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

**EXECUTIVE REPORT** 

March 5, 2013

## I. INTRODUCTION

## **Purpose and Use of This Report**

This Executive Report sets out the key conclusions and recommendations of the National Immunization Strategy (NIS) Task Group (NIS-TG), an expert committee (see Annex) established by the Communicable and Infectious Disease Steering Committee (CIDSC) of the Pan-Canadian Public Health Network (PHN) in June 2011, to undertake a review of the NIS—its strengths, weaknesses and gaps—and report with conclusions, options and recommendations for the future of immunization in Canada. The review focused on opportunities to build on the current ongoing NIS, in particular through enhanced federal, provincial and territorial (F/P/T) collaboration in those areas that are of mutual and collective interest and benefit.

The review entailed numerous teleconferences and face-to-face meetings of the NIS-TG and its various issue-specific sub-groups, complemented by a review of discussion papers, evaluation reports, program information sources, academic and expert papers and other relevant review materials, including most notably the report on Improved National Structures and Processes for Making Immunization Recommendations (the "INSPIR Report"), which addressed the central question of vaccine guidance.

This Executive Report is supported by a Technical Report that provides details on NIS background and context, analysis of issues and opportunities, and the rationale for NIS-TG's proposals set out further below. The Technical Report is designed to play a role in interpreting the spirit and intent of the NIS-TG recommendations, in particular how they build on existing approaches, mechanisms and capacities and address the identified gaps and shortcomings.

The NIS-TG advocates the strengthening of immunization as a vital public health tool, and encourages F/P/T jurisdictions to continue to invest in immunization as one of the most cost-effective ways to protect health and reduce costly burdens of vaccine-preventable diseases. (Note: The term "jurisdictions" throughout this report—often preceded by "F/P/T," for emphasis—refers to the appropriate authorities responsible for vaccine-related policies and programs in *all* federal, provincial and territorial administrations.)

The recommendations address identified gaps—and related opportunities for improvement—in all key areas of immunization programming. In some instances, options are set out to highlight alternative ways of achieving the proposed improvement objectives. While all options are considered feasible, the *first*-listed option in each case is the one recommended by the NIS-TG because it will help achieve the stated objectives in a more timely, comprehensive and/or efficient manner. In all cases, the recommendations and options constitute improvement upon the *status quo*, the weaknesses and shortcomings of which are detailed in the Technical Report. The recommendations and options also provide a foundation for *future* potential enhancement of F/P/T collaboration, wherever this may advance shared interests and objectives.

Based upon guidance from the PHNC in response to NIS-TG's recommendations, the proposal is for a revised National Immunization Strategy that would integrate all of the agreed-upon directions, and chart a course for the future of immunization in Canada. This would include shared vision and objectives, planning and coordination mechanisms, and priority initiatives for ongoing F/P/T collaboration on immunization issues of mutual interest and benefit.

## The National Immunization Strategy

In 2003, the Federal/Provincial/Territorial Conference of Deputy Ministers of Health approved a National Immunization Strategy that provides a framework for inter-jurisdictional collaboration to improve the relevance, effectiveness and efficiency of immunization programming in Canada.

Supported by an initial federal investment of \$45 million over five years (now \$5.6 million per year ongoing), and with corresponding investments and in-kind contributions from provincial and territorial (P/T) authorities, the NIS is a collaborative pan-Canadian initiative that provides a vehicle for F/P/T 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 complementarity of effort, economies of scale and sharing of best practices, the NIS has focused most heavily on:

- collaboration on information sharing, strengthening of professional competencies, surveillance, and reporting/response for adverse events following immunization
- 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

## **Overview of NIS-TG Findings**

#### **NIS Contributions and Successes to Date**

As detailed in the corresponding Technical Report, the NIS has been instrumental in helping F/P/T authorities achieve several notable successes in their immunization programming:

#### • Review and Guidance

- o facilitation of vaccine introduction through expert review and guidance (e.g., NACI, CIC)
- o some knowledge translation to support evidence-based decisions (e.g., *Canadian Immunization Guide; Canadian Immunization Conference*)

#### Uptake and Coverage

o strengthening of core competencies for program design and delivery (e.g., guides and tools)

#### • Safety and Public Confidence

- o improvements to adverse event reporting (e.g., pandemic H1N1 vaccine)
- o some capacity to coordinate response to safety and supply issues (e.g., Quadracel)

#### • Security of Supply

- $\circ$  lower prices (10%-75% below U.S.) (e.g., helped through F/P/T bulk procurement)
- o more reliable supply through better use of multiple suppliers and industry engagement (e.g., flu vaccine)
- o emerging ability to trace and share stocks (including substitutes) in response to shortages (e.g., pilot bar coding)

#### • Federal/Provincial/Territorial Collaboration

o 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)

#### **Building on Success—Addressing Outstanding Gaps and Opportunities**

Despite the above-noted NIS successes, a number of critical challenges and opportunities remain, as detailed in the description and analysis of current approaches and future needs and opportunities in the accompanying Technical Report. The NIS-TG concludes that an ongoing renewed NIS can continue to serve an important role in leading, facilitating and coordinating collaborative F/P/T initiatives of mutual interest and benefit, by addressing the key gaps and responding to the evolving needs and opportunities identified in detail in the 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

## **Anticipated Benefits**

An enhanced, reinvigorated and redirected NIS along the lines set out in this report will help achieve the following benefits:

- greater and more equitable health protection for Canadians, especially high-risk and hard-to-reach populations
- further 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 integrated, 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

## II. FUTURE DIRECTIONS FOR IMMUNIZATION IN CANADA

Set out below are the NIS-TG's ideas and recommendations to enhance immunization across Canada, both overall, and for individual critical elements. While not explicitly referred to as "recommendations," the proposed statements of Vision and Objectives are, in fact, recommended as core principles for the NIS. They are designed to encourage and guide ongoing F/P/T collaboration and continuous improvement in all aspects of immunization programming, and to serve as "touchstones" against which progress and success can be regularly assessed.

## **Overarching Direction and Coordination**

#### Vision

All Canadians enjoy protection against vaccine-preventable diseases through timely and equitable access to effective, sustainable, targeted, adequately funded and well-coordinated immunization programs focused on minimizing health risks and reducing disease burdens, as a vital element of public health strategy.

### **Objectives**

- Prevent, contain and mitigate the risks to all Canadians from vaccine-preventable diseases, particularly for the most vulnerable.
- Maintain stable, equitable and secure supplies of safe, effective and affordable vaccines.
- Ensure timely and effective detection, investigation and response to vaccine-preventable disease outbreaks, adverse events following immunization, and other vaccine safety triggers.
- Optimize the ease, convenience and efficiency of vaccine delivery, for the public and professionals alike.
- Instill high public confidence in the relevance, effectiveness and safety of vaccines.
- Reduce burdens on the health system, on individuals and families, and on the economy.

## **Guiding Principles**

- Focused on vaccine-preventable diseases of priority public health concern, with explicit and meaningful goals and targets.
- Evidence-based, supported by timely, credible and adequate knowledge, and delivered with competent professional expertise reflecting best international standards and practices.
- Planned and managed as a vital, integral and cost-effective element of a comprehensive strategy for health protection and disease prevention overall.
- Maximize efficiencies, economies of scale and complementarity of effort, and facilitate collaboration in areas of mutual interest and benefit.
- Take account of: disease-relevant circumstances of different populations, communities and regions; epidemiological and public health intelligence; scientific evidence; and public values.
- Support innovation and sharing of best practices.

#### Recommendations

- 1. F/P/T jurisdictions endorse the statements of *Vision* and *Objectives* for immunization in Canada, as set out throughout this document as core principles, to guide ongoing collaboration in areas of mutual interest and benefit, and to assess progress and continual improvement.
- 2. F/P/T jurisdictions commit to strengthening collaboration and cooperation—within the framework of a renewed *National Immunization Strategy*—to improve and coordinate their approaches to immunization programming across the full spectrum of interests, as reflected throughout this document.
- 3. The Public Health Network (PHN) establish clear accountability and effective, efficient mechanisms for the ongoing monitoring, guidance and coordination of collaborative F/P/T efforts under a renewed NIS, ensuring that such arrangements are inclusive and transparent, while maintaining flexibility and respecting jurisdictional autonomy. (Note: This Executive Report does not include specific options or recommendations for such overall "governance" arrangements, as this goes beyond the technical expertise and mandate of the NIS-TG.)

## **Vaccine Guidance and Coordinated Schedules and Programs**

#### Vision

A common vaccine review and guidance process that: is timely, efficient, effective and credible; enjoys the confidence and acceptance of immunization authorities; and facilitates coordinated vaccine schedules and closely-paced introduction of immunization programs at the earliest practical opportunity.

#### **Objectives**

- Support timely, credible and evidence-based decisions on the initiation or updating of immunization programs in support of public health priorities.
- Facilitate consistent and mutually complementary approaches and messages that support
  equitable protection and reinforce public confidence and sense of security, while retaining
  sufficient flexibility in jurisdictional approaches to accommodate the needs of special
  populations, circumstances and public health priorities.
- Minimize the exposure of Canadians to vaccine-preventable diseases, and maximize equity and protection, by avoiding unnecessary gaps and delays in immunization programs for recommended vaccines.

#### Recommendations

4. Jurisdictions develop and employ a robust, inclusive and transparent common vaccine guidance process that ensures timeliness and efficiency, maintains requisite standards of quality, credibility and integrity, and facilitates innovation in vaccine program design and implementation.

#### **Options**

Implementation of Recommendation 4 would be along the lines of one of the following options, reflecting guidance from the Public Health Network.

**OPTION 1: NACI-Plus**—A Public Health Agency of Canada-led process building on the existing National Advisory Committee on Immunization (NACI) with: a clear relationship with, and accountability to, the PHN; greater input from P/Ts on setting priorities and articulating guidance criteria, processes and standards; integration of both technical and socio-economic factors in the guidance process; and enhanced sensitivity towards diverse public health circumstances across Canada.

**OPTION 2: F/P/T PHN Mechanism**—An F/P/T-led "National Immunization Technical Advisory Group" (NITAG) that is accountable to the PHN, and responsible for equally robust and integrated common vaccine guidance that would: operate directly under the auspices of the Public Health Network Council (PHNC); be coordinated by the Communicable and Infectious Disease Steering Committee (CIDSC); and engage F/P/T experts as required.

**OPTION 3: F/P/T Non-PHN Agency**—Establishment or engagement of an F/P/T-accountable agency *outside* of PHN to assume responsibility for the common vaccine guidance process. This could be through a new dedicated vaccine review process/mechanism within the Canadian Agency for Drugs and Technologies in Health (CADTH) that is akin to its Common Drug Review process or, alternatively, some comparable process in a vaccine-focused CADTH-like agency.

NOTE: As with all options throughout this document, PHN guidance might entail some *hybrid* of the options presented and/or variations in details that reflect strategic policy and operational considerations.

Key Features of the Broad Options for Common Vaccine Guidance			
Function	OPTION 1:	OPTION 2:	OPTION 3:
	NACI-Plus	PHN NITAG	F/P/T CADTH or CADTH-
			Like Non-PHN Agency
Initiation	NACI-Plus (NACI with boosted expert participation from P/Ts), following regulatory approval	CIDSC	Governing body of the non- PHN Agency
Membership	Public Health Agency of	CIDSC	Vaccine Review Steering
Selection	Canada (PHAC), with P/T input		Committee of the non-PHN Agency
Technical	PHAC responsibility, with	NITAG with F/P/T	Vaccine Review Working
Assessment	NACI-Plus and others as	accountability and expertise	Group of the non-PHN Agency
	required	(technical and cost-benefit)	
Cost-Benefit and	PHAC responsibility, with	NITAG with F/P/T	Vaccine Review Working
Program Analysis	NACI-Plus and others as	accountability and expertise	Group of the non-PHN Agency
	required	(technical and cost-benefit)	
Guidance	PHAC responsibility, with	NITAG with F/P/T	Vaccine Review Working
Document	NACI-Plus and others as	accountability and expertise	Group of the non-PHN Agency
	required		

Key Features of the Broad Options for Common Vaccine Guidance (cont'd)			
Function	OPTION 1:	OPTION 2:	OPTION 3:
	NACI-Plus	PHN NITAG	F/P/T CADTH or CADTH-
			Like Non-PHN Agency
Guidance	PHAC	CIDSC	Vaccine Steering Committee of
Acceptance			the non-PHN Agency
Program Approval	Individual jurisdictions	Individual jurisdictions	Individual jurisdictions
and Scheduling			
Funding of Core	Federal (per current NACI	F/P/T cost sharing	F/P/T cost sharing with
Process	arrangement within existing		possible cost recovery from
	resource levels)		industry

COMMON VACCINE GUIDANCE			
Common Features	<ul> <li>Tighter and more disciplined timetable for guidance process and issuance of statement following licensure</li> <li>Integration of technical and socio-economic/programmatic analysis processes</li> <li>Minimization of need for additional assessments and statements by jurisdictions</li> <li>Maintenance of high standards of quality and integrity of guidance process and statements</li> <li>Input from all jurisdictions on priority setting and articulation of assessment criteria and statement content requirements</li> <li>Early consideration of guidance on related evaluation, research, surveillance, messaging (including vaccine hesitancy), security of supply and risk management issues</li> </ul>		
ASSESSMENT	1. NACI-Plus	2. PHN NITAG	3. CADTH or CADTH-Like
Pros	<ul> <li>Builds on expertise, institutional framework and reputation of NACI</li> <li>Minimal disruption/ maximum continuity in shift to broader mandate</li> </ul>	<ul> <li>Direct F/P/T oversight and accountability</li> <li>Balanced cost sharing</li> <li>Integration with PHN mandate and priorities</li> </ul>	<ul> <li>Builds on an existing F/P/T mechanism for common drug review that enjoys high credibility and a disciplined track record, with new dedicated expertise and resources to meet unique needs of vaccine guidance</li> <li>Well-established F/P/T cost-sharing arrangements</li> <li>Efficiencies/economies of scale</li> </ul>
Cons	<ul> <li>Federally run (although with enhanced P/T input, including possible PHN program decisions)</li> <li>Dependent on federal funding within existing resource levels</li> </ul>	<ul> <li>Complicated and cumbersome relationships</li> <li>Risk of loss of NACI expertise, visibility and "branding," and process continuity</li> </ul>	<ul> <li>Requires transfer/building of new competencies and processes (including "public health sensibilities")</li> <li>Risk of loss of NACI expertise, "branding" and continuity</li> </ul>

#### Recommendations

5. Jurisdictions commit—to the maximum extent practical—to the coordinated introduction of both new and updated vaccine schedules and programs, so as to: optimize timely implementation of vaccine programs that meet public health needs; enable early consideration of plans and guidance for program evaluation, research, surveillance, messaging, risk mitigation, and security of supply measures; and maintain flexibility for occasional strategic testing and assessment of alternative programs and schedules in different jurisdictions to support innovation and sharing of best practices.

## **Options**

Implementation of Recommendation 5 would be along the lines of one of the following options, reflecting guidance from the Public Health Network.

**OPTION 1: Advance Commitment in Principle**—Advance commitments in principle to implement vaccine programs that meet mutually agreed threshold criteria (e.g., some measure of disease burdens that are avoided or reduced by the immunization, per unit cost), so as to provide reasonably solid indication of the likelihood that a program would eventually be approved and funded within a predetermined timeframe. Vaccines not meeting the threshold criteria would still be considered by individual jurisdictions, so as to maximize opportunities for coordination of schedules among those jurisdictions that choose to implement the vaccine.

**OPTION 2: Early Signals of Interest**—A basic commitment on the part of all F/P/T jurisdictions to undertake early testing of the waters with their respective decision makers on their prospective interest in implementing programs for vaccines under review, within a prescribed timeframe.

COORDINATED PROGRAMS AND SCHEDULES			
Common	"Best efforts" commitment of each jurisdiction to seek and obtain early signals, if not final		
Features	decisions, on intentions/commitments to adopt coordinated schedules and to implement		
	their programs within a reasonably short predetermined timeframe		
	Commitment to early planning and coordination of approaches to evaluation, research,		
	surveillance, messaging (including vaccine hesitancy) and risk management issues		
	Flexibility to test alternative approaches and share best practices		
ASSESSMENT	1. Advance Commitment in Principle	2. Early Signals of Interest	
Pros	Strongest possible signal of likelihood of	Most pragmatic and reliable means to get	
	coordinated schedules	early signals of likely approval	
Cons	Difficult to secure and not fully reliable, as	No indication, let alone guarantee, that	
	ultimate decisions might vary widely from	ultimate decisions would be favourable	
	early commitments	artificate decisions would be lavourable	
	early commitments		

## **Program Evaluation and Research**

#### Vision

A robust, accessible, credible, responsive and adequately funded mechanism/arrangement that supports timely and relevant immunization program evaluation and research whose findings are actively and meaningfully integrated into immunization program planning, guidance, implementation and improvement processes.

#### **Objectives**

- Provide timely, relevant and objective evidence to support the needs of diverse government, industry, academic, NGO and public stakeholders in all critical facets of immunization program design, delivery and continual improvement.
- Identify evolving needs and opportunities related to immunization and how it is targeted and delivered.
- Support credible and effective public and professional education and engagement efforts in support of immunization objectives.
- Support evidence-based decision making to encourage and support greater investments in immunization programming.

#### Recommendations

6. F/P/T jurisdictions strengthen program evaluation and research in their respective administrations and enhance linkages and collaboration with other F/P/T jurisdictions, supported by: dedicated, adequate and stable funding (with earmarked dedicated funds in an overall envelope for evaluation and research in the amount of 1%–3% of the aggregate value of vaccine procurement costs); formal integration into planning and decision-making processes; and active consideration and use in surveillance, public and professional education and engagement, vaccine guidance, risk management, and vaccine hesitancy strategies and initiatives.

#### **Options**

Implementation of Recommendation 6 would be along the lines of one of the following options, reflecting guidance from the Public Health Network.

**OPTION 1: Third Party Collaborative Mechanism**—An organization along the lines of the PHAC/CIHR Influenza Research Network (PCIRN) (but with a broad mandate spanning immunization and vaccine-preventable diseases) that: is capable of receiving funds from governments and industry to undertake priority program evaluation and research; and has a governance mechanism that ensures accountability and responsiveness to the needs and priorities of F/P/T jurisdictions.

**OPTION 2: Decentralized Network**—All F/P/T jurisdictions establish their own dedicated resource envelopes to undertake program evaluation and research, with enhanced pooling and collaboration with other jurisdictions wherever efficiencies and economies of scale can be leveraged.

PROGRAM EVALUATION AND RESEARCH		
Common Features	<ul> <li>Greater and more stable investment in program evaluation and research, with an earmarked dedicated evaluation and research funding envelope in each jurisdiction (e.g., 1%–3% of aggregate vaccine procurement costs), sufficiently flexible to address priorities across the spectrum of immunization issues, including pooling of data across multiple jurisdictions, sharing of resources and expertise, and collaboration across multiple F/P/Ts, with industry and academic partners</li> <li>Enhanced profile, higher quality and more active and meaningful use of program evaluation and research</li> <li>Increased emphasis on collaboration and industry funding</li> </ul>	
ASSESSMENT	1. Third Party Collaborative Mechanism	2. Decentralized Network
Pros	<ul> <li>Maximum leveraging and optimal use of available expertise and resources</li> <li>More comprehensive, hence more useful, data because of larger populations under study and the potential for comparing different programs</li> <li>Regularized mechanism to initiate and support program evaluation</li> </ul>	Maximum flexibility and autonomy, while retaining ability to collaborate on an ad hoc basis
Cons	Real or perceived "loss" of independence and flexibility (although jurisdictions could safe-haven certain portions of their available resources to fund their own unique projects)	<ul> <li>Diminished ability to leverage outside funds (industry) and undertake larger scale and longer term initiatives</li> <li>Requires establishment of ad hoc F/P/T mechanisms for each new project or initiative; inefficient and duplicative</li> </ul>

#### Surveillance

#### Vision

Cohesive and well-coordinated registry and surveillance systems providing relevant, accurate, timely and compatible data on immunization programming and coverage, vaccine-preventable disease outbreaks, adverse events following immunization, and risk factors to support evidence-based decision making.

#### **Objectives**

- Provide more timely, reliable and well-coordinated information on immunization coverage to: plan and target immunization efforts; avoid unnecessary duplication of vaccinations; provide evidence of protection to reinforce public confidence; support performance monitoring of vaccination programs; and facilitate planning/forecasting of vaccine needs and related procurement, supply and inventory management.
- Provide more timely, reliable and well-coordinated information on vaccine-preventable disease outbreaks, risk factors, and disease susceptibility of diverse groups, to support: evidence-based policy and program decision making; evaluation and sharing of best practices; public and professional education and messaging; and setting of priorities for collaboration.
- Provide more timely, reliable and well-coordinated information on adverse events following immunization and on safety concerns, to trigger and guide timely and effective response.
- Support compliance with international obligations on disease reporting.

#### Recommendations

- 7. F/P/T jurisdictions reaffirm their commitment to the development of comprehensive immunization registries and to the strengthening of pan-Canadian networks and linkages to ensure ready availability of critical coverage information for health service planners, providers, researchers and evaluators.
- 8. F/P/T jurisdictions reaffirm their commitment to completing and implementing the Multilateral Information Sharing Agreement (MLISA), or equivalent data-sharing arrangements.
- 9. F/P/T jurisdictions strengthen routine, enhanced and sentinel surveillance systems and capacities to ensure ready availability of critical information on: vaccine-preventable disease outbreaks; risk factors, attitudes and practices; disease susceptibility of diverse groups; adverse events following immunization; and other vaccine safety triggers, to meet current and future immunization program planning, evaluation, research and risk management needs.

## **Options**

Implementation of Recommendation 9 would be along the lines of one of the following options, reflecting guidance from the Public Health Network.

**OPTION 1: F/P/T Coordinated Enhanced Surveillance Under New Joint Funding Arrangements**—The oversight and coordination of the process would be through a PHN mechanism to ensure F/P/T jurisdictions commit to jointly investing in strengthened surveillance, including enhanced and/or sentinel methods where appropriate. The oversight of this process would be undertaken and coordinated by PHN, to ensure F/P/T input to planning and priority setting and mutually agreeable investment of joint resources. With formal and more substantial F/P/T commitments and investments, this option would provide scope for establishment of comprehensive sentinel surveillance networks.

**OPTION 2: F/P/T Coordinated Enhanced Surveillance Within Existing Funding Arrangements**—F/P/T jurisdictions support enhanced surveillance systems and networks, coordinated through a mechanism to facilitate F/P/T planning and priority setting. However, in absence of a formal partnership arrangement, funding would likely need to rely largely on existing arrangements, with the federal government remaining the major leader and investor. With less formal and substantial P/T participation, the scope for enhanced surveillance, especially more comprehensive sentinel networks, would be limited.

	SURVEILLANCE		
Common	Completion and ongoing operation of registries and data-sharing agreements		
Features	Strengthening of surveillance systems, capacities and active use for the full range of immunization programming needs		
ASSESSMENT	1. F/P/T Coordinated Enhanced	2. F/P/T Coordinated Enhanced	
	Surveillance Under New Joint	Surveillance Within Existing Funding	
	Funding Arrangements	Arrangements	
Pros	<ul> <li>Scope for more substantial enhancement of surveillance, including sentinel networks</li> <li>More effective and mutually agreeable F/P/T partnerships in design and implementation of surveillance systems</li> </ul>	Orderly continuation of ongoing and new improvements while avoiding distraction and disruption of new collaborative and funding arrangements	
Cons	Requires new P/T commitments and investments	Limited leveraging of P/T commitments and investments, resulting in reduced scope for surveillance enhancements	

## **Outbreak and Adverse Event Response**

#### Vision

Well-planned, clearly articulated and pre-tested plans, protocols and capacities to provide timely, effective and well-coordinated determination, investigation, mitigation and containment of outbreaks of vaccine-preventable diseases, and response to adverse events following immunization and safety concerns.

#### **Objectives**

- More effectively prevent and minimize threats to health and associated costs and burdens from vaccine-preventable disease outbreaks and adverse events following immunization.
- Maintain high public confidence in the safety and effectiveness of vaccines.
- Support the orderly and cost-effective response of authorities to outbreaks and adverse events following immunization.
- Enhance understanding of the nature and risks of outbreaks and adverse events following immunization, and how they can be prevented and managed effectively.

#### Recommendations

10. F/P/T jurisdictions establish and strengthen pan-Canadian coordinated response capacity, with well-established protocols, along the lines of the Foodborne Illness Outbreak Response Protocol (FIORP), for timely and effective detection, investigation and response to outbreaks of vaccine-preventable diseases and adverse events following immunization.

## **Public and Professional Education and Engagement**

#### Vision

Timely, credible, consistent and effective public and professional information, messages, education and outreach to support achievement of immunization coverage goals and the responsible, efficient and effective delivery of vaccinations.

#### **Objectives**

- Achieve vaccination coverage goals in a more timely and cost-effective manner.
- Promote high public confidence in the relevance, effectiveness and safety of vaccines.
- Promote competent, efficient and safe delivery of immunization programs and administration of vaccines.
- Reduce vaccine hesitancy and address challenges from anti-vaccine movements.
- Respond to information needs and concerns of the public and professionals regarding vaccines and immunization programs.

#### Recommendations

- 11. F/P/T jurisdictions strengthen collaboration on public and professional education and engagement focused on more coordinated implementation of new vaccine programs and related information and outreach strategies, facilitated by a common clearinghouse for exchange of information resources, tools and best practices, and by other collaborative mechanisms.
- 12. F/P/T jurisdictions support the development of a coordinated pan-Canadian strategy to address "vaccine hesitancy" (i.e., addressing the complex array of "human/social" issues and factors such as knowledge, attitudes, behaviours, fears and concerns, as well as "institutional" issues and factors, such as the convenience, accessibility and cost of immunization that contribute to reluctance on the part of the public to participate in immunization programs, in particular for—but not limited to—seasonal influenza).

## **Security of Vaccine Supply**

#### Vision

Systems and mechanisms for vaccine supply, acquisition, deployment and management that ensure that F/P/Ts enjoy reasonably timely, responsive, reliable, cost-effective, affordable and equitable access to vaccines and vaccine technologies that meet public health needs and circumstances of their diverse populations.

#### **Objectives**

- Encourage and facilitate vaccine industry responsiveness to evolving public health needs and priorities.
- Support prudent and optimal acquisition of vaccines so as to achieve best value for money, avoid unnecessary inventories, facilitate equitable access, and maintain adequate supply.
- Support reasonable prevention and mitigation of supply shortages and disruptions, and timely and
  effective response to unanticipated and unavoidable shortages and disruptions, however caused.
- Support responsible and effective quality assurance throughout the vaccine life cycle.

#### Recommendations

13. F/P/T jurisdictions strengthen risk-based measures for security of supply, by continuing to enhance the vaccine Bulk Procurement Program, and by establishing new F/P/T protocols and supply risk management plans (both general and, in the case of priority vaccines of concern, vaccine-specific contingency plans) aimed at preventing and mitigating supply risks, and ensuring timely and well-coordinated responses in the event of shortages or recalls.

## **Vaccine Innovation and Development**

#### Vision

A highly focused and proactive domestic vaccine industry and research community (public, academic and private) that anticipates and responds to evolving public health needs and priorities for new and enhanced vaccines and vaccine technologies.

#### **Objectives**

- Support pan-Canadian vaccine-preventable disease strategies through the timely development of vaccines and vaccine technologies that respond to public health needs and priorities.
- Enhance opportunities for Canadian-based and Canadian-focused R&D and commercialization in support of industrial, economic and security of supply objectives.
- Advance Canada's international cooperation and collaboration objectives and commitments.

#### Recommendations

14. The Public Health Agency of Canada—in consultation and collaboration with the National Research Council, the Canadian Institutes for Health Research, Industry Canada and other interested parties in F/P/T governments, industry and academia—lead and coordinate the exploration and development of mechanisms to identify, encourage and facilitate the development of vaccines to meet evolving public health needs and priorities, in partnership with governments, industry and academia.

## **No-Fault Vaccine Injury Compensation**

#### Vision

Canadians enjoy access to expeditious, efficient, predictable and fair compensation for those unavoidable and unintended vaccine injuries for which civil litigation is either not applicable or not practical.

#### **Objectives**

- Provide a convenient, predictable and fair no-fault process for injury compensation for those cases where civil litigation is either not applicable or not practical.
- Focus compensation on meeting the needs of the innocent injured rather than punishing the innocent agents of harm.
- Provide for greater predictability, efficiency, consistency and timeliness in setting eligibility criteria, review and appeal provisions, and compensation terms.
- Significantly reduce unnecessary and counter-productive legal burdens on vaccine manufacturers, enabling them to devote their resources to vaccine innovation and the enhancement of efficiency and safety of vaccine production.
- Provide a stimulus and focus for effective and responsible surveillance of and response to adverse events following immunization.

#### Recommendations

15. Jurisdictions establish no-fault injury compensation programs, and collaborate in the sharing of best practices so as to maximize consistency, complementarity and efficiency in their respective program approaches.

#### **Options**

Implementation of Recommendation 15 would be along the lines of one of the following options, reflecting guidance from the Public Health Network.

**OPTION 1: Common Basic Administrative Support**—Create a central mechanism, funded on a cost-recovery basis, to: provide basic common-service administrative support (e.g., program information, receipt and initial screening/processing of applications, etc.) for jurisdictions with no-fault compensation programs that wish to opt in; and facilitate sharing of best practices and adoption of consistent approaches and terms/conditions. Jurisdictions that choose to opt in would remain responsible for design and funding of their programs, including accountability to their respective service populations.

**OPTION 2: Central Program**—Jurisdictions would establish a mutually agreeable mechanism to jointly deliver and manage a common no-fault injury compensation program for all jurisdictions that choose to opt in. Participating jurisdictions would agree to a funding formula that covers both program benefit costs and associated administrative overhead costs of the central program mechanism.

	NO-FAULT INJURY COMPENSATION		
Common Features	<ul> <li>Cost sharing on an equitable pro rata basis</li> <li>Flexibility for jurisdictions to "opt in" with no-fault compensation programs for their respective constituencies</li> <li>Collaboration and cooperation on their program criteria and approaches, to optimize consistency and share best practices</li> </ul>		
ASSESSMENT	1. Common Basic Administrative	2. Central Program	
	Support		
Pros	Low-cost/low-risk means to provide economies of scale and avoid need for jurisdictions to invest unnecessarily in redundant administrative processes	<ul> <li>Convenient mechanism for jurisdictions to opt in if/when they choose</li> <li>Maximum opportunities for efficiencies, economies of scale and consistency of policies and practices, while still retaining independence, flexibility and cost sharing</li> </ul>	
Cons	<ul> <li>Requires investment in some form of new common administrative infrastructure and negotiation of cost-sharing arrangements</li> <li>May raise false expectations that all jurisdictions will have a program and/or that it will lead to a centralized national program</li> </ul>	Real or perceived diminishment of jurisdictional flexibility to establish their own policies and procedures	

## **ANNEX: National Immunization Strategy Task Group**

#### **NIS-TG MEMBERS**

#### Dr. John Spika, MD

(Federal Co-Chair)
Director General, Centre for Immunization and Infectious Respiratory Diseases
Public Health Agency of Canada

#### Dr. Martin Lavoie, MD, FRCPC

(Provincial/Territorial Co-Chair)
Deputy Chief Medical Officer of Health
Alberta Health

## Dr. Natasha Crowcroft, MA, MSc, MD, MRCP, FFPH

Chief, Communicable and Infectious Diseases, Public Health Ontario

Associate Professor, Laboratory Medicine and Pathobiology and Dalla Lana School of Public Health, University of Toronto

#### Dr. Philippe De Wals, MD, PhD

Department of Social and Preventive Medicine, Université Laval, et Direction des risques biologiques et de la santé au travail, Institut national de santé publique du Québec

#### Martine Dubuc, RN, BScN

A/National Immunization Program Coordinator First Nations and Inuit Health Branch Health Canada

#### Anita Hanrahan, RN, MN

Director, Communicable Disease Control Alberta Health Services

#### Dr. Monique Landry, MD

Médecin conseil

Direction de la santé publique, Ministère de la Santé et des Services sociaux du Québec

#### Dr. Monika Naus, MD, FRCPC, FACPM

Director, Immunization Programs, and Associate Director Epidemiology Services British Columbia Centre for Disease Control

#### Danielle Poulin, MSc

Director, Immunization Division Centre for Immunization and Infectious Respiratory Diseases Public Health Agency of Canada

#### Dr. Barbara Raymond, MD

Director, Pandemic Preparedness Division Centre for Immunization and Respiratory Infectious Diseases Public Health Agency of Canada

#### Dr. David Williams, MD, MHSc, FRCPC

Medical Officer of Health Thunder Bay District Health

#### Dr. Kumanan Wilson, MD, FRCPC, MSc

Canada Research Chair in Public Health Policy, and Senior Scientist, Clinical Epidemiology, Ottawa Hospital Research Institute, and Associate Professor of Medicine, University of Ottawa

#### Dr. Paul Van Buynder, MBBS, MPH, FAFPHM

VP Public Health and Chief Medical Health Officer

Fraser Health Authority, British Columbia

#### Lianne Vardy, MA

Associate Director General, Centre for Immunization and Infectious Respiratory Diseases

Public Health Agency of Canada

#### **NIS-TG SECRETARIAT**

#### Dominique Baker, BA Cand.

A/Project Officer
Centre for Immunization and Respiratory
Infectious Diseases
Public Health Agency of Canada

#### Jane Coghlan, BA, MA Cand.

Research and Editorial Consultant

#### Paula DeBeck, BA

Strategic Policy Advisor to Public Health Network Liaison Deputy Minister (New Brunswick Health and Inclusive Communities)

#### Jessica Ellison, MPP

Office of the Chief Medical Officer of Health Alberta Health

#### Dan Markel, MA

A/Senior Policy Analyst Centre for Immunization and Respiratory Infectious Diseases Public Health Agency of Canada

#### J. Phillip Nicholson, MA, MCP

President, Nicholson Policy and Management Consultants Inc. Policy Advisor to Public Health Agency of Canada

#### Agathe Richard-Dallaire, MSc

Policy Manager Centre for Immunization and Respiratory Infectious Diseases Public Health Agency of Canada

#### Dan Wong, MA

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