with 70 other countries, participated in the World Summit for Children at the United Nations (UN) and was signatory to a declaration establishing a number of child health goals with respect to disease reduction or elimination and immunization coverage. This resulted in Health Canada's commitment to developing national child health goals through the Children at Risk Initiative Program. National goals and objectives for the control of measles, mumps, rubella, pertussis, diphtheria, tetanus, poliomyelitis, *haemophilus influenzae* type b (Hib) invasive disease and hepatitis B were developed through a series of four consensus conferences sponsored by the Laboratory Centre for Disease Control (LCDC), which took place between December 1992 and October 1994.

The development of these national goals was an expression of the commitment (political, policy and programmatic) of public health officials to improve the health status of Canadians, and specifically of children in whom the greatest burden of these vaccine-preventable diseases occur. The goals provided all provinces and territories with a coordinated framework for policy development and for priority setting for budget and resource allocation among competing, and often equally important, public health programs. More specifically, the national goals provide a rational and coordinated approach to program planning, evaluation and modification; define achievable and measurable endpoints in public health programs; help identify improvements and gaps in health status; and help to establish national strategies for achieving and maintaining elimination of selected diseases.

One such goal was to reduce measles cases by 90% (compared to pre-immunization levels) by 1995, as a major step towards the global eradication of measles in the long term. As described in the *Canadian National Report on Immunization, 1996* (Health Canada 1996): "In 1995, with only 3.6% of the population in the Americas, Canada accounted for 40% of all reported cases of measles and nearly 80% of all confirmed cases." That same year, the Conference of F/P/T Deputy Ministers of Health endorsed the national goal of eliminating measles by 2005, which was subsequently endorsed by the F/P/T Ministers of Health. National data show that the number of measles cases decreased from 523 cases in 1994 to 7 cases in 2002. Despite this success, measles elimination is the only national goal which has been officially endorsed.

UN Millennium Declaration

In September 2000, at the start of the millennium, world leaders adopted the United Nations Millennium Declaration with eight key Millennium Development Goals to be achieved by 2015. Two of these are of

relevance to Canada's immunization commitments: reduce child mortality; and combat HIV/AIDS, malaria and other diseases. These two mutually complementary goals reflect the fact that much of childhood mortality can be reduced through low-cost prevention measures, including immunization.

PAHO Regional Immunization Vision and Strategy

As a Member State of the Pan American Health Organization (PAHO)—a Regional Office of the WHO—Canada is a committed partner with other countries of the Americas in supporting implementation of PAHO's Regional Immunization Vision and Strategy 2007−2015. The primary focus is to reduce inequities by supporting efforts to target under-served communities with low immunization coverage. Canada is also committed to contributing to and achieving PAHO regional disease elimination targets, including the provision of reports with indicators documenting elimination of measles, rubella, congenital rubella syndrome, and polio, and progress in immunization coverage.

Canada's participation in PAHO takes place in the broader context of its commitments and activities as a member of the WHO, a UN Agency.

Global Immunization Vision and Strategy

Of particular significance is Canada's endorsement of the Global Immunization Vision and Strategy (GIVS) 2006−2015, which was launched in 2005 as the first 10-year strategic framework to realize the potential of immunization. GIVS envisages a world in 2015 in which:

- Immunization is highly valued.
- Every child, adolescent and adult has equal access to immunization as provided for in their national schedule.
- More people are protected against more diseases.
- Immunization and related interventions are sustained in conditions of diverse social values, changing demographics and economies, and evolving diseases.
- Immunization is seen as crucial for the wider strengthening of health systems and a major element of efforts to attain the Millennium Development Goals.
- Vaccines are put to best use in improving health and security globally.
- Solidarity among the global community guarantees equitable access for all people to the vaccines they need.

Under GIVS, all those working on immunization and related product development should strive to prevent morbidity and mortality by achieving the following goals and targets between 2006 and 2015:

By 2010 or earlier:

- *Increase coverage.* Countries will reach at least 90% national vaccination coverage and at least 80% vaccination coverage in every district or equivalent administrative unit.
- *Reduce measles mortality.* Globally, mortality due to measles will have been reduced by 90% compared to the 2000 level.

By 2015 or earlier:

- *Sustain coverage.* The vaccination coverage goal reached in 2010 will have been sustained.
- *Reduce morbidity and mortality.* Global childhood morbidity and mortality due to vaccine-preventable diseases will have been reduced by at least two thirds compared to 2000 levels.
- *Ensure access to vaccines of assured quality.* Every person eligible for immunization included in national programs will have been offered vaccination with vaccines of assured quality according to established national schedules.
- *Introduce new vaccines.* Immunization with newly introduced vaccines will have been offered to the entire eligible population within five years of the introduction of these new vaccines in national programs.
- *Ensure capacity for surveillance monitoring.* All countries will have developed the capacity at all levels to conduct case-based surveillance of vaccine-preventable diseases, supported by laboratory confirmation where necessary, in order to measure vaccine coverage accurately and use these data appropriately.
- *Strengthen systems.* All national immunization plans will have been formulated as an integral component of sector-wide plans for human resources, financing and logistics.
- *Assure sustainability.* All national immunization plans will have been formulated, costed and implemented so as to ensure that human resources, funding and supplies are adequate.

Global Vaccine Action Plan

A Global Vaccine Action Plan submitted to the Sixty-Fifth Session of the World Health Assembly in 2012 builds on GIVS, by setting out six strategic objectives:

- All countries commit to immunization as a priority.
- Individuals and communities understand the value of vaccines and demand immunization as both their right and responsibility.
- The benefits of immunization are equitably extended to all people.
- Strong immunization systems are an integral part of a well-functioning health system.
- Immunization programs have sustainable access to predictable funding, quality supply and innovative technologies.
- Country, regional and global research and development innovations maximize the benefits of immunization.

World Health Organization International Health Regulations

As a Member State of the WHO, Canada is subject to the International Health Regulations (IHR), a binding international legal instrument aimed at helping the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide. Of relevance to Canada's domestic immunization strategies are emerging infections like SARS or a new human influenza pandemic. The IHR, which entered into force in June 2007, require countries to report certain disease outbreaks and public health events to the WHO. The IHR also require countries to strengthen their existing capacities for public health surveillance and response. Finally, the IHR require

countries to develop and implement plans of action to ensure that the relevant core capacities are functioning.

Domestic Goal Setting and Collaboration

Pan-Canadian Public Health Network

The Pan-Canadian Public Health Network (PHN) was established by Canada's F/P/T Health Ministers in 2005, as a key intergovernmental mechanism to:

- strengthen and enhance Canada's public health capacity
- enable F/P/T governments to better work together on the day-to-day business of public health
- anticipate, prepare for, and respond to public health events and threats

PHN's mandate as directed by F/P/T Deputy Ministers is to:

- facilitate information sharing among all jurisdictions
- disseminate information regarding best practices in public health
- support the public health challenges jurisdictions face during emergencies
- provide advice and regular reporting to F/P/T Deputy Ministers of Health on public health matters and the activities of the Network
- collaborate on the day-to-day operations of public health
- respect jurisdictional responsibilities in public health
- be accountable to the Conference of F/P/T Deputy Ministers of Health

The work of the PHN is governed by a 17-member Pan-Canadian Public Health Network Council (PHNC) composed of F/P/T government officials, including the Chief Public Health Officer of Canada and senior government officials from all jurisdictions who are responsible for public health. The PHN Council is accountable to the Conference of F/P/T Deputy Ministers of Health. Deputy Ministers of Health provide direction and approve public health policy priorities for Canada.

The work of the PHN is managed by three F/P/T Steering Committees:

- Healthy People and Communities Steering Committee
- Communicable and Infectious Disease Steering Committee
- Public Health Infrastructure Steering Committee

The Steering Committees are accountable to the PHN Council. Steering Committees may establish time-limited, expert-based Task Groups to advance the development of studies, reports and proposals addressing PHN priorities and work plan items.

Council of Chief Medical Officers of Health

The Council of Chief Medical Officers of Health (CCMOH) is a Canadian F/P/T body established in 1996 to strengthen public health in Canada. CCMOH membership includes the Chief Medical Officer of Health from each provincial and territorial jurisdiction, a representative from the Public Health Agency of Canada, the most senior Public Health Physician of the First Nations and Inuit Health Branch of Health Canada, and the Chief Public Health Officer of Canada (*ex officio* member).

The CCMOH provides a forum for promoting excellence in population and public health practice through communication, collaboration and the exchange of ideas, knowledge, experience, and best practices on public health issues, activities and concerns.

The CCMOH advocates and provides specific advice on measures that prevent disease and injury, and protect and promote the health of Canadians. It also facilitates discussion and collaborative action on professional practice issues related to strengthening public health—for example, identifying generic functions of Medical Officers of Health, standards of practice and ethical issues. In addition, and as circumstances evolve, the CCMOH identifies and proposes work on a broad range of emerging public health issues.

The CCMOH may provide direction, guidance and recommendations on technical issues relating to PHN work—such as the National Immunization Strategy—to PHN Council and Steering Committees, as appropriate. The CCMOH reports to the Conference of F/P/T Deputy Ministers of Health through PHNC.

Canadian Immunization Committee

The mandate of the Canadian Immunization Committee (CIC) is to provide advice and recommendations to contribute to the implementation of the NIS and help address emerging immunization issues in Canada, in support of F/P/T efforts to:

- Prevent, control, reduce, eliminate, and eradicate vaccine-preventable diseases within Canada.
- Enhance the long-term security of quality vaccine supply at an affordable cost for Canada.
- Develop recommendations for publicly funded immunization programs, including new programs and changes in policies.
- Promote immunization awareness, and provide information tools and resources that will enhance public and professional confidence in immunization programs.
- Improve vaccine safety monitoring and response, and reporting.
- Advance the concepts of research into immunizations and immunization programs.
- Ensure accessible, affordable availability to immunization opportunities for special populations.
- Meet the goals of the National Immunization Strategy as presented in the *National Immunization Strategy: Final Report 2003*, or any update to this strategy as it may be approved, and the expected current outcomes.

ASSESSMENT: OVERARCHING DIRECTION AND COORDINATION

Since the PHN's mandate and interests in immunization are intertwined with its broader mandate and interests in public health, including comprehensive disease prevention strategies, the broadest aspects of strategic direction and coordination extend beyond the mandate and technical expertise of the NIS-TG.

However, the NIS-TG notes that immunization programming in general, and the NIS in particular, would benefit from more substantial and continuous high-level PHN oversight, direction and coordination, to provide strategic and policy guidance to the CIDSC. This would address one of the most significant shortcomings of how the NIS has been managed to date, namely, that it has largely been left to the

individual jurisdictions to pursue issues and opportunities identified through NIS work in a relatively *ad hoc* fashion. Monitoring of, and reporting on, collective progress has been inconsistent and sporadic. Apart from an interim evaluation led by PHAC covering the 2003−2007 period, and this review by the NIS-TG, there has been no comprehensive assessment of evolving needs, opportunities and priorities. National goal setting has been largely overlooked.

What is needed is regular and explicit high-level PHN planning, oversight and coordination that can encourage, guide and facilitate more cohesive, significant and sustained F/P/T participation in areas of mutual interest and benefit. This includes the setting of domestic and international immunization goals and commitments, and vigilant tracking, oversight and coordination of their achievement.

B. Common Vaccine Guidance

SITUATION

Roles and Responsibilities for Vaccine Guidance

Currently, a number of organizations are involved in various aspects of developing, approving, disseminating and adopting recommendations for the use of new vaccines and/or new indications for vaccines (referred to throughout this report as vaccine recommendations). The process is triggered by the regulatory authorization of a vaccine for use in Canada by Health Canada's Biologics and Genetic Therapies Directorate (BGTD), or by the public health system in certain situations when new vaccines are needed. Once a vaccine receives regulatory authorization, it undergoes reviews by one or more of three national expert committees and by committees in most P/Ts, each providing vaccine recommendations to a different authority:

- The **National Advisory Committee on Immunization** (NACI) is Canada's version of what the WHO refers to as a national immunization technical advisory group (NITAG), defined as a technical resource providing guidance to national policy makers and program managers to enable them to make evidence-based immunization-related policy and program decisions. NACI reviews and makes recommendations to the Assistant Deputy Minister, Infectious Disease Prevention and Control, PHAC, on the medical, scientific and public health aspects of a vaccine (which has to date excluded economic analysis).
- The **Canadian Immunization Committee** (CIC) is a federal/provincial/territorial committee that reports to the Public Health Network on a variety of immunization program planning issues. While CIC's mandate does not explicitly direct it to develop vaccine statements, CIC has conducted reviews of, and recommendations on, the cost-benefit economic analysis of six vaccines, subsequent to NACI recommendations on those vaccines.
- The **Committee to Advise on Tropical Medicine and Travel** (CATMAT) makes recommendations to the Assistant Deputy Minister (ADM), Infectious Disease Prevention and Control Branch (PHAC), relating to the prevention and treatment of infectious diseases and other health hazards that may be encountered by Canadians travelling outside Canada. This currently includes making vaccine recommendations on some of the same vaccines reviewed by NACI. CATMAT also makes independent vaccine recommendations on some vaccines that are strictly for travelling Canadians, without NACI involvement.

While the above committees make national recommendations, provinces and territories are each responsible for immunization program decisions following their own review and recommendations (made by scientific advisory committees or immunization leads); they also review vaccine recommendations (from NACI and/or CIC) and are responsible for implementing immunization programs that meet their epidemiological and financial circumstances.

NACI and CATMAT are both federal committees that report to the Assistant Deputy Minister (ADM) responsible for PHAC's Infectious Disease Prevention and Control Branch (IDPCB). As noted above, CIC is an F/P/T committee that reports to the PHN.

Current Review and Guidance Processes

Overview

NACI and CIC both use a system of working groups to develop vaccine recommendations. CATMAT has recently begun to make more use of this approach, moving away from the sub-committee and whole committee approaches employed in the past. NACI and CATMAT have also been reviewing and refining evidence-based medicine (EBM) guidelines for the development of vaccine recommendations, along with documented processes for summarizing and evaluating the evidence to support specific recommendations.

CIC's population-based vaccine program recommendation development is guided by *An Analytical Framework for Immunization Programs in Canada*, developed by Erickson, De Wals and Farand (2005), which addresses the following factors:

- disease characteristics
- burden of disease
- vaccine characteristics
- alternative immunization strategies
- cost-effectiveness
- feasibility
- acceptability
- program evaluability
- research questions
- equity, ethical, legal and political considerations

NACI Process and Timelines

As Canada's NITAG, NACI plays a central role in developing vaccine recommendations in Canada. Following are highlights of the process followed by NACI and its Secretariat (in PHAC):

- When a vaccine manufacturer submits a product submission to BGTD for approval, NACI is notified by BGTD (and sometimes by the manufacturer). NACI usually engages an existing or starts a new Working Group (WG) of relevant experts to gather and review information and evidence, focusing in particular on review of information provided by manufacturers. NACI delegates tasks to WG members according to their expertise, and determines what needs to be included in the recommendation.

- In January 2009, NACI formally introduced its process to develop and grade evidence-based recommendations through the publication of its Statement: *Evidence-based recommendations for immunization—Methods of the National Advisory Committee on Immunization*.
- The development process of a NACI statement takes at least eight months and the approval and production phase undertaken by the NACI Secretariat takes at least two months.

In general, the stages for the development of a NACI recommendation are:

- Knowledge synthesis (retrieval and summary of individual studies on vaccine safety, efficacy, immunogenicity, effectiveness, ranking of the level, and quality of evidence of each study).
- Synthesis of the body of evidence of benefits and harms, considering the relevance, quality of the evidence and magnitude of effects observed.
- Translation of summarized evidence into recommendations associated with a qualitative recommendation grade.

The relevant NACI Working Group is responsible for establishing the scope of, and requirements for, a literature review, which may be contracted out to an external group/consultant, or performed by PHAC. Full knowledge synthesis includes a review of the product monograph as well as scientific literature on: the burden of disease (epidemiology, morbidity, mortality) in the population in general and in specific risk groups; vaccine characteristics (e.g., safety, immunogenicity, efficacy, effectiveness); and other relevant scientific and technical factors. Recommendations from other groups (e.g., WHO, Advisory Committee on Immunization Practices, Canadian Paediatric Society) are also reviewed.

The WG prepares recommendation options for consideration by the full NACI committee. The Medical Lead and the NACI Working Group Chair review all individual studies, but all the assembled evidence is available to the Working Group and to NACI. The full NACI committee reviews and discusses the data, the draft Advisory Committee Statement, and the recommendation options prepared by the WG, following which it votes on the recommendation options.

The final NACI Advisory Committee Statement, incorporating results of the NACI full committee discussion and vote, is circulated by e-mail for approval. After this approval, and a final review by the NACI Chair and Executive Secretary, the document is sent to the ADM, IDPCB in PHAC for final government approval and to the Chief Public Health Officer (CPHO) for approval to publish. Once edited and translated into both official languages, approved NACI statements are usually published in the *Canada Communicable Disease Report* and posted on PHAC's website.

CIC Process and Timelines

The Canadian Immunization Committee was created in 2004 to support implementation of the National Immunization Strategy. Under its broader mandate, which includes vaccine program planning, CIC developed recommendations in support of two vaccines. In both cases, the statements specifically addressed the economic analysis aspect of the analytical framework CIC uses in its work. Also in both cases, as the need for and approach to conducting economic analysis in support of vaccine recommendations had not yet been established, CIC led the work on a pilot basis. Since then, CIC has developed an additional four vaccine statements. Some of CIC's work has duplicated that of NACI.

In general, CIC has followed a development process similar to that of NACI (i.e., establishing a group to lead the work, seeking input and approval from the group and from CIC, and seeking approval from CIC's authority. The processes of development, approval and preparation for publishing CIC

recommendations have each taken one year or more. Of note, CIC reports to a different authority than NACI, with CIC's recommended statements routed through the Public Health Agency of Canada's Director General, Centre for Immunization and Respiratory Infectious Diseases (CIRID), the Agency's Office of Public Health Practice, PHN's Communicable Disease Control Expert Group (CDCEG; now CIDSC), and finally by the Public Health Network Council (PNHC). Once approved by PHNC, the publication process is similar to that for NACI vaccine recommendations, described above.

CATMAT Process and Timelines

As with NACI and CIC, CATMAT's broader mandate includes the development of vaccine recommendations. Some of its vaccine recommendations are for the benefit of travelling Canadians; in other cases, CATMAT contributes to NACI vaccine statements that address new or existing vaccine in use for Canadians at home and for those travelling.

CATMAT submits its recommendations to the ADM, IDPCB for approval before they are prepared for publishing on the PHAC website. This process can take several months.

PHAC Support

NACI, CIC and CATMAT each have detailed and written terms of reference. Each committee is supported by staff (a secretariat) within PHAC. Both NACI and the CIC are supported by CIRID, while CATMAT is supported by the Agency's Centre for Foodborne and Zoonotic Disease. PHAC support for NACI includes the provision of medical/technical expertise and epidemiological data.

In general the secretariat of each committee provides a range of support services, which may include: preparing and maintaining a project plan with timelines; securing outside resources when needed to supplement those of committee members and/or PHAC staff; managing the review and approval process and all preparation for publication in English and French on the web (NACI and CATMAT); and preparing information for the media.

Provincial and Territorial Processes

In addition to their participation in the CIC, all provinces and territories have their own processes and mechanisms for considering new vaccines and immunization programs, albeit in varying forms and to varying degrees of formality from one jurisdiction to the next. Typically this entails an expert immunization advisory committee, often as a sub-committee of, or advisory body to, a broader P/T infectious or communicable disease advisory body. For example:

- *British Columbia*: The B.C. Immunization Committee is one of several sub-committees reporting to the provincial Communicable Disease Policy Committee, which reports to the Deputy Minister of Health through the Provincial Health Officer. The Communicable Disease Policy Committee itself is supported by the B.C. Centre for Disease Control and is composed of representatives from the province's five health authorities (Medical Health Officers and Public Health Nursing Representatives), the Ministry of Health, Health Protection Directors and Health Canada's First Nations and Inuit Health Branch. Advice from the Immunization Committee on vaccines and immunization programs is offered to enable the Communicable Disease Policy Committee to form its own evidence-based recommendations to government decision makers in fulfilment of its mandate to establish priorities for communicable disease control and to lead the development of cost-benefit analyses for new and existing programs, including immunization programs.

- *Ontario:* The Ontario Immunization Committee is one of four expert advisory committees and an overall coordinating committee reporting to the Provincial Infectious Diseases Advisory Committee, which provides expert, evidence-based knowledge products (best practice documents) and advice on potential prevention, surveillance and control measures for infectious diseases.
- *Manitoba:* The Manitoba Immunization Advisory Committee reports to the Manitoba Advisory Committee on Infectious Diseases.
- *Alberta:* The Alberta Advisory Committee on Immunization provides expert support and advice in the implementation of Alberta's Immunization Framework for Introducing New Vaccine Programs, including data collection, research, literature review, strategic policy advice for new or enhanced immunization programs, and coordination of projects.
- *Québec:* The Québec Immunization Committee supports the Québec Ministry of Health by, among other things, undertaking evidence-based evaluations of available vaccines and of possible vaccination strategies and schedules. This uses an established assessment guide that takes into account a broad range of technical and socio-economic factors, and presents findings in the form of an objective assessment of factors and options, and their implications.

Provinces and territories typically initiate their vaccine and immunization program assessment processes following, or in line with, the above-mentioned NACI (and, where applicable, CIC) processes. In very rare cases P/T vaccine assessment processes and related schedule and program decisions have preceded the NACI process, to deal with a perceived P/T priority and take advantage of immediately available P/T funding and government support. To varying degrees, the P/T vaccine review processes assess the merits of a particular immunization program in the context of local P/T needs, conditions and priorities, including any variations to deal with unique diverse population circumstances.

There are several important reasons why P/Ts need to undertake some form of custom assessment, design and delivery of their respective immunization programs, for example to: identify and respond to unique circumstances and immunization needs/priorities of sub-groups of the overall P/T population; address immunization program resource availability and/or constraints; proactively test and assess alternative immunization schedules that may deviate from those recommended by NACI and/or CIC. However, to a considerable extent, the P/T processes and considerations are redundant with those of NACI and CIC, and there are prospects for a considerable streamlining, provided P/T interests and concerns could be adequately addressed through a more integrated approach acceptable to all F/P/T authorities.

International Approaches

Approaches vary across the United States, the United Kingdom and Australia—each offers some approaches that can address the key challenges facing Canada. For example:

- Recommendations are made by a single body in the U.S. and the U.K. The U.K. adopts a very proactive approach to planning for new immunization programs, including securing early scientific advice on outstanding research questions, and establishes early surveillance of disease burden and patterns.
- All three countries set up an approach for overall efficient development of immunization recommendations by minimizing duplication with state and territorial governments through the leadership provided by the national government.

- In the U.K. and U.S., economic analysis is considered in the development of vaccine recommendations; moreover, the U.S. uses a standardized content and process format for the review of cost-benefit studies. Australia has in place a process to engage the vaccine industry as a meaningful partner with governments through an annual "immunization day" (meeting) with industry representatives.
- All three countries have extensive resources and expertise for development of vaccine recommendations.

Australia

Australia has some direct similarities to Canada, including: vast geographic distances with the population sparsely distributed, except for a few large cities; a substantial indigenous (Aborigine) population; and parallel immunization structures/committees with similar mandates and public health network functions, most notably: the Australian Technical Advisory Group on Immunization (ATAGI), which is akin to Canada's NACI; Australia's National Immunization Committee (NIC) which equates to Canada's CIC; and the Communicable Disease Network Australia which roughly parallels Canada's PHN.

Differences are also evident. Unlike Canada, the Australian Government has implemented national funding for the purchase of vaccines (in exchange for the implementation of a standardized immunization schedule by states and territories). It also funds a national immunization registry for children up to age 7 years, manages an HPV vaccine registry, and provides vaccination incentives for both the public and providers, with the goal of maintaining high immunization rates. Australia also uses contracts to hire required scientific expertise. For specific new vaccines, such as for HPV vaccine programs for women and girls, early and broad catch-up programs have been implemented, which are already having an impact on a population basis. By comparison, in most of Canada, HPV vaccine uptake in P/Ts has varied from 43% to 91% of the targeted population. There are limited or no catch-up programs in many jurisdictions.

The apparent advantages of the Australia initiatives are: equitable access to vaccines and immunization programs; long-term sustainability of vaccine programs; clarity of roles of key players; collaborative relationships with the public, primary health care professionals and academic experts; capacity to assess effectiveness of vaccine recommendations and program implementation; and overall efficient development of vaccine recommendations by minimizing duplication with state and territorial governments. At the same time, these jurisdictions have some autonomy with respect to the selection of specific vaccines and in addressing special programs (such as for Aboriginal populations). Where immunization rates can be/are evaluated, vaccine uptake rates in Australia are higher than in most of Canada. To support its efforts to plan in advance for new vaccines, Australia also holds annual meetings with all vaccine manufacturers, in which vaccine pipelines from each manufacturer are described up to five years in advance.

Of note, Australia has contracted with the National Centre for Immunization Research and Surveillance (NCIRS) of Sydney University to provide secretariat and scientific support to ATAGI, to conduct research and surveillance, and to be a resource also to its regulator and the Department of Health in general. The quality of this arrangement is monitored through regular external assessments of performance.

Apparent disadvantages of Australia's system, when compared to that of Canada, are that Australia does not have formal scientific publications on its recommendations; nor does it have a single government reporting line for review of updates, such as that in Canada which supports timely and efficient updates to the *Canadian Immunization Guide*.

United Kingdom

Immunization planning and program implementation in the U.K. are directly led by the national government, through the Immunization Unit (IU) of the Department of Health. The IU is considered to be an efficient coordinator of the countries' entire immunization program—including for planning, communication, implementation and evaluation. While currently effective and efficient in the U.K. context, this organizational approach has not yet been fully tested and assessed under the recent devolution of health authorities to individual countries in the U.K., and in any case is not consistent with the historical and legislated responsibilities for health care in Canada. Nevertheless, a number of specific features of structure and process are worthy of closer consideration for use in Canada. These include the use of contracts by the IU to the Health Protection Agency (HPA), an independent organization set up by the U.K. Government in 2003 to protect the public from threats to their health from infectious diseases and environmental hazards. In the field of immunization, the HPA secures scientific advice on surveillance, epidemiology and research, complemented by regular surveillance by the IU of knowledge and attitudes of the public about immunization to strengthen planning, education and communication efforts.

The U.K.'s expert advisory group, the Joint Committee on Vaccines and Immunization (JCVI) has a clear set of conflict of interest guidelines, and transparent methods for applying the guidelines to committee deliberations. For example, while JVCI meetings are closed meetings, minutes are published within pre-established timelines and are posted openly on the web. Annual reports are also published.

The JCVI scientific deliberations must include an economic assessment. Carried out by the HPA, the assessment uses a predetermined government threshold for all health interventions (£20,000/quality-adjusted life year, or QALY) that a new vaccine program must meet before it is recommended to be a publicly funded program. It only includes consideration of direct (not indirect) costs in its assessments. While a threshold likely creates some challenges in analysis due to some of the imprecision associated with cost-benefit estimations, the advance clarity appears to help new vaccine programs (that meet this threshold) obtain government funding support, thus minimizing delays in introducing new vaccine recommendations and programs.

The U.K. Government takes a proactive approach to the consideration and strategic planning of new vaccine programs by making requests for early assessment to the JCVI. At the same time, the JVCI actively anticipates the need for early scientific advice and research for new vaccines. Historically, where evidence has warranted special action (such as for the early production of conjugated meningococcal C vaccine to address epidemics), the U.K. Government has directed vaccine manufacturers to produce vaccine to meet health needs. Budget planning for vaccines also anticipates new vaccine programs, in three-year advance budget planning cycles.

United States

The U.S. Strategic National Vaccine Plan provides a long-term approach which assists all components of the U.S. immunization system in planning, coordination of efforts, clarity of roles, the efficiency of execution of actions and public accountability.

The U.S. Government, through the Department of Health and Human Services (HHS), has clearly defined immunization policy and public health programming responsibilities. Under its Vaccines for Children Program, the HHS provides federally purchased vaccines for children who qualify for Medicare. The Advisory Committee on Immunization Practices (ACIP) works with professional societies to produce uniform national U.S. immunization schedules for both children and adults, and identifies which childhood vaccines should be part of the Vaccines for Children Program.

The major process for developing new vaccine recommendations in the U.S. occurs within the ACIP working groups, which are supported by the surveillance and research expertise from within the Centers for Disease Control and Prevention (CDC). In many cases, medical staff and/or epidemiologists from other CDC divisions are assigned to the working groups. Each ACIP Working Group has one lead physician and additional CDC staff and support staff. In its deliberation, ACIP considers economic analyses conducted by economic experts from other areas of government with the use of a standardized format. ACIP conducts open meetings in accordance with laws and rules of U.S. federal committees.

A second U.S advisory committee is the National Vaccine Advisory Committee (NVAC), which reports to the Assistant Secretary, HHS. The NVAC advises on immunization policy issues, such as mandatory immunization of health workers, vaccine supply, vaccine hesitancy, and implementation issues under the *Affordable Care Act*.

ASSESSMENT: COMMON VACCINE GUIDANCE

Strengths

Experts and stakeholders familiar with current vaccine guidance processes in Canada generally recognize and value the following features:

- the overall high quality and reputation of the process, which is characterized by well-regarded professionalism and dedication, the experts involved, and the usefulness and high quality of the outputs
- that Canada's system supports use of Canadian expertise on immunization issues at many different levels of decision making
- the objective nature of both processes and results, and the use of evidence-based practices, reflecting a commitment to solid science, and supported by the use of a grading system for level of evidence, and by the use of a framework for immunization program review and analysis
- the engagement which characterizes the system, reflecting outreach and cooperation with provinces/territories, industry and stakeholders—and commitment to broader national public health and individual health interests

Issues and Concerns

Despite the above strengths, over the past five years, there has been growing concern from a range of stakeholders that, under the current approach, the development of vaccine recommendations in Canada is not timely and does not facilitate equitable access to vaccines by all Canadians. In general:

- Despite the existence of NACI and CIC, there is no single review process for consideration of new vaccines that addresses both technical and economic/programmatic factors in an integrated way, directly accountable to all jurisdictions. The current patchwork of federal, national and P/T review processes is duplicative, inefficient, and often contradictory and counter-productive.

- There are also no common guidance documents for new vaccines that can be formally recognized and accepted as reasonably definitive guidance on the part of all jurisdictions, meaning that guidance on vaccine use can be inconsistent across Canada.

More specifically, there are several problems and challenges with the current approach to vaccine guidance:

- *An overly lengthy process and unpredictable timing of development and release of vaccine recommendations.* As detailed in the tables further below, the process of developing and disseminating immunization recommendations (by any one of NACI, CIC or CATMAT) typically takes 10 months or more from the time a vaccine receives regulatory authorization through the issuance of a Notice of Compliance (NOC). The vaccine recommendations review and approval process is also not guided by predetermined timelines. Development of CIC vaccine recommendations, when required, has only been initiated subsequent to completion of the NACI recommendation on the same vaccine, further prolonging completion of a comprehensive set of recommendations for a particular vaccine. CATMAT vaccine recommendations that include both a domestic and travel component are also subject to lengthy processes, given the involvement of both CATMAT and NACI, and their separate development processes and approval authorities.

- *Heavy and growing demand on a limited pool of expert volunteers to contribute to guidance in an increasingly complex and demanding immunization environment.* The vaccines reviewed each year by NACI, CIC and CATMAT are increasingly complex, given: the diversity of vaccines available for the same infectious disease; the complexity of vaccine preparation and composition (such as new adjuvants); the complex profile of vaccine recipients and target populations; the growing number of vaccine-preventable diseases of priority public health concern; the complexity of immunization schedules across jurisdictions; stakeholder demands for faster release of vaccine recommendations; public demands and preferences for more convenient immunization; and increasing sensitivity to the costs of vaccines and immunization program delivery. The human and material resources to support the significant increase in workload by the committees, their secretariats and departmental organizations are not in place.

- *Duplication of effort and inefficiencies across the system, with inadequate sharing of information.* Overlap of research and analysis occurs at several points in the recommendation development process between NACI/CIC and the various P/T review committees.

- *Absence of systematic evaluation of vaccine recommendations, their dissemination, and programs to implement the recommendations, in most parts of Canada.* This is especially important because of the variability of both recommended vaccine schedules and the range of programs offered across jurisdictions, and because the recommendations of NACI either may not be known or may not be followed by stakeholders. Evaluation of the effectiveness of the different vaccine schedules and programs and their promotion is not currently systematically and consistently built into the different P/T approaches, in order to assess whether they meet the objectives of the vaccine recommendations and to identify and share best practices.

- *Other initiatives and approaches that could enhance the timeliness and efficiency of the vaccine guidance process.* A number of suggestions have been advanced to provide greater support for Canada's vaccine guidance and recommendations processes, including: broaden the mandate of NACI to enable it to undertake more comprehensive evaluations, as is done in Québec; engage more public health experts with experience in vaccinology, immunization programs, psychosocial programs and economics; re-invite former members to add expertise and experience; provide greater support to assist the committee in the recommendation/statement writing process, freeing

up Committee members to focus more fully on provision of their expert opinions; greater liaison with P/T committees (most notably British Columbia, Ontario and Québec) to facilitate knowledge exchange and address diverse issues and interests of relevance to vaccine guidance; avoid excessive reliance on product monographs by supporting more independent scientific evidence; and strengthen the consideration of European approaches and experience to complement insights gained from ACIP in the U.S.

As detailed further below, there are specific issues and challenges associated with the significant time lags—often a matter of years—between critical decision stages leading to the implementation of immunization programs across jurisdictions in Canada. These delays begin with the time that elapses between the issuance of a Notice of Compliance (NOC) for a vaccine and the initiation and completion of a guidance statement from NACI. These delays are further compounded by delays between the completion of a NACI statement and the issuance of vaccine guidance statements, to the implementation of the first immunization program by a P/T, to the last program by a P/T.

By definition, the delays mean that Canadians remain avoidably unprotected against a number of vaccine-preventable diseases for periods of several months to several years from the time that an effective and safe vaccine is approved for use.

The delays, especially the uncertain, uncoordinated and patchwork adoption of immunization programs over time by P/Ts, also diminish opportunities for F/P/Ts to collaborate on the timely consideration and coordination of plans for such facets as program evaluation, surveillance, research, information, and coordinated bulk procurement, so as to: take advantage of opportunities for efficiencies and economies of scale; reinforce complementarity of F/P/T efforts; and strengthen the cohesiveness and consistency of messages about vaccine necessity, safety and effectiveness.

C. Coordinated Immunization Schedules and Programs

SITUATION

Factors Influencing Decisions on Immunization Schedules and Programming

Overview

Recent years have seen an increase in the number of new vaccines available on the Canadian market, and increasing divergence in provincial and territorial immunization programs as jurisdictions must choose among available health interventions with limited funding and without common science-based data.

Vaccine expert committees are faced with many different types of choices when making recommendations. They must deliberate on the adoption of new vaccines, the type of coverage (an entire cohort or high-risk groups only), combinations of vaccines, alternative dosing schedules, and vaccine delivery methods. In many instances, they are faced with an array of potential recommendations; for example, whether to recommend a vaccine for an entire cohort or for high-risk groups only. Each intervention has its associated costs and implications.

To add to the complexity of the decisions, different alternative interventions must sometimes be examined. The alternative to a vaccine is not always a "do nothing" alternative. For example, when considering whether or not to offer HPV vaccine, one has alternative public health interventions such as sex education and screening. Each of these other choices examined may also require a significant investment of public funds. Even "do nothing" alternatives can prove very costly as significant diseases with associated costs may occur, which may otherwise have been prevented.

Socio-Economic Considerations

Since vaccines not only prevent the disease of the individual immunized person, but also reduce the risk of the spread of disease to non-immunized persons and can lead to disease eradication within a population, the consideration of relative costs and benefits of immunization programs requires a combination of economic and infectious disease epidemiological expertise in modelling and assessing options.

Developed in the late 1960s, health economics brings together information from economics, production sciences, epidemiology, psychology and accounting disciplines about the costs and health consequences of alternative courses of action, deriving an "economic efficiency" measure which compares how well resources are being used. It provides a framework in which decision makers can identify alternative interventions and then compare the costs and outcomes of these interventions.

Socio-economic analysis of immunization program proposals and options can typically entail one or more of the following analyses:

- *Cost-benefit analysis* is a popular economic measure in which the health outcomes (benefits) are translated into dollar terms, often using experimental measures, and compared against the costs to determine if there is a net benefit.

- *Cost-effectiveness analysis* is practical and realistic in that both costs and health outcomes (e.g., cases with a specific disease, life years saved) of different optional interventions are compared. Outcomes are physical health measures, such as life years saved of persons who are diagnosed with a disease and subjected to the intervention option being assessed. Sometimes more than one type of outcome exists and, if all are important to the study, they should be included. For example, the use of influenza vaccine saves lives, but it may also reduce the severity of disease for those who do get influenza; in this case both health outcomes are important, and should be included in the study. One uses cost-effectiveness analysis when outcomes and costs differ between interventions to determine how much additional outcome is achieved for a unit of extra expenditure. The ratio of added cost to added outcome is often called the "incremental cost-effectiveness ratio," or ICER.

- *Cost-utility analysis* is growing in popularity, because it incorporates mortality and health status into a single health outcome index used to compare the differences in costs with differences in health outcomes. The index, called a Quality-Adjusted Life Year (QALY), ranks all health states from a level of 0 (death) to 1 (good health). The index is convenient for economists, because it allows interventions to be compared in the same index, along a single scale. Most importantly, outcomes in instances where there are both deaths and morbidity, or different kinds of morbidities, can all be compared along the QALY scale. The cost-per-QALY measure has become widely adopted in many policy quarters, though it has its drawbacks, most notably, that it does not readily apply to children and infants, and does not generally adequately reflect differences in circumstances and health outcomes impacts amongst diverse populations in diverse settings.

Measurement of Health Outcomes

In the methods above, health outcomes can include clinical measures (whether a disease occurs), demographic measures such as deaths or life years, or health care outcome indices. Many guidelines used by public health authorities and other agencies recommend QALY as the outcome of choice, as these are extremely convenient measures and allow a wide variety of outcomes to be compared.

Examples of QALY measures include: the QALY used by the Canadian Agency for Drugs and Technologies in Health (CADTH); the EQ-5D health outcomes questionnaire developed by the EuroQOL Group (research network in England, Finland, Netherlands, Norway and Sweden); the Health Utilities Index (HUI), a health index developed in Ontario; HALYs (health-adjusted life years), a composite health gap measure used by Ontario authorities to assess disease burden; and the Finnish-developed 15-D health-related quality of life (HRQoL) instrument. All are widely used, but they do not always correspond to one another, so the results between studies that use different QALY systems may vary because of differences in the instruments.

QALYs have been developed for adults and older teens but there are no such measures for young children, many of whom are targets for the immunization. Although proxy measures have sometimes been used to measure health outcomes for these excluded groups, these are artificial and have not been validated. In the absence of using a QALY for childhood populations with illnesses such as measles and mumps, economists can use life years saved, or can use several different health indicators simultaneously (leading to "cost-consequences" analyses).

Potential Threshold Criteria for Decision Making

Public priorities regarding interventions are sometimes expressed in terms of a "threshold" value, which is established by governments in order to determine the level of cost-effectiveness as a factor in determining the merits and appropriate target and level of funding. A commonly used threshold for the ICER has been $50,000 per QALY, which means that the government would be willing to fund an intervention if the additional cost per QALY is equal to or less than this amount. Not all countries use such a threshold. It is sometimes presented in ranges and, even when a specific threshold is stated, it is not usually the *sole* basis for policy. In a decision-making context, economic efficiency ratios are one of a number of criteria that can be used to reach a decision on the public provision of a new vaccine. Other criteria include safety, efficacy, acceptability, and disease burden. But none of these other criteria squarely addresses the issue of choice when there is a scarcity of funds and many other competing demands on health resources, especially the pressures of addressing immediate illnesses and imminent threats to specific patients and populations at risk, as opposed to the longer term and more generalized risk reductions linked to population-based immunization programs.

Immunization Scheduling in Canada

As noted above, each of the 14 jurisdictions in Canada has responsibility for making decisions about whether, when and in what manner it will initiate a new or modified immunization program, whether for the general population or targeted sub-groups.

As evidenced in the chart below, while there are many areas of consistency among jurisdictions with respect to adopted schedules for immunization for particular vaccine-preventable diseases, there is also considerable variation. This does not imply that any particular approach is inappropriate—not that all schedules should be identical—but, as noted in the assessment further below, it does present some

challenges in how immunization programs are designed and implemented in ways that are efficient and complementary, and how they are presented and explained to the public. The table offers a recent snapshot of the general pattern of complexity across Canada in immunization programming.

Routine Vaccine Schedules for Infants and Children as of December 2012*

P/T	DTaP-IPV-Hib	DTaP-IPV	Tdap; Tdap-IPV	HB	MMR	Var	MMRV	Men-C	Men-C-A, C, Y, W-135	Pneu-C-13	Inf	HPV	Rot
NACI Rec.	2, 4, 6, 18 months	4–6 years	14–16 years	Infancy (3 doses) OR Pre-teen/teen (2–3 doses)	12 months AND 18 months OR 4–6 years	12–18 months (1 dose)	12 months AND 18 months OR 4–6 years	Infancy (1–4 doses) AND Pre-teen (1 dose)	Pre-teen (1 dose)	2, 4, 6, 12–15 months	6–59 months (1–2 doses)	Females 9–13 years (3 doses at 0,2, 6 months)	2, 4, 6 months
BC	2, 4, 6 months (DTaP-HB-IPV-Hib); 18 months (DTaP-IPV-Hib)	4–6 years	Tdap, Gr. 9	2, 4, 6 months (DTaP-HB-IPV-Hib)	12 months, 4–6 years	12 months, 4–6 years; Catch-up Gr. 6		2, (4 HR), 12 months, Gr. 6		2, 4, (6 HR), 12 months	6–59 months	Females Gr. 6	2, 4 months
AB	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 9	Gr. 5			12 months, 4–6 years	2, 4, 12 months	Gr. 9 (1 dose)	2, 4, (6 HR), 12 months	≥ 6 months	Females Gr. 5	
SK	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 8	Gr. 6	Catch-up Gr. 6, Gr. 8 until Aug. 2013	Catch-up Gr. 6 until Aug 2015	12, 18 months	12 months	Gr. 6	2, 4, (6 HR), 12 months	≥ 6 months	Females Gr. 6	2, 4 months
MB	2, 4, 6, 18 months	4–6 years	Tdap, 14–16 years	Gr. 4	4–6 years		12 months	12 months, Gr. 4 until 2017		2, 4, (6 HR), 12 months	2012–2013 ≥ 6 months	Females Gr. 6; Catch-up ≤ Gr. 10 in 2012–2013	
ON	2, 4, 6, 18 months		Tdap-IPV 4–6 years; Tdap, 14–16 years	Gr. 7	12 months	15 months	4–6 years	12 months	Gr. 7	2, 4, (6 HR), 12 months	≥ 6 months	Females Gr. 8	2, 4 months
QC	2, 4, 6, 18 months		Tdap-IPV 4–6 years; Tdap, 14–16 years	Gr. 4	18 months		12 months	12 months; Catch-up < 18 years		2, 4, 12 months	6–23 months	Females Gr. 4 (2 doses), 3rd year of high school (1 dose); Catch-up females < 18 years	2, 4 months

Routine Vaccine Schedules for Infants and Children as of December 2012* (cont'd)

P/T	DTaP-IPV-Hib	DTaP-IPV	Tdap; Tdap-IPV	HB	MMR	Var	MMRV	Men-C	Men-C-A, C, Y, W-135	Pneu-C-13	Inf	HPV	Rot
NB	2, 4, 6, 18 months	4 years	Tdap, Gr. 9	0, 2, 6 months	12–18 months; Catch-up Gr. 12 2007–2011	12–18 months (children born in 2009 or later); one dose children born 2000–2008	12–18 months (in place of MMR and Var; Catch-up children born in 2009	12 months	Gr. 9	2, 4, 12 months	6 months–18 years	Females Gr. 7	
NS	2, 4, 6, 18 months		Tdap-IPV 4–6 years; Tdap, Gr. 7	Gr. 7			12 months, 4–6 years	12 months Gr. 7		2, 4, 12 months	≥ 6 months	Females Gr. 7	
PE	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 9	2, 4, 18 months			12, 18 months	12 months	Gr. 9	2, 4, (6 HR), 18 months	6–59 months	Females Gr. 6	2, 4 months
NL	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 9	Gr. 6	18 months		12 months	12 months	Gr. 4	2, 4, 12 months	6–59 months	Females Gr. 6	
NT	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 9	0, 1, 6 months; Catch-up Gr. 9	12, 18 months; Post-secondary students attending school outside NT	12 months; Catch-up < 5 years; Gr. 9		2, 12 months; Catch-up < 5 years; Gr. 9	Post-secondary students attending school outside NT	2, 4, 6, 18 months	≥ 6 months	Females Gr. 4; Catch-up Gr. 9–12 2009–2014	
YT	2, 4, 6 months (DTaP-HB-IPV-Hib); 18 months (DTaP-IPV-Hib)	4–6 years (DTaP-IPV or Tdap-IPV)	Tdap, Gr. 9	2, 4, 6 months (DTaP-HB-IPV-Hib); Catch-up ≤ 19 years	12 months, 4–6 years	12 months, 4–6 years		2,12 months; Catch-up Gr. 6; post-secondary students not previously immunized		2, 4, (6 HR), 12 months (3 + 1 doses)	> 6 months	Females Gr. 6; free to females 9–18 years; available for males 9–26 and females 19–26 at cost	2, 4 months starting Sep. 2012
NU	2, 4, 6, 18 months	4–6 years	Tdap, Gr. 9 (14–16 years)	0, 1, 9 months	12, 18 months; Catch-up Gr. 12	15 months		12 months; Catch-up Gr. 9 (14–16 years)		2, 4, 6, 15 months, plus PP23 (1 dose) 2–3 years	Universal ≥ 6 months	Females Gr. 6 (≥ 6 years)	

DTaP—diphtheria, tetanus, acellular pertusssis
HB—hepatitis B
Hib—*haemophilus influenzae* type b
HPV—human papillomavirus
HR—children at high risk only
Inf—influenza
IPV—inactivated poliomyelitis
Men-C—meningococcal conjugate
MMR—measles, mumps, rubella
MMRV—measles, mumps, rubella, varicella
Pneu-C-7, Pneu-C-10, Pneu-C-13—pneumococcal conjugate 7, 10, 13 valent
PP23— pneumococcal polysaccharide 23 valent
Rot—rotavirus
Var—varicella

*Publicly funded programs, including special and catch-up programs.
Source: Public Health Agency of Canada; see: http://www.phac-aspc.gc.ca/im/ptimpt/table-1-eng.php

International Comparison of National Coordination in Selected "Federated" States

The chart below compares 11 "federated" OECD countries with respect to their degree of national coordination, reflecting:

- the nature of their federated health system structures
- which level(s) is/are responsible for decisions on the use of vaccines in immunization programs
- the degree of coordination of vaccine schedules nationwide
- which level(s) is/are responsible for payment of vaccine procurement

As the table shows, Canada is the least cohesive and coordinated among the 11 "federated" states with respect to vaccine decisions, coordination of vaccine schedules, and responsibility for vaccine procurement.

International Approaches of Selected "Federated" States				
Country	**Health System**	**Decisions on New Vaccines**	**Coordinated Schedules**	**Procurement Funding**
Australia	▪ Federal ▪ 8 States/Territories ▪ Local	Federal	Same schedule nationwide	100% Federal (through immunization agreements)
Austria	▪ Federal ▪ 9 Länder ▪ 27 Corporatist Funds	Federal	Same schedule nationwide	2/3 Federal 1/6 Länder 1/6 Corporatist Funds
Belgium	▪ Federal ▪ 3 Communities ▪ 7 Corporatist Funds	Conference of Federal and Community Ministers	Same vaccines nationwide, but may target different groups	2/3 Federal 1/3 Communities
CANADA	▪ Federal ▪ 10 Provinces ▪ 3 Territories ▪ Local	Provincial and territorial	Provincial and territorial schedules that may or may not align	Provinces and Territories
Germany	▪ Federal ▪ 16 Länder ▪ Local Corporatist Funds	Länder and Public insurance companies	National recommendations	90% Public insurance companies 10% Länder
Italy	▪ Federal ▪ 21 Regional ▪ 200 Local	Federal (national committee of National Ministry, Regional Health Authorities, National Institute of Health, and scientific societies)	National schedule mandatory for children, plus additional formal agreements between Federal and Regional Health Authorities	Local Health Authorities

International Approaches of Selected "Federated" States (cont'd)				
Country	**Health System**	**Decisions on New Vaccines**	**Coordinated Schedules**	**Procurement Funding**
Spain	▪ Federal ▪ 19 Autonomous Communities ▪ Local	Council of Federal and Community Ministries	National recommendations, with options for Autonomous Committees to add to	100% Communities
Sweden	▪ Federal ▪ 21 Regions/Counties ▪ Local	Federal	National recommendations, with options for Regions/Counties to add to	Mostly Regions/Counties and Local
Switzerland	▪ Federal ▪ 26 Cantons ▪ Communes	Federal Vaccination Commission	National recommendations	Statutory private health insurance companies providing services defined by federal commission
United Kingdom	▪ Federal ▪ 152 Primary Care Trusts	Health Ministers of the four countries	Same schedule nationwide	100% Federal (through Federal purchasing)
United States	▪ Federal ▪ 50 States ▪ Local	Vaccine for Children Fund, and private insurance providers	*Public*: Vaccine for Children Program recommendations *Private*: usually follow ACIP recommendations	55% Federal (through Federal purchasing) 45% Private (insurance)

Sources: *Report of the International Forum on National Immunization Programs*, Toronto, Ontario, December 4−5, 2008. Prepared by Jenna Hall, Consultant, February 2009; supplemented by information from state health authority websites.

ASSESSMENT: COORDINATED IMMUNIZATION SCHEDULES

To a certain extent, the variability in vaccine schedules amongst jurisdictions reflects a consideration of the particular needs, priorities and circumstances of each distinct jurisdiction. However, in many cases, it reflects the reality of a number of otherwise avoidable challenges along the path toward acceptance by P/Ts of a particular vaccine schedule:

- urgency to proceed with a program without being able to wait for completion of a NACI and/or CIC statement
- inconsistencies between/amongst different guidance processes (NACI, CIC and/or processes of the individual P/Ts)
- exclusion from consideration in NACI and CIC guidance processes of factors that are of importance to one or more P/T jurisdictions
- inability of P/Ts to directly and meaningfully set priorities and parameters for NACI guidance processes, and to influence urgency and timing

Compounding the impacts of the delays described further above, the wide variation in adopted schedules by P/Ts across Canada diminishes opportunities for F/P/Ts to collaborate on the timely consideration and coordination of plans for such facets as program evaluation, surveillance, research, information, and coordinated bulk procurement, so as to: take advantage of opportunities for efficiencies and economies of scale; reinforce complementarity of F/P/T efforts; and strengthen the cohesiveness and consistency of messages about vaccine necessity, safety and effectiveness.

The variation in schedules also presents some very specific and immediate problems for Canadians, especially those who relocate from one jurisdiction to another where schedules are different:

- individuals, especially infants and school-aged children, may get "out of sync" with the timing of their required vaccinations, risking either missing a vaccination altogether or unintentionally being subjected to an unnecessary, publicly costly, and inconvenient duplication of a vaccine already received
- keeping track of immunization records is more challenging, especially where linked or compatible records or registries are not in place or fully functional
- unless objective reasons can be provided by authorities for any variation in schedules amongst jurisdictions, especially where these deviate from NACI recommendations, the public and professionals alike tend to question the credibility of the rationale advanced for vaccine relevance and effectiveness, especially where they may be exposed to different messaging and information about diverse programs addressing the same vaccine-preventable disease

At the same time, vaccine experts recognize that it can sometimes be strategically useful to creatively "experiment" with different vaccine schedules, to track and compare their results, and share best practices among jurisdictions. However, such positive knowledge transformation benefits can only be achieved if such variations are well-planned and well-coordinated, and the required program evaluation, research and surveillance strategies are fully considered and integrated into the design and implementation of the immunization programs.

Immunization Programming in Canada

For a variety of reasons, immunization programs—whatever particular schedule is adopted—have been initiated by jurisdictions in widely varying timeframes. These range from being closely paced together and implemented relatively shortly after the issuance of Notice of Compliance (NOC) and the subsequent NACI guidance statement, to being strung out as many as seven years apart from the first initiating jurisdiction to the last. In a number of cases, even the NACI statement was not issued until many months or years after the NOC. In some cases as well, the first initiating jurisdiction did not implement a program until many months or years after the NACI statement. The tables below provide selected examples of these variations in program introduction times.

Timing for Introduction of Selected Recent Immunization Programs in Provinces and Territories (P/Ts) as of December 2012						
Disease/ Antigen	**Notice of Compliance**	**NACI Statement**	**CIC Statement**	**First P/T Introduction**	**Last P/T Introduction**	**P/Ts with Programs**
HB	May 1987	Aug 1991 Jul 2000[a]	N/A	1992	Sep 1998	All 13
HPV-4 (HPV-2)	Jul 2006 (Feb 2010)	Feb 2007 (Jan 2012)	Dec 2007	Sep 2007	Mar 2010	All 13
Men-C-C	Apr 2001[b]	Oct 2001[c]	N/A	Apr 2002	Jan 2007	All 13
Men-C-ACYW135[d]	May 2006	May 2007[d]	Jan 2010	Nov 2006	Feb 2011	7 of 13
Pneu-C-7 (Pneu-C-10) (Pneu-C-13)	Jun 2001 (Dec 2008) (Dec 2009)	Jan 2002 (Apr 2010) (Nov 2010)	N/A	Sep 2002 (Jun 2009) (Jun 2010)	Jan 2006 (Dec 2009) (May 2011)	All 13
Rot-5 (Rot-1)	Aug 2006 (Oct 2007)	Jan 2008 (Jul 2010)	Estimated 2013	Dec 2010	Sep 2012	6 of 13
Varicella 1 dose	Dec 1998[e] Oct 1999	May 1999[f]	N/A	Mar 2001	Sep 2007	All 13
Varicella 2 dose	Jul 2007[g]	Sep 2010	Estimated 2013	Feb 2011	Apr 2012	9 of 13

a Statement on Alternate Adolescent Schedule for Hepatitis B Vaccine—July 1, 2000; Statement on the recommended use of pentavalent and hexavalent vaccines—February 1, 2007; see: http://www.phac-aspc.gc.ca/naci-ccni/recs-eng.php

b Menjugate—April 18, 2001; see: http://www.prnewswire.com/news-releases/menjugate-tm-chirons-meningococcal-c-vaccine-chosen-for-quebec-vaccination-program-71383227.html

c Update on the Invasive Meningococcal Disease and Meningococcal Vaccine Conjugate Recommendations—April 2009; Meningococcal C Conjugate for Infants statement—November 2007; Update on Meningococcal C Conjugate Vaccines—April 15, 2005; Supplementary Statement on Conjugate Meningococcal Vaccines—September 1, 2003; Statement on Recommended Use of Meningococcal Vaccines—October 15, 2001

d October 2001 NACI Statement was for Men-C-conjugate + polysaccharide meningococcal vaccines; Men A, C, Y, W-135 conj. = Men-C-ACYW135

e Varivax—December 2, 1998; see: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/04vol30/acs-dcc-1/index-eng.php

f Update on Varicella—February 1, 2004; NACI Update to Statement on Varicella Vaccine—February 15, 2002

g Varivax III—June 2002

Elapsed Time Between Key Immunization Decision Points for Introduction of Selected Recent Immunization Programs in Provinces and Territories (P/Ts)						
Disease/ Antigen	**From NOC to NACI**	**From NACI to CIC**	**From NACI to First P/T**	**From NACI to Last P/T**	**From First P/T to Last P/T**	**From NOC to Last P/T**
HB	4 years 3 months	N/A	At least 5 months	7 years 1 month	At least 5 years 9 months	10 years 4 months
HPV	7 months	10 months	7 months	3 years 1 month	2 years 6 months	3 years 8 months
Men-C-C	6 months	N/A	6 months	5 years 3 months	4 years 9 months	5 years 3 months
Men C-ACYW135	1 year	2 years 8 months	6 months	3 years 9 months	4 years 3 months	4 years 9 months
Pneu-C-7	7 months	N/A	8 months	4 years	3 years 4 months	4 years 7 months
Rot-5	1 year 5 months	At least 5 years 2 months	2 years 11 months	4 years 9 months	1 year 9 months	6 years 2 months
Varicella 1 dose	5 months	N/A	1 year 10 months	8 years 4 months	6 years 6 months	8 years 9 months
Varicella 2 dose	3 years 2 months	At least 2 years 6 months	5 months	1 year 7 months	1 year 2 months	4 years 9 months

Canadian Paediatric Society Assessment of Immunization Programs in Canada

The table below provides recent ratings by the Canadian Paediatric Society (CPS) of the availability of selected publicly funded immunization programs in Canada, based on the number of P/T jurisdictions that offer all or only some of the selected vaccines recommended by CPS and NACI.

CPS Assessment of Publicly Funded Immunization Programs in Canada*		
CPS Rating	**2009 Status**	**2011 Status**
Excellent (all recommended vaccines provided)	1 P/T	3 P/Ts
Good (all but one recommended vaccine provided)	12 P/Ts	3 P/Ts
Fair (all but two recommended vaccines provided)	0 P/Ts	7 P/Ts

*Based on provision by P/Ts of the following vaccines, in accordance with CPS and NACI recommended schedules, at no cost to individuals: meningococcal, adolescent pertussis, varicella, rotavirus, influenza and HPV.

Source: Canadian Paediatric Society website.

ASSESSMENT: COORDINATED IMMUNIZATION PROGRAMS

There is neither a formal commitment nor a mechanism for jurisdictions to ensure that the introduction of new immunization programs is well-coordinated and closely paced. As a consequence:

- it can take several years for the introduction of a recommended vaccine to be implemented across the country

- vaccine programs that are offered can vary appreciably from one jurisdiction to another
- some vaccines are not (yet) made available in some jurisdictions

Staggered and varied introduction of new vaccine programs across provinces and territories, especially in the case of high-profile vaccine-preventable diseases, presents several problems and challenges. A wide variation in the initiation of immunization programs by P/Ts across Canada diminishes opportunities for F/P/Ts to collaborate on the timely consideration and coordination of plans for such facets as program evaluation, surveillance, research, information, and coordinated bulk procurement, so as to: take advantage of opportunities for efficiencies and economies of scale; reinforce complementarity of F/P/T efforts; and strengthen the cohesiveness and consistency of messages about vaccine necessity, safety and effectiveness.

By definition, delays in the introduction of immunization programs mean that, where implementation is lagging, populations remain unprotected. This not only diminishes the overall effectiveness of immunization as strategy for prevention of disease, but means that Canadians have inequitable protection from one region to another.

Conversely, more coordinated and closely paced implementation of immunization programs by jurisdictions across Canada can greatly improve the effectiveness and nationwide equity of health protection while enhancing opportunities for the early planning and coordination of more consistent and mutually complementary approaches to program evaluation, research, surveillance, messaging, risk mitigation, and security of supply measures. This need not—and should not—prevent jurisdictions from consciously planning and testing alternative approaches to immunization schedules and programs, so that they can assess relative cost-effectiveness and share insights and best practices.

D. Program Evaluation and Research

SITUATION

The Scope and Nature of Program Evaluation and Research

Program evaluation and research was identified in the NIS (2003) as a very important component of immunization programming. It consists of a variety of activities, methods, tools and approaches, all designed to build an understanding and appreciation of some facet of immunization programming, spanning the following spectrum of potential elements:

- objectives of the program
- priority setting
- target populations
- rationale
- vaccines and schedules
- vaccine administration technology, strategies and techniques
- guidance and support in delivery
- linkage with related disease prevention programs and initiatives
- resources/funding

- roles and responsibilities
- education, awareness and training
- outreach/take-up
- adverse events
- outcomes (expected and unexpected)
- causality
- success factors
- barriers/impediments

Research ranges across a different spectrum from that of evaluation, from basic science through vaccine discovery and development to clinical trials, for example. Some overlap with program evaluation may occur.

The methods and tools used for program evaluation and research are diverse, and are selected and adapted for the particular study objectives, including:

- economic analyses (e.g., cost-effectiveness, cost-benefit), mathematic modelling for planning or evaluation purposes
- population surveys (polls on knowledge, attitudes, practices, etc.)
- vaccine coverage surveys
- pre- and post-marketing surveillance of disease, coverage, safety, and other aspects such as susceptibility and attitudes
- efficacy, effectiveness and feasibility studies
- gap analysis (e.g., targets and leads versus coverage and participation)
- basic laboratory investigator-led research

Practical Applications

While research is investigator driven and wide-ranging, program evaluation serves diverse practical purposes, by helping to answer the following kinds of critical questions about immunization:

- ***Accountability and Due Diligence:*** Was the program delivered as designed and agreed, and the committed resources used as approved? If not, why not, and with what consequence?
- ***Program Design Integrity:*** Were the research models used for vaccine assessment, vaccine program planning and design effective? Did any ethical, political or legal issues arise from how the program was designed, structured or implemented?
- ***Relevance and Effectiveness:*** Was the vaccine program needed and did it achieve its target objectives (e.g., general take-up, special populations) and desired outcomes (disease prevention), within the required/desired timeframe? If not, why not, and with what consequence?
- ***Adequacy of Resources and Other Required Inputs:*** Were the resources adequate (too much/too little) to achieve program objectives, and were other supports and guidance (e.g., technical expertise) similarly adequate?
- ***Program Gap Analysis:*** Are there gaps or limitations in the comprehensiveness, quality and integrity of the vaccine approval and delivery processes?

- ***Delivery Quality, Effectiveness and Efficiency:*** Was the program delivered in a responsible, efficient and cost-effective way?
- ***Impacts and Effects:*** Were there any meaningful changes in health in target population(s) as a result of program delivery? What were the results in terms of disease prevention, and also in terms of adverse or other unintended/undesired effects/outcomes?
- ***Understanding of Causality:*** Does the evidence support attribution of disease prevention outcomes (favourable or unfavourable) to the vaccine program and its design and delivery?
- ***Success Factors:*** What other factors (beyond basic program design and delivery) were relevant in program success or shortcomings, and to what extent were they crucial in affecting outcomes (e.g., public awareness and engagement; consistency and clarity of messages; and complementary disease prevention initiatives such as hand washing, etc.)?
- ***Alternatives and Improvements:*** How did the program approaches and methods of delivery compare in effectiveness and efficiency with other programs, other potential approaches and other jurisdictions? What modifications or alternatives to the vaccine program approach might reinforce positive elements and/or address shortcomings?
- ***Safety and Quality:*** What issues and concerns are there about safety and/or other aspects of quality of vaccines and how they are delivered? How significant are they? How can they be prevented or mitigated?

Current Initiatives and Support

Most vaccine-related research in Canada is either led by single investigators working in universities, or takes place in specific centres or networks of investigators.

The PHAC/CIHR Influenza Research Network (PCIRN), a national network of key influenza vaccine researchers, develops and tests methodologies related to the evaluation of influenza vaccines as they pertain to safety, immunogenicity and effectiveness, and program implementation and evaluation. The Network consists of some 100 investigators and more than 30 institutions, including universities, hospitals, and provincial and regional agencies across Canada.

The Canadian Association for Immunization Research and Evaluation (CAIRE) is a leading organization for researchers to share ideas and findings, build collaborative relationships, foster credible linkages with stakeholders and agree on common priorities. This group is focused on clinical trials and pre-marketing studies and less involved in program evaluation and research, which is conducted in a more *ad hoc* fashion. As well, it has no formal linkages to P/T immunization programs processes.

ASSESSMENT: PROGRAM EVALUATION AND RESEARCH

Some provinces, most notably Québec, Ontario and British Columbia, have undertaken a number of significant program evaluations and research initiatives, and Québec earmarks a percentage of the value of its vaccine purchases to support program evaluation. However, the general state of development of program evaluation and research in Canada is inadequate to provide the support needed for timely planning, design and updating of cost-effective immunization programs. Outlined below are critical areas of concern.

Profile and Status

In general, jurisdictions pay inadequate attention to program evaluation and research, both in terms of the resources dedicated to these functions and the degree to which outputs and findings from what research and evaluation *is* undertaken are formally, actively and meaningfully taken into account in critical stages of decision making, policy development, program planning and implementation. At the heart of this issue is the generally poor appreciation of the practical applications and benefits of well-designed and properly funded program evaluation and research studies.

A compelling rationale for investment in program evaluation and research needs to be strengthened, to capture the interest of governments in funding program evaluation and research for their vaccine programs. This can emphasize that evaluation findings can be used to identify and pursue enhanced program efficiencies and/or effectiveness, for example, through discovery of opportunities for reduced dose schedules or more effective targeting of at-risk populations, or other areas for cost-effective implementation. The business rationale for increasing investments in program evaluation and research, and using the results more actively and effectively to inform decision making, can be strengthened through the conduct of analyses that demonstrate net benefits of investing in immunization overall and in targeting and/or adapting programs where net benefits can be maximized. Program evaluation is too often neglected and should be part of the guidance document on vaccines.

Funding

Overall, there is extremely limited funding (federal, provincial and territorial) for program evaluation and research, compounded by limited incentive and opportunity for suppliers to undertake the kinds of research needed for program planning and evaluation. There is need and scope for jurisdictions to increase their funding commitments for program evaluation and research related to immunization programming. As noted above, Québec sets aside dedicated funds for evaluation in advance of program implementation, with the source of such funding relatively diverse (industry, government, research councils). In other areas of public policy and programming, jurisdictions frequently earmark a fixed proportion of overall program funds to be dedicated to research and/or evaluation.

The answer is not with governments alone. There is a need to strengthen creative partnerships between governments and industry to support this work, for which different funding arrangements need to be explored. For example, consideration might be given to whether Health Canada's regulatory framework can be used to allow for increased requirements for post-marketing research relevant to use of the product in Canada by the Market Authorization Holder. However, incorporating supply requirements for research and evaluation in the request for proposals (RFP) process for vaccine supply creates conflicts.

Those involved in program evaluation and research generally—though not unanimously—recognize that industry can potentially play a role in supporting research and evaluation, including funding, but are clear that scientific leadership needs to remain unconflicted by industry interests and influences. At the very least, this requires the handling and allocation of industry-sourced research and evaluation funds by an independent third party, operating at arm's length from those responsible for immunization program decisions.

Collaborative Mechanisms

As noted above, CAIRE is one of the few vehicles supporting collaboration amongst immunization researchers and evaluators; however, it is *ad hoc* in membership and currently focused heavily on clinical

trials and pre-marketing studies. It has no formal linkages to P/T immunization programs. Similarly, PCIRN is a national network of influenza vaccine researchers, but is currently dedicated to influenza issues and not the full range of vaccine-preventable diseases. Whether building on CAIRE or PCIRN, or creating some new mechanism, there is a need to strengthen opportunities for joint ventures, strategic leveraging of funds and sharing of insights and best practices.

Of particular concern is that there is no overall cohesive pan-Canadian vision or plan for priority program evaluation and research, around which a compelling case might be made for leveraged funding for a variety of government and industry sources for collaborative research and evaluation of mutual F/P/T interest and benefit. There is a need for mutually agreeable criteria and a suitable process to set program evaluation and research, with a discipline to distinguish between essential versus desirable studies. Effective and responsive program evaluation and research should have a bottom-up design and proposal process, supported by top-down resources.

Expertise

Health economics is an area of increasing need since strong and domestically relevant analyses are required to support evidence-based decision making. The problem is that expertise in immunization economic analysis and programmatic modelling/analysis is limited to two or three centres of excellence, with extremely limited—or no—capability in many jurisdictions. Moreover, data for such economic and program analysis models may be missing or of poor quality. These areas need to be strengthened.

There is a need to recognize that some jurisdictions have stronger expertise in program evaluation and research than others, and that collaboration and pooling of special rare expertise on joint program evaluation and research initiatives can yield benefits for all jurisdictions not achievable by any one jurisdiction working alone. While expertise to conduct scientifically sound studies may be localized in Canada, all jurisdictions can consider participating in some mutually beneficial way, such as by providing data to the process; making studies as “national” or all-inclusive as possible will maximize contribution and relevance to all P/Ts.

Supporting Data

There is a lack of adequately developed supporting mechanisms and processes vital for an effective program evaluation and research strategy, particularly: a well-developed National Surveillance System with high quality of data on cases, including immunization status; a National Immunization Registry (or reasonable network of registries); a common and consistent framework for program evaluation and research across Canada; and a viable evaluation framework and systematic evaluation of the NIS itself.

Coordination, Synthesis and Integration

Program evaluation and research needs to take place in a more coordinated and cohesive federated approach that is inclusive of all relevant F/P/T authorities, where priorities are set, data from different sources are integrated and synthesized, and the whole process and use of results are aligned with the structures and decision-making processes at the F/P/T level. This currently happens only in some provinces.

Scope

There are a number of areas where key aspects of program evaluation and research are either inadequately developed or poorly linked or integrated. Program evaluation and research initiatives need to more

actively and vigorously support the testing and sharing of different contexts, approaches and experiences in vaccine program design and delivery, so as to maximize mutual benefits from limited resources and expertise. More emphasis needs to be placed on the dissemination of results to stakeholders, as a vital aspect of supporting decision making and demonstrating the practical benefits of investing in research and evaluation. Program evaluation needs to increase its focus on understanding underlying values, perceptions, attitudes and practices of program participants, to enrich insights into program barriers, opportunities and success factors. Finally, there is a need to strengthen the linkages between evaluation and surveillance so that evaluation needs—and findings—are integrated into surveillance system design maintenance and use.

E. Surveillance

SITUATION

Public health surveillance in any country is complex. In a federal country such as Canada it is particularly complex, with different systems in place to meet different specific needs, applications, responsibilities, authorities and privacy regimes that differ amongst the different jurisdictions. The sections below address clusters of surveillance activities and mechanisms currently used in Canada under four themes:

- Vaccine Safety Surveillance
- Vaccine-Preventable Disease Surveillance
- Immunization Registries and Coverage Surveys
- Information Sharing and Electronic Records

1. Vaccine Safety Surveillance

The scope of vaccine safety surveillance includes the ongoing monitoring for signals that could indicate a problem with a vaccine marketed for use in humans in Canada. This surveillance entails:

- identification of increases in the frequency or severity of previously identified vaccine-related reactions (e.g., anaphylaxis, Guillain-Barré syndrome, etc.) and previously unknown adverse events following immunization (AEFIs) that might be related to vaccines
- triggering of timely and effective responses to emerging concerns
- identification of issues requiring further investigation and/or research
- timely reporting and communication obligations
- providing a means to assure the public that vaccines are safe

Canadian Adverse Events Following Immunization Surveillance System (CAEFISS)

The Canadian Adverse Events Following Immunization Surveillance System (CAEFISS) is Canada's integrated surveillance system addressing AEFIs. It includes passive and active components, and some enhanced passive reporting whereby P/Ts focus on ensuring that certain AEFIs of public health importance are reported according to national standard operating procedures (SOPs).

CAEFISS provides for national reporting of adverse events and suspected adverse events following immunization based on voluntary reporting by all provinces and territories. Within these jurisdictions, reporting to public health is also voluntary except in Ontario, Saskatchewan, Nova Scotia, Québec, Manitoba, New Brunswick and Northwest Territories, which have mandatory reporting requirements.

A critical component of CAEFISS is the Vaccine Vigilance Working Group (VVWG) within PHN that was created as a result of NIS (2003). The VVWG has federal and P/T co-chairs, and representatives from each P/T and federal (First Nations and Inuit Health Branch, Department of National Defence, RCMP, Correctional Service of Canada) immunization program. The VVWG also has liaison members from IMPACT (Immunization Monitoring Program ACTive), PCIRN and the Biologics and Genetic Therapies Directorate (BGTD) and Marketed Health Products Directorate (MHPD), Health Canada. The VVWG has done a great deal to strengthen adverse events following immunization (AEFIs) surveillance in Canada by adopting harmonized approaches to vaccine safety surveillance (e.g., reporting guidelines) along with standard AEFI case definitions and common data elements, as captured in the national AEFI report form. All P/Ts have agreed to meet the timelines required of Market Authorization Holders by the *Food and Drug Act Regulations* in reporting serious AEFIs—i.e., to report them within 15 days of their receipt by the P/T.

In addition to ongoing AEFI surveillance for routine immunizations, CAEFISS monitors AEFIs during the annual influenza campaigns. It greatly augmented its surveillance activities during pandemic H1N1 immunization campaigns. The success of CAEFISS is a result of the close collaboration of dedicated F/P/T vaccine safety contacts, which can rapidly share and disseminate information to appropriate stakeholders regarding emerging vaccine safety issues or signals. During each annual influenza campaign, there are weekly calls of VVWG members to capture any emerging concerns from the field. In addition to routinely filed AEFI reports, members provide weekly aggregate numbers of all AEFI reports generated in their jurisdiction the prior week, along with a breakdown of serious adverse events, including anaphylaxis, Guillain-Barré syndrome, hospitalizations or fatal outcomes. In this way, a national profile can be assembled even before routine AEFI reports are received by PHAC.

As with a number of other national surveillance systems, CAEFISS utilizes outputs from the Canadian Immunization Monitoring Program ACTive (IMPACT), described further below. In particular, CAEFISS utilizes IMPACT's syndromic surveillance component that gathers more complete information in a timely fashion for serious AEFIs in children.

For future evolution of the development and applications of CAEFISS, there is the potential to link it to administrative health databases, especially those that include immunization registries, for routine vaccine safety surveillance. This has been used to great effect in the United States by the Centers for Disease Control and Prevention (vaccine safety data link) and in the United Kingdom (General Practice Research Database), and has been set up for monitoring drug safety in the U.S. (mini-sentinel) and Canada (C-nodes). While the main focus of such systems has been for testing hypotheses of possible causal linkages between vaccines and adverse events, they have been used for real-time safety signal assessments.

Issues: Vaccine Safety Surveillance

Vaccine safety surveillance improved in Canada after the implementation of NIS (2003). This was very apparent during pandemic H1N1 which demonstrated a timely, rapid, flexible, scalable response to provide needed pharmacovigilance activities. In contrast, some key NIS vaccine safety priorities have not yet been operationalized due to the struggle to deal with the added workload and response to anything other than the most critical issues.

NIS priorities for vaccine safety include:

- All F/P/T immunization programs should have a comprehensive, uniform and compatible approach to immunization safety that includes consideration of surveillance, research, communication and crisis management.
- The F/P/T and local health authorities should each designate a person to be responsible for immunization safety issues, with the understanding that enough time will be available for the work involved. It would be ideal if these individuals have some research training.
- In designing systems for immunization safety monitoring, capability should be built in to link to other health information systems within the jurisdiction and between reporting levels (including international linkages) to allow for enhancements of the monitoring process, such as tracking of persons immunized with a specified product and lot number.
- Public health authorities at all levels should have a detailed action plan for ongoing management of immunization safety issues.
- The active surveillance system should include a provision for clinical assessment of all serious, severe or unusual reactions.
- For ongoing management of immunization safety issues, an arm's length advisory committee with broad representation from experts, immunization opponents, stakeholders and the public should be able to: identify potential issues; identify research priorities; review research data/scientific evidence; review surveillance data; and review cases/clusters of concern.

2. Vaccine-Preventable Disease Surveillance

Effective systems for surveillance of current and potentially new vaccine-preventable diseases are needed to:

- support the investigation, containment and management of vaccine-preventable disease outbreaks
- identify and quantify risk factors and assess disease burden to enable and support public health policy decisions
- assist in the development of evidence-based guidelines
- provide information to the public and media on the status of the diseases and outbreaks
- monitor progress toward the achievement of goals and targets
- provide a readily available infrastructure that can be adapted and scaled up to meet specific needs or in response to an emergency event such as a pandemic

There are a number of disease surveillance systems/activities currently providing important data. PHAC, in collaboration with all P/Ts, administers the Canadian Notifiable Disease Surveillance System (CNDSS), to which reports of nationally notifiable diseases are submitted annually by the provinces and territories. In Canada, communicable diseases are made notifiable in the P/Ts by provincial and territorial statute. The list of Canadian notifiable diseases (CNDs) at the federal level is agreed upon by consensus among provincial, territorial and federal health authorities.

The purpose of making a specific communicable disease reportable in a jurisdiction is to facilitate both tracking and required control efforts by public health personnel. The CND list helps to promote uniformity among the P/T efforts and conformity. A national surveillance guidance document with

protocols and case report forms has been developed in consultation with P/Ts and other experts, and facilitates timely reporting of targeted diseases for enhanced surveillance, for example, measles, polio, novel influenza viruses, severe respiratory illnesses, and novel respiratory viruses of known origin (e.g., novel coronaviruses).

The Canadian Network of Public Health Intelligence (CNPHI) is an important enabler of surveillance as a secure, web-based collection of applications designed to facilitate national, integrated, real-time collection and dissemination of laboratory and epidemiological surveillance data, and coordination of public health response. The system is used for receiving, posting and distributing alerts concerning confirmed/probable outbreaks/events under investigation. Alerts allow registered users the opportunity to see nation-wide communicable disease event activity, which may be similar to local/regional occurrences.

In addition to CNDSS, a number of enhanced surveillance activities are done to improve the timeliness and granularity of data collected nationally. These include:

- ***Measles and Rubella Surveillance (MARS)***—A PHAC-led pilot project that augments the national measles and rubella surveillance conducted through the routine Canadian Measles and Rubella Surveillance System (CMRSS), through the collection of an expanded set of data elements at participating provincial and federal MARS pilot sites. The augmented data are collected via a MARS web-based surveillance application to support: more complete integration of laboratory and epidemiology data; timely, centralized access to all relevant data by provincial and federal investigators; and automated, real-time alerting of all relevant stakeholders as soon as an IgM-positive measles/rubella laboratory result is entered. Development of the MARS application uses tools from the CNPHI.
- ***Invasive Pneumococcal Disease (IPD) Surveillance***—A planned pilot for an enhanced national population-based IPD surveillance system for all cases in children under 15 years of age, and a representative sample of persons 15 years and older. The Canadian Immunization Monitoring Program ACTive (IMPACT) and the International Circumpolar Surveillance System (ICS), both described further below, will continue as complementary surveillance systems. The IPD surveillance initiative will serve as a pilot for one of the technical schedules under the Multi-Lateral Information Sharing Agreement (MLISA) initiative described further below.
- ***Invasive Meningococcal Disease (IMD) Surveillance***—A comparable pilot for an enhanced national population-based IMD surveillance system.

There are also a number of *sentinel* disease surveillance systems/activities providing important data that contribute to their understanding, including disease severity, hospitalization, sequelae and death, helping to evaluate the effectiveness of certain vaccines administered to particular target populations, including children and Northern populations. Sentinel surveillance—focused on cases in selected defined populations and settings—provides a more timely alternative and complementary method to CNDSS. Sentinel and enhanced surveillance methods allow one to collect more detailed information about the patient and microbe, providing information useful for identifying and responding to emerging trends, typically well before routine notifiable disease surveillance is able to identify a disease outbreak or risk pattern of concern.

Canadian Paediatric Surveillance Program (CPSP)

The Canadian Paediatric Surveillance Program (CPSP), funded by PHAC through a contract with the Canadian Paediatric Society (CPS), contributes to the improvement of the health of children and youth in Canada by national surveillance and research into childhood disorders that are high in disability, morbidity and economic costs to society. The CPSP gathers data from over 2,500 paediatricians and

paediatric sub-specialists each month to monitor rare diseases and conditions in Canadian children. These physicians provide health care to over seven million Canadian children and youth.

International Circumpolar Surveillance System (ICS)

The International Circumpolar Surveillance System (ICS) project is an infectious disease surveillance network of hospital and public health laboratories throughout the Arctic countries. The Canadian component is supported by PHAC. The initial priority for the ICS project was surveillance of invasive bacterial diseases caused by *streptococcus pneumoniae*, *haemophilus influenzae*, *neisseria meningitidis*, and groups A and B *streptococcus*. More recently, tuberculosis and HPV have been included.

FluWatch Surveillance

FluWatch, Canada's national flu surveillance system, is designed to provide a national picture of influenza activity and trends in Canada. Influenza data are collected at the local/provincial/territorial level and forwarded to the federal government on a voluntary basis. FluWatch is comprised of six surveillance components:

- *Influenza-Like Illness (ILI) Consultations:* Data are sent from family physicians to PHAC, indicating how many patients they saw on a single day each week, and how many of these were judged to have the "flu."

- *Laboratory Detections:* Participating laboratories report the total number of influenza tests performed and the total number of tests positive for influenza.

- *Outbreaks and Activity Levels:* Provincial and territorial representatives assess the weekly influenza activity level in their respective jurisdictions according to laboratory reports of influenza detections, ILI rates, and reports of outbreaks occurring in long-term care facilities, hospitals, schools and/or worksites.

- *Strain Characterization and Antiviral Resistance:* Each week, the National Microbiology Laboratory (NML) sends the results of strain characterization and antiviral sensitivity testing to PHAC for inclusion in the weekly FluWatch report.

- *Hospitalizations and Deaths:* FluWatch monitors hospitalizations and deaths in three ways:
    - Canadian Immunization Monitoring Program ACTive (IMPACT)—a network of paediatric tertiary care hospitals ($\leq$16 years)
    - PHAC/CIHR Influenza Research Network (PCIRN) Serious Outcomes Surveillance (SOS) Network—PHAC recently began including hospital-based surveillance of influenza in adults ($\geq$16 years)
    - Provincial/territorial hospitalizations and deaths—currently, eight P/Ts report on hospitalizations and deaths among individuals with laboratory-confirmed influenza on a weekly basis (Northwest Territories, Prince Edward Island, Ontario, Manitoba, Alberta, Saskatchewan, Newfoundland and Labrador, and Yukon)

- *Pharmacy Surveillance*: Pharmacy sales data are provided to PHAC by Rx Canada Inc., and sourced from major retail drug chains representing over 3,000 stores nationwide. This is an example of innovative syndromic surveillance to provide early signals of flu trends, including the

pharmacy surveillance of over-the-counter medications, complemented by internet (e.g., Google) monitoring of flu trend topics.

The *FluWatch* program consists of a network of labs, hospitals, doctors' offices, and provincial/territorial ministries of health, and related reporting arrangements. Fluwatch helps to:

- detect flu outbreaks across the country as early as possible
- provide timely up-to-date information on flu activity in Canada and abroad to health professionals and interested Canadians
- monitor circulating strains of the flu virus (such as H1N1) and assess their sensitivity to antiviral medications, such as Tamiflu and Relenza, which are used by doctors to treat flu, by helping to reduce the severity of the illness and speed the recovery time for the patient
- provide information that the WHO can use to make its recommendations on the best vaccine to use for seasonal flu shots

Respiratory Virus Detection Surveillance System (RVDSS)

In addition to influenza, this system monitors coronaviruses, respiratory syncytial viruses, adenoviruses, parainfluenza viruses, rhinoviruses, and human meta-pneumoviruses, with laboratory-based respiratory virus detections reported through the sentinel laboratory RVDSS, comprised of 33 laboratories across Canada and coordinated by the National Microbiology Laboratory.

Immunization Monitoring Program ACTive Surveillance System (IMPACT)

IMPACT is a sentinel surveillance system that utilizes 12 hospital-based Canadian centres to monitor and report on adverse events following immunization, as well as selected vaccine-preventable diseases. Administered by the Canadian Paediatric Society (CPS) and funded through an annual contract with PHAC, IMPACT provides weekly reports on serious paediatric hospitalizations, outpatient visits and deaths related to adverse events and vaccine-preventable diseases. IMPACT does not currently include all paediatric hospitals or paediatric admissions, but it covers about 90% of all tertiary care paediatric beds in Canada. As a supporting element of CAEFISS, IMPACT reports AEFIs to PHAC and to all P/Ts, to enable coordinated public health action at all levels.

Severe Respiratory Illness (SRI) Surveillance System

The SRI surveillance system is used to detect unusually severe morbidity and mortality caused by both unknown and known respiratory pathogens that may have the potential for large-scale epidemics or pandemics. A pilot project funded by PHAC is assessing the feasibility of using intensive care units (ICUs) to monitor SRIs and, if successful, will be expanded into a national surveillance system.

Canadian Public Health Laboratory Network (CPHLN)

The Canadian Public Health Laboratory Network (CPHLN) supports provincial laboratories to increase readiness to detect the arrival and spread of novel/pandemic influenza viruses. In partnership with this network, most provinces now have laboratories able to identify new strains of influenza using standardized molecular technology. The National Microbiology Laboratory reports the results/information of novel strains, as soon as testing has been completed/validated, to the requesting authority. Information is communicated to all public health laboratories through CPHLN, using various communication methods (e.g., e-mail, telephone/teleconference and video conferencing).

PHAC-CIHR Influenza Research Network (PCIRN) Serious Outcomes Surveillance (SOS) Network

The SOS Network is a sentinel hospital-based network that conducts surveillance of adult hospitalizations and deaths due to influenza. The system is used to monitor the severity of circulating influenza strains (as well as novel strains) type/sub-types and to identify high-risk groups for severe outcomes. It is also designed to monitor influenza vaccine effectiveness. It is currently receiving $1.4 million per year from PHAC, complemented by other corporate and government grants.

Sentinel Platform to Evaluate Influenza Vaccine Effectiveness and New Variant Circulation

This is a community-based sentinel surveillance system that collects nasal/nasopharyngeal and epidemiologic details from patients presenting to sentinel sites within seven days of the onset of influenza-like illness. The data are collected from a network of a half dozen participating medical centres across Canada. The surveillance system is designed to provide early information on genetic variants in influenza and assess vaccine effectiveness, in particular whether vaccines in use are keeping pace with ongoing changes in circulating virus strains, to support evidence-based decisions to reformulate and re-administer annual flu vaccines.

Canadian Nosocomial Infection Surveillance Program (CNISP)

The Canadian Nosocomial Infection Surveillance Program (CNISP) is a collaborative effort of the Canadian Hospital Epidemiology Committee (CHEC), a sub-committee of the Association of Medical Microbiology and Infectious Disease (AMMI) Canada, and PHAC. The objectives of CNISP are to: provide rates and trends of health care-associated infections at Canadian health care facilities, enabling a comparison of rates (benchmarks); and providing data that can be used in the development of national guidelines on clinical issues related to health care-associated infections. At present, 54 sentinel hospitals from 10 provinces participate in the CNISP network, supported through PHAC contracts.

Global Public Health Intelligence Network (GPHIN)

The Public Health Agency of Canada also undertakes and funds surveillance globally through the Global Public Health Intelligence Network (GPHIN). It provides an "early warning" system that gathers preliminary reports of public health significance in seven languages on a real-time basis and disseminates relevant alerts/information on public health events, by monitoring global media and other sources.

Issues: Vaccine-Preventable Disease Surveillance

For vaccine-preventable disease surveillance, a more robust, federal approach to surveillance and monitoring is needed, where F/P/T jurisdictions jointly participate in decisions about disease conditions requiring specialized surveillance, as well as more robust networks, going beyond basic case reports, including:

- pre-licensure surveillance on disease burden, range of illness severity, affected populations and age cohorts, and organism characteristics
- pre-implementation surveillance for economic analysis, cost-benefit analysis and modelling/projections of program impact
- post-implementation surveillance for monitoring and evaluating vaccine effectiveness, and identifying any changes in the epidemiology of the disease and shifts in the burden of illness

However, many of the gaps and limitations outlined in the 2003 National Immunization Strategy for vaccine-preventable disease persist today:

- For many vaccine-preventable diseases, there is tremendous variance in the quality and quantity of data.
- There is insufficient laboratory and epidemiological-linked data at the national level to inform public health action and policy decisions.
- The publication of final figures is generally two years behind.
- Data analysis at the national level is typically only basic.
- Computer and system development support is needed.
- Lack of amalgamated data between First Nations populations and the general population.
- Only limited support to manage, evaluate and improve internal information systems.
- IMPACT has been beneficial for monitoring diseases in children, but there is no complementary system for adults, since adult Serious Outcomes Surveillance (SOS) is limited to Community-Acquired Pneumonia (CAP) and influenza.
- There are large gaps in the monitoring of certain diseases considered as "orphans," including travel-related vaccine-preventable diseases such as Japanese encephalitis, yellow fever and cholera. PHAC, through the *Canadian Immunization Guide*, provides guidance and advice related to these diseases, but there is no defined lead or centre responsible for ongoing monitoring and advice for outbreak management and control.
- There is limited access to content experts with specialized knowledge of given conditions and diseases.
- There is inadequate knowledge translation and active dissemination and follow-up. Sharing of surveillance results is often limited to simple web posting of information.
- Currently, only about one half of the 13 P/T jurisdictions have some reasonably complete form of immunization registry.

3. Immunization Registries and Coverage Surveys

Accurate and timely immunization information on those who have received vaccines (including what vaccine and at what age), along with information on what immunization coverage levels have been achieved in specific population groups and regions are important to:

- provide information on the level of protection against specific vaccine-preventable diseases in a population
- monitor progress on national goals and targets for immunization coverage and the elimination of vaccine-preventable diseases
- identify areas of sub-optimal immunization coverage
- help evaluate the effectiveness and impacts of immunization programs and policies
- help target priority regions and populations for immunization during vaccine-preventable disease outbreaks and avoid unnecessary and costly re-immunization

Immunization coverage data can be obtained in two ways:

- immunization registries (e.g., whether paper-based and/or electronic), which are population-based information or software applications and databases that have the capacity to perform the scheduling of immunization appointments, the management and recording of immunization events, and the notification of when immunizations are due
- population surveys, which obtain estimates of general immunization coverage and identify any general patterns of apparent under-coverage (especially useful where immunization registries are non-existent or incomplete), and which also obtain information on such factors as public attitudes, knowledge and practices related to immunization, which can help in the design of immunization strategies and approaches

At the individual and family levels, immunization registries also serve a practical role in enabling care providers and immunizers to keep track of what vaccines have been administered, in what doses, and at what ages. This helps ensure that vaccinations are neither missed nor duplicated—especially for the several hundred thousand Canadians who move inter-provincially each year (i.e., where schedules and programs may vary amongst P/Ts). It also assists in the identification and management of cases where adverse events following immunization and/or where issues of vaccine quality or safety may be of concern.

Canadian Immunization Registry Network (CIRN)

In 1998 the Canadian Immunization Registry Network (CIRN) was established with the mandate to develop and validate standards, guidelines and best practices for the development of Electronic Immunization/Health Record and immunization coverage surveys. At the time, few electronic registries existed and there were no pan-Canadian standards to help ensure consistency and interoperability amongst P/T registries as they developed. Since 2003, CIRN has operated as a working group reporting to the Canadian Immunization Committee (CIC) with the following objectives:

- Share expertise and information related to national functional and data standards for immunization registries with stakeholders, including other committees involved in national standards-setting initiatives related to immunization.
- Enhance the accuracy and reliability of national surveillance of vaccine coverage rates (e.g., percentages of the recommended population having received a vaccine).
- Facilitate standardization of immunization rate assessment across provinces and territories.
- Facilitate exchange of data and information sharing from standardized P/T registries.
- Facilitate information sharing and promote linkages between systems related to surveillance of vaccine-preventable diseases, adverse events following immunization and vaccine coverage rates.
- Collaborate with committees involved in national standards-setting initiatives related to immunization.
- Advise on jurisdictional updates on immunization registries and inventory systems.

At the time of writing this report six P/Ts had their own immunization registers: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, and Newfoundland and Labrador. In addition Québec has established a register in conjunction with the immunization module of Panorama, which is described further below. British Columbia and Ontario have also initiated the immunization modules of Panorama. Thus, a total of seven of the thirteen P/Ts have some form of immunization registry in place.

National Immunization Coverage Surveys (NICS)

The Public Health Agency of Canada conducts population-based surveys to assess immunization coverage for vaccines available in Canada. More specifically, the *childhood* National Immunization Coverage Surveys (NICS) examines up-to-date coverage in 2-, 7- and 17-year-old children for routine childhood vaccines part of publicly funded programs, and the *adult* NICS examines immunization coverage in adults in the general population, those with chronic medical conditions and health care workers. Both surveys are carried out by conducting telephone interviews. Results from the childhood NICS are based on parents/guardians reporting information from their child's immunization records, further validated against medical records. Results from the adult NICS are based on adult respondent recall (i.e., memory), and therefore are less accurate and reliable, although useful for identifying general coverage patterns. The Agency conducts the surveys approximately every two years and intends to do so until a fully functional network of immunization registries is capable of providing accurate real-time immunization coverage data.

Canadian Community Health Survey (CCHS)

The Canadian Community Health Survey (CCHS) provides health information for 126 health regions across Canada. The CCHS is conducted by Statistics Canada, in partnership with Health Canada, the Public Health Agency of Canada, the Canadian Institute for Health Information (CIHI) and P/T Ministries of Health. The primary objective is to provide timely cross-sectional estimates of health determinants, health status and health system utilization at a sub-provincial level on an annual basis. The CCHS has played only a relatively minor role in gathering some information on influenza vaccination, with past survey cycles having asked if respondents have ever received the influenza vaccine, when the last dose was received, and reasons for not having received the vaccine. The results have not been used to provide estimates of influenza vaccine coverage.

Issues: Immunization Registries and Coverage Surveys

Progress is being made in the development of complete, compatible and accessible immunization registries in jurisdictions across Canada, but the work remains incomplete, and needs to continue. In the meantime, surveys will continue to be needed to address critical knowledge gaps about overall immunization coverage and patterns, and to provide supplementary information useful in program planning and evaluation. More specifically:

- There is not a complete, cohesive and linked system of immunization registries for all jurisdictions. This presents direct challenges in the jurisdictions where registries are incomplete, inadequate or even non-existent. It also limits the ability to undertake national studies that can help assess relative needs and priorities and compare different immunization approaches and results amongst several or all P/T jurisdictions.
- Where immunization records and registries are incomplete or inadequate, the inability to determine immunization status at the individual level and to link this information with vaccine safety and disease status undermines the ability to respond effectively to outbreaks and risks of concern.
- There is a reliance in some jurisdictions on hand-held (i.e., paper format) immunization cards, which is problematic because the cards are often incomplete or contain errors, and information sent to the surveillance systems often arrives in an untimely fashion.

- Because of the incomplete system of immunization registries, national estimation and reporting of immunization uptake and coverage is overly dependent on general estimates obtained from national survey data.
- There is limited to no ability to assess accurately the coverage of special populations or target groups for specific immunization programs, including those groups which may be under-immunized, Aboriginals, new immigrants, refugees, travellers, certain religious groups, those groups with low socio-economic status, the elderly and various other age groups, health care workers and the immuno-compromised.

4. Information Sharing and Electronic Records

There are several major cross-cutting mechanisms and initiatives to support responsible and convenient access to and sharing of data relevant to vaccine surveillance and response needs:

Multi-Lateral Information Sharing Agreement (MLISA)

In their 2006 communiqué, F/P/T Ministers of Health recognized the need to complete a pan-Canadian public health information system and an agreement on the timely sharing of information in preparing for and responding to a public health emergency. The Multi-Lateral Information Sharing Agreement (MLISA) is designed as a ministerial-level agreement for sharing public health information on infectious diseases and urgent public health events amongst F/P/T jurisdictions. It formalizes details on the collection, use, disclosure, provision, retention and disposal of information and biological substances, and strengthens the sharing of information amongst F/P/T jurisdictions for national surveillance, assessment and response, and for public health emergencies and urgent events.

MLISA has a generic main body that is supported by detailed technical schedules that define how information will be shared in accordance with public health principles and practices. It is being developed collaboratively through the Pan-Canadian Public Health Network. Federal, provincial and territorial governments are involved in developing, signing and managing the commitments established under MLISA. Of relevance to immunization, the technical schedules include provisions for sharing of information on AEFIs and vaccine-preventable diseases. However, while originally envisioned for MLISA, the technical schedules will not for the foreseeable future deal with sharing of information on immunization schedules and programs, immunization coverage, and immunization delivery mechanisms and funding.

While MLISA will be important for some aspects of disease surveillance in Canada, it does not address specific information on immunization programs such as coverage data.

Panorama

In March 2004, responding to the lessons learned from the SARS outbreak, the Government of Canada initiated the development—in partnership with P/Ts—of a country-wide public health surveillance system. The work was commissioned through Canada Health Infoway, a not-for-profit organization created and funded by the federal government to accelerate the use of electronic health records (EHRs) in Canada through collaboration with P/Ts, health care providers and technology solution providers.

In pursuing this initiative, Infoway has been collaborating with the Canadian Immunization Registry Network (CIRN) through the participation of some CIRN members in Infoway's Standards Collaborative Working Group in developing agreed-upon standards to be used in EHRs. The public health surveillance

system developed through the partnership with Infoway was eventually called Panorama. The initiative entailed the following commitments:

- $100 million in federal funding to advance the development of application software
- P/T commitments to provide the resources for training, equipment and implementation of the surveillance system
- an additional allotment of $100 million in federal funding to advance the development and the implementation of Panorama

Initially, Panorama had seven modules that were to be developed using existing commercially available software applications, and that could be modified to respond to specific P/T needs. Two of the modules, immunization management and inventory management, were envisioned to provide the basis for a national network of immunization registries. These modules were to be developed to include nationally agreed-upon functional and data standards. Moreover, the modules were to eventually provide each jurisdiction access to a standardized electronic immunization registry and an inventory management system. These modules would enable P/Ts to better manage immunization events and vaccine supply, assess immunization coverage in their jurisdictions, and report standardized vaccine uptake data nationally. Panorama allows users to view the immunization history for individuals, such as reported cases and particular groups in the population. In addition, lists of individuals who are eligible and overdue for immunization can be identified by vaccine antigen, demographic variable (e.g., age, gender) or particular risk factor(s).

While the original scope of Panorama was to include, among other things, a pan-Canadian approach to immunization registries, some individual provinces and territories have developed and are currently using other immunization registry systems. These systems vary among jurisdictions in both the extent of the data that they capture, and the degree to which they are readily available to immunization providers. They also vary in terms of the validation procedures that are used to screen and accept immunization data that are maintained in the registry. The currently available registers differ in terms of the age groups for which information is captured, and there is only limited capacity to link data from immunization registries to clinical outcome databases, meaning that there is not a full capacity to link immunization status to clinical outcome in all jurisdictions. Some feature of relevance to immunization surveillance, such as scanning of vaccine bar codes and immunization forecasting, are no longer part of the standard Panorama package, meaning that participating jurisdictions must provide extra funding to access these functions. To date, take-up is incomplete and inconsistent across Canada.

When the Panorama project was initiated in 2005, it had an expected implementation date of 2008, but was made available for licensure only in 2011. Canada Health Infoway's original date for a pan-Canadian Electronic Health Record was 2015, which has since been pushed back to 2020.

At the time of writing this report, six provinces and territories had signed licensing agreements with Panorama: British Columbia/Yukon (joint agreement), Ontario, Québec, Saskatchewan and Manitoba. The remaining seven P/Ts are in varying stages of either exploring options with IBM and Panorama, developing their own system, or considering other options.

Issues: Information Sharing and Electronic Records

Under the guidance and support of the PHN, progress is being made by F/P/Ts in data-sharing arrangements and the development of useful electronic records systems, standards and protocols. This needs to continue.

ASSESSMENT: SURVEILLANCE

The overall state of vaccine-relevant surveillance and data sharing (as well as program evaluation and research) across Canada remains inadequate to meet the needs of sound evidence-based planning, priority setting, decision making and accountability for public health results. Data gaps lead to an inability to conduct timely and quality surveillance on vaccine coverage, vaccine-preventable diseases and their severity, and adverse events following immunization. This may lead to an inability to effectively manage an outbreak or an emergency. Incomplete/inaccurate immunization records lead to unnecessary re-immunizations, which can increase adverse events, contribute to supply shortages, and add unnecessarily to immunization program costs.

The following issues have consistently been identified by jurisdictions and stakeholders with respect to the overall state of vaccine-related surveillance in Canada:

- There is limited F/P/T collaboration in the overall planning, direction and oversight of surveillance (and related research and evaluation) activities in a strategic and coordinated manner, including the setting of priorities, the leveraging of funds, the pooling of expertise and resources, and the timely sharing of results for mutual benefit.
- Many jurisdictions allocate the majority of their immunization funding toward the direct costs of program delivery, leaving few resources for surveillance, research and evaluation. The result is that there is insufficient surveillance overall, hence limited availability of quality data to inform program evaluation and research and support decision making.
- Canadian expertise and institutional capacity for surveillance is underdeveloped and there are few training opportunities for public health professionals in the area of surveillance.

While specific surveillance elements and individual sub-systems are needed to address unique aspects of surveillance and distinct sources of surveillance data, what is needed overall is a more coherent "systems" model that can ensure comprehensive, balanced and cohesive coverage of factors and trends of priority concern. In addition, surveillance data need to be made more readily accessible through some form of "data warehouse" application that can permit the collection of data elements from multiple sources and multiple forms and makes them available for user-friendly retrieval. The objective of such an arrangement would be to:

- modernize the surveillance process, utilizing appropriate computer and web-based technologies
- obtain data management efficiencies, including interoperable data systems
- define and optimize F/P/T roles with respect to surveillance and response
- determine appropriate surveillance to address needs regarding immunization and infectious diseases
- align surveillance practices of key partners in the immunization field, with broader disease and adverse event surveillance initiatives

F. Response to Outbreaks and Adverse Events

SITUATION

Overview

Response to vaccine-preventable disease outbreaks, adverse events following immunization (AEFIs), and other risk factors and health and safety triggers is an important facet of responsible immunization programming, and a key objective and application of surveillance systems and outputs. Incidence response systems and protocols are designed to ensure the well-planned, organized, pre-tested and coordinated response of all relevant parties to issues, trends and events of concern identified through surveillance. The response focuses on the determination, investigation, mitigation and containment of outbreaks of vaccine-preventable diseases, management of risk factors, response to adverse events and safety concerns, and provision of supporting information and communications.

Responses to such events involve not only multiple levels of government (federal, provincial/territorial, Regional Health Authorities and possibly Public Health Units), but also legally distinct entities at the federal level (PHAC, Health Canada regulators for issues relating not only to vaccine safety but also lack of vaccine effectiveness). For their effective response to outbreaks and adverse events, formal agreements and mechanisms are needed to facilitate their collaboration, including the sharing of critical information that may be considered proprietary and/or that requires management of confidentiality.

In Canada, incidence response is emerging as an important focus of the public health community, with strong interest on the part of F/P/T authorities responsible for disease prevention in general, and immunization in particular.

Given the complexity of issues and events that may trigger the need for response, the potential for rapid escalation of issues of concern, the multiplicity of F/P/T agencies with mandates, interests and capabilities, and the potential serious consequences of any gap, delay or misstep in response, there is a need for clearly articulated response protocols to trigger and guide the timely and effective engagement of all players. This needs to include an "umbrella" incidence response protocol mapping roles and procedures for any predefined event or issue of concern, as well as issue-specific protocols dealing with vaccine-preventable disease outbreaks, adverse events following immunization, or other particular risk factors, and health and safety triggers. A vital aspect is that protocols not only be developed and communicated, but pre-tested through suitable simulations, drills or "table-top" exercises.

Comparative Approach with the Foodborne Illness Outbreak Response Protocol (FIORP 2010)

The recently-adopted Foodborne Illness Outbreak Response Protocol (FIORP 2010) stands as a potentially useful model to guide the design and testing of a comparable protocol that meets the needs of the immunization world. A single ("all-ORP") outbreak response protocol is not generally feasible, especially as P/T contact points vary depending upon the type of incident, so a response protocol for immunization cannot simply be an expansion of FIORP 2010. However, individual response protocols can benefit from a consistency of approach and a common look and feel, so that users would find familiarity amongst protocols, hence the attractiveness of ensuring some degree of consistency between response protocols for immunization and those for foodborne illness (or other similar public health issues).

FIORP 2010 is an ongoing F/P/T measure initiated in 2010, following lessons learned from the response to the 2008 national listeriosis outbreak. It is a technical and operational protocol aimed at improving the timeliness, effectiveness and coordination of responses by jurisdictional authorities to known or suspected foodborne illness outbreaks and related public health and safety triggers. Key features are:

- clearer scope so that partners better understand when the protocol should be used
- clarified roles and responsibilities of F/P/T partners during outbreaks
- improved processes that F/P/T partners are to follow during outbreaks
- guidelines designed to facilitate faster decision making and to resolve differences of opinion
- a provision to revise the FIORP every five years, with the possibility of more frequent updating of the document if warranted

Under FIORP 2010, when a foodborne illness outbreak occurs in a single city or province, that city or province is responsible for managing the response. However, when a national (spanning more than one province or territory) or an international (more than one country, including Canada) outbreak occurs, the Government of Canada leads the response. This often involves the coordinated efforts of several federal departments and agencies, and the engagement of appropriate authorities in the affected provinces and territories. FIORP 2010 clearly defines the responsibilities of each partner, and the process for dealing with the outbreak.

ASSESSMENT: RESPONSE TO OUTBREAKS AND ADVERSE EVENTS

In general, the lack of clear protocols, criteria and processes to respond to vaccine-preventable disease outbreaks, adverse events following immunization (AEFIs) and other safety triggers is of priority concern. More specifically, the following gaps have been identified in the period since the initiation of the NIS in 2003:

- Lack of ability to rapidly determine distribution of vaccine lots within a region, and to recall field samples for use in root cause analysis.
- Lack of defined protocols setting out responsibilities of Health Canada regulators and the Marketing Authorization Holders (MAHs).
- Lack of mechanisms to rapidly coordinate and follow through on issues that involve both regulatory and public health actions at the federal and P/T jurisdictional levels.
- Lack of mechanisms to rapidly initiate research to address risk factors or root cause analyses in response to vaccine safety signals and disease outbreaks, i.e., the ability to rapidly move funds into researchers' hands, secure federal Research Ethics Board (REB) approvals, and privacy, confidentiality and ethical requirements within P/Ts and in university settings.

What is needed is an umbrella incidence response protocol that outlines the common principles and procedures that apply to all response protocols, to ensure timely, effective and well-coordinated investigation and response. This needs to embrace elements unique to each specific type of response required. These unique responses would permit specific or different approaches with different P/T jurisdictions. Such an umbrella agreement would need to be sanctioned by all jurisdictions, possibly through the PHN, but there also could be procedural agreements with each P/T jurisdiction to account for their specific approaches and circumstances.

As noted above, the FIORP 2010 approach stands as a potentially relevant model to guide design of a similar protocol for vaccine-preventable disease outbreaks, adverse events following immunization, and other risk factors and health and safety triggers.

G. Public and Professional Education and Engagement

SITUATION

Current Initiatives and Approaches

Immunization education and engagement efforts focused on the public are essential facets of an effective strategy to protect Canadians against disease. The object is to encourage individuals to get immunized, thereby maintaining or improving overall population immunization coverage rates. The object is also to ensure that immunization is complemented by other preventive measures such as hand washing, covering up coughs and avoiding exposure to others—especially vulnerable populations—while contagious.

Similarly, immunization education and efforts focused on public health professionals are vital to ensure responsible, efficient and effective promotion and administration of immunization programs and the maintenance of high public confidence in the effectiveness and safety of vaccines.

In 2005, the Public and Professional Education Working Group (PPEWG) was established to foster greater collaboration with F/P/T health jurisdictions and non-government stakeholders in order to address immunization promotion and education issues that would benefit from a national approach. PPEWG is a sub-group of the Canadian Immunization Committee (CIC), an F/P/T group of public health officials who provide leadership, advice and recommendations to the Public Health Agency of Canada on issues affecting immunization in Canada.

The mandate of the PPEWG is to provide advice to CIC on:

- strategic directions for the immunization education of the general public
- priorities for the implementation of evidence-based and innovative strategies that help to improve immunization coverage rates of the Canadian population
- professional development strategies and learning opportunities for health professionals, in order to support the achievement and maintenance of a safe and competent practice and to ensure high coverage rates throughout the community

The Canadian Immunization Conference is widely acknowledged as Canada's pre-eminent conference on immunization. It draws both expert and novice vaccine providers from across the country. The Conference provides an exceptional opportunity for health professionals to expand their knowledge in immunization and learn about the latest developments in immunization research, policies, programs and practice. The program for the Conference is varied and tailored to address important and timely issues.

The PHAC-led development of the *Immunization Competencies for Health Professionals* was designed to support the application of the National Guidelines for Immunization Practices, published in the *Canadian Immunization Guide*. Development of the Competencies was done in consultation with immunization

program planners from F/P/T jurisdictions; expert advisory committees on immunization; health professional educators; licensing bodies and professional societies; health professional education accreditors; vaccine regulators; and vaccine manufacturers. These Competencies are recognized as national best practice standards, covering the essential topics for safe and effective immunization practices that are universal to a wide range of health professionals. These can be adapted and incorporated into all immunization training or performance evaluations.

The Canadian Paediatric Society (CPS), in collaboration with PHAC, has developed an online learning program on the Immunization Competencies.

The Immunization Competencies Education Program (ICEP) provides an overview of the *Immunization Competencies for Health Professionals*, and aims to improve the skills of Canadian immunization providers and to promote safe and competent immunization practices, through an inter-professional learning environment. The course is open to residency programs in paediatrics, community, family medicine, adult infectious disease and internal medicine (complementary registration), as well as physicians, nurses and pharmacists. ICEP provides health professionals with knowledge and skills to:

- understand the importance of the key principles of the *Immunization Competencies for Health Professionals* when integrating immunization into their practice setting
- counsel patients regarding many of the key immunization issues
- increase the public's confidence in vaccines
- promote safe and competent immunization practices
- work collaboratively with other professionals to promote cooperation on important public health issues such as immunization

Other public and professional education and engagement initiatives include:

- free online learning programs to train vaccine providers on the new influenza H1N1 vaccine and on considerations for the immunization of pregnant women against influenza H1N1, and another entitled *Managing Seasonal and Pandemic Influenza in Infants, Children and Youth*
- a multi-component public education campaign targeting parents of children 0−2 years of age entitled *It's Time to Immunize*, including an interactive website; and a popular publication entitled *A Parent's Guide to Immunization*, available in 12 languages and including clear information to dispel common myths about vaccines
- collaborative outreach between PHAC and Health Canada's First Nations and Inuit Health Branch (FNIHB) promoting immunization initiatives targeted to First Nations, Inuit and Métis
- special outreach to new immigrants and refugees, focusing on understanding immunization needs and barriers

Considerations in Future Collaborative Efforts

Following are some general considerations in determining suitable new directions and approaches in F/P/T collaboration on public and professional education and engagement, including possible coordinated efforts to address the issue of vaccine hesitancy.

Priority target audiences of common interest to F/P/Ts, for effective education and engagement, are likely:

- active participants in vaccine programs ("the converted"), where the primary goal is to address their evolving issues about immunization, especially with the introduction of new vaccines and/or new vaccine technologies
- the "ambivalent," where the primary goal is to strengthen their confidence and increase their take-up of vaccines
- anti-vaccine "holdouts," where the goal is primarily to counteract their negative messaging so that it does not undermine general public confidence and commitment

It will likely be challenging—and not particularly valuable or relevant—to develop fully common campaigns across Canada involving all jurisdictions, given the different audiences, players, issues, decision makers, and, at least to date, often different vaccine schedules and immunization programs amongst jurisdictions. For these reasons, jurisdictions will be reluctant to commit resources to collaboration, unless there are prospects for leveraging mutual benefits through cohesive joint initiatives.

Successful new and improved approaches to vaccine hesitancy and confidence will need to consider the following:

- Engagement of public health and medical community leaders, opinion influencers will be key.
- Engagement of other sectors will also be vital (e.g., schools, major employers, unions).
- There is a need to: undertake research to identify and understand reasons for vaccine hesitancy in specific groups; learn from past approaches (successes and failures); and maximize sharing of insights, expertise, materials and messages wherever practical.
- Public/private partnerships offer one source of resources to support education and outreach programs but there are appreciable ethical and other considerations that may limit such possibilities.
- There is a need to reinforce and regularize commitments to public education and engagement as a necessary budget item and strategic element of every vaccine program, supported by a common understanding and acceptance of the need for dedicated budgets, such as a "standard" percentage of overall vaccine programming resources dedicated to education and information/engagement.

ASSESSMENT: PUBLIC AND PROFESSIONAL EDUCATION AND ENGAGEMENT

Findings from an informal canvassing of key informants in a cross-section of jurisdictions and other sectors indicated that the most practical and viable focus for collaboration on education and engagement activities of mutual interest across jurisdictions would be in the establishment and operation of some form of "warehouse" or "clearinghouse" service that could accumulate and make available source material that might be readily adapted and used for information and outreach initiatives by interested jurisdictions, i.e., without charge to the users, and with little or no restrictions on intellectual property (IP). All materials should be open access with shared IP or clear mechanisms for purchase if talent costs are involved.

An overall agenda and warehouse content could be agreed to with little difficulty, especially if this was based on inclusivity rather than absolute consensus. A common annual program—for example, to deal with annual flu messaging and promotion or to collectively address vaccine hesitancy—need not be part of the activity but could be, if jurisdictions wish to collaborate (respecting autonomy).

Such a collaborative arrangement could be supported through F/P/T cost sharing, including the prospects of some form of public-private partnership (PPP) arrangement to support outreach and information activities of common interest. While there is interest from industry in supporting this through grant-in-aid activity, in some jurisdictions there are no mechanisms for accepting this in any format; industry linkages will need to be somewhat removed from any final model, for the following key reasons:

- PPP arrangements are sometimes seen as supporting those profiting from activity, raising doubts about the integrity and impartiality of public health messaging.
- There is the risk of favouring one organization, thereby rendering unfair advantage, although a third party agent such as Public Works and Government Services Canada (PWGSC) could handle contracting in an open and fair manner.
- Optics of private involvement in public health messaging is bad in some jurisdictions.
- Activity from a PPP perspective may be most practical if arranged through a third party.

Key possible leaders of the work include either an existing group such as the Promotions Sub-Group of CIC, or an external group such as Immunize Canada (the former Canadian Coalition for Immunization Awareness and Promotion, or CCIAP).

H. Security of Vaccine Supply

SITUATION

Vaccine security requires: long-term sustainability of the vaccine market (e.g., stability or growth in both supply and demand; predictability in immunization program implementation and financing; willingness of the industry to invest in R&D; and openness of the market to innovation); continuity of supply (e.g., robust, assured production technologies; multiple supplier base; and active contingency planning); and affordable access (e.g., demonstrable value for money spent).

In Canada, all provinces and territories except Québec (which participates for influenza, rotavirus and HPV vaccines only) purchase all of the vaccines used in their public immunization programs through a national Bulk Procurement Program (BPP) administered by Public Works and Government Services Canada (PWGSC), with annual purchases now in excess of $240 million. The BPP was introduced in 1976, with two objectives: to achieve overall savings by reducing the price of vaccines through combined purchasing power; and to ensure equality in the prices and services extended to P/Ts by vaccine manufacturers regardless of the size of the individual requirement of a province or territory. In addition to cost savings, the BPP also provides a single "window" for contract administration which allows for early identification of potential supply issues and provides a mechanism for a coordinated response, and integration of contracting strategies that enhance the security of vaccine supply (e.g., "split" contract awards, manufacturer held stockpiles, etc.).

The Vaccine Supply Working Group (VSWG), a full F/P/T working group of the Public Health Network Council (PHNC), reporting to the Communicable and Infectious Diseases Steering Committee (CIDSC) via the Canadian Immunization Committee (CIC), provides direction to PWGSC in awarding of contracts under the BPP, as well as the development of strategies for accessing a high-quality and secure supply of vaccine at the best international prices. The VSWG's greatest strength has been its capacity to work collaboratively to reach consensus decisions on strategies to enhance security of supply and to address vaccine supply concerns that do arise (e.g., through agreement on equitable allocation of limited supply and protection of core immunization programs).

ASSESSMENT: SECURITY OF VACCINE SUPPLY

While progress has been achieved through the National Immunization Strategy in improving the supply management of vaccines in Canada, jurisdictions in recent years have experienced disruptions in the supply of critical vaccines (both active and passive immunizing agents—i.e., traditional vaccines plus other biologics such as immune globulin products and antitoxins). These disruptions highlight that, despite a long-standing collective procurement process that has actively sought to incorporate strategies for enhancing security of supply, problems in the vaccine supply structure can, and do, still occur. Ensuring a secure vaccine supply requires ongoing strategic analysis, effective supplier engagement and longer term strategies and planning.

There is a range of threats or risks to security of vaccine supply, some of which are more or less foreseeable or predictable than others, each requiring specific strategies to mitigate the risks of vaccine supply disruptions to immunization programs:

- Supply disruption may result from unforeseeable, isolated incidents that can occur during manufacturing (e.g., loss of product or product/facility quality issue) or during transport or storage (e.g., broken cold chain, expiry or other damage). This type of shortage may be limited in duration and scope, but can have longer lasting, broader potential to interrupt/disrupt immunization programs (e.g., Quadracel).
- Newly developed vaccines may be in limited supply due to pent-up global demand and/or difficulties on the part of manufacturers in ramping up production or addressing quality issues for achievement of full-scale manufacturing.
- Manufacturers may elect to discontinue an established vaccine with low market value in favour of next generation vaccines at increased cost. For example, when new combination vaccines (such as Tdap-IPV and MMRV vaccines) were launched, the previous versions of these vaccines (Dtap-IPV and MMR vaccines, respectively) and their single-vaccine predecessors (IPV and varicella, respectively) tended to be in short supply. Similarly, manufacturers might elect to discontinue low-demand vaccines, such as rabies vaccine and tuberculosis (BCG) vaccine. These types of supply constraints typically require that alternate/substitute products be integrated into existing immunization programs.

Even if alternate suppliers do exist for a given vaccine it is not certain that more than one vendor will seek market approval in Canada due to the relatively small market size. Overall, the profitability of several biopharmaceutical companies has decreased in recent years. As a counter-measure, industry may choose to undertake some degree of cost-cutting measures that could contribute to vaccine shortages (e.g., staff reductions that could affect the ability to reliably produce vaccine; vendors decreasing their in-house storage of vaccines and relying to a greater degree on just-in-time delivery; vendors having decreased

production surge capacity, leading to reduced ability to meet potential increases in demand). These conditions may contribute to significant shortages on a global scale on an ongoing basis.

What is needed are:

- ongoing operation and expansion, where warranted, of the current Bulk Procurement Program (BPP)
- continued collaboration and cooperation in preventing and mitigating threats to vaccine supply, supported by the ongoing F/P/T Vaccine Supply Working Group (VSWG)
- a new, formal F/P/T protocol setting out roles, procedures and mechanisms to ensure timely, coordinated and effective response to supply threats and disruptions
- a regime of risk-focused plans for maintenance of security of supply, especially for vaccines of priority concern (i.e., those where supply disruption is most likely and would have particularly significant consequences)

Addressing vaccine supply concerns in a cooperative and collaborative way enhances the achievement of the NIS objectives. The BPP and VSWG together provide an effective mechanism for addressing these issues. While the VSWG continues its efforts to enhance the security of Canada's vaccine supply, shortages will occur occasionally, hence the need for a clear and pre-tested Vaccine Supply Protocol, complemented by an appropriate Risk Management Approach, in particular to prevent and respond to supply disruptions and shortages for critical vaccines.

Vaccine Supply Protocol

An F/P/T supply protocol would need to have both proactive ("supply") dimensions and reactive ("shortage") dimensions in addressing common issues related to vaccine procurement, deployment and stock management. At the heart of the "supply" dimensions should be the following kinds of considerations:

- timely notification of proposed program changes affecting demand and of supply incidents (e.g., large cold chain breaches) that may have an impact on vaccine requirements and supply nationally
- policies and practices that aim to reduce wastage of vaccine without undermining program delivery
- timely and reliable forecasting of demand, including reasonable contingencies to meet non-routine demand
- contingency plans to deal with the possibility of prolonged shortages
- national approaches to decision making and communication that addresses individual and collective needs while being respectful of each jurisdiction's individual responsibilities and authorities
- mutually agreeable principles and commitments regarding individual and collective response to shortages
- special arrangements to deal with serious outbreaks and/or critical and long-term shortages

Risk Management Approach

Jurisdictions should collaborate on the regular periodic assessment of individual and collective vulnerabilities with respect to security of supply of vaccines, in particular those of priority concern. The assessments should identify priority vulnerabilities along the supply chain, with the findings being used to guide the development of corresponding vaccine-specific security of supply risk management plans and to set priorities for more general security of supply remedial measures along the vaccine supply chain.

For *illustrative purposes only*, the matrices below describe the kind of "risk management" sensibilities that should be applied to vaccine supply management.

The matrix immediately below shows how individual vaccines can first be ranked in terms of the risks and impacts of any possible supply disruption or shortage. Such a first-stage Risk/Impact Assessment serves to identify vaccines of priority concern, based upon the *probability* of a supply disruption or shortage for the vaccine, and the relative *consequences* of any such disruption or shortage of the vaccine.

Stage 1: Risk/Impact Assessment of Potential Vaccine Supply Disruption/Shortage

Very High (5)	**5**	**10**	**15**	**20**	**25**
High (4)	**4**	**8**	**12**	**16**	**20**
Moderate (3)	**3**	**6**	**9**	**12**	**15**
Low (2)	**2**	**4**	**6**	**8**	**10**
Very Low (1)	**1**	**2**	**3**	**4**	**5**
PROBABILITY OF SUPPLY DISRUPTION	Very Minor (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
	CONSEQUENCES OF SUPPLY DISRUPTION/DISRUPTION				

The Risk/Impact Assessment score in each box = Probability rating x Consequences rating
The scales and related assessment criteria need to reflect the views and values of the users

The matrix immediately below shows how the findings from the first stage risk/impact assessment above can/should be subsequently used to undertake the second stage vulnerability assessment of each vaccine of priority concern. This vulnerability assessment takes into account the combined effects of the risk/impact assessment and the degree of difficulty (and/or likelihood of success) of any measures available to prevent and/or mitigate the risks and consequences of a vaccine supply disruption or shortage.

The vulnerability assessment results are subsequently taken into account by the appropriate authorities to make decisions about where they may wish to place greatest emphasis in their risk prevention and mitigation efforts. For example, they may generally wish to avoid investing in mitigation measure where the challenges and costs of intervention are major or extreme while the risks and impacts are very minor. Typically, greatest emphasis is placed on issues where the risks and impacts are relatively substantial and the challenges and costs of mitigation interventions are relatively moderate, i.e., where maximum benefits can be achieved with reasonable and acceptable investments and efforts.

Stage 2: Vulnerability Assessment of Potential Vaccine Supply Disruption/Non-Supply					
Very High (25)	**25**	**50**	**75**	**100**	**125**
High (20)	**20**	**40**	**60**	**80**	**100**
Moderate (15)	**15**	**30**	**45**	**60**	**75**
Low (10)	**10**	**20**	**30**	**40**	**50**
Very Low (1–5)	**1–5**	**10**	**15**	**20**	**25**
RISK/IMPACT ASSESSMENT	Very Minor (1)	Minor (2)	Moderate (3)	Major (4)	Extreme (5)
	CHALLENGES/COSTS OF EFFECTIVE MITIGATION OF RISK				
Vulnerability Assessment score = Risk Assessment rating x Challenge/Cost of Effective Mitigation rating The scales and related assessment criteria need to reflect the views and values of the users.					

In assessing risks and vulnerabilities, jurisdictions should identify and agree on what key considerations and factors are relevant, what the relative weighting of risks and vulnerabilities should be, and what prevention and mitigation measures are available and relevant.

Criteria related to the health and/or economic impacts of supply disruptions or shortages include:

- public health value (burden of disease, risk of re-emergence)
- emergency use versus regular schedule
- "vulnerability" of target populations (type of vulnerability, size of those populations, etc.)
- regular childhood immunization programs versus adults or other groups
- cost-effectiveness and cost per QALY of prevention and mitigation measures
- programmatic impacts and feasibility

Criteria related to the likelihood of supply disruptions or shortages include:

- production-related criteria (multivalent vaccines versus monovalent because of the complexity of production and long production lead times)
- supplier base (single-source versus multi-supplier vaccines)
- known fragility of supply chain, ranging from production to administration; historical experience can inform this

In undertaking the risk and vulnerability assessments, jurisdictions should appreciate that the supply chain can be vulnerable at any point on its continuum, and not just at the manufacturer level. This includes transport, cold chain management, operational wastage, safety concerns, product recalls, etc. These criteria can be applied to whole immunization programs or portions of immunization programs. (For example, if there were a shortage of MMR vaccine, there is the possibility of maintaining the first dose at 12 months of age and delaying the second dose, i.e., until adequate supplies are available.)

I. Vaccine Innovation and Development

SITUATION

Overview and Context

The number of vaccines in the Canadian market has grown substantially, and this is an opportunity for the Canadian public health community to be more strategic in identifying its immunization needs. Canadians may be nearing threshold of parental acceptance regarding the number of shots deemed acceptable for children, and yet new vaccines will further decrease the risk of disease. There is a need to seek "more protection with fewer shots" and to facilitate development of vaccines for the aging population, including preventative and therapeutic vaccines. In addition, more complex vaccines are being produced by fewer companies; only two multinationals exist in Canada with domestic manufacturing capabilities. While many foreign firms have a sales presence in Canada, and while there are a number of smaller domestic biotechnology firms, the general dependence on foreign supply, and the limited domestic manufacturing presence, presents risks to Canadians with regard to secure and timely access to existing and new vaccine products.

While Canada remains a minor market for vaccines ($322 million per year in vaccine purchases represent only 1.6% of the global market), Canada does have the scientific, technical and manufacturing capacity to be more innovative and strategic in the way it identifies short-, medium- and long-term immunization needs.

In addition to the federal roles in public health, disease prevention and immunization programing described above, the Government of Canada also has long-standing roles and responsibilities in developing commercially applicable research to support the development of Canadian industry through the National Research Council and its network of government and industry partners.

Limitations and Constraints on Vaccine Innovation and Development in Canada

There are several known and/or potential reasons why vaccine development may not always respond to the needs and priorities of the public health community:

- The vaccine industry and research communities have inadequate knowledge about Canada's evolving vaccine innovation needs and priorities.
- Canada has too small a market for a specific vaccine to be developed solely for domestic needs, (i.e., given the expected price that users might be willing to pay, it is deemed by industry to be not worth the costs of innovation and development, clinical trials, etc., and scaling-up of production simply, or primarily, to meet Canadian needs).
- The high risks and uncertainty of outcomes and commercial benefits of innovation and development dampen the willingness to invest in innovation.
- Inadequate valuation on the part of the public health community regarding the real or perceived public benefit versus cost of a potential new vaccine.

- Limited (or no) advance knowledge or certainty, on the part of industry and the research community, of the intentions and commitments of immunizing authorities to purchase innovative vaccines if/when they are available for use.

What Can Be Done to Facilitate Innovation and Development

Following are general strategies and means to address some of the above critical factors:

- Send clear and consistent market signals about Canada's public health needs, interests and priorities.
- Ensure full cost-benefit valuation of vaccine innovations to maximize commercial viability for industry.
- Maximize market purchasing power, including advance commitments (both domestically and internationally).
- Share available government knowledge and technical expertise in the fields of vaccine development, including providing industry and the research community access to publicly-developed technologies and innovations.
- Undertake and/or underwrite elements of risk and uncertainty, where justified in the public health interest, including possible public/private development (at least to certain stages).
- Highlight to industry the advantages of early trial, approval and use of vaccine innovations in Canada as a potential stepping stone to scale up to world markets.
- Leverage innovation commitments through purchasing terms and conditions for other vaccines.

ASSESSMENT: VACCINE INNOVATION AND DEVELOPMENT

The Public Health Agency of Canada (PHAC), the Canadian Institutes of Health Research (CIHR) and the National Research Council (NRC) convened an initial exploratory workshop in the fall of 2012, with the following objectives:

- Identify ways to strengthen public health input into priorities for Canadian vaccine development.
- Assess critical factors to improve translation of bench research to vaccine products available to Canadians that are of high public health priority.
- Explore potential mechanisms to improve support for the development of vaccine products of highest priority for Canadian public health.

The workshop was attended by a broad cross-section of experts involved in vaccine research, development and manufacture, as well as government representatives. There were ten vaccine researchers from universities across the country and eight representatives from industry, including Vaccine Industry Committee representatives. The public health community was represented, including a representative from the Council of Chief Medical Officers of Health. Officials from the three sponsoring agencies, PHAC, CIHR and NRC attended, as did officials from Industry Canada, Health Canada, and the Department of National Defence. The U.S. Deputy Assistant Secretary for Health, National Vaccine

Program Office, Department of Health and Human Services, provided an overview of the approach to vaccine development in the United States.

The participants noted that Canada has several strengths that can support vaccine innovation and development:

- a respected and competent scientific capacity
- a globally respected regulator
- supporting government agencies such as NRC and CIHR
- public health approach to health care that provides data management opportunities
- while a relatively small share of the vaccine market, Canada tends to be an early adopter of new vaccines
- large enough depth in the vaccine area, but not so large that all the main players cannot be in one room at one time

Nevertheless, participants also recognized that there are some realities and challenges:

- period of fiscal restraint
- uncertain international economy
- multiple jurisdictions involved in vaccine procurement decisions
- branch plant vaccine industry with little influence over its multinational owners
- innovative biotechnology companies that face venture capital challenges
- fragmented vaccine area that lacks focused leadership

The workshop demonstrated considerable interest in a coordinated and focused effort to develop Canada's research and industry in support of public health objectives, and identified several potential areas for such concerted action:

- *Coordinate federal actors in the vaccine area to provide focused support for vaccine research and industry in support of public health vaccine objectives:* In addition to PHAC, NRC and CIHR, there are several other federal bodies with significant roles to play, including: Health Canada as the regulator; Industry Canada; Department of National Defence, particularly its medical countermeasures area; Department of Foreign Affairs and International Trade, if there is an interest in any international consortia; and Canadian International Development Agency (CIDA), if targeting low and middle income countries. Before any effort in the vaccine area can be expected, the federal government must bring its collective activities together in a focused fashion.

- *Identify the F/P/T vaccine priorities with sufficient lead time to be able to influence vaccine development:* Public health priorities are required to influence research and vaccine development. A two-pronged approach might be considered: the first would focus on vaccines in the pipeline with the intent to identify the ones that Canada is interested in and where in Canada clinical trials might be held to facilitate their adoption; the second would identify longer term interest to signal areas where Canada would like to see vaccine development. Some form of vaccine innovation program coordinating office or centre could facilitate the identification of vaccine priorities. Consideration could eventually be given to developing a strategic procurement approach in support of the identified priorities.

- *Explore means to support vaccine evaluation studies and vaccine readiness studies:* Vaccine evaluations have been identified as significant in influencing the development of vaccine improvements. Since Canada is an early adopter of many newer vaccines it might be in a position to provide a significant contribution in this area. Vaccine readiness studies would facilitate the introduction of new priority vaccines.

- *Address perceived conflict of interest issues with the regulator working with the industry early in the vaccine development stage and industry funding research, particularly socio-economic cost-benefit studies:* There are benefits to having the regulator be involved in the early stages of clinical studies so that these studies conform to regulatory requirements; however, the mechanism for such cooperation will need to guarantee real and perceptual regulatory independence and impartiality. Industry's funding of and/or participation in vaccine research often leads to a perception that the research findings are biased in favour of the funding industry. Agriculture and Agri-Food Canada has had some success in developing research approaches with industry that could be examined and possibly emulated.

J. No-Fault Vaccine Injury Compensation

SITUATION

To be effective in reducing the incidence and severity of vaccine-preventable diseases, immunization programs seek to achieve very high levels of vaccination on the part of populations at risk, including those who may pass the disease on to more vulnerable populations. High rates of vaccination are not only of direct benefit to those who are successfully inoculated but also of value to those who, for a variety of reasons, cannot be vaccinated, are ineffectively vaccinated, or refuse to be vaccinated. High levels of vaccination contribute to "herd immunity" by providing a kind of "firewall" (i.e., the large numbers of vaccinated individuals) between those who are infected and those who are susceptible.

The problem is that current high standards for establishing vaccine safety may miss risks that fall below a detection level, which at the population level can be significant. Thus, there is always the rare possibility of serious harm resulting from adverse immunization events. The achievement of high levels of vaccination constitutes a significant public good and a highly cost-effective method of achieving public health goals. It is therefore important that those who suffer serious harm from adverse events in the course of contributing to this public good receive appropriate compensation. It is also important that the processes by which their claims are handled are expedient and just and in particular do not "re-victimize" the injured by presenting bureaucratic and costly hurdles that might even discourage them from seeking the compensation they deserve.

Reliance on traditional tort ("civil wrong") litigation ("suing for damages") is generally inadequate and often counter-productive in addressing vaccine injuries, since adverse vaccine events most often relate to idiosyncratic *unavoidable* or *unintended* injuries arising from the administration of regulated vaccines that have been developed, approved and delivered in good faith and to high standards of risk management. Since the goal is the provision of appropriate, predictable and fair *compensation* to the injured rather than the *punishment* of wrong-doing or *deterrence* from doing harm to others, no-fault compensation is more appropriate.

As an alternative to tort litigation, a no-fault program for victims of adverse events following immunization can provide more expeditious, efficient, consistent, predictable and fair compensation for unavoidable and unintended vaccine injuries. As noted above, in providing such compensation—and doing so in a highly visible and transparent manner—one source of opposition to large-scale and/or mandatory vaccine programs can be removed, namely, fear of uncompensated injuries and burdens.

Key reasons for the establishment of no-fault vaccine injury compensation programs in Québec, the U.S. and other jurisdictions centre on the following:

1. *It's the right and fair thing to do for those who are injured from vaccines.*

    - Those who participate in vaccine programs should receive fair, prompt and convenient consideration, support and compensation for their injuries.
    - This is particularly true when vaccines are mandatory and when participation provides a broad public benefit beyond that for the individual being vaccinated.
    - A no-fault program provides the most direct, accessible, convenient, non-complicated and predictable support and compensation for those injured.
    - Since most injuries cannot be attributed to negligence on the part of anyone in the vaccine supply chain, a no-fault program is vital to ensure appropriate compensation for the rare cases of unexpected and unavoidable injuries.
    - Costs of the no-fault program can readily be shared by society at large, whether directly funded by governments or recovered from vaccine suppliers and shared equally and equitably across all relevant vaccine programs.

2. *A publicly managed no-fault injury compensation program reduces costs and burdens to individuals, governments, and industry alike.*

    - *Injured individuals* avoid the expenditure of personal time, effort and money that would otherwise be required to pursue civil suits (tort) to seek compensation; given the low likelihood of successful claims, this would largely be a waste, made all the worse by protracted processes whose outcomes are highly uncertain.
    - *Governments* avoid the legal defence costs, adverse publicity and distraction of being embroiled in lawsuits initiated by injured individuals, as governments would almost certainly be named in civil suits, given their roles in vaccine regulation, the making of vaccination mandatory, vaccine delivery and vaccine risk communication. (Note: Even if not named as respondents directly by the injured individuals, they would likely be named as third parties by vaccine manufacturers when they are sued.) While governments would in almost all cases be able to successfully defend claims, they would not likely be able to recover their costs, let alone overcome adverse publicity and distraction from their primary mission. (Note: Direct legal costs would be borne by the respective Health and Justice/Attorney General functions of the respective F/P/T jurisdictions. Moreover, the tendency would be for ALL relevant jurisdictions to be named, especially in class action suits.)
    - *Governments* also reduce the general administrative and procedural costs associated with hearing and overseeing civil claims in the courts, not all of which (and likely little of which) can be recovered through judgments on "costs" in unsuccessful claims. Since most cases would likely result in dismissal, this would be seen as a waste of public resources, especially if much less costly processes such as a no-fault program could otherwise be made available.

- *Vaccine suppliers* avoid the legal defence costs, adverse publicity and distraction of being embroiled in lawsuits initiated by injured individuals; while suppliers would in almost all cases be able to successfully defend claims, they would not likely be able to recover their costs, let alone overcome adverse publicity and distraction from their primary mission.
- *Society in general* avoids the general negative fall-out that would otherwise be associated with civil claims, especially high-profile class action suits, which are increasingly a possibility for consumer injuries in Canada. Even though it is likely that most cases would be successfully defended against negligence, there is a risk that the public will generally conjure the mistaken notion that vaccines are much riskier than they are.

3. *A no-fault injury compensation program is vital to maintaining the active participation of a suitably competitive number of drug manufacturers in the generally non-lucrative vaccine business.*

    - The avoidance of costly legal defence and adverse publicity associated with civil suits helps ensure that drug manufacturers can remain involved in vaccine supply, which they generally see as a non-lucrative aspect of their business, undertaken largely as a matter of public service. The chilling effect on industry of exposure to civil claims—even where such claims can be successfully defended—has been empirically demonstrated with the U.S. experience before the introduction of the U.S. no-fault program, compared to after.

4. *A no-fault injury compensation program helps remove one of the arguments against vaccination put forward by the anti-vaccine movement.*

    - While there is no evidence (thus far) to indicate whether the existence of no-fault vaccine injury compensation programs either enhances vaccine take-up (overcome fear that any injuries would go uncompensated or require costly and uncertain legal claims) or diminishes vaccine take-up (implicitly remind/signal that vaccines *do* have risks), the presence of a no-fault injury compensation program at least takes away one potential anti-vaccine argument.

5. *Waiting for a crisis related to potential AEFIs before instituting a no-fault compensation program can result in a problematic response to the handling of compensation demands.*

    - Reactive development of a no-fault compensation program in response to a crisis in confidence related to vaccines or an increase in vaccine-related injury litigation would likely result in a sub-optimal program. Increasingly complex immunization schedules, with the periodic introduction of new vaccines, add to the probability of AEFIs. At the same time, evolving changes in the legal environment also increase the likelihood of class action lawsuits. Pre-emptively designing a program to address anticipated increases in the risk of lawsuits related to AEFIs and the impact they would have on public confidence and vaccine manufacturers would allow for the careful development of such a program that takes into account all relevant considerations.

Government Sector Considerations

Provinces and territories have strong and direct interests in the issue of no-fault compensation for vaccine injury because they have primary responsibility for the design and implementation of vaccine programs for their respective populations. They have an interest in ensuring high levels of participation and high levels of public confidence in, and support for, immunization programs, and in avoiding costly and time-consuming legal actions in the event of injuries that may reasonably be attributed to vaccination.

At the same time, P/Ts generally wish to ensure that their handling of public concerns—such as injury compensation—in their own jurisdiction is reasonably consistent with the handling of such issues by their counterparts in other jurisdictions. They also wish to minimize the risk of dubious, let alone frivolous, claims, and to ensure that whatever compensation may be made available is reasonable and sustainable. A well-designed no-fault injury compensation program can achieve that by minimizing the need for tort litigation, setting well-prescribed and limited terms for compensation, and offering an accessible and efficient application process for claimants. Collaboration amongst the provinces and territories can help ensure reasonable consistency, sharing of best practices, and possibly even achievement of administrative efficiencies through some form of shared services or processes. The latter would be particularly important for smaller provinces, for which the establishment of their own administrative mechanisms would not be cost efficient.

As noted above, Québec already has a no-fault injury compensation program. Law reform commissions in Saskatchewan and Manitoba had also earlier concluded that some form of no-fault injury compensation scheme would be appropriate, although uncertainty at the time of the magnitude of financial and other implications prevented those jurisdictions from proceeding with programs. Since that time, however, the practical experience in Québec, the U.S., the U.K., New Zealand and other jurisdictions has shown that the rate of claims is modest and the magnitude of compensation relatively low. In Québec, for example, the number of cases between 1988 and 2009 averaged only 4.5 per year (99 cases in total in the time period, amounting to 0.7 cases per million population annually), with about one third resulting in compensation. Very few claimants had need for legal representation, with the greatest use being in appeals. Anecdotal evidence suggests that the program averted the need for civil litigation. Even in the U.S., where civil litigation is more prominent than in Canada, the number of claimants from 1988 to 2009 amounted to only 2.15 cases per million population.

While provinces and territories have responsibility for vaccination programs for their respective general populations, the Government of Canada is also interested and engaged because it regulates vaccines, recommends them for P/T programs, actively promotes their importance and benefit, and administers them to federal populations. (Indeed, with interests in and certain responsibilities for First Nations, Inuit, federal inmates, incoming immigrant and refugee populations, RCMP, forces personnel, veterans and others, the Government of Canada ranks fifth among Canadian jurisdictions in terms of the size of population for which it has immunization responsibilities.)

Like the provinces and territories, the federal government generally has an interest in minimizing the risks of civil suits, which can be costly and can serve as a deterrent to vaccine innovation. It also has an interest in seeing Canada enjoy high levels of participation and high levels of public confidence in, and support for, immunization programs, particularly those that are the subject of guidance under the federal-led NACI process. The federal government is also generally interested in encouraging P/T measures that support federal (and broader common F/P/T) objectives in the public health field, including reduction of vaccine-preventable diseases. To the extent that a system of P/T no-fault injury compensation programs might help sustain public participation and confidence and minimize public costs associated with immunization programs, the federal government has an interest in facilitating P/T collaboration on such programs, including sharing of best practices, promotion of consistent approaches, and facilitating efficient administrative procedures and mechanisms among P/Ts.

ASSESSMENT: NO-FAULT INJURY COMPENSATION

The problem is that, while Québec has a no-fault vaccine injury compensation program, the rest of Canada does not. Indeed, Canada and Russia are the only G8 nations without state-wide no-fault vaccine injury compensation programs.

Absence of a Canada-wide no-fault compensation program is problematic for several reasons:

- Residents of all provinces and territories other than Québec lack access to no-fault compensation and must rely on tort litigation, with all of the drawbacks, burdens and limitations noted above.
- Since many—if not most—of such uncovered individuals lack the knowledge, time or financial ability to pursue litigation if injured, or believed to be injured, they either bear the costs and burdens of injury themselves, or they refuse to participate in vaccine programs because of the risk of uncompensated injury. The latter results in reduced coverage of the population overall, thereby undermining the effectiveness of vaccine programs in protecting against vaccine-preventable diseases.
- Gaps and inconsistencies in the level of support—including injury compensation—for vaccine programs from one jurisdiction to another weakens overall cohesiveness and consistency of Canada-wide vaccine programs, and militates against the achievement of what could otherwise be mutually supporting programs and public messages.

For the reasons set out above, there is a need in Canada for a nation-wide no-fault compensation program (or system of programs) that would fairly and expeditiously compensate those likely injured from any vaccine that is recommended.

Considerations

To ensure objectivity, fairness and transparency, such (a) no-fault compensation programs should be administered by an arm's length agency(ies), and operate independently of the branches of government responsible for the promotion and safety of vaccines.

To ensure efficiency, pragmatism and expediency, a reasonably short statute of limitations for filing claims should be set (e.g., three years from injury onset), in addition to requiring sufficient documentation to substantiate the injury and its etiology.

To avoid costly redundancy or overlap with other sources of support for the injured, and to avoid frivolous or punitive claims, the injury itself must result in some measurable *uninsured* damages or costs. In the case of death, a death benefit should be paid out similar to an accidental death insurance benefit.

Needs and Costs

Experience in Québec and in other jurisdictions internationally has shown that the overall rate of applications for compensation is very low (fewer than three cases annually per million population in the U.S., the U.K. and New Zealand, and less than one third that rate in Québec). It has also shown that well-designed no-fault vaccine injury compensation programs are very low cost, especially in relation to the overall costs of the immunization programs to which they apply. Informal estimates for a nation-wide system of programs for Canada, based largely on the Québec experience, would amount to about $4

million to $5 million for compensation payouts and overall program administration. In comparison, a single legal case in 1988 resulted in legal costs alone in excess of $1 million.

Management of Claim Risks

As highlighted immediately below, an effective, responsible and sustainable no-fault injury compensation program requires suitable provisions to avoid dubious or frivolous claims, set realistic limits on eligibility and compensation terms, and ensure timely and efficient consideration of claims and handling of appeals. Practical experience in Québec and in other jurisdictions internationally has demonstrated that this can readily be achieved.

Potential Program Elements

Drawing upon the experience with the 13 jurisdictions around the world that have established no-fault compensation programs, there is considerable flexibility in how a program for Canada that would address domestic needs, values and priorities might be designed and implemented. This includes the following potential elements, approaches and options that reflect international practices and experiences:

- Administration by state ministries/agencies related to health, social welfare or labour or under legislation that governs an arm's length overseeing agency. (Note: Sweden is the only state whose no-fault program is covered under a *private* insurance compensation scheme.)
- Universal application to *all* populations experiencing adverse events OR, more restrictedly, to programs that target infants and school-age children, AND/OR to mandatory vaccinations required by state edict.
- A clearly articulated administrative review of the vaccine-related injury, in a manner similar to other accident insurance or disability schemes that do not require legal representation or the solicitation of expert representation of medical review (beyond the attending physician's report).
- Claims assessment overseen by a medical director taking into account administrative review of eligibility criteria and medical assessment by outside consultation from medical experts.
- Coverage of *uninsured* medical costs and, possibly, also special disability benefits, death benefits, economic damages (lost wages) and possibly even certain non-economic damages. This includes consideration of some threshold definition of eligible damages (e.g., serious injury or death, comparable to criteria for compensation applicable to accident or disability schemes).
- Funding of the program (typically modest in scale) from general government appropriations or possibly by a special vaccine excise tax paid by the purchaser or an injury premium paid by the manufacturers.
- Administration of the no-fault compensation program at arm's length from government branches or bureaus responsible for the approval, promotion and safety of vaccines and vaccine programs.

V. CONCLUSION

This Technical Report has provided an overview summary and assessment of Canada's experiences and accomplishments to date with immunization programs and related support initiatives for the management of vaccine-preventable diseases. Particular emphasis was placed on experiences with, and future prospects for, collaboration and cooperation among federal, provincial and territorial (F/P/T) partners in pursuit of common goals and mutual benefits.

The findings in this report provide the context and rationale for the recommendations for the future of immunization programming in Canada that are set out in the corresponding Executive Report. Wherever relevant, the descriptive, analytical and contextual information in this Technical Report are to serve as a guide in the interpretation and potential implementation of the recommendations of the Executive Report.

The review of recent experiences with the National Immunization Strategy (NIS) and related immunization issues offers the following macro-level observations, details of which are provided above in the body of this Technical Report:

- Immunization remains a vital and highly cost-effective element of disease prevention and health protection, both in Canada and globally. Despite great progress in immunization programming across Canada, critical gaps and challenges remain.

- Advances in vaccines and vaccine technologies, growing complexities in immunization programming and delivery, increasing emphasis on cost-effectiveness and value for money, and evolving public attitudes and professional practices all place growing pressures for innovation, evidence-based decision making and accountability for results in the field of immunization.

- F/P/T jurisdictions have strong mutual interests in continuing to collaborate on immunization issues and initiatives, so as to enhance their individual and collective approaches to immunization:
    - articulation and coordination of mutually complementary goals, approaches and messages
    - evidence-based decision making in the setting of immunization priorities, the design and delivery of immunization and related programs, and the evaluation of results and lessons learned
    - identification and targeting of priority public health needs and gaps of broad and common concern
    - innovation and sharing of best practices, guides and tools

- Continued and enhanced F/P/T collaboration and cooperation will continue to be a vital means of advancing mutually complementary goals in disease prevention and control in general, and immunization in particular:
    - better and more equitable health protection
    - economies of scale and efficiencies in both immunization program development and delivery and in the full range of ancillary and supporting F/P/T activities

- The NIS has proven to be a cost-effective and flexible mechanism to encourage and facilitate F/P/T collaboration for mutual interest and benefit, including: economies of scale; intelligent and

efficient deployment of limited expertise and resources; innovation and sharing of best practices; and avoidance and reduction of disparities in health protection across jurisdictions.

- Much progress has been achieved over the last decade in addressing the challenge and threats of vaccine-preventable diseases. There is considerable scope for similar success through ongoing F/P/T collaboration in addressing continuing and emerging threats from vaccine-preventable diseases.

- The agenda for the next decade of F/P/T collaboration on the NIS might consider the following overarching goals:
    - Continue *ongoing beneficial initiatives*, for example:
        - vaccine guidance
        - bulk vaccine procurement
        - surveillance
    - Deal with *unfinished business* under the initial 2003 NIS:
        - immunization registries
        - data-sharing arrangements
        - program-related research
        - targeting of special populations
    - Address key *new challenges and opportunities*:
        - common vaccine guidance
        - coordinated immunization schedules and programs
        - strengthened and sustainable program evaluation and research
        - enhanced and sentinel surveillance
        - outbreak and adverse event response protocols
        - vaccine hesitancy
        - security of vaccine supply
        - vaccine innovation and development to meet public health needs
        - injury compensation

The NIS-TG recommendations in the accompanying Executive Report focus on ways to continue, and to strengthen, F/P/T collaboration in the field of immunization, and to do so in a more concerted and cohesive way under the auspices of the Public Health Network. With such enhanced collaboration focused on mutual objectives and shared priorities, implementation of the recommendations of the NIS-TG report will help achieve the following:

- greater and more equitable health protection for Canadians, especially high-risk and hard-to-reach populations
- reduction in vaccine-preventable diseases
- reduced burdens on health systems and on individuals and families
- savings on vaccine program implementation
- more reliable security of vaccine supply and more timely and effective response to shortages and recalls
- more focused, well-targeted and cost-effective vaccine program design and implementation

- delivery on domestic and international commitments for disease reduction/elimination, enhancing F/P/T credibility as effective leaders and reliable partners in disease prevention
- innovation in Canada's vaccine industry and research community for public health, industrial and economic benefits
- mutually respectful and effective F/P/T relationships, with reciprocal benefits for broader intergovernmental cooperation on public health initiatives in general

ANNEX 1: Acronyms

ACIP—Advisory Committee on Immunization Practices (United States)

ADM—Assistant Deputy Minister

AEFI—adverse event(s) following immunization

AMMI—Association of Medical Microbiology and Infectious Disease Canada

ATAGI—Australian Technical Advisory Group on Immunization

BGTD—Biologics and Genetic Therapies Directorate

BPP—Bulk Procurement Program

CADTH—Canadian Agency for Drugs and Technologies in Health

CAEFISS—Canadian Adverse Events Following Immunization Surveillance System

CAIRE—Canadian Association for Immunization Research and Evaluation

CAP—Community-Acquired Pneumonia

CATMAT—Committee to Advise on Travel Medicine and Tropical Health

CCDIC—Centre for Communicable Diseases and Infection Control

CCHS—Canadian Community Health Survey

CCIAP—Canadian Coalition for Immunization Awareness and Promotion (now Immunize Canada)

CCMOH—Council of Chief Medical Officers of Health

CCPH21—Canadian Coalition for Public Health in the 21st Century

CDC—Centers for Disease Control and Prevention

CDCEG—Communicable Disease Control Expert Group

CHEC—Canadian Hospital Epidemiology Committee

CIC—Canadian Immunization Committee

CIDA—Canadian International Development Agency

CIDSC—Communicable and Infectious Disease Steering Committee

CIHI—Canadian Institute for Health Information

CIHR—Canadian Institutes of Health Research

CIRID—Centre for Immunization and Respiratory Infectious Diseases

CIRN—Canadian Immunization Registry Network

CMRSS—Canadian Measles and Rubella Surveillance System

CNA—Canadian Nurses Association

CNDs—Canadian notifiable diseases

CNDSS—Canadian Notifiable Disease Surveillance System

CNISP—Canadian Nosocomial Infection Surveillance Program

CNPHI—Canadian Network of Public Health Intelligence

CPHLN—Canadian Public Health Laboratory Network

CPHA—Canadian Public Health Association

CPHO—Chief Public Health Officer

CPS—Canadian Paediatric Society

CPSP—Canadian Paediatric Surveillance Program

CRS—congenital rubella syndrome

DM—Deputy Minister

EBM—evidence-based medicine

EHR—electronic health record

FIORP—Foodborne Illness Outbreak Response Protocol

FNIHB—First Nations and Inuit Health Branch (Public Health Agency of Canada)

F/P/T—federal/provincial/territorial

GIVS—Global Immunization Vision and Strategy 2006−2015

GPHIN—Global Public Health Intelligence Network

HALY—health-adjusted life year

HB—hepatitis B

HHS—Department of Health and Human Services (United States)

Hib—*haemophilus influenza* type b

HPA—Health Protection Agency (United Kingdom)

HPV—human papillomavirus

HRQoL—health-related quality of life

HUI—Health Utilities Index

ICEP—Immunization Competencies Education Program

ICER—incremental cost-effectiveness ratio

ICS—International Circumpolar Surveillance System

ICU—intensive care units

IDPCB—Infectious Disease Prevention and Control Branch

IHR—International Health Regulations

ILI—influenza-like illness

IMD—Invasive Meningococcal Disease Surveillance

IMPACT—Immunization Monitoring Program ACTive

INSPIR—Improved National Structures and Processes for making Immunization Recommendations

IP—intellectual property

IPD—Invasive Pneumococcal Disease Surveillance

IPV—inactivated polio vaccine

IU—Immunization Unit (United Kingdom Department of Health)

JCVI—Joint Committee on Vaccines and Immunization (United Kingdom)

LCDC—Laboratory Centre for Disease Control

MAH—Marketing Authorization Holder

MARS—Measles and Rubella Surveillance

Men-C—meningococcal conjugate

MHPD—Marketed Health Products Directorate

MLISA—Multi-Lateral Information Sharing Agreement

MMR—measles, mumps, rubella

MMRV—measles, mumps, rubella, varicella

NACI—National Advisory Committee on Immunization

NCIRS—National Centre for Immunization Research and Surveillance (Australia)

NIC—National Immunization Committee (Australia)

NICS—National Immunization Coverage Surveys

NIS—National Immunization Strategy

NIS-TG—National Immunization Strategy Task Group

NITAG—National Immunization Technical Advisory Group

NML—National Microbiology Laboratory

NOC—Notification of Compliance

NRC—National Research Council

NVAC—National Vaccine Advisory Committee (United States)

OECD—Organisation for Economic Co-operation and Development

ORP—outbreak response protocol

PAHO—Pan American Health Organization

PCIRN—PHAC/CIHR Influenza Research Network

PHAC—Public Health Agency of Canada

PHN—Public Health Network

PHNC—Public Health Network Council

PPEWG—Public and Professional Education Working Group

PPP—public-private partnership

PWGSC—Public Works and Government Services Canada

P/T—provincial/territorial

QALY—quality-adjusted life year

R&D—research and development

REB—Research Ethics Board

RFP—request for proposals

RVDSS—Respiratory Virus Detection Surveillance System

SARS—Severe Acute Respiratory Syndrome

SOPs—standard operating procedures

SORD—Surveillance and Outbreak Response Division (Public Health Agency of Canada)

SOS—Serious Outcomes Surveillance

SRI—severe respiratory illness

UN—United Nations

VIC—Vaccine Industry Committee

VIDO-Intervac—Vaccine and Infectious Disease Organization International Vaccine Centre

VSWG—Vaccine Supply Working Group

VVWG—Vaccine Vigilance Working Group

WG—Working Group

WHO—World Health Organization

ANNEX 2: Definitions

Active immunity—The production of antibodies against a specific disease by the immune system, acquired by either contracting the disease or through vaccination.

Active immunizing agent—Any substance or organism that provokes an immune response (produces immunity) when introduced into the body.

Active surveillance—Based on public health legislation, active surveillance refers to daily, weekly or monthly contacting of physicians, hospitals, laboratories, schools, or others to actively search for cases. This type of surveillance is usually seasonal to coincide with periods of high disease frequency and generally yields a much higher percentage of actual cases as compared to passive surveillance. Active surveillance is used also during outbreaks to identify additional cases.

Adverse event following immunization (AEFI)—An undesirable experience or any unexpected medical occurrence in a patient occurring after immunization. Although a temporal relationship exists, a causal relationship is not necessarily established with the treatment or vaccine. An AEFI is classified as being rare, uncommon, common, or very common.

Adverse vaccine reaction—Any unexpected or dangerous reaction or unwanted effect caused by the administration of a vaccine. The adverse reaction may occur suddenly, or develop over time.

Antibody—A protein found in the blood that is produced in response to foreign substances (i.e., bacteria or viruses invading the body). Antibodies protect the body from disease by binding to these organisms and destroying them.

Antigen—Any substance, usually a protein, that is capable of inducing an adaptive immune response.

Booster—A second, third or greater immunization with a specific vaccine that may be necessary to ensure that the individual is protected against the infectious disease.

Catch-up program—An arrangement to offer vaccinations to those individuals who had missed being vaccinated at the age prescribed under the routine vaccination schedule.

Cold chain—An unbroken series of storage and distribution activities that maintains a proper temperature range during storage and handling in order to preserve the potency of the vaccine.

Combination vaccine—A single vaccine that includes antigens for the prevention of several different diseases, or that protects against several strains of a single infectious agent that causes the same disease such as the measles, mumps and rubella (MMR) vaccine.

Communicability—The capability to spread disease from person to person, or from species to species. Also referred to as being infectious.

Community/herd immunity—The resistance of a group (hence community or herd) to the invasion and spread of an infectious agent, based on the resistance to infection (e.g., through vaccination) of a high proportion of individual members of the group, i.e., thus limiting the probability of exposure of unprotected individuals to infected ones.

Conjugate vaccine—The joining together of two compounds (usually a protein and polysaccharide) to increase a vaccine's effectiveness.

Contagiousness—The degree of transmissibility; the ability for a disease to be transmitted from person to person through direct or indirect contact with a bodily discharge of such a patient, or with an object touched by such a patient or by bodily discharges.

Contraindication—A symptom or condition that makes it likely a life-threatening problem would occur if a vaccine is given.

Cost-benefit (analysis)—An analysis comparing the costs (however defined) of a particular program, policy or initiative with the benefits of that initiative (however measured). Measurement of costs and benefits typically includes some calculation or estimate of direct public costs and benefits as well as broader socio-economic costs and benefits.

Council of the Federation—A forum, established in 2003, to provide opportunities for Provincial and Territorial Premiers to promote inter-provincial/territorial cooperation on a range of issues, including health.

Coverage (immunization)—A measure of the proportion of the applicable population at any point in time that has been protected against the specific disease by immunization.

Disease—Generally, any condition that causes pain, dysfunction, distress, social problems or death to the person afflicted, or similar problems for those in contact with the person.

Dose—A specified quantity of a therapeutic agent, such as a drug or medicine, prescribed to be taken at one time or at stated intervals.

Effectiveness (vaccine)—The ability of a vaccine to produce the desired beneficial effect(s) under real-world circumstances.

Efficacy (vaccine)—The maximum ability of a vaccine to produce the desired beneficial effect(s) under ideal conditions.

Elimination—A reduction in the presence of a disease in a population to a sufficiently low level that the disease may be considered no longer endemic.

Endemic—The constant presence of a disease or infectious agent within a given geographic area or population group.

Epidemic—The occurrence of disease within a specific geographical area or population that is in excess of what is normally expected.

Epidemiology—The study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to control of health problems.

Eradication—Termination of all transmission of infection by extermination of the infectious agent through surveillance and containment, whereby no further cases of a disease occur anywhere and continued control measures are unnecessary.

Evidence-based decision making—A systematic and rational approach to researching and analysing available evidence to inform decision making on policies, programs and strategies.

Guidance statement (vaccine guidance)—A formal statement that provides medical, scientific and public health advice on the use of vaccines, consisting of systematically developed evidence-based recommendations and supporting information that assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions. Whether called a statement, guidelines, a protocol or recommendations, the purpose is to advise on which vaccines are likely to improve health outcomes, and under what conditions.

Health promotion—The process of enabling people to increase control over and improve their health. This involves the population as a whole in the context of their everyday lives, rather than focusing on people at risk for specific diseases, and is directed toward action on the determinants or causes of health.

Herd immunity—*See community/herd immunity*.

Immune system—The complex system in the body responsible for fighting disease. Its primary function is to identify foreign substances in the body (bacteria, viruses, fungi or parasites) and develop a defense against them. This defense is known as the immune response. It involves production of protein molecules called antibodies to eliminate foreign organisms that invade the body.

Immunity—The protection against a disease. There are several types of immunity: passive, active and humoral. The immunity is indicated by the presence of antibodies in the blood and can usually be determined with a laboratory test.

Immunization—The process by which a person or animal becomes protected against a communicable or infectious disease. It entails the administration of a living modified agent (as in yellow fever), a suspension of killed organisms (as in whooping cough), or an inactivated toxin (as in tetanus). Temporary passive immunization can be produced by administration of antibody in the form of immune globulin in some conditions. This term is often used interchangeably with vaccination or inoculation.

Immunization coverage—The percentage of a population protected against a disease by having been immunized against the disease.

Immunization record—Documentation providing information about some or all of the immunizations that a person has received. This may include some or all of the following: the trade name of the vaccine product administered; the disease(s) against which it protects; the date administered (day, month and year); the dose provided; the site and route of administration; the manufacturer of the vaccine; the lot number of the vaccine; and the name and the title of person administering the vaccine. The record may be kept by the health care provider who gave the immunizations (professional chart), a local or provincial authority (registry), and/or the immunized individual or their parent or guardian (take-home record).

Immunization registry—A confidential, population-based, computerized information system that attempts to collect vaccination data about all persons within a geographic area. It consolidates the immunization records from multiple sources for each person living in its jurisdiction and aims to: provide current immunization status information to each individual and/or health care provider as necessary; identify children due or overdue for immunization; notify parents or guardians and supply providers with information necessary to support follow-up; provide information to parents or guardians and providers to avoid inappropriate immunization and to assist in determining the relationship between immunization and adverse events and follow individual patients if necessary.

Immunization schedule—A series of vaccinations, including the content and timing of all doses that is either recommended or compulsory within a particular jurisdiction or target population.

Immunization status—A client's immunization status conveys whether they are eligible, due or overdue for a specified vaccine:

- ***eligible***—the earliest acceptable time period during which an immunization is considered a valid dose for immunization coverage reporting
- ***due***—the time period during which an immunization is considered up to date according to the NACI schedule
- ***overdue***—this time period is one month after an individual is due for an immunization, unless otherwise specified

Immunizing agent—Any substance or organism that provokes an immune response (produces immunity) when introduced into the body. These agents can be monovalent (single antigen) or multivalent (multiple antigens—e.g., MMR) vaccines. The term "vaccine" can be used interchangeably with immunizing agent.

Immunogenicity—The ability of an infectious agent to induce specific immunity.

Incidence—The number of instances of illness commencing, or of persons falling ill, during a given period in a specified population. More generally, the number of new events, for example, new cases of a disease in a defined population, within a specified period of time.

Incidence response protocol—A framework to coordinate the response of member agencies to a respiratory infectious disease incident or risk. The protocol formalizes arrangements between agencies and defines roles and associated responsibilities required of them during the response to a national respiratory infectious disease incident.

Infectious disease—An illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or reservoir to a susceptible host, either directly or indirectly through an intermediate plant or animal host, vector, or the inanimate environment.

Inoculation—The placement of something that will grow or reproduce, most commonly used in the introduction of a serum, vaccine or antigenic substance into the body of a human or animal, especially to produce or boost immunity to a specific disease. This term is often used interchangeably with immunization or vaccination.

Mandatory immunization—The immunizations that are required by law in a jurisdiction.

Medicare—The U.S. federal health insurance program for certain eligible populations.

Morbidity—Any departure—subjective or objective—from a state of physiological or psychological well-being; illness.

Mortality rate—The proportion of a population that dies during a specified period. A disease-specific mortality rate is the proportion of the population that dies of the specific identified disease during a specified period.

National Immunization Strategy—A comprehensive strategy to enable collaboration among levels of government to improve the effectiveness and efficiency of immunization programs across Canada.

Notice of Compliance (NOC)—The Notices of Compliance are issued to a manufacturer following the satisfactory review of a submission to Health Canada. NOCs indicate that a manufacturer has complied with sections C.08.002 or C.08.003 and C.08.005.1 of the *Food and Drug Regulations*.

Outbreak—An epidemic limited to localized increase in the incidence of a disease, for example, in a community, village, town or closed institution or among a specific population.

Pandemic—An epidemic occurring worldwide, or over a very wide area, crossing international boundaries, and usually affecting a large number of people.

Passive immunity—Immunity conferred by an antibody produced in another host and acquired naturally by an infant from its mother or artificially by administration of an antibody containing preparation (antiserum or immune globulin).

Passive surveillance—Refers to the receipt of reports of infections/ disease from physicians, laboratories, and other health care professionals who are required to submit such reports as defined by public health legislation.

Pharmacovigilance—The science of collecting, monitoring, researching, assessing and evaluating information from health care providers and patients on the adverse effects of medications, biologicals and medicines (including vaccines).

Post-marketing surveillance—A procedure implemented after a vaccine has been licensed for public use, designed to provide information on the actual use of the vaccine for a given indication and on the occurrence of side effects, adverse reactions, etc.

Prevalence—The number of events, e.g., instances of a given disease or other condition, in a given population at a designated time.

Program evaluation—The systematic application of scientific methods to assess the design, implementation, improvement or outcomes of a program and to account for public health actions.

Recall—The removal of a product from market. Recalls may be voluntary or mandatory.

Registry (immunization registry)—*See immunization registry.*

Response—A series of planned, organized and coordinated activities of all relevant parties related to the determination, investigation, mitigation and containment of outbreaks of vaccine-preventable diseases, management of risk factors, response to adverse events and safety concerns, and provision of supporting information and communications.

Risk—The likelihood that an event will occur, e.g., that an individual will become ill or die within a stated period of time or by a certain age.

Risk behaviours—The behaviours that increase the likelihood that an individual will experience a certain event or may be harmed.

Risk communication—An exchange of information aimed at increasing the understanding of health risks.

Schedule (immunization schedule)—*See immunization schedule.*

Sentinel surveillance—A surveillance system in which a designated group of reporting sources—hospitals and agencies—agree to report all cases of one or more identified conditions, typically health conditions and risk factors that are not included in routine passive surveillance systems. Sentinel surveillance is used to provide early signals of disease and/or risk factor patterns that may be of concern and that may warrant more specific and detailed investigation.

Special populations—Population groups, distinguished by a range of possible factors (e.g., age, gender, geographic location, ethno-cultural characteristics, mobility status) whose needs may not be fully addressed by traditional service providers and/or service methods, or who feel they may not comfortably or safely access and use the standard resources offered.

Susceptible person—A person not possessing sufficient resistance to a particular infectious agent to prevent contracting infection or disease when exposed to that agent.

Surveillance—The process of timely and systematic collection, orderly consolidation and objective evaluation of data relevant to the detection, prevention and management of vaccine-preventable diseases, with ready access and prompt dissemination of the results for those who need to know, particularly those who are in a position to take action. *See active surveillance, passive surveillance and sentinel surveillance and syndromic surveillance.*

Syndromic surveillance—Surveillance method or system that uses individual and population health indicators that are available before confirmed diagnoses or laboratory confirmation to identify outbreaks or health events and monitor the health status of a community. By getting early symptom (prodrome) information in or near real-time, it enables authorities to detect and respond to more outbreaks and health events more quickly.

Targeted immunization—The immunization program aimed at a specific group(s) or population(s).

Vaccination—The introduction into humans of microorganisms that have previously been treated to make them harmless for the purpose of inducing the development of immunity. This term is often used interchangeably with immunization or inoculation.

Vaccine—Immunobiological substance used for active immunization by introducing into the body a live, modified, attenuated, or killed inactivated infectious organism or its toxin. The vaccine is capable of stimulating immune response by the host, who is thus rendered resistant to infection. Vaccines may be administered through needle injections, by mouth and by aerosol spray.

Vaccine guidance—*See guidance.*

Vaccine-preventable disease (VPD)—An infectious disease for which an effective preventive vaccine exists. Examples of a vaccine-preventable disease include: cholera, diphtheria, hepatitis A, hepatitis B, influenza, invasive haemophilus influenzea, invasive meningococcal disease, Japanese encephalitis, measles, mumps, pertussis, pneumococcal, poliomyelitis, rabies, rubella, smallpox, tetanus, typhoid, varicella, and yellow fever.

Virulence—The relative capacity of a pathogen to overcome body defences.

ANNEX 3: NIS-TG Membership

NATIONAL IMMUNIZATION STRATEGY TASK GROUP MEMBERS

Dr. John Spika, MD
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Director General, Centre for Immunization and Infectious Respiratory Diseases
Public Health Agency of Canada

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Dan Wong, MA
Strategic Advisor to Public Health Network P/T Co-Chair, Government of the Northwest Territories

ANNEX 4: NIS-TG Meetings and Teleconferences

Date	Event
2011	
August 26	NIS-TG Teleconference
September 2	NIS-TG Teleconference
September 8	NIS-TG Teleconference
September 15	NIS-TG Teleconference
September 22	NIS-TG Teleconference
September 29	NIS-TG Teleconference
October 13	NIS-TG Teleconference
October 20	NIS-TG Teleconference
November 1	NIS-TG Face-to-Face Meeting (Winnipeg)
November 17	NIS-TG Teleconference
December 1	NIS-TG Teleconference
December 15	NIS-TG Teleconference
2012	
January 12	NIS-TG Teleconference
January 26	NIS-TG Teleconference
February 23	NIS-TG Teleconference
February 28–29	NIS-TG Face-to-Face Meeting (Ottawa)
April 5	NIS-TG Teleconference
April 30	NIS-TG Teleconference
May 17	NIS-TG Teleconference
June 6–7	NIS-TG Face-to-Face Meeting (Edmonton)
August 16	NIS-TG Teleconference
September 6	NIS-TG Teleconference
September 20	NIS-TG Teleconference
October 4	NIS-TG Teleconference
October 18	NIS-TG Teleconference
November 8	NIS-TG Teleconference
November 22–23	NIS-TG Face-to-Face Meeting (Toronto)
December 6	NIS-TG Teleconference
December 20	NIS-TG Teleconference

NOTE: In addition to the above, NIS-TG members convened numerous teleconferences for each of several sub-groups (two to three NIS-TG members per group), each of which focused in detail on a unique element of the overall NIS review.

ANNEX 5: Selected Source Documents

Canadian Paediatric Society. *Are We Doing Enough: A status report on Canadian public policy and child and youth health—2012 Edition*. Ottawa: Canadian Paediatric Society, 2012.

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Report of the International Forum on National Immunization Programs, Toronto, Ontario, December 4−5, 2008. Prepared by Jenna Hall, Consultant, February 2009.

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Standing Senate Committee on Social Affairs, Science and Technology. *Reforming Health Protection and Promotion in Canada: Time to Act*. November 2003. Chair: The Honourable Michael J.L. Kirby.