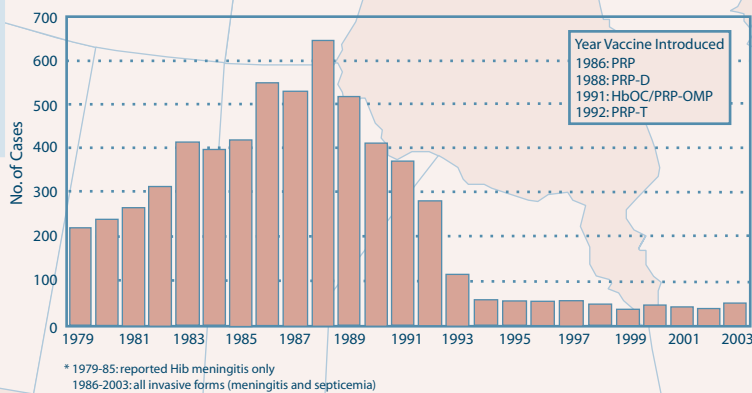


Haemophilus influenzae type b (Hib) Disease –
Reported Cases, Canada, 1979-2003*



National Immunization Strategy

FINAL REPORT 2003

A Report
from the F/P/T Advisory Committee on
Population Health and Health Security (ACPHHS)
to the
Conference of F/P/T Deputy Ministers of Health

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Cat. No. H39-4/15-2003
ISBN 0-662-68164-9

(on line)
Cat. No. H39-4/15-2003E-PDF
ISBN 0-662-37114-3

H39-4/15-2003E-HTML
0-662-37115-1

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Preamble

Over the past several years, the Advisory Committee on Population Health and Health Security (ACPHHS) has supported development of a national approach to addressing immunization issues in Canada. During this period, numerous meetings and consultations with federal, provincial, and territorial (F/P/T) public health representatives and other relevant stakeholders were undertaken to identify and develop collaborative approaches to strengthening immunization in Canada.

The value of this collaborative work was reflected in the February 2003 First Ministers' Accord on Health Care Renewal, which included direction to Health Ministers to continue their pursuit of a national immunization strategy. The 2003 Federal Budget provided \$45 million over five years to assist in the continued pursuit of a national immunization strategy, as directed by First Ministers. Specifically, Health Canada is to receive \$5 million in 2003-04 and \$10 million in 2004-05 and ongoing. This funding will enable strengthened collaboration with the provinces, territories and key stakeholders to improve the effectiveness and efficiency of immunization programs in Canada, but will not be used for vaccine procurement.

The "Final Report: National Immunization Strategy," describes the key components and supporting activities associated with a national immunization strategy in Canada. In June 2003, the Conference of

F/P/T Deputy Ministers of Health accepted this document as advice in moving forward with immunization issues in Canada. It was recognized, however, that not all jurisdictions would have the necessary funding available to implement the approach outlined in this document, particularly as it relates to the collaborative purchase of new vaccines.

To continue working towards a national immunization strategy, Health Canada will facilitate ongoing discussions with the provinces, territories and key stakeholders. As part of this process, immunization programming activities at Health Canada will be expanded or developed, such as enhancing surveillance of vaccine-associated adverse events and vaccine-preventable diseases, coordinating common approaches to immunization registries, enhancing F/P/T vaccine procurement processes, strengthening immunization research activities, developing approaches to special populations, and public and professional education.

Continued discussion with federal, provincial and territorial public health representatives to address current and future immunization issues will contribute to pursuing a national immunization strategy. Provinces and territories will continue to be responsible for planning, funding, and delivering immunization programs to their respective populations and to contribute to the shared activities that support a national immunization strategy.

Executive Summary

The development of a national immunization strategy (NIS) was first endorsed by the F/P/T Deputy Ministers of Health (CDMH) in June 1999. In June 2001, the CDMH approved the development of an NIS, with the following five components:

- National Goals and Objectives
- Immunization Program Planning
- Vaccine Safety
- Vaccine Procurement
- Immunization Registry Network

The purpose of this paper is to present a final report on a comprehensive strategy to address immunization issues in Canada.

The development of this strategy has been conducted through the Federal Provincial/Territorial (F/P/T) Advisory Committee on Population Health and Health Security (ACPHHS). In developing the strategy, input was received from various officials, experts, and stakeholders across Canada, including provincial and territorial jurisdictions, Health Canada, the Council of Chief Medical Officers of Health (CCMOH), the Canadian Institutes of Health Research (CIHR), the Canadian Paediatric Society (CPS), the Canadian Immunization Awareness Program (CIAP), vaccine manufacturers, and others.

The strategy has been designed to address a number of challenges to immunization, which are currently being faced by all jurisdictions in Canada. For instance, expensive new vaccines will be coming onto the Canadian market in both the immediate and long-term horizon, and decisions will be required regarding their use in publicly-funded vaccine programs. In addition, provincial/territorial (P/T) vaccine expenditures have been increasing substantially in recent years (due to both the introduction of new vaccines and escalating prices of existing vaccines) and concerns have been raised regarding security of supply, particularly given the supply shortages recently experienced in the United States. Public attitudes about immunization, which

can include complacency, concerns regarding vaccine safety, and fear of outbreaks, are also important considerations.

These issues and challenges reinforce the need for national collaboration. A national strategy is a means for F/P/T jurisdictions to work in partnership to improve the effectiveness and efficiency of immunization programs in Canada. The benefits of strengthening collaboration are anticipated to include the following:

- Reduction in vaccine-preventable diseases
- Improved access to timely immunization programs
- Improved efficiencies of immunization programs
- Better vaccine safety monitoring and response
- Enhanced affordability of vaccines
- Improved security of vaccine supply
- Public confidence in vaccines/response to growing anti-immunization concerns

The specific objectives and activities to be addressed by each component of the strategy are listed below:

National goals and objectives – to reduce vaccine preventable diseases and improve vaccine coverage rates by developing national goals and objectives for immunization programs, leading to recommendations for endorsement by all F/P/T governments, where appropriate.

Immunization program planning – to reduce duplication of effort, improve access to vaccines, and facilitate policy analysis of new vaccines, through national collaboration on the assessment and prioritization of new vaccines using common criteria.

Vaccine safety – to improve vaccine safety monitoring and public health response, by setting up a network of F/P/T vaccine safety contacts in all jurisdictions, establishing a clinical assessment/referral system, and addressing potential vaccine safety issues (e.g., through improved data analysis, feedback/risk communication, and development of national guidelines).

Vaccine procurement – to achieve best value for vaccines, long-term security of supply, quality of supply, and improved accountability, by making enhancements to the existing F/P/T procurement process, such as use of multi-year contracts, inclusion of value-added products/services as part of procurement process, collaboration with the vaccine regulator to ensure timely communication, and improvements in the administrative processes.

Immunization registry network – to improve national surveillance and the transfer of (and access to) individual immunization records, by establishing and maintaining a comprehensive, compatible national immunization registry network, with a core data set and minimum standards.

In addition, there are a number of activities which cut across, and support, the five components of the strategy. These are: immunization research, public and professional education, approaches to special populations and vaccine preventable disease surveillance.

A. Introduction

Immunization programs have had a major impact on the health status of the population, as many diseases are prevented through immunization. Since the introduction of mass immunization efforts, infectious diseases which used to be common, are now rare. For instance, smallpox was globally eradicated in 1977 and paralytic poliomyelitis was eliminated from the western hemisphere in 1994, as a result of immunization¹. Such immunization programs resulted in substantial savings to the health system and improvements in length and quality of life. Newer immunization programs, where cost *savings* can be more difficult to demonstrate, still remain among the most cost *effective* (cost per life saved and/or serious disability prevented) interventions available², and the net benefit to society in terms of wellness and disease prevention is substantial.

In Canada, immunization is a shared responsibility between federal, provincial and territorial governments. Nevertheless, national collaboration on immunization issues could be improved in the current system. The large majority of costs are borne by the provinces and territories, as each province and territory plans, funds, and delivers their respective immunization programs to their populations. In planning their immunization programs, provinces and territories adjust their recommended schedules and selection of vaccines based on the National Advisory Committee on Immunization (NACI) or other expert advisory committee recommendations, as well as on local epidemiological, program, and financial considerations³.

Unlike Canada, other countries (United States⁴, Australia⁵ and the United Kingdom⁶) have structures with central mechanisms for immunization planning and funding which contribute significantly to the quality of the overall immunization program, including the procurement process.

Canada would benefit from a national mechanism to move from discussion and recommendations to national collaboration and coordinated provincial/territorial policy decisions within a comprehensive

national plan. Such a mechanism would support the following:

- Equitable access to recommended vaccines
- More efficient use of public health human and other resources
- Timely introduction of new immunization programs across Canada
- Commitment to international health initiatives
- Intersectoral collaboration on immunization issues

The proposed goals of a national immunization strategy (NIS) are to

- i) Provide high, achievable and measurable coverage of publicly funded immunization programs for all Canadians.
- ii) Provide complete coverage of all children with routine childhood vaccines recommended by the proposed national immunization committee.
- iii) Ensure equitable access to these routinely recommended vaccines – among jurisdictions and in special populations – while considering jurisdictional program implementation differences.
- iv) Promote public and professional acceptance of recommended programs.
- v) Provide optimal program safety, effectiveness and acceptance.
- vi) Improve coordination and efficiency.
- vii) Provide optimal cost-effectiveness and affordability of programs.
- viii) Ensure security of vaccine supplies.
- ix) Provide national intervention when required.

This strategy has been designed so that all five components and related support activities are interconnected and work together to achieve these goals

B. Description of Each Strategy Component

A summary of each component of the NIS is provided below. For each NIS component, objectives of that component will be outlined, followed by a description of the existing system as it relates to that component, a summary of the gaps and limitations of the existing system, and an overview of the proposed approach.

B.1 National Goals and Objectives

a) Objectives

The purpose of having national goals and objectives for immunization programs would be to support the following:

- Reductions in vaccine-preventable diseases
- Improved vaccine coverage rates
- Objective measurement of progress/program evaluation

b) Existing System

In the current system, national goals and objectives for immunization have been developed by Health Canada-sponsored “consensus conferences”, with broad stakeholder participation, including representation from each province and territory. National goals and objectives have been developed for many vaccine preventable diseases, including poliomyelitis, measles, mumps, rubella and congenital rubella syndrome, tetanus, diphtheria, pertussis, invasive *Haemophilus influenzae* type b (Hib) infections, and hepatitis B. These goals involve either achieving or maintaining the elimination of disease (e.g., polio), or reducing morbidity and mortality (e.g., pertussis), as well as identifying proper handling of vaccines and good delivery programs⁷. At this time, the national goal to eliminate measles by the year 2005 is the only national goal which has been endorsed by the Conference of F/P/T Deputy Ministers of Health.

c) Gaps/Limitations of Existing System

Without the official F/P/T endorsement of national goals and objectives, their full integration into immunization program planning and delivery efforts, and associated effects on vaccine coverage and disease rates, may not be maximized.

Furthermore, Canada’s ability to commit and contribute to international health initiatives could be improved if we had a mechanism to effectively endorse recommended national goals and objectives. As an example, in 1990, Canada, along with 70 other countries, participated in the World Summit for Children at the United Nations, and was a signatory to a declaration establishing a number of child health goals with respect to disease reduction or elimination and immunization coverage. 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 term⁸. As described in the 1996 Canadian National Report on Immunization³, “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 federal, provincial, and territorial (F/P/T) Deputy Ministers of Health (CDMH) 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 1994⁹ to 7 cases in 2002 (Dr. P. Varughese, Centre for Infectious Disease Prevention and Control, Ottawa: personal communication, 2003). Despite this success, measles elimination is the only national goal which has been officially endorsed.

d) Proposed Approach

The long-term vision of this component of the NIS is to develop national goals and objectives for immunization, and the recommendation of these national goals and objectives for endorsement by all F/P/T governments, where appropriate.

B.2 Immunization Program Planning

a) Objectives

Immunization program planning is a key component of the proposed National Immunization Strategy. The goal of this NIS component is to support collaborative, national assessment and prioritization of new vaccines, using common criteria.

b) Existing System

Currently, immunization programs are planned and delivered primarily at the provincial/territorial level, so decisions are independently taken by 13 individual jurisdictions. In planning an immunization program, most jurisdictions have advisory bodies that adapt NACI recommendations on the use of specific vaccines to local situations, based on epidemiological, program, and financial considerations¹⁰. In planning their immunization programs, provinces and territories may also consider the advice and input from various national groups, such as the Council of Chief Medical Officers of Health, the Canadian Nursing Coalition on immunization, the Canadian Paediatric Society, and the Canadian Public Health Association.

c) Gaps/Limitations of Existing System

Within the current system, expert recommendations on immunization are made, but there is no coordinated, national mechanism for assessing and prioritizing new vaccines, from a policy perspective. It is therefore difficult to move from discussion and scientific recommendations on immunization program planning, to national collaboration and coordinated provincial/territorial policy decisions within a comprehensive national plan. This can lead to the following issues:

- Differences in vaccine programs across jurisdictions

Most jurisdictions have a recommended schedule of routine childhood immunization programs similar to that recommended by NACI, for the older vaccines¹⁰. However, there are some notable differences in other, special immunization programs.

For instance, publicly-funded influenza and pneumococcal immunization programs have varied by jurisdiction in terms of the risk groups covered. Differential schedules, such as the hepatitis B immunization programs in Canada, which target school-aged children of different ages/grades, can have an impact when an individual moves from one jurisdiction to another.

Furthermore, we are in a time of rapid technological advances, which have the potential to further diversify vaccine programs across the country. Certain new vaccines (e.g., varicella, pneumococcal conjugate, acellular pertussis vaccine for adolescents and adults, meningococcal conjugate vaccines) are available on the Canadian market, but have yet to be added to the publicly-funded immunization programs of many provinces or territories, as they consider both the implications and cost of doing so. During the next few years, there will continue to be many new vaccines, new combinations of vaccines, and improved formulations of old vaccines (see text box below). These new products will share the ability to prevent or ameliorate serious diseases but at increased cost.

New Vaccines on the Horizon

Mid-Term (3-6 years): nasal influenza vaccine, rotavirus vaccine, other meningococcal vaccines, Group A streptococcus, Group B streptococcus, respiratory syncytial virus (RSV) for the elderly, human papillomavirus (HPV).

Long-Term (7-10 years): RSV for infants, parainfluenza virus (PIV), non-typeable *Haemophilus influenzae* and other otitis media pathogens, herpes simplex virus (HSV), hepatitis C virus, human immunodeficiency virus (HIV).

■ Use of public health human and other resources

Each jurisdiction conducts its own reviews of vaccine recommendations and policy analyses before making recommendations on new and existing immunization programs. Furthermore, jurisdictions spend considerable time and resources (e.g., materials, communications) in activities related to the other components of the NIS, such as vaccine procurement and safety. Efficiencies could be realized through national collaboration on these issues.

■ Timing of introduction of vaccine programs across jurisdictions

The introduction of new vaccine programs occurs in some jurisdictions in advance of others. The two-dose measles immunization program is one such example. Although the incidence of measles declined substantially after introduction of a one-dose measles program in the mid-late 1960s (reducing the annual number of reported cases from an estimated 300,000 cases per year before immunization to less than 2000 per year in 1995¹¹), outbreaks persisted, mostly in school-aged children, even in populations with virtually 100% documented one-dose coverage¹¹. It became increasingly clear, both from Canadian and international evidence, that a routine one-dose program would not achieve the goal of measles elimination⁹. Recommendations for a routine second dose of measles vaccine were made at Canadian consensus conferences, the Pan American Health Organization, and NACI between 1992 and 1995. Introduction of a routine two-dose program occurred in all provinces/territories between 1996 to mid-1997, and various catch-up programs were completed in eight provinces and territories.

As another example, all provinces and territories in Canada currently have a universal childhood hepatitis B immunization program in place. The grade levels which are targeted for immunization vary by jurisdiction, with the most common being Grade 4¹². The school vaccination programs in Canada have been very successful, reaching over 90% of eligible children¹³. These programs were

introduced over a number of years across the country, resulting in some delays in access to this vaccine program.

■ Intersectoral collaboration on immunization issues could be improved

Vaccine-preventable diseases and immunization programs can have major impacts on areas other than health, such as education, labour and productivity, and early childhood development. The impact of influenza on workplace productivity¹⁴ and school attendance¹⁵ are two cases in point. Influenza immunization has been shown to lead to significant reductions in the frequency of absenteeism from work due to respiratory illness, as well as to reductions in school absenteeism. Efforts to collaborate with other departments and agencies in the area of immunization could be enhanced with a national strategy.

d) Proposed Approach

To address the gaps and limitations described above, it is proposed that an analytical framework/common criteria be used for the assessment and prioritization of new vaccines by all F/P/T governments. Such a tool would ensure that important, agreed-upon factors and criteria are considered in the decision-making process.

A draft analytical framework/tool was developed by Erickson, De Wals and Farand (unpublished document) for information and consideration by F/P/T jurisdictions. The criteria for decision making, adapted from this framework, are classified into the following broad categories:

- Disease characteristics and burden
- Vaccine characteristics
- Alternative immunization strategies and programs
- Social and economic costs and benefits of alternate programs
- Feasibility and acceptability of alternative programs
- Ability to evaluate programs
- Research questions
- Other considerations

The draft framework is meant to be practical and to facilitate rather than replace existing decision-making processes, allowing for more efficient long-term planning and information sharing between F/P/T stakeholders in the area of immunization. National participation will be required to develop further and to refine this draft framework and to move from theory to practice; however, it represents a potentially valuable tool to assist with immunization program planning. The long-term vision of this component of the NIS is to develop an approach that would involve all F/P/T jurisdictions in collaborative decision making on all new vaccines, using common criteria.

B.3 Vaccine Safety

a) Objectives

Vaccine safety is an integral component of a national immunization strategy. Objectives of this component are to optimize the vaccine safety system, maintain professional and public confidence in the safety of vaccines, and address growing anti-immunization concerns by improving the following:

- The vaccine safety monitoring system (i.e., the passive surveillance system, the active surveillance system, and the ability to flag potential threats to safety).
- The public health response (i.e., the review and follow-up of potential vaccine-associated adverse events and the ability to mobilize capacity to respond to urgent situations).

b) Existing System

The current vaccine safety system in Canada can be described as follows:

(i) Vaccine Safety Monitoring

- *Passive Surveillance System:* All professionals involved in the administration of vaccines are encouraged to report any potential vaccine-associated adverse events (VAAEs) to their local public health authorities, who report them to the provincial/territorial (P/T) level. P/Ts then report these events to Health Canada,

which maintains a federal database of VAAEs. This passive surveillance system is nationwide, but reporting rates vary. The responsibility to report these events is legislated in some jurisdictions, but not in all. The format (i.e., paper versus electronic reporting) and timeliness of the reports to Health Canada from the individual jurisdictions vary, and jurisdictions have different activities and processes in place to verify that the suspected VAAEs meet the case definitions.

- *Active Surveillance System:* The Immunization Monitoring Program, Active (IMPACT), funded by Health Canada, and operated at 12 paediatric hospitals in Canada (representing most paediatric hospital admissions in Canada), conducts active surveillance for serious VAAEs through nurse monitors. IMPACT then reports the VAAEs to local health authorities, and assists in evaluating vaccine effectiveness.
- *Signal Generation:* “Signal generation” refers to the ability of the system to flag potential VAAE threats. Unusual or severe events are typically detected at the local level and reported to the P/T level, where an investigation may be initiated. Communications are also made with the federal level, and are usually by telephone.

(ii) Public Health Response

- *Review/Follow-up of VAAEs:* Health Canada’s Advisory Committee on Causality Assessment (ACCA) is an expert advisory committee, with volunteer membership. It meets twice a year, with the mandate to select potential VAAE cases for review, to determine whether they were causally linked to the vaccine. Cases are selected from the federal VAAE database if they are severe or unusual, or they may generate research needs. Findings are communicated to P/Ts, and dissemination of feedback is left up to their discretion.

- *Urgent Response or “Surge” Capacity:* “Surge” capacity, which refers to capacity to respond to urgent situations or potential threats, is dependent on mobilizing human resources that are already functioning in positions with full-time commitments or other research priorities.

c) *Gaps/Limitations of Existing System*

The very success of immunization programs has proven to be one of their “weaknesses”, as generations grow up in the absence of diseases that used to wreak havoc on the population and provided the stimulus for people to seek protection. There is a resulting low risk tolerance for vaccines, which has raised public expectations for vaccine safety, especially considering that vaccines are administered to healthy people. The presence of organized action groups opposed to immunization and capable of broad dissemination of information/opinions also highlights the need to address safety concerns in a more coordinated and effective manner.

The following are specific gaps/limitations of the current system, which need to be addressed to optimize the vaccine safety system in Canada:

(i) *Vaccine Safety Monitoring*

- *Passive Surveillance System:*
 - ▶ National data could be available in a more timely manner.
 - ▶ Standardization of data/reporting could be improved through the development of national guidelines for reporting and verification of VAAEs.
 - ▶ Identification of rare but serious potential VAAE threats could be improved, since (1) P/T databases may be too small for this, (2) denominator data on the number of vaccine doses administered may be difficult to access at a national level, and (3) more comprehensive analyses on the VAAE database could be conducted.
 - ▶ The capacity for data linkage with the existing federal VAAE database could be enhanced.

- *Active Surveillance System:* The primary focus of the active surveillance system has been on children, as opposed to adults.
- *Signal Generation:* Improvements in flagging potential VAAE threats could be made through better communication of information from the local level to the P/T level, to the national level, and through enhancements to the VAAE database.

(ii) *Public Health Response*

- *Review/Follow-up of VAAEs:*
 - ▶ Development of national guidelines on the management of VAAEs, and more extensive information sharing of existing P/T guidelines would improve the review/follow-up of VAAEs.
 - ▶ Advice/consultation on VAAEs could be provided to physicians and the public through a more organized network.
 - ▶ The ability to trace a problem “lot” (or batch) of vaccine could be improved.
- *Urgent Response or “Surge” Capacity:* There is a need for an enhanced surge capacity, as the ability of experts in the field to dedicate time to investigate/research an urgent issue would depend on their competing priorities/responsibilities.

d) *Proposed Approach*

The following changes could be made in order to address any limitations of the current system related to vaccine safety monitoring and public health response:

First, it is proposed that a network of dedicated F/P/T vaccine safety contacts be established in all jurisdictions. Such a network could improve signal generation and surge capacity. These individuals would be expected to identify and address potential vaccine safety issues, and would have a multi-purpose role of conducting surveillance, VAAE reporting, communication, signal generation, and environmental scanning. They could also be drawn upon in urgent situations requiring coordinated national action.

The second aspect of the proposed approach is to improve the current system of public health response. It is proposed that a clinical assessment/referral system be established to clinically assess and follow up individuals with suspected VAAEs. If physicians and other medical professionals require assistance in making the clinical assessment or determining the appropriate follow-up, they could contact the appropriate referral centre with expertise in this area for advice. One option under consideration is to expand the current role of IMPACT (i.e., which conducts active surveillance for serious VAAEs presenting at paediatric hospitals) to include an assessment and referral capacity.

The third aspect of the proposed approach is to have a vaccine safety committee to address any limitations of the current vaccine monitoring and public health response systems. The specific activities required by such a mechanism would be the following:

- Identification of potential issues
- Review of data/evidence
- Review of surveillance data and cases/clusters of concern
- Enhancing the ongoing vaccine safety monitoring through the passive system, including
 - ▶ Producing timely national surveillance reports on VAAEs
 - ▶ Developing national guidelines on reporting, verification, and management of VAAEs
 - ▶ Improving the current VAAE database (including data linkage capacity and provision of local access to data) and support registry network development
- Exploring opportunities for enhancing ongoing vaccine safety monitoring through the active surveillance system (e.g., increased focus on the adult population)

Other important aspects of the Vaccine Safety component of the proposed NIS are research and communication. Research on vaccine safety issues is necessary to support evidence-based practice on VAAEs. Communication of safety data and monitoring activities are essential to maintaining professional and public confidence in vaccine safety, as well as to responding to potential VAAE threats.

However, since research and communication are activities that cut across other components of the NIS, they will be discussed separately in section C of this paper.

B.4 Vaccine Procurement

a) Objectives

The objectives for the vaccine procurement component of the NIS are to ensure the best value for vaccines, the long-term security of supply for vaccines, the quality of supply, and improvements in accountability.

b) Existing System

Most vaccines in Canada (i.e., over 75% of the total dollar value of vaccines in 2001/02) are purchased through direct contract with vaccine suppliers by individual provinces/territories. The remaining 25% of vaccines are purchased through the existing F/P/T procurement process, which is coordinated by Public Works and Government Services Canada (PWGSC).

The F/P/T Committee on Group Purchasing of Drugs and Vaccines, led by PWGSC, has representation from P/T ministries of health, Health Canada, and National Defense, but does not report to the CDMH. This F/P/T procurement process is low cost (\$100K annually, shared equally among the participating jurisdictions) and vaccines are generally purchased at a price equal to or lower than the lowest prices in Canada. Vaccine contracts issued through this process are generally issued on a one-year basis, to the lowest bidder.

c) Gaps/Limitations of Existing System

The current mix of F/P/T bulk purchasing of vaccines, combined with purchase through direct contract by individual jurisdictions, has resulted in differential vaccine prices across Canada.

Without full support and participation in the F/P/T bulk purchase process, the ability to address concerns regarding rising prices or supply issues (described below), using a coordinated national approach, is reduced.

■ Escalating vaccine prices

As illustrated in the following table, based on data collection from each P/T, P/T vaccine expenditures have increased substantially. Although much of this increase is due to the introduction of expensive new vaccines, the prices of existing vaccines have also increased in recent year. (figures for 2002-2003 are not available).

	Year			
	1998/ 1999	1999/ 2000	2000/ 2001	2001/ 2002
Total P/T Vaccine Expenditures (in millions)*	\$83.7	\$93.8	\$114.8	\$224.9*

* includes one-time catch-up meningococcal program in Quebec and Alberta

Note: Vaccine purchases by the federal government and PEI are not included in these totals. However, in 2000/01, the federal government vaccine purchases totaled approximately \$1.5M.

■ Concerns regarding security of supply

The supply of vaccines in Canada has generally been quite stable, as vaccines needed for immunization programs have usually been available in the quantities required. However, in recent years, supply problems have begun to occur in Canada, and are attributable to a variety of causes, including product changes, lot testing failures, and increased demand. Supply problems are also occurring in the United States. According to the United States General Accounting Office, incidents of vaccine shortages in the United States began in fall 2000 and, by fall 2001, the Centers for Disease Control and Prevention (CDC) reported shortages of five vaccines used for childhood immunization: tetanus and diphtheria booster (Td); diphtheria, tetanus, and acellular pertussis (DTaP); pneumococcal conjugate vaccine; measles, mumps, and rubella (MMR); and varicella vaccine¹⁶.

The existing F/P/T bulk purchase process could be improved to address the following:

- P/Ts currently lose some individual control, particularly with respect to value-added products/services.
- The current process is not always timely.
- Current funding and infrastructure may not be able to sustain required activities.
- The current process is “winner takes all”.
- The current process often awards one-year contracts.
- The current process does not report to an F/P/T governing body.

d) Proposed Approach

To address any limitations of the existing system, the following enhancements to the existing F/P/T procurement process could be made:

- Increase the capacity to ensure security of supply (e.g., multi-year contracts).
- Improve the ability to respond to escalating vaccine prices (e.g., proactive planning of longer-term vaccine needs/orders, use of multi-year contracts).
- Develop a mechanism to include value-added products/services as part of the process and to redistribute these funds as part of the NIS.
- Collaborate with vaccine regulator to ensure timely communication on newly developed or released vaccines.
- Improve information-sharing regarding P/T contracts.
- Improve the administrative process, including development and use of the following:
 - ▶ Standardized forms and communication tools to streamline process
 - ▶ Standards for specifications concerning vaccine products and delivery processes
 - ▶ Clear contract parameters and bid evaluation criteria before the tendering process
 - ▶ Performance evaluation standards for contracts

B.5 Immunization Registry Network

a) Objectives

The key objectives of this component of the proposed NIS are to:

- Enhance national surveillance of immunization coverage rates (i.e., percentages of the recommended population who received the vaccine).
- Facilitate the transfer of and access to individual immunization records.
- Measure progress towards national immunization goals and objectives.
- Facilitate linkage of surveillance data of vaccine preventable diseases and vaccine-associated adverse events (VAAEs).

b) Existing System

Each province and territory maintains their own system for tracking immunization coverage. In most provinces and territories, immunization information is collected primarily on children, and there is variability between jurisdictions with respect to the type of data being collected. The collection of childhood immunization data often begins at the time of enrollment in licensed daycare facilities or schools. Some jurisdictions have electronic databases to track this information, whereas others use paper-based systems.

Most provinces and territories are currently establishing electronic immunization registries, which would be consistent and compatible with standards established in a national network. As part of an existing F/P/T initiative, work is being conducted to develop a long-term strategy for the surveillance of communicable diseases, which includes developing data standards and data definitions for immunization, communicable diseases, and vaccine associated adverse events¹⁷.

c) Gaps/Limitations of Existing System

Program planning, evaluation, and research, at a national level, could be improved with a national network of immunization information. For instance, a registry network could provide better access to vaccine coverage data, thereby reducing the need for coverage surveys, which have limitations in terms of timeliness, quality, and cost. It could also provide data to support program planning, such as the identification of populations who are under-immunized and could benefit from targeted efforts. Furthermore, an immunization registry network could provide better access to denominator data on the number of persons immunized, which would support assessments of vaccine safety.

Improvements in the standardization of data across jurisdictions would facilitate the transfer of immunization records when a child moves from one jurisdiction to another, and would help to ensure that immunizations continue on schedule.

d) Proposed Approach

Health Canada is currently funding a project to establish a network of provincial/territorial registries. It is proposed that this work continue as a component of the NIS, as follows:

- Development of a minimum (core) data set to be collected by each province/territory.
- Development of business, technical, and functional standards for use by each province/territory.
- Development and provision of tools and software to interested jurisdictions by Health Canada, to assist in achieving the technical capacity to establish an electronic registry.
- Establishment of a national profile for immunization registries, in respect of laws regarding confidentiality of and access to data.
- Development of strategies to populate immunization registries, including bar coding immunization agents.

C. Description of Supporting Activities

There are certain activities that cut across, and support, the five components of the NIS. There is potential to incorporate these activities into the overall NIS; however, further work is required to determine how these activities could best be integrated. These supporting activities are as follows:

C.1 Immunization Research

The objectives of this supporting NIS activity would be to:

- Improve the immunization research capacity in Canada, including surge capacity to deal with urgent issues (e.g., vaccine safety).
- Improve coordination of current and future immunization research activities in Canada, to support governmental needs and NIS goals.
- Facilitate the availability of timely, reliable information and evidence to support informed decision-making in all jurisdictions.

The current immunization research community in Canada is better established for the development and pre-licensure testing of new products, with funding predominantly coming from government grants or private industry. Research on effective program implementation and monitoring once vaccines are licensed (e.g., models to predict the effect of the new program, determining the most effective uptake measures, assessing cost-effectiveness, evaluation of education needs of professionals/the public) could be enhanced. Furthermore, the immunization research community in Canada is small, consisting mainly of senior specialists with multiple commitments, clustered in “pockets” across Canada.

There is a need to identify, document, and prioritize immunization research needs in Canada, as well as to pro-actively identify gaps in research funding envelopes and discuss strategies for prioritizing future needs. In doing this, strong partnerships must be established with research groups, industry, and funding agencies, such as the Canadian Institutes of Health Research (CIHR), the Canadian Association for Immunization

Research and Evaluation (CAIRE), Canadian Population Health Institute (CPHI), and the Canadian Network for Vaccines and Immunotherapeutics (CANVAC). A preliminary list of immunization research priorities was developed using information from a meeting of key stakeholders held in February 2002, and could serve as a basis for further work on this topic.

C.2 Public and Professional Education

National organizations, such as the Canadian Immunization Awareness Program (CIAP), are currently the main sources of national information on immunization and vaccine safety issues and educational materials. There are also local, P/T, federal and professional organizations that provide information on these issues through existing websites. Messages are not always coordinated or consistent. International sources of information may not be relevant as licensed vaccines differ from those in Canada.

A national communication strategy for immunization (including vaccine safety issues) to develop national communication and educational tools/materials, and to disseminate immunization information in a coordinated, consistent way would be valuable. Strong partnerships with existing national organizations, such as CIAP, would be important. Consideration could also be given to establishing a communications network of key stakeholders, including F/P/T governments, which would be capable of disseminating pertinent information on immunization and immunization safety issues in a timely manner.

C.3 Approaches to Special Populations

The Aboriginal peoples require partnership in the NIS. It is proposed that Aboriginal organizations be linked into the NIS and that linkages be developed with the First Nations and Inuit Health Branch.

Other special populations, such as immigrants, refugees, travelers, certain religious groups, populations with low socio-economic status, and the elderly, will also require specific program attention as part of the NIS.

C.4 Vaccine-Preventable Disease Surveillance

Currently, Health Canada administers the Notifiable Diseases Reporting System (NDRS), in which reports of “notifiable diseases” are submitted by the provinces and territories across Canada based on a general agreement and recognition of the importance of a centralized data source. Health Canada uses these data to monitor national vaccine-preventable disease trends and provides summary reports through the Health Canada website. Health Canada also facilitates the development and implementation of national standards, such as case definitions and data models, and provides some support for P/T surveillance through material resources (e.g., computer tools),

financial resources (e.g., CIPHS collaborative), and human resources (e.g., gap analysis, field epidemiologist support).

Other surveillance initiatives include the Canadian Paediatric Surveillance Program (CPSP), sentinel and targeted surveillance for viral hepatitis and influenza, and international circumpolar surveillance for specific vaccine-preventable diseases.

There are a number of important limitations to the current vaccine-preventable disease surveillance system, which fall generally into the following categories:

- Data quality and comprehensiveness could be improved, as variations exist between jurisdictions.
- Data analysis is mostly basic.
- Feedback/reporting could be more timely.
- Coordination and priority-setting could be improved.

A national mechanism for working with stakeholders to improve the current vaccine-preventable diseases surveillance system would be beneficial.

D. Concluding Remarks

This final report represents a vision for moving forward with a national strategy on immunization. It represents a new way of doing business in Canada with regard to one of our most important and proven public health program areas.

The five components of the strategy, outlined in the body of this report, are as follows: national goals and objectives; immunization program planning; vaccine safety; vaccine procurement; and immunization registry network. The supporting activities, which cut across and support the five strategy components, include immunization research; public and professional education; approaches to special populations; and vaccine-preventable disease surveillance.

If fully implemented, it is anticipated that the strategy will improve our ability to face the new challenges ahead and will be associated with the following important benefits:

- Reduction in vaccine-preventable diseases
- Improved access to timely vaccine programs
- Improved efficiencies
- Better vaccine safety monitoring and response
- Enhanced affordability of vaccines
- Improved security of vaccine supply
- Public confidence in vaccines/response to growing anti-immunization concerns

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