

Université de Montréal

Development and Testing of an Analytical Framework  
for Immunization Program Planning in Canada

par

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Faculté des études supérieures

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Development and Testing of an Analytical Framework for Immunization  
Program Planning in Canada

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## Résumé

Ce projet a consisté à adapter et à tester un cadre théorique intégratif de transfert de connaissances, dérivé de celui proposé par Kemmis et McTaggart (2001) et incluant les trois catégories de connaissances proposées par Habermas (1972,1974). Ce cadre fut employé dans la planification des programmes d'immunisation au Canada, utilisant une méthodologie de recherche-action. L'intervention principale dans ce projet a été le développement et l'implantation d'un cadre analytique pour la prise de décision concernant des nouveaux programmes d'immunisation. Bien que toutes les 13 juridictions provinciales et territoriales du Canada aient été exposées à cette intervention, ce projet a ciblé deux contextes en particulier : le niveau fédéral et le niveau provincial au Québec. En terme des trois niveaux de connaissances proposés par Habermas, seulement les niveaux *technique* et *pratique* étaient présents au début du projet. Par contre, l'approche par recherche-action a permis au projet de répondre spécifiquement aux besoins des acteurs impliqués, questionnant la structure actuelle en immunisation et proposant des changements organisationnels. Ceci correspond au niveau *critique* proposé par Habermas. Le résultat de cette approche est le développement et l'implantation réussie de l'outil et du changement organisationnel, qui ont été supportés par les acteurs-clés. En ce qui concerne la relation entre ces trois niveaux de connaissances, les résultats obtenus indiquent que le niveau *critique* englobe le niveau *pratique* qui à sa tour englobe le niveau *technique*, tel que proposé dans la littérature. Ces résultats indiquent que ce cadre théorique et cette méthodologie d'intervention sont complémentaires aux théories existantes, et peuvent aider à mieux réaliser des interventions et comprendre le transfert de connaissances. Cet élargissement de perspective intégrant les facteurs contextuels ressemble aux tendances récentes en recherche sur les services de santé au Canada, en ce qui a trait à la prise de décision et au transfert de connaissances. Des efforts similaires à ce projet devraient être entrepris dans d'autres champs de services de la santé et de la coordination inter-juridictionnelle au Canada, pour implanter des changements bénéfiques et développer ce modèle théorique intégratif pour le transfert de connaissances.

Mots-clés: planification des programmes d'immunisation (Canada), cadre analytique, transfert de connaissances, prise de décision, recherche-action, Habermas

## Summary

This project adapted and tested an integrative theoretical framework for knowledge transfer derived from a model proposed by Kemmis and McTaggart (2001), including the three categories of knowledge-constitutive interests proposed by Habermas (1972,1974). This framework was applied to an intervention in the area of immunization program planning in Canada, using an action research methodology. This intervention was centered on the development and implementation of an analytical framework for decision-making regarding new immunization programs. While all 13 provincial and territorial jurisdictions in Canada were exposed to this intervention, the project focused on two contexts in particular: the federal context and the provincial context in Quebec. Regarding the three levels of knowledge-constitutive interests proposed by Habermas, only the *technical* and *practical* levels were present at the outset of this project. However, the action research approach allowed the project to be responsive to the specific needs of the actors involved, questioning the current structures in immunization and proposing organizational changes. This corresponds to the *critical* level proposed by Habermas. The overall result of this approach was the successful development and implementation of organizational change and the tool for decision-making in Canada. Concerning the relationship between these three levels of knowledge-constitutive interests, these results indicate that the *critical* level encompasses the *practical* level, which in turn encompasses the *technical* level, as proposed in the literature by certain authors. This project also indicates that the integrative theoretical framework and this methodology of intervention are complementary to existing theories, and can help to achieve successful implementation and understanding of specific knowledge transfer efforts. This broadening of perspective to integrate contextual factors parallels recent directions of health services research in Canada regarding decision-making and knowledge transfer. Efforts similar to this project should be conducted in other areas of health services and interjurisdictional coordination in Canada, to implement beneficial changes and also continue to develop this integrative theoretical model for knowledge transfer.

Keywords: planning of immunization programs (Canada), analytical framework, knowledge transfer, decision-making, action research, Habermas

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## List of Abbreviations

ACCD	Advisory Committee on Communicable Diseases
ACPH	Canadian Advisory Committee on Population Health
AETMIS	<i>Agence d'évaluation des technologies et des modes d'intervention en santé du Québec</i>
CCDR	Canada Communicable Disease Report
CCMOH	Council of Chief Medical Officers of Health
CCOHTA	Canadian Coordinating Office of Health Technology Assessment
CBS	Canadian Blood Services
CDC	Centers for Disease Control
CETS	<i>Conseil d'évaluation des technologies de la santé du Québec</i>
CHSRF	Canadian Health Services Research Foundation
CIC	Canadian Immunization Committee
CIHR	Canadian Institutes of Health Research
CIQ	<i>Comité d'immunisation du Québec</i>
CMOH	Chief Medical Officer of Health
COHRED	Council on Health Research for Development
DPTP-Hib	diphtheria-polio-tetanus-pertussis- <i>Haemophilus influenzae type b</i> vaccine
DSPPE	<i>Direction de la santé publique, de la planification et de l'évaluation</i>
INSPQ	<i>Institut de santé publique du Québec</i>
ISC	Immunization Subcommittee of the Public Health Working Group
LCDC	Laboratory Center for Disease Control, Health Canada
JASP	<i>Journées annuelles de santé publique</i>
MMR	measles-mumps rubella vaccine
MOH	Medical Officer of Health
MSSS	<i>Ministère de la santé et des services sociaux du Québec</i>
NACI	National Advisory Committee on Immunization
NIS	National Immunization Strategy
PCV-7	Heptavalent conjugate pneumococcal vaccine
PHWG	Public Health Working Group
PPHB	Population and Public Health Branch, Health Canada
RRSSS	<i>Régie régionale de la santé et des services sociaux</i>
SARS	Severe Acute Respiratory Syndrome
WHO	World Health Organization

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## **Introduction**

Many efforts in health services research in Canada in recent years have aimed to improve the use of research in decision-making at the clinical, institutional, regional, provincial and federal levels. A considerable quantity of health-related research is produced in Canada each year, however, current practices across the country are often quite variable and do not reflect the best current evidence (Tranmer, 1998). Therefore, there is interest in improving the links between research and practice in various areas of health care, and numerous structures and processes and research funds have been created to assist in the coordination and diffusion of research results to improve decision-making in Canada. At the clinical level, an example is the evidence-based medicine movement, which encourages systematic literature review by clinicians to promote clinical practice based on the best current evidence. At the institutional level, hospitals are increasingly developing expertise on health technology assessment (Battista et al., 2003), to ensure optimal use of available technologies. At the provincial level, health technology assessment agencies have been established in many jurisdictions to advise Ministries of Health regarding the optimal use of new health technologies. At the national level, the Canadian Institutes of Health Research (CIHR) and the Canadian Health Services Research Foundation (CHSRF) are increasingly concerned with knowledge transfer and initiatives to improve decision-making.

There is considerable interest in how to better transfer research into practice, which has led to the development of new terms and areas of study (such as 'knowledge transfer', 'knowledge brokering' etc.), which reflect a broadening of perspective, with increased interest in and attention to contexts in decision-making. It has become apparent that simple production

of research is not enough to influence decision-making. It has been recognized that the classical linear conception of this relationship in which research is transmitted to decision-makers who implement this research into practice is incomplete, and must be replaced by a more complex model that recognizes the complex nature of decision-making and the various links between decision-makers and research. While various theoretical approaches exist, there have been few efforts to integrate the various theoretical approaches, and an integrative theoretical approach is lacking and needed in this area. This project focuses on the area of decision-making in the area of immunization in Canada to test such an approach, as well as the action research method of inquiry, to implement positive changes in knowledge transfer in this area and draw general theoretical and practical conclusions to guide future efforts in this area.

Existing decision-making structures and processes were studied, and key persons involved in this process were involved in wide and multiple consultations. An analytical framework was developed in collaboration with key experts in this area in Canada in an effort to make this decision-making and knowledge transfer process more efficient and systematic. This framework was then distributed across the country in multiple contexts and its use was evaluated. Because of the flexible, action research approach of this project, its scope was unexpectedly broadened on the national level to evaluate organizational structures and processes in the area of immunization planning in Canada, and propose new ones. Indeed, this contributed to the emergence of a new Canadian Immunization Committee (which first met in November 2003), and discussion of an expanded role of the National Advisory Committee on Immunization (NACI).

Overall, the project aimed to develop a method that combined a research synthesis or information component with an organizational development

component, which can be applied in other contexts in which increased support and coordination of decision-making in Canada are desired. While this type of effort cannot overcome the various budgetary limitations and political constraints and tensions present in Canadian federal-provincial relations, it can help to optimize the use of the considerable expertise in this area, leading to better use of immunization across Canada and ultimately better health benefits for Canadians. There are many other contexts in which such an effort could be beneficial in the coordination of health services across Canadian jurisdictions. In the broader context of knowledge transfer, this effort enabled development and refinement of a comprehensive theoretical framework for knowledge transfer activities integrating subjective and objective elements, at the level of the individual and the system, and also the technical, practical and critical levels of knowledge-constitutive interests proposed by Habermas.

This project aimed to facilitate the decision-making process pertaining to publicly funded immunization programs in Canadian provinces and territories by developing and testing an analytical framework for immunization program planning. This project also examined organizational structures and processes for immunization program planning in Canada, and made proposals for change. General criteria that are important in the process of consideration and evaluation of a candidate vaccine in Canada were collected from experts, literature review, and a questionnaire administered to key persons involved in immunization planning across Canada. The resulting framework was then tested on the federal level in various national meetings on immunization in collaboration with Health Canada as part of a larger project associated with the development of the National Immunization Strategy. In Québec, the analytical framework was tested by integration into activities of the *Comité d'immunisation du Québec* (CIQ). A follow-up questionnaire was administered to key persons across Canada to examine awareness and appreciation of the framework. The

framework was also used as an educational tool for health professionals and has been proposed for use by the general public. In the fall of 2003, the framework was presented to the National Advisory Committee on Immunization (NACI) for use with the new Canadian Immunization Committee (CIC). By integrating the analytical framework with existing and emerging structures and processes for immunization program planning in Canada, the impact and number of interactions should be maximized. It is proposed that using a systemic action research approach and integrative theoretical framework for knowledge transfer in other health services research initiatives in Canada will also maximize benefits.



## **CHAPTER I: CONTEXT- IMMUNIZATION PROGRAM PLANNING IN CANADA**

### ***Background***

Vaccination has been recognized as one of the great public health achievements of the last century (CDC, 1999a), with eradication, elimination or drastic reductions in smallpox, polio, measles, and Hib invasive disease, to name a few. Remarkable progress has been made in the development and use of immunization, which has created an increasingly complex vaccination schedule. Many new (and more costly) vaccines will soon be available. Furthermore, many new modes of vaccine administration other than injection are being developed, such as nasal spray vaccines, transdermic 'patches', and even edible vaccines (Liu, 1999; WHO, 2002; Tacket et al., 1998). This situation has resulted in many challenges such as informing the public and health-care providers about new developments and recommendations, vaccine procurement and financing. Increasingly complex questions must be addressed regarding safety, efficacy, vaccine delivery, information and administration systems.

There has been some recent progress in funding of new programs in Canada. However, there have been some examples of inertia, lack of coordination and situations in which improvement is possible (Duval, 2000; McDonald, 1997; Spika & Duclos, 1997). Currently, despite the supposedly universal nature of health care in Canada, the Canada Health Act requires provinces and territories to fund 'medically necessary' services, however individual jurisdictions do not have to respond to national standards and therefore have a certain leeway in interpretation of this requirement and the resulting coverage of services such as immunization, long term care or rehabilitation services (CHSRF, 2002). Therefore, the selection of publicly funded vaccines depends on the province of residence as is illustrated in

Table I, with variable funding of meningococcal conjugate, adolescent pertussis, pneumococcal conjugate and varicella vaccine programs among Canadian provinces and territories (Sibbald, 2003).

**Table I: Vaccination programs funded by Canadian jurisdictions, January 2003**

Province /territory	Childhood vaccines <sup>1</sup>	Meningococcal conjugate	Adolescent pertussis	Pneumococcal conjugate	Varicella
British Columbia	X				
Alberta	X	X		X	X
Saskatchewan	X			X <sup>†</sup>	
Manitoba	X				
Ontario	X	X <sup>†</sup>			
Quebec	X	X		X <sup>†</sup>	X <sup>†</sup>
New Brunswick	X	X <sup>†</sup>			
Nova Scotia	X				X
Prince Edward Island	X	X <sup>†</sup>		X <sup>†</sup>	X
Newfoundland & Labrador	X		X		
Yukon	X				
Northwest Territories	X		X		X
Nunavut	X		X	X	X

\*. Diphtheria, hepatitis B, Haemophilis influenzae type b, measles, mumps, pertussis, polio, rubella and tetanus.

†. limited implementation

Source: Health Canada, Jan 6, 2003 in Sibbald (2003);

Hepatitis B, varicella, and influenza are examples of immunization programs having an important variability in goals and objectives, target groups, and delivery strategies between provinces and territories in Canada. Another problem is the lack of knowledge about immunization coverage (Squires & Pelletier, 2000), or how many Canadian children receive all recommended immunizations on schedule (CIHI, 2000a). While recognizing the strengths of immunization in the current health system in Canada, we must also examine areas which can be improved and take appropriate action. Evaluations of different international approaches to immunization indicate

that countries having the most successful immunization programs are those with the best coordination of national activities (Spika & Duclos, 1997). This is definitely an area in which there is a need for improvement in Canada.

### ***The Decision-making Process for Immunization Programs in Canada***

At an ever-increasing pace, new vaccines are being developed, licensed, and commercialized in Canada due to initiatives of pharmaceutical companies. New products are evaluated by the National Advisory Committee on Immunization, which determines the optimal conditions of use of the vaccine in the epidemiological context of Canada (Canadian Immunization Guide 2002). Other expert committees such as the Canadian Task Force on Preventive Health Care or the Committee to Advise on Tropical Medicine and Travel may also produce recommendations or guidelines for health professionals. Integration of a new vaccine into a publicly-funded immunization program is the responsibility of provinces and territories, and each jurisdiction decides which products will be purchased and offered free of charge to certain target groups.

In Canada, vaccine licensing is a federal responsibility. However, determination of immunization policy and the implementation of publicly funded vaccination programs are provincial and territorial responsibilities. Health Canada has a coordinating role, organizing national consensus conferences on certain candidate immunization programs, setting national goals, as well as supporting committees of scientific experts and provincial/territorial officials. National expert committees that treat vaccination issues include the National Advisory Committee on Immunization (NACI) and the Task Force on Preventive Health Care.

However, these committees make recommendations for optimal use of licensed vaccines by individual clinicians in private and public practice, and do not address decision-making involving publicly financed immunization programs. Specifically, NACI produces recommendations for the Canadian Immunization Guide, while the Task Force on Preventive Health Care produces recommendations regarding vaccination for the Canadian Guide to Clinical Preventive Health Care (Canadian Task Force on the Periodic Health Examination, 1994).

### ***Federal Decision-Making Process for Publicly Funded Immunization Programs***

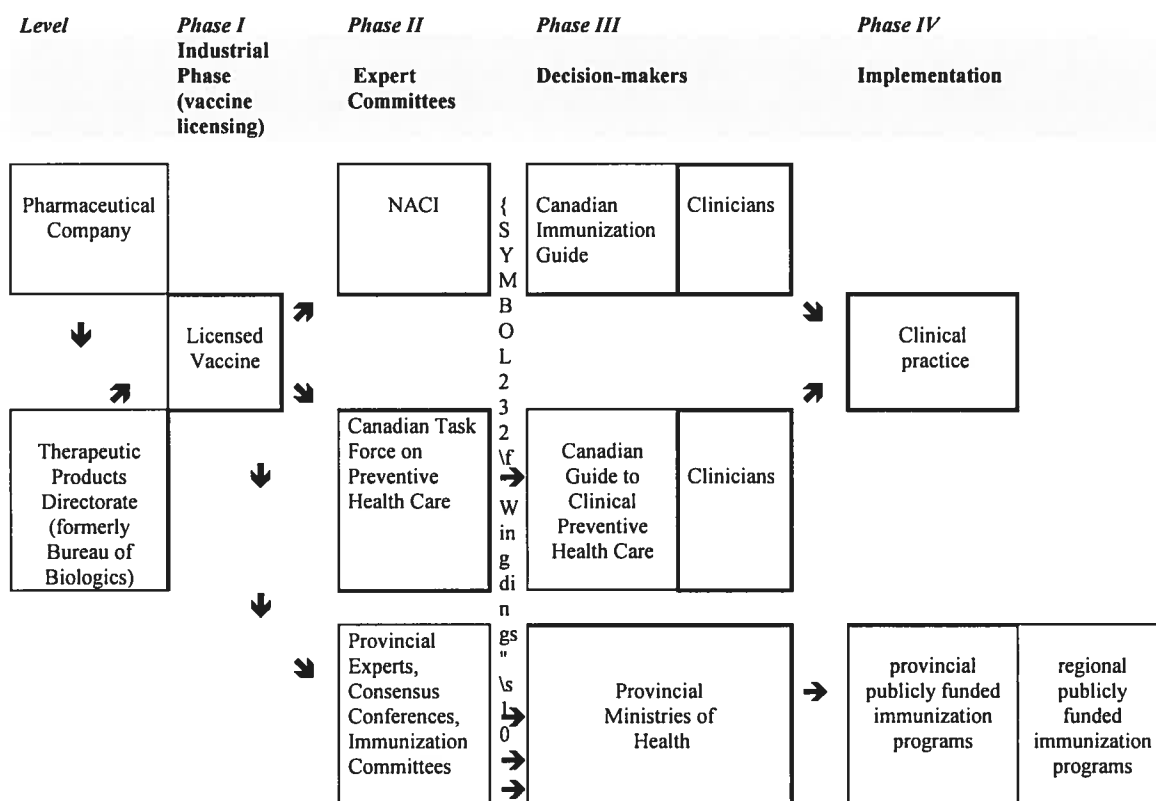
An important federal body is the Therapeutic Products Programme (TPP, formerly the Bureau of Biologics), which is responsible for licensing of vaccines. Another federal structure is the *Bureau of Infectious Diseases*, which is one of four bureaus of the *Centre for Infectious Disease Prevention and Control*, which in turn is one of 9 directorates of the *Population and Public Health Branch* of Health Canada. The Bureau of Infectious Diseases “provides leadership and expertise in infectious diseases of national and/or provincial/territorial importance” (Health Canada, 2000). Activities are stated to focus on surveillance of infectious diseases, identification and quantification of risk factors and emerging threats to health, assessment of proposed prevention strategies, evaluation of existing surveillance, prevention and control activities and the pursuit of research initiatives (Health Canada, 2000).

### ***Implementation of new Vaccines & Immunization programs in Canada***

The process leading to implantation of new immunization programs can be divided into 4 successive phases (Figure 1):

1. The « **industrial phase** », which is the initiative of a private company, which develops a vaccine. A license is obtained from the Bureau of Biological Products specifying conditions of use of the vaccine.
2. Scientific **expert committees** specify conditions of use of the vaccine (which can be different from those specified by the vaccine manufacturer) and make recommendations for health professionals and public health authorities. These expert committees exist at the national level (i.e. NACI, the Task Force on Preventive Health Care) and also in some provinces (i.e. the *Comité d'immunisation du Québec*).
3. Provincial **decision-makers** determine policy regarding financing and implementation of vaccination programs to be offered (free of charge) to specific populations in their jurisdictions.
4. Immunization programs are planned by public health authorities in various provinces and territories and **implemented** by regional and local health units and private practitioners.

Figure 1: Phases in Vaccine Licensing and Utilization in Canada



### ***Shortcomings of the Current Situation***

At the national level, there is no committee specifically mandated for making recommendations to provincial/territorial public health authorities or to play a permanent role in coordination. The policy-making process for immunization programs varies greatly between provinces and territories (Duclos & Spika, 1997). For example, Québec has a formal expert Committee on Immunization (CIQ), whereas the other provinces have less formal groups of scientific experts. Experience in recent years has shown that the decision-making process is quite different between provinces and also from one vaccine to another (Duclos & Spika, 1997). National goals and targets have been established for a majority of vaccine-preventable diseases, but they have not been endorsed at political level in all jurisdictions (LCDC, 1999a; 1998a). At the present time, significant differences are seen in schedules and age of administration of several vaccines in different jurisdictions (Sibbald, 2003; LCDC, 1999a; Duclos & Spika, 1997, Embree 2003, Naus et al. 2003). In several instances, total disharmony was observed in the implementation of a new program and catch-up programs (Duclos & Spika, 1997).

Decision-making structures and processes for immunization vary greatly between Canadian provinces and territories, and it has been observed that decision-making criteria may vary between different vaccines in the same jurisdiction (Erickson & De Wals, 2003). This lack of standardization and reproducibility in the vaccine evaluation process has negative consequences on the homogeneity and equity of immunization programs across Canada (Sibbald, 2003). To help improve this situation, in the context of the development of a National Immunization Strategy (Embree 2003, Naus et al. 2003), there have been calls for greater harmonization and accessibility of vaccines recommended by experts in Canada.

### ***Proposals for Change***

At the National Immunization Conference in 1996, NACI passed a formal resolution calling for national coordination in immunization program planning (NACI, 1996). At the National Consensus Conference on Varicella in 1999, a recommendation expressed the need for development of « *a mechanism to prioritize and introduce new vaccines with a view to harmonizing programs across the country.* » (LCDC, 1999b). A recommendation that Health Canada act as a clearing house for information, providing each province and territory with a critique of current literature on cost-effectiveness to assist provincial and territorial decision-makers was expressed at a previous consensus conference on the pneumococcal polysaccharide vaccine in 1998 (LCDC, 1998b). In addition, the Director of the Division of Immunization at Health Canada has recently proposed a national program to support provincial and territorial immunization programs, citing the general observation that excellent national coordination is observed in countries with the most successful immunization programs (such as Australia, which has a similar division of responsibilities between federal and state/provincial authorities) (Duclos & Spika, 1997).

Also, the National Sub-Committee on Immunization of the Public Health Working Group (PHWG) has identified the priority of ensuring that vaccines are delivered in a cost-effective manner across Canada, in concordance with national immunization objectives (PHWG, 2000). The PHWG receives its mandate from, and serves as a resource and advisor to, the Advisory Committee on Population Health (ACPH). The PHWG's work and deliberations focus on, but are not limited to, public health issues and services delivered through government-funded public health agencies at the

federal, provincial/territorial and regional/local levels. Part of the PHWG's mandate is to develop recommendations to achieve more effective and better integrated federal/provincial/territorial public health systems. The PHWG's activities in the area of immunization planning have demonstrated both the need and the expressed interest of stakeholders for improved organization and availability of information relevant for policy-making in Canada.

Provincial and territorial authorities ultimately make policy in this area in collaboration with scientific experts; therefore efforts to facilitate policy-making should be targeted at this level. While these entities face similar problems when making policy decisions about a particular immunization program, there is much difference between their respective contexts. This project proposal aims to facilitate Canadian immunization program planning in collaboration with these policy-makers across Canada.



### ***International examples: National Coordination of Immunization Planning***

To guide efforts for improvement in this area in Canada, it is useful to consider some international examples of national coordination of immunization, specifically in the United Kingdom, the United States, and Australia. The case of Australia is particularly interesting in that their national strategy on immunization has been particularly successful and the structure of governance is similar to the federal system in Canada. A summary of similarities and differences between immunization planning structures in these countries is presented in Table II.

#### ***The United Kingdom***

The United Kingdom has made great progress in increasing immunization coverage in recent years, and several initiatives, including the development of a National Immunization Communication Strategy, developed jointly by the Department of Health and the Health Education Authority, with a budget equivalent to \$ 2 million U.S per year (Salisbury & Dillman, 1999). These funds are used for market research (public perceptions of immunization), and media and information campaigns including television ads regarding immunization programs (i.e. varicella and more recently, meningococcal). Also, physicians have pay incentives tied to reaching immunization targets; there is central purchase of vaccines, computerized cold chain management, and weekly distribution of vaccines to general practitioners. High national profile of immunization and government commitment has been seen in the recent mass immunization campaign with meningococcal conjugate vaccine.

Table II: Comparative Table- Immunization Planning in Selected Countries

	UK	USA	Australia (Australian Department of Health, 2003)	Canada- Existing	Canada- Proposed
Technical Advisory Committees on Immunization	Joint Committee on Vaccination and Immunisation Services	ACIP AAP AAFP	ATAGI	NACI	
National Committee on Immunization Programs		NVAC	NCI	Canadian Immunization Committee (fall 2003)	
National Goals and Objectives for Immunization			Yes -closely monitored	Yes  No specific goals yet for all P/Ts	
Centralized vaccine purchase	yes	minimal-	Yes	Current program being reviewed	Proposed- being studied
Coordinated National Media & Communications Strategies	Yes		Yes	some	
Incentives for Physicians	Yes		Yes		
Financial or other Incentives for Parents		some examples (Orenstein & Bernier, 1994)	Yes		
National Immunization Registry	yes (at birth)		Since 1996- Australian Childhood Immunization Register (ACIR)	Being developed	...
Framework for Decision-Making	OVCD- Overview of Communicable Disease tool for priority-setting in communicable disease(PHLS, 1999),  broader framework proposed	Vaccines for the 21 <sup>st</sup> Century Tool (cost-effectiveness rankings) (IOM, 2001)		National and Provincial Frameworks	Proposed National Framework
Other	Chief Medical Officer has chaired a "Communicable Disease Strategy Group" mandated to recommend a national strategy in 2001 (DOH-UK, 1999)				

There is a national advisory committee: the *Joint Committee for Vaccination and Immunisation Services*. The terms of reference are to "advise secretaries of state for Scotland, Wales and Northern Ireland on matters relating to communicable disease, preventable and potentially preventable through immunisation". A project entitled the "Overview of Communicable Diseases (OVCD)" aims to guide rational planning and priority setting in communicable disease control (PHLS, 1999). This project involved using a priority-setting process in which key stakeholders were asked to rank diseases using the following criteria (on a scale of importance from 1 to 5):

- Burden of ill-health
- Social/economic impact
- Potential threat
- Health gain opportunity
- Public concern

Stakeholders were also asked to identify in which areas further work was needed. Work is ongoing and there are plans to create a decision-making framework which integrates other concerns (political, national initiatives, etc.). More study of immunization planning in the UK is warranted.

### ***Australia***

Australia has many impressive initiatives in the area of immunization, including the *Immunise Australia* program, and the *Seven Point Plan*. These initiatives include financial incentives to general practitioners and parents, special immunisation days, and education campaigns (Australian Department of Health, 2003). There is a *National Childhood Immunisation Program*, which includes the provision of free vaccines to all providers. The *Australian Childhood Immunisation Register* has also been established.

The Commonwealth provides funds to States and Territories for the purchase of vaccines. It is the responsibility of State and Territory

governments to implement programs to deliver these vaccines. In specific instances the Commonwealth contributes directly to service delivery costs, such as for hepatitis B vaccine school-based programs. A *National Immunisation Committee (NIC)* exists to provide leadership and take responsibility for policy development, implementation and review of the *National Immunisation Program*. The NIC has representatives from Commonwealth, State, and Territorial health authorities, the Royal Australian College of General Practitioners, Australian Divisions of General Practice and the National Aboriginal Community Controlled Health Organisation. The *Australian Technical Advisory Group on Immunisation (ATAGI)*, provides expert advice on the Immunise Australia Program and works on issues such as the Australian Standard Vaccination Schedule (Australian Department of Health, 2003).

The *Seven Point Plan* was launched in 1997, and initiatives include linking of maternity and childcare benefits to immunization status, incentives for general practitioners for immunization coverage, and release of data on immunization rates from the Australian Childhood Immunisation Register to encourage competition and increased coverage. There is also implementation of communication strategies for immunization service providers and the community, and the establishment of a National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases. School entry requirements have been introduced so that parents must submit details of a child's immunization history. Other initiatives include provision of funds to States and Territories for purchase of DTPa (diphtheria-tetanus-acellular pertussis) vaccine (from 1999), free influenza vaccines for those over 65 (from 1999), universal infant hepatitis B vaccination, including a birth dose of monovalent hepatitis B vaccine (from 2000), \$ 20 million for MMR (measles-mumps-rubella) vaccination for 18-30 year olds (Australian Department of Health, 2003). This initiative is a definite success story from which much can be learned for immunization in Canada.

### ***The United States***

In the United States only an estimated 10% of adult immunization is publicly funded (Fedson, 1994). National bodies make recommendations regarding the use of various vaccines; the Advisory Committee on Immunization Practices (ACIP), the American Association of Pediatrics (AAP), and also the American Association of Family Practitioners (AAFP). They also contribute to the revision of the Childhood Immunization Schedule, which is revised and published every 2-4 years. In 1986, a National Vaccine Program was established with a National Vaccine Advisory Committee. This committee was to concentrate on program policies and strategies in contrast to ACIP which provides primarily technical recommendations. The program and committee are described as follows (Fedson, 1994):

"The National Vaccine Program was established in 1986 by the Public Health Service Act to achieve optimal prevention of infectious disease through immunization and optimal prevention of adverse reactions to vaccines. The program is responsible for coordination and direction of government and non-government activities on research, licensing, production, distribution, and use of vaccines. The director is the assistant secretary for health, with the National Vaccine Advisory Committees serving as advisors. The committee consists of 15 voting members appointed by the director, in consultation with the National Academy of Sciences, including individuals in vaccine research or manufacture, physicians, members of partner organizations, and representatives of health agencies and public health organizations. The committee also includes five nonvoting members from the National Institutes of Health, the Food and Drug Administration, the Centers for Disease Control and Prevention, the Agency for International Development, and the Department of Defence."

A key federal program is the Section 317 immunization program (Public Health Service Act, US Congress, 1970), which provides grants to states and localities for vaccine purchase and activities to improve vaccination coverage. Grants can support immunization infrastructure including outreach, service delivery, surveillance, outbreak control, public education and registry development (Johnson et al., 2000). The program is

administered by the CDC (Centers for Disease Control and Prevention) as part of the National Immunization Program. A recent report (IOM, 2000) stated that "the public health infrastructure that supports the national immunization system is fragile and unstable", citing three trends contributing to this: 1) rapid acceleration in the science of vaccine research and production; 2) increasing complexity of the health care services environment of the United States; 3) recent reductions in federal immunization grants to states.

Several problems within the national system were also identified, such as the need to sustain and document high levels of immunization coverage for a growing number of vaccines delivered within multiple health care settings. Persistent disparities in childhood levels of immunization coverage were also identified, as well as low coverage rates and racial and ethnic disparities for adult vaccines, and serious gaps and inconsistencies in the co-ordination, support, and documentation of immunization efforts. The report reached several conclusions, mentioning in particular that the instability of funding for state immunization programs has created instability and uncertainty, eroding planning and the success of immunization activities. It was also noted that immunization policy needs to be national in scope, but implementation must be flexible enough to respond to special circumstances at the state and local levels. Also, federal and state governments have important roles in supporting vaccine purchase, and also infrastructure efforts that can achieve and sustain national immunization goals.

An analysis of the history of federal immunization policy and funding in the United States has concluded that there is a "history of responding to crises" (Johnson et al., 2000), noting that many recommendations for policy change have only been implemented following the occurrence of crises. The capacity of the federal government to commit resources to improving immunization in the absence of a crisis is questioned. In the 1980s, low

coverage levels were noted in young children, but a lack of consensus among experts on how to improve them coupled with budgetary pressures at various levels of government led to inaction on this issue.

In 1987 a report from the Children's Defense Fund warned that the nation would fail to meet many of the Surgeon General's 1990 objectives for immunization (Johnson K, 1987). In addition to poor coverage levels, increased vaccine prices and complacency were additional problems. Lack of consensus about the nature of the problem, the role of federal financing, and the policies continued into policy discussions into the 1990s (Johnson et al., 2000). However, in 1990 response to the measles epidemic was shaped by a new force in policy analysis, the NVAC (National Vaccine Advisory Committee) took unprecedented leadership, producing a *Measles White Paper* making key recommendations for response to this epidemic. A federal interagency coordinating committee was then formed to outline an implementation plan, and met quarterly for 18 months, creating an action plan with 14 goals and 120 action steps for improving immunization services. This plan received attention from the President and the national media (Johnson et al., 2000). The NVAC also issued a report in 1998 entitled *Strategies to Sustain Success in Childhood Immunization*. Unfortunately, there has been little policy action, perhaps because there is no apparent crisis. For Canada, we should retain the fact that additional funding is usually available in times of crisis, and is facilitated by having a well-defined problem. As in other areas of prevention, proactive measures are desirable but are difficult to implement.

A decision-making framework has also been created in the project Vaccines for the 21<sup>st</sup> Century: A Tool for Decision-making (IOM, 2001). The goal of this report is to consider provide a mechanism for determining priorities for vaccine licensure and research in coming years. The model is essentially based on cost-effectiveness and ranks potential programs in terms of cost-

effectiveness indices into 3 categories: most favorable, favorable, and least favorable. However, it is uncertain to what extent this type of method based primarily on rankings of cost-effectiveness can effectively include important factors in decision-making. Therefore, broader approaches considering contextual factors should be considered.

### ***Examples of Federal/Provincial/Territorial Coordination in the Canadian Health Sector***

Some examples from the health sector follow. A recent publication mentions the importance of intersectorial action in population health in Canada (ACPH, 1999). While there are some positive examples in specific health areas, there is much room for improvement in this area.

### **1999 Auditor General's Report- Observations and Recommendations**

This report (Office of the Auditor General, 1999) mentioned the lack of a structure for federal coordination in public health:

*'14.21 The provinces and territories are responsible for providing many public health services; Health Canada is responsible for protecting Canadians against risks to health and the spread of diseases. However, there is no specific legislation, policy, or agreement that links separate components of public health functions at the various levels of government.*

...

*14.24 While each province and territory has a legislated public health function, at the national level there is no formal public health function established that links the separate components in the provinces and territories. Instead, there is an informal system that relies on personal contacts rather than formal arrangements. As we note later in the chapter, there is a void; current health surveillance activities are largely carried out on an ad hoc basis.'*

The report goes on to discuss the need for this type of coordination for



influenza pandemic preparation- this initiative is an important model for this type of needed collaboration, which could be useful in preparing for improvement in the area of regular immunization.

### **CCOHTA**

The Canadian Coordinating Office of Health Technology Assessment (CCOHTA) has the mandate of conducting and coordinating research on medical technologies and providing useful information to decision-makers regarding these technologies. Their board of directors has individuals representing the Provincial/Territorial Deputy Ministers and meets twice a year to determine priorities. The Canadian Health Technology Assessment Network regroups CCOHTA and provincial organizations, which also meet periodically and exchange information (i.e. ongoing research projects). The objective of CHTA Network is to develop and maintain a systematic, effective and efficient programme of government-funded health technology assessment in Canada. Following the Romanow Report, funding of approximately \$ 45 million has been proposed for national coordination of health technology assessment by CCOHTA. Some of these resources may be available for evaluation of vaccines of national interest, but this remains to be determined.

### ***National Transplantation Council***

One interesting example of F/P/T coordination in the area of health is the current initiative in organ transplantation, entitled *Principles for a coordinated, comprehensive and integrated donation and transplantation strategy for Canada*, which includes many initiatives to improve F/P/T coordination in this area and can provide some potential paths of action in the area of immunization (Health Canada, 1999). This includes a national goal,

and a co-ordinated, comprehensive strategy, directed by a Council appointed by the Federal, Provincial and Territorial Governments with a regular reporting link to Ministers of Health through the Advisory Committee on Health Services. The Council should have an ongoing Secretariat to support Health Ministries and services providers to create and maintain components of the strategy, and should be funded by Health Canada. This initiative should be studied in more detail to examine the pertinence of this model for a National Immunization Strategy.

### ***Canadian Blood Services***

Following careful consideration, Federal, Provincial and Territorial Health Ministers (with the exception of Québec) decided to create a new national blood authority, Canadian Blood Services (CBS, 2000). This was consistent with the conclusions of the Krever report, which called for a single integrated entity responsible and accountable for Canada's blood supply (the Province of Québec created their own entity for this purpose, *Héma-Québec*). On September 10, 1996, some key guiding principles were articulated, including the pursuit of national self-sufficiency, adequacy and security of supply, safety of all blood components and fractions, achievement of a cost-effective, cost-efficient program, and maintenance of a national blood program. It was agreed that this new authority should operate at arms length from all governments and that it would be responsible for managing all aspects of an accountable and fully integrated blood supply system. The shareholders of CBS are the Provincial and Territorial Health Ministers, and appoint the board of directors, which is composed of representatives from different regions, the general public, and those providing medical, scientific, technical, business and public health expertise. Overall, the management structure for CBS is said to 'balance the need for ministerial/territorial responsibility and accountability for spending public monies and for setting health policy objectives' (CBS, 2000).

***Hepatitis C Initiatives***

These include the creation of a Hepatitis C Division of the Centre for Infectious Disease Prevention and Control of Health Canada, which administers a \$50 million Hepatitis C prevention, support and research program, will manage a transfer of over \$300 million over 20 years to the provinces, and will also administrate \$25-50 million to cover half of the cost of provincial/territorial hepatitis C tracing initiatives (Health Canada, 1998a).

***Social Union Framework***

This agreement was ratified on February 4, 1999, and includes respecting the 5 underlying principles of Canadian Medicare. Within 3 years, governments have committed to eliminating "any residency based policies or practices which constrain access to post-secondary education, training, health and social services" unless they can "be demonstrated to be reasonable and consistent with the principles of the Social Union Framework" (Government of Canada, 1999).

There is also a commitment to joint planning and collaboration when this will result in more effective and efficient service to Canadians, including as appropriate joint development of objectives and principles, clarification of roles and responsibilities, and flexible implementation to respect diverse needs and circumstances, complement existing measures and avoid duplication. The federal government is committed to working collaboratively with all provincial and territorial governments to identify Canada-wide priorities and objectives, and not to introduce such measures without the agreement of a majority of provincial governments. The existence of this agreement represents an opportunity to get immunization on the national political agenda and increase financial support for planning and implementation of immunization programs.

Following the Romanow Report and the report on the SARS crisis (National Committee on SARS and Public Health, 2003), there is increased interest in collaboration between jurisdictions in the area of public health. More recently, a Council of the Federation has been proposed as a mechanism for collaboration between provinces, which could provide new links and modes of exchange between Canadian jurisdictions. This resulted in the signing of a formal agreement between the leaders of the 13 Canadian provinces and territories on December 5<sup>th</sup>, 2003. This council is scheduled to meet twice yearly and to focus on issues of interprovincial-territorial cooperation in areas of common interest, having health care as a priority (Dougherty, 2003).

### ***Canadian Initiatives- Coordination in the Area of Immunization***

At the National Consensus Conference on Varicella in 1999, a recommendation expressed the need for development of a mechanism to prioritize and introduce new vaccines with a view to harmonizing programs across the country (LCDC, 1999). A recommendation that Health Canada act as a clearing house for information, providing each province and territory with a critique of current literature on cost-effectiveness to assist provincial and territorial decision-makers was expressed at a previous consensus conference on the pneumococcal polysaccharide vaccine in 1998 (LCDC, 1998). The National Advisory Committee on Immunization (NACI) stressed the conclusion reached at the National Immunization Conference in December 1996 regarding the need to raise the national profile of immunization as a useful population health strategy, and passed a formal resolution emphasizing the following points:

“ Immunization against infectious disease is amongst the oldest, most important and most effective public health measures for primary prevention in Canada. The success of immunization in reducing disease transmission and incidence, in reducing short and long term health costs and extending health life have been well documented. Provinces and territories have been actively engaged in immunization for decades and continue to refine, modify and expand programs, as one of the primary public health priorities, because of its demonstrated success.

While immunization policy and program implementation are the primary responsibility of provinces and territories, infectious disease control needs a more coordinated, interjurisdictional approach than non-transmissible disease. It is therefore essential that there be national recommendations, guidelines, coordination and leadership for immunization programs and practices in Canada. Health Canada has an integral role to play in ensuring that this national effort occurs. The role includes but is not limited to surveillance and must also include:

- regulatory activities to ensure vaccine efficacy and safety (licensure)
- consensus development
- facilitating national goal development
- national advisory committee support
- targeted research on vaccine efficacy, cost-utility and safety
- monitoring of vaccine program impact
- general and specific support to provincial and territorial immunization programs
- leadership in issues of national concern

It is only through partnership and participation of all levels of government that Canadians will achieve optimum benefit from immunization.” (NACI, 1996).

These examples indicate the expressed need for improved national coordination in the area of immunization in Canada, as expressed publicly in many different forums. This has also been confirmed in many recent publications (Embree, 2002, Naus & Scheifele, 2003, Sibbald, 2003).

### ***Global Initiatives- Coordination in the Area of Immunization***

In a 1997 report entitled *National Program on Immunization to Support Provincial and Territorial Immunization Programs* (Spika & Duclos, 1997), the authors cite these examples of global initiatives from the World Health Organization (WHO), and the Pan-American Health Organization (PAHO). Canada is a member of the WHO, which has recommended that there be a national authority in each vaccine producing country to license vaccines, evaluate clinical performance and monitor performance via post-market surveillance, control and release each batch or lot of vaccine individually (for risk management and quality control purposes), perform laboratory testing, and inspect manufacturing facilities and processes regularly.

Canada is also a member of the PAHO Technical Advisory Group on Vaccine-Preventable Diseases, which recommended in 1997 that national governments maintain capabilities to effectively monitor the implementation of immunization programs at the state and local level and to take corrective actions wherever warranted. This recommendation reflects PAHO's recognition of the importance of a national perspective in the planning, implementation and ongoing monitoring of immunization programs, especially in countries such as Canada where responsibility for immunization programs is vested in provincial/state-level authorities (Spika & Duclos, 1997).

### ***Use of Research for Policy-Making in the area of Immunization***

With rapid development of numerous new vaccines, this area represents a challenge for policy decisions. Long-term benefits and costs of a particular program have to be estimated, in addition to the relative benefits and costs of different vaccination strategies within a program, of different immunization programs targeting different diseases. This situation has increased interest

in, and use of cost-effectiveness analysis (CEA) to support decision-making. In Canada, economic evaluation studies have been commissioned for all recent candidate immunization programs such as varicella (Getsios, 2002) and measles second dose programs (Magna P, 1997), pneumococcal conjugate vaccine (De Wals et al, in press), and meningococcal conjugate vaccine (De Wals, et al., in progress) with varied methodologies and impacts (King & DeWals, 1999). In the United States, this has led to the *Vaccines for the 21<sup>st</sup> Century* Project of the American Institute of Medicine, which strives to improve decision making for development of new vaccines with a standard cost-effectiveness model which can be applied to all vaccines (IOM, 2000). Perhaps the most innovative aspect of this project is the inclusion of Excel spreadsheets to allow interaction and modification of various parameters for a candidate vaccine by decision-makers. The pertinence of this type of approach should be examined for decision-making in Canada. However, a strict cost-effectiveness approach is limited in that it often does not take important social and political factors into account.

***Study on use of evidence in decision-making for immunization-measles second dose programs***

As part of the National Forum on Health, Tranmer and collaborators (1998) conducted a study examining the use of evidence in various health care planning decisions. One of these cases was the decision to implement a program giving a second dose of measles immunization in Canada. In 1995, the Measles Consensus Conference recommended national measles eradication by 2005. However, in this study, results were collected in March 1996 for the 12 Canadian provinces and territories. At that time, three regions still had not implemented the second dose program, despite the national consensus statement (Table III).

Table III: Measles Second Dose Immunization Programs in Canada, 1996

Province or Territory	Routine Second Dose Measles Immunization Program
British Columbia	Yes
Alberta	Yes
Saskatchewan	Yes
Manitoba	Yes
Ontario	Yes
Québec	Yes
Nova Scotia	Possible in 1996-97*
New Brunswick	No*
Prince Edward Island	Yes
Newfoundland	Possible, January 1997*
Yukon	Yes
Northwest Territories	Yes

\* at time of study

Source: Kingston, Frontenac, and Lennox and Addington Health Unit, Kingston, Ontario; in: Tranmer et al., 1998)

Despite this, the authors observed that this program was relatively well adopted. However, an obstacle to implementation observed was the weakness of the relationship between available evidence, local planning and implementation of programs. Factors favoring implementation of the program were the quality of data, the existence of a national goal for this disease, and diffusion of this recommended program via a national consensus conference.

Several observations regarding the use of evidence in Canadian jurisdictions were noted in this case. For example, epidemiological data from other countries, especially those having implemented a second dose measles program, were very convincing. However, some regions noted that this evidence did not apply to their local setting as they observed only sporadic cases of measles. In the Northwest Territories, cost-effectiveness of a second dose of this vaccine was easy to estimate, as most of those infected received a medical certificate to permit air transportation to a hospital. In addition, recrudescence of this disease recurred in 6-7 year



cycles. In contrast, in Nova Scotia, disease costs were considered to be minimal as only very few sporadic cases were reported.

The National Consensus Conference on Measles was seen as an important mechanism to reach a consensus regarding this immunization program. The presence of international experts having experience in measles vaccination campaigns was very important, and this conference created dynamism that favored implementation. Evidence regarding content and implementation of the program was diffused by various means (such as newsletters or communiqués) to physicians. Nationally, political orientations had great influence. In provinces, there was a domino effect in which provinces did not want to deviate from the national trend. On the administrative level, little data were available to facilitate planning and implementation of policy including timelines for the second dose programs. Other factors were important, such as communities, responsibilities of physicians, other immunization programs (such as hepatitis B), and other priorities in public health. There were some concerns about relationships between political factors and evidence. For example, an administrator noted that the evidence often did not reach the appropriate provincial authority in a timely manner. It was also observed that when experts make recommendations, they should consider the repercussions on policy and the context in which decisions are made. It was also suggested that research follow a direction indicated by decision-makers according to their priorities instead of bringing new information that obliges them to make changes not necessarily planned in advance.

This study concluded that the best available evidence was considered as essential for decision-making in Canada. However, decision-makers also considered economic, political, and geographical aspects of the evidence. The National Consensus Conference and the existence of national policy for measles allowed each jurisdiction to receive relevant information. A strong

best available evidence. One recommendation of this report was that the federal government and provincial health ministers establish groups or systems that collate, analyze, interpret, diffuse and ensure continuity of documentation relevant to health care. This could facilitate integration of data into complete, accessible databases and therefore improve the availability of information to decision-makers. In addition, it was recommended the integration of evidence into the decision-making process must be the result of an organized planning process including all parties involved. Finally, a quality assurance process should evaluate decisions (Tranmer et al., 1998).

This study confirms observations and information from other sources of the need for improved knowledge management and planning processes for immunization in Canada. In the next sections, we will propose an integrative theoretical framework to apply to the case of immunization, and the bases for such a model in the literature on knowledge transfer, research utilization, the diffusion of innovations, and organizational studies.

## CHAPTER II: LITERATURE REVIEW

### Introduction- Integration of multiple perspectives

The theoretical framework adopted in this intervention and analysis is the model proposed by Kemmis and McTaggart (2000), which integrates different research traditions and different knowledge constitutive interests, and proposes a framework to reach a *reflexive / dialectical* view and integrate these perspectives and connect them to major groups of theories and research approaches. (Figure 2). This aims to avoid many of the polarities that afflict much of social science, such as quality vs. quantity, structure vs. meaning, and macro vs. micro (Astley & Van de Ven, 1983; Silverman, 1993).

**Figure 2: General Relationships Among Different Research Traditions and Different Knowledge-Constitutive Interests (Kemmis & McTaggart, 2000)**

Traditions in the study of practice			Knowledge-constitutive interests		
<i>Perspective:</i>	<i>Focus:</i>	<i>View of practice</i>			
<i>Objective</i>	<i>Individual</i>	(1) Practice as individual behavior	<i>Technical</i>		
	<i>Social</i>	(2) Practice as social behavior – i.e. ritual, system-structured			
<i>Subjective</i>	<i>Individual</i>	(3) Practice as intentional action, shaped by values	<i>Practical</i>		
	<i>Social</i>	(4) Practice as socially-structured, shaped by discourses and tradition			
<i>Reflexive/dialectical view of relationships between subjective-objective and individual-social</i>		(5) Practice as socially, historically, and discursively constituted by human agency and social action	<i>Critical-emancipatory</i>		

The model proposed by Kemmis and McTaggart is a combination of two existing models. One component integrates an existing framework for

classification of sociological theories originally proposed by Burrell and Morgan (1979), which includes a two-dimensional system with subjective/objective and individual/social divisions. A 'reflexive-dialectical' perspective is proposed which integrates the various perspectives within these two poles. Building on Habermas' critique about the lack of connections among different streams of social theory (Habermas, 1987), they integrate his three types of knowledge-constitutive interests which frame and justify the search for knowledge through research, namely technical (instrumental) reason, practical reason, and critical or emancipatory reason (Habermas, 1974; 1972). Kemmis & McTaggart propose an adaptation of the four-category table to relate these different types of approaches to the study of practice to the three types of knowledge-constitutive interests proposed by Habermas. It is also proposed that action research is a method that can integrate various approaches to the study of practice (Kemmis & McTaggart, 2000).

First of all, justifications for this integrative model from the literature on research utilization, and the diffusion of innovations will be considered. In addition, current knowledge transfer theories will be classified and examined in comparison to this model to illustrate their limitations in integrating perspectives to give a comprehensive view of knowledge transfer. This model is based on various similar integrative frameworks in the knowledge management literature that oppose subjective and objective levels and individual and social levels. This will be examined in the section discussing organizational studies and knowledge management literature.

The second element of this framework is the relationship to the three categories of knowledge-constitutive interests proposed by Habermas (1972, 1974), which have seen some limited discussion in the knowledge transfer literature. The three types of knowledge constitutive interests differ

in scope. The technical level is concerned with theoretical efficacy, whereas the practical level is more concerned with real-life decisions or problems in context. The critical-emancipatory perspective is even larger in scope, and questions current social arrangements. Finally, this model will be modified for this project to develop a new integrative theoretical framework in which to consider knowledge transfer initiatives in various perspectives.

These authors consider action research as a way to integrate these perspectives, combining the subjective 'insider' perspective on a given context with the objective external context. While this alternation of perspectives may be a negative factor for certain research methodologists, it is argued that this permits a more encompassing perspective (Meyer, 2001, Wateman et al., 2001). The importance of integration of evidence and context is being increasingly recognized (Dobrow et al., 2004; forthcoming), which also supports the choice of an action research approach for this project.

### **Three knowledge-constitutive interests as proposed by Habermas**

Three different kinds of knowledge interests were expressed by Habermas (1974, 1972): *instrumental* or *technical* reason, *practical* reason, and *critical* reason. Various adaptations of these three types have been mentioned in recent knowledge management (Schultze, 1999; Varey et al., 2003; Ulrich, 2001) and qualitative literature (Burton et al., 1998; Kemmis & McTaggart, 2000).

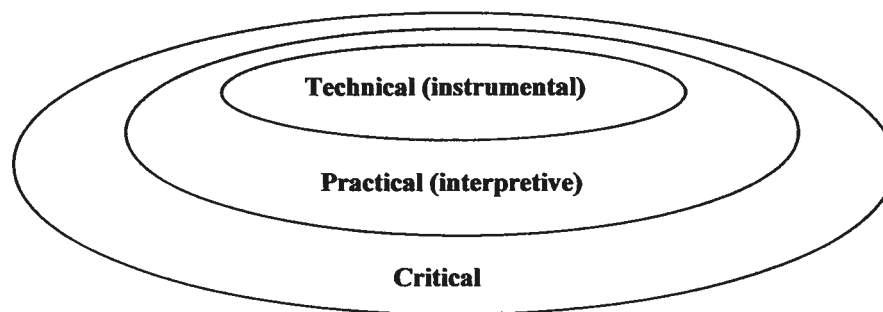
*Technical* reason dates back to the Greek philosopher Aristotle, and is concerned with improving efficiency, and is close to an objective or physical science perspective in its approach.

*Practical* reason is more concerned with the application of science to reality, and admits the contribution of various conditions in the context of actors. This can consider complex situations and conflicting values, or simply day-to-day problems. Actors can be educated to understand the nature and consequences of their actions.

*Critical* reason is claimed to encompass and extend both practical and technical reason. It goes beyond the perspective of the individual actor and considers how a situation is a result of past occurrences and present arrangements, and also questions how the current situation may be changed for improvement.

This categorization has inspired recent literature on knowledge management, mentioning three corresponding categories of objectivist/positivist (technical), interpretivist (practical), and critical approaches (Schultze, 1999; Varey et al., 2003). It has also been proposed that each knowledge category is broader than and inclusive of the previous one (Varey et. al, 2003; Ulrich, 2001, Kemmis & McTaggart, 2000), illustrated in Figure 3.

Figure 3: The relationship between three facets of knowledge proposed by Habermas



Source : Adapted from Varey et al., 2003

This vision of the relationship between these three categories agrees with that presented in Figure 2. This vision is useful in that it can help to more clearly define the scope and potential impact of individual knowledge transfer initiatives according to individual contexts.

### **Knowledge Transfer: the need for an integrative model**

The study of knowledge transfer and the links between theory/research and practice/policy has been especially popular in recent years, experiencing

exponential growth (Dunn & Holzner, 1988). An immense, growing body of literature exists, more than 10 000 publications according to the estimate of Backer (1991). Numerous domains of research contribute to the study of the use of scientific knowledge, such as the study of technology transfer, dissemination and use of information, research utilization, diffusion of innovations, the sociology of knowledge, organizational change, research on policy-making and interpersonal and mass communications studies (Roy et al., 1995).

The spheres of research and policy-making are often described as 'two solitudes'. Indeed, while evidence is important, it is but one factor in the very complex process of decision-making (Woodward et al., 1997). Consider also that there are many types of knowledge such as tacit and explicit knowledge, which add to the complexity of this field (Nonaka, 1994). In recent years, more attention has been paid to the context of application of certain types of research. There has been a growth of research outside of the traditional objective science domain, and a shift towards interdisciplinary research. Knowledge production that is policy-oriented is interdisciplinary, referred to as 'domain-based' (Trist, 1972) or as 'Mode 2' knowledge (Gibbons et al., 1994). This change in perspective has been accompanied by an increasing interest in the process of research utilization and knowledge transfer and underlying associated theories. In addition, the original tendency to consider optimizing diffusion has evolved into a more complete, context-sensitive perspective (Dobrow et al., 2004; forthcoming), of 'contextualizing knowledge' (Denis et al., 2003). This evolution and the need for more integrative models is logical if we consider the complexities of research utilization and the diffusion of innovations as presented in the literature.

Originally, the conception of research utilization perhaps did not adequately address the complexities of utilization in a given context. This lead to assertions in the literature such as '*Research is not used as a can opener is*

*used.*' (Huberman, 1987), referring to the complexity of research utilization. Indeed, the term 'utilization' of information is not clear, and can mean many things in reality, depending on the context, the type of information and many other factors Machlup (1993). We can also divide the research utilization process into major stages, such as *introduction*, *interpretation* and *application* (Oh, 1996; Rich 1997), or *reception*, *cognition*, *reference*, *effort*, *adoption*, *implementation*, and *impact* (Knott & Wildavsky (1980). In reality, there is a spectrum of possibilities of increasing utilization between simply 'getting information' and actually using it in a meaningful manner. An example of this is presented in Figure 4.

Figure 4: Degrees of 'Utilization' of Research

<i>Progressive levels of research 'Utilization'</i>	<i>Example of stages of utilization</i>
Receiving information...	<i>introduction</i>
... and reading information ...	
... and understanding information...	<i>interpretation</i>
...and appreciating information ...	
...and using information in a decision...	
... and using information in a decision that follows from the information	<i>application</i>

Adapted from Machlup, 1993; Oh, 1996; Rich, 1997

Therefore, there are many degrees of 'use' of research, which involve both subjective and objective and individual and social concerns. We must also consider that there are many types of use of research (Astley & Zammuto, 1992; Dunn et al., 1997; Lavis et al., 2002; Weiss, 1998). For example, use can be *instrumental* in that it is directly used in policy formulation. Research can also be used *conceptually* as a form of enlightenment or deepening of



understanding. *Symbolic* or *tactical* use can occur when research is used to support an existing position or decision. There are many components which must be considered when analyzing research transfer process (Lavis et al., 2003; NCDDR, 1996). For example, the *content* or *message* is important, as well as the *users* (*target audience*), the *source of information* (*messenger*), and the *medium* of dissemination. Again, uniquely subjective / objective or individual / social perspectives do not fully address these various types of research utilization.

We can also consider the stream of research that studies patterns of diffusion and adoption of innovations, as there are many parallels with knowledge transfer. One definition of an innovation is '*the elaboration, acceptance, and implementation of new ideas, processes, products and services*' (Thompson, 1965). *Diffusion* is described as the process by which an innovation is communicated over time among the members of a social system (Rogers, 1995). As with research utilization, adoption of innovations was originally simply considered as the straightforward replication of innovations (Nutley et al., 2002). However, innovations may be changed by a user in the process of their adoption or implementation, due to multiple factors (Rogers, 1995). For example, users may lack full knowledge about the innovation, or complex innovations may be simplified. An abstract tool with many possible applications may often be simplified, and changes may also be made so that users may have pride of ownership of their innovation, or so that they can integrate the innovation with their pre-existing tacit and explicit knowledge bases (Rogers, 1995). Like research utilization, innovation is therefore seen as a multistep process, which includes multiple steps such as *awareness, conceptualization, elaboration* of an idea, *evaluation, persuasion, resource acquisition, initiation, testing, adoption, implementation, routinization, confirmation, institutionalization, and continuation*. (Rogers, 1995; Collette & Delisle, 1993; Milo, 1971; Shepard, 1967; Hage & Aiken 1970; Wilson, 1966; Thompson, 1965; Pierce

& Delbecq, 1970, Zaltman et al., 1973). Therefore, the question of whether an innovation has been 'adopted' or not is a complex one, and depends on how exactly this term is defined. Partial adoption, modification, and other influences are possible; therefore one must consider the diverse range of possibilities, which adds to the complexity of analysis in this area. These examples from the literature on research utilization and the adoption of innovations indicate that many different factors are at play when research is used or innovations are adopted. We can also consider the literature that indicates factors that increase impact of research on decision-making.

Empirical research has indicated many factors that can increase the impact of research on decision-making (Beyer & Trice, 1982; Buxton, 1996; Davies et al., 1994; Hanney et al, 2003; Innvaer et al., 2002; Jan, 1998; JRF, 2000; Lavis et al, 2003a; Lyles et al., 1977; NCDDR, 1996; Stamm, 1999; Trostle et al., 1999; Weiss & Bucuvalas 1980; Wood, 1998). These observations included a variety of contextual factors that highlight the incompleteness of models that concentrate solely on the methodological quality of research as a determinant of its impact on decision-making. These observations also indicate the complexity and importance of individual decision-making contexts. Consider some examples of these factors that have been observed to increase the impact of research on decision-making, presented in Table IV.

**Table IV: Examples from the literature of factors which optimize the impact of research on decision-making**

<b>Factors Which Optimize Impact of Research on Decision-Making</b>
➤ Personal contact between researchers and policy-makers
➤ Perception that research is of high quality
➤ Trusted source of info
➤ Timeliness of research
➤ User participation
➤ Relevance to the current policy agenda
➤ Manipulability of data
➤ Expanding the scope of research to include political, social, ethical and legal factors
➤ Commissioning of research reviews to synthesize data
➤ Publication in user-friendly journals
➤ Target the material to needs of audience
➤ Extract the policy and practice implications of research
➤ Combine dissemination methods
➤ Senior management support
➤ Encourage focus on local ideas, practices and attitudes
➤ Clear summaries, actionable messages from a body of research rather than a single study

Sources : Beyer & Trice, 1982; Buxton, 1996; Davies et al., 1994; Hanney et al, 2003; Innvaer et al., 2002; Jan., 1998; JRF, 2000; Lavis et al, 2003a; Lyles et al., 1977; NCDDR,1996; Stamm, 1999; Trostle et al., 1999; Weiss & Bucuvalas 1980; Wood, 1998.

It is interesting to note the wide range of factors observed in the literature, and to consider to what extent these generally context-based observations relate to traditional objective scientific approaches and the various theories of knowledge transfer presented in following sections. Overall they indicate a complex process that depends on many factors in a given situation. This further supports the need for a broad framework that can integrate these various perspectives and account for the whole picture of reality.

### ***Categories of models for knowledge transfer***

Models for knowledge transfer are often divided into three or more categories in recent literature (Denis et al., 2003, Caplan et al., 1975; Fourez, 2002; Habermas, 1973; Wingens, 1990; Weiss 1977; Weiss 1979). The literature consistently refers to two typical approaches to knowledge transfer, the 'push' or knowledge-driven model and the 'pull or problem solving' model. Despite somewhat differing terminologies in the literature, these two models are relatively well-defined and similar in the literature. Many authors refer to a third category of models, often termed as exchange or interactive models (Landry, 1999; Lavis 2003; Denis et al., 2003; Habermas, 1973; Yin & Moore, 1998). These models emphasize the interactions or exchanges between various actors, often researchers and decision-makers. Some authors also mention another type of model: the diffusion or enlightenment model (Landry, 1999; Denis et al., 2003; Champagne 1999; Weiss 1979). Finally, other types of approaches are often mentioned in the literature, such as the strategic, political, tactical, incrementalist and 'garbage can' models (Denis et al., 2003; Champagne 1999; Weiss 1979; Lindblom & Cohen, 1979; Cohen et al, 1972; Janovsky & Cassels, 1996). A comparison of some of these groupings commonly found in the literature is presented in Table V.

Table V: Selected Groupings of knowledge transfer approaches in recent literature

Groupings of knowledge transfer approaches/theories					
Authors	'Push' Model (diffusion* knowledge-specific,...)	'Pull' Model (information-seeking problem-solving...)	Interactive Model (exchange deliberative)	Enlightenment Model (diffusion*, percolation)	Other types
Habermas (1973)	Technocratic	Decisional	Two communities or exchange model		
Lavis (2003b)	Producer-push model	User-pull model	Exchange model		
Yin & Moore, (1998)	Knowledge Production	Problem-solving	Social interaction		
Landry (1999)	'Push'	'Pull'	Interaction	Diffusion	
Denis et al. (2003)	Knowledge-driven	Problem-solving	Deliberative	Enlightenment	Strategic
Champagne (1999); Weiss (1979)	Knowledge-driven	Problem-driven, problem-solving, decision-driven	Interactive	Enlightenment	Political, tactical

\* 'diffusion' is used in the literature to refer to both the 'push' model and the enlightenment model

We will now consider the general characteristics of each of these categories of models, and some other approaches and models that are perhaps not specifically addressed in these categories of models. Denis et al. (2003) presented a useful review of key characteristics of each of the five types of models. Using this review as a starting point, we can combine the five categories named by these and other authors indicated in Table V with some observations from the literature to identify some key points of these grouped categories of knowledge transfer theories.

### **The classical/purist/knowledge-driven 'push' model**

This model corresponds to the traditional positivist approach in science (Denis et al., 2003), and envisions a linear sequence in which research generates knowledge that impels action. This model can also be called the 'push' model or the agricultural extension model. It reflects a rational, linear conception of the process of knowledge utilization. It can be referred to as technocratic in that experts are in the best position to decide, without negotiation and neglecting politics and ethics (Habermas, 1973). The assumption is that good ideas will be implemented by those who are made aware of them (Rogers, 1988). This type of approach is similar to that of 'functionalist' thinkers such as Williamson (1975), which considers that individual rational actors combine to produce rational decision-making in organizations. A model that is similar in its approach to knowledge is the enlightenment model, which places more emphasis on the diffusion of knowledge. However, in recent years, understanding about knowledge use has revealed that this vision neglects many aspects of a process that is extremely, complex, transactional, and dependent on characteristics of intended users (NCDDR, 1996).

### **The information-seeking/ policy-driven/ problem-solving 'pull' model**

In contrast to the knowledge-driven model, which is centered on the researcher, the problem-solving model focuses on the decision-maker (Weiss, 1979; Denis et al., 2003). This can also be termed as a decisional model in which users determine the ends, and experts determine the means (Habermas, 1973). This follows a sequence that begins with the identification of a problem by a customer who requests the researcher to

identify and assess alternative solutions. It is assumed that policy-makers identify problems, then gather and review all data about alternative possible solutions and their consequences, and then select the solution that best matches their goals.

According to this model, knowledge utilization can be increased by improving the ability of decision-makers to frame problems and the ability of scientists to translate knowledge into local and practical applications (Denis et al., 2003). This approach is similar to the evidence-based medicine movement, which strives to improve decision-making by practitioners by training them in methods to analyze and evaluate the quality of evidence in the area of medicine. Evidence-based decision-making can be defined as *'the conscientious, explicit, and judicious use of the best available evidence from health care, management and policy research in the care of individual patients, the management of the health system, and health policy formulation'* (HEALNet, 1998). This definition is a modification of the definition of 'evidence-based medicine' (Sackett et al., 1996; HEALNet, 1998) originally devised for clinical practice. In recent years when examining knowledge transfer processes, researchers have begun to use the term 'receptor capacity' to refer to the decision-makers capacity to receive and process research. Therefore, improvement of problem-solving skills of decision-makers is another potential target for improvement of knowledge transfer and decision-making. Therefore, like the knowledge-driven model, the problem-based model addresses an important aspect of knowledge transfer and decision-making processes, but does not address other important factors in the overall decision-making process in health organizations. The interaction model addresses some of these factors.

### **The /exchange/interactive/social interaction model**

This model considers a set of interactions and negotiations between researchers and users rather than a linear move from research to decisions (Habermas, 1973; Fourez, 2002; Landry et al, 2001). These interactions help expose both groups to each other's worlds and needs, and increased interactions should be sought throughout the knowledge production process (Denis et al., 2003). A decision-relevant culture can be created among researchers, and a research-attuned culture can also be created among decision makers (Lavis et al., 2003; Roos & Shapiro 1999; Huberman, 1994). Such cultural shifts can facilitate long-term use of research in decision-making.

A similar area given much attention in recent years is the study of networks as an organizational form that can promote innovation. While there are many definitions of networks, one example considers a network to be a grouping of individuals, organizations and agencies organized on a non-hierarchical basis around common issues or concerns, which are pursued proactively and systematically, based on commitment and trust. There is often an emphasis on knowledge, usefulness, sharing and innovation (Pedler, 2001). In addition to formal networks, it is important to recognize the existence and importance of informal networks when analyzing the overall processes of knowledge transfer and decision-making. The term 'policy communities' is also used to refer to the powerful, long-term relationships between government officials and interest groups (Rhodes & Marsh, 1992; Kogan & Hanney, 2000; von Walden Laing, 2001). Researcher involvement in 'social networks' is considered important for research utilization (Yin & Gwaltney, 1981), and groups of experts with a similar approach on a given issue can influence policy (Haas, 1992). Development of 'communities of practice' is important, as are opportunities for face-to-face interaction (Nutley 2003; Prusak & Lesser 1999).



### **Enlightenment/percolation/limestone /diffusion model**

Like the knowledge-driven model, the enlightenment model considers knowledge in itself to be valuable (Weiss, 1979; Denis et al., 2003). This model puts the accent on the need for a distribution mechanism for research and considers that it is more likely to be used through the gradual sedimentation of insight, theories, concepts and perspectives. According to the enlightenment model, increasing the diversity and circulation of knowledge in society should improve decision and actions (Denis et al., 2003). This model has the advantage of extending the range of ways in which research is seen to be utilized. This model seems to be a logical extension of the knowledge-driven model, as the 'push' name may imply, in that the process of diffusion of knowledge is simply added to the appreciation of the intrinsic value of knowledge in decision-making and society.

### **Political and Strategic models**

Political models consider that research findings become ammunition in an adversarial system of policy-making (Weiss, 1979). Indeed, it has been observed that as decision-making moves from the individual level to the managerial and policy-making level, the organizational and political factors with which research knowledge must compete to influence the decision-making process become more apparent (Lavis et al., 2003; Black 2001; Walshe & Rundall, 2001). The political negotiation process in decision-making occurs between members with diverging interests. Political models can also be applied to organizational innovations, which can be regarded as internal political processes (Elkin, 1983), which will succeed if support is

received from actors who exercise important controls on the organization (Denis, 1988).

### **Tactical Model**

An extension of the political or strategic model is the tactical model which considers that research can be manipulated to legitimize particular positions or for gain in specific organizations. For example, research can be used when there is pressure for action to be taken on an issue, when policy-makers respond by commissioning a research study on the matter, not to acquire knowledge but rather as a delaying tactic (Weiss, 1979).

### ***Other Models and Approaches***

These major categories of models address different aspects of knowledge transfer, but do not integrate various perspectives. In addition, there are other approaches in the literature which address issues not specifically addressed in these five models of knowledge transfer. We can consider in particular *incrementalist* models, *structural* models, the '*garbage can*' model, *bounded rationality*, *social learning theory*, *cognitive* approaches, *reflexive learning* and *situated knowledge*.

*Incrementalist* models recognize that policy-making is a complex process. It can involve scientific knowledge and a range of other factors including interests, values, established positions within institutions, and personal ambitions. Evidence from research must compete with 'ordinary knowledge' (Lindblom & Cohen, 1979), which involves common sense, causal empiricism, and thoughtful speculation and analysis. In this view, policy-making is not a clear movement towards predetermined goals, but rather a series of small steps in a process of 'muddling through' (Lindblom, 1959). Incrementalists allow for a greater role for interests in policy-making debates

and emphasize the many sources of information that impinge on policy-makers.

*Structural* models focus on organizations, and consider that it is important to be aware of the impact of structural characteristics of an organization (organizational attributes, context, and nature of administrators) on organizational change, and act by adjusting this structure to succeed in implementing a structural change (Mintzberg, 1979). Consider also the *congruence model of organizational behaviour* (Nadler & Tushman, 1997). This model considers how components of an organization exist together in various states of balance and consistency- which can be referred to as 'fit'. The higher the degree of 'fit' (or congruence) among the various components, the more effective the organization. Analysis of knowledge transfer using these models would consider these processes in the larger context and functioning of organizational structures.

The '*garbage can*' model suggests that solutions that might have been discarded may remain in the policy-making system, and occasionally there are problems to which they become attached, highlighting to what extent policy-making is an untidy process which does not in reality have a neatly defined series of phases (Cohen et al, 1972; Janovsky & Cassels, 1996).

*Bounded rationality* is not specifically or clearly addressed in the various theories on knowledge transfer in the previous section, to address practical limits on rationality. Cyert & March (1963) propose the term 'Problemistic Search' in the situation where limitations may cause actions to stem from the immediate problem instead of following a long-term orderly process addressing the overall situation. Similarly, the concept proposed by Simon (1957) of 'bounded rationality' considers decision-making to have a rational element which is bounded by contextual constraints, which limit the range of possible solutions to a given problem. Simon (1957) also made an important

distinction between types of decisions: there are different types of decisions: *programmed decisions* which are made frequently, and have an established procedure, and *non-programmed decisions*, which lacks an established procedure.

Bandura (1977) proposes a *social learning theory* to explain human behaviour, which considers interaction between cognitive, behavioural and environmental factors. Actors are neither totally controlled by the environment nor free individuals capable of acting according to their wishes. Learning occurs by direct experience and by observation of the behavior of others by a process of reflexive thought of observers.

*Cognitive* approaches can be considered as an extension of problem-solving models, which consider the perspective and sense-making processes of individuals. Individual cognitive styles may differ, ranging from analytical (deductive, formal, convergent, rigorous) styles to synthetic (inductive, informal, divergent, creative) styles (Allison & Haynes, 1996). Decision-makers have different knowledge processing structures that may give more importance to existing theories in the interpretation of information or conversely may give more importance to information on the current situation (Walsh, 1995). While cognitive approaches were initially based on psychology of cognition, more recent approaches take a more social approach, considering cognitive aspects in relation to the context of individuals (Farand & Arocha, 2003).

Schön's theories on *reflexive learning* are useful in considering the processes of knowledge development and use (Schön, 1983), and address the issues of expert or tacit knowledge (Nonaka, 1994). It is maintained that in practice, through a process of reflection in action, practitioners cope with uncertainty by reflecting on what they are doing in a unique situation and restructure their understanding as a result. Professional judgement is based

on an interplay of personal, scientific, and experiential knowledge (Schön, 1987). There is an emphasis on application of knowledge in a given context.

A similar approach is that described as '*situated knowledge*'. This approach gives increasing importance to contextualization, arguing that health professionals do not apply abstract knowledge, but collaborate in discussions and engage in work practices that interpret the local validity and value of scientific research. Evidence is a contested domain that is in a constant state of 'becoming', and varies according to the context. Within particular contexts, research is related to '*situated knowledges*', structured local ways of thinking and acting. Implementation involves reconnecting research to practice (Wood et al., 1998).

### ***Evaluation of models and other considerations***

Given the variety of organizational situations and possible perspectives for analysis of research utilization and knowledge transfer, it is evident that each category of models can provide useful, but incomplete pictures of reality. While recent analyses often take a position of exclusion or rejection of certain types of models because of their limitations, this attitude ignores the fact that certain models may be perfectly applicable in certain contexts. Consider for example, the knowledge-driven model, which is also known as the agricultural extension model (Rogers, 1988). This term refers to the diffusion of agricultural innovations in recent decades, in which the technological advances were simply adopted as a result of research. Other examples can surely be found to support all of the other theories, therefore it is more important to try to complete the gaps in existing theories and try to combine them in an integrative approach. Indeed, some efforts have been made to integrate the various approaches in recent literature. To reach a

better understanding of knowledge transfer, it is necessary to go beyond restricted theoretical approaches that address only one aspect of complex realities.

Huberman (1989) considers that as the field of research utilization has grown and differentiated, there is a need for more integrative conceptualization. Huberman presents two dominant models for knowledge utilization, the *instrumental* (imperativist) model, which is similar to objective or rational models and the *constructivist* (transactional, conflict-theoretic) model which considers a more active role of users. This is similar to learning or cognitive models. In their simplest form, instrumental approaches can be referred to as the 'RD & D perspective (Research, Development, Dissemination), however more recent work is more socially interactive in nature (Huberman, 1989). Constructivist approaches consider individual frames of reference and information processing within the user's mind and social setting, taking into account the reconstruction and transformation of data, and also the more political, bargained, or strategic aspects of information use.

Huberman stresses that findings on knowledge utilization in empirical research are accounted for by a blend of both approaches, therefore exclusive use of one approach leaves certain aspects of data unaccounted for and overly simplifies the analysis (Huberman 1989, Huberman 1987). He suggests using both models to understand research utilization, 'looking through both eyes', and proposes that the field of research utilization would benefit from integration of both approaches. The type of integration of multiple perspectives proposed by Huberman can be examined by considering the integrative framework proposed by Burrell & Morgan (1979).

### ***The Burrell & Morgan framework for integration of theoretical approaches***

Overall the groups of models of knowledge utilization can be seen to be incomplete, corresponding to certain individual schools of thought. To clarify the underlying assumptions and contradictions in these approaches, it is useful to situate these approaches relative to each other on a more global level. Consider the fourfold schema proposed by Burrell & Morgan (1979) and its various adaptations in recent literature applied to organizational studies; sociological theories, and knowledge management approaches (Figure 5). This framework was developed to classify social theories according to their underlying philosophy of science and theory of society.

Figure 5: Burrell & Morgan schema for sociological theories

<b>Focus</b>	<b>Presuppositions</b>	
	<b><i>Subjectivity</i></b>	<b><i>Objectivity</i></b>
<b><i>Sociology of radical change</i></b>	Radical Humanism	Radical Structuralism
<b><i>Sociology of regulation</i></b>	Interpretivism	Functionalism

Source: Burrell & Morgan (1979)

One set of poles concerns the *objective* approach (which considers that reality is independent of human perception), versus the *subjective* stance (which considers that reality is socially constructed as a result of actors interactions and experience). The other poles oppose the *sociology of*

*regulation* (representing a society which tends toward integration and order), *versus the sociology* of radical change (representing a society where there is conflict, change and coercion).

Much recent work, including the framework suggested by Kemmis & McTaggart (2000), has employed adaptations of this schema to discuss the contradictions in sociological theories (Alexander, 1982; Waters, 1994), organizational studies, (Astley & Van de Ven, 1983), decision-making (Miller, 2000), knowledge transfer (Armistead and Meakins, 2002; Schultze, 1999), or in qualitative and action research (Kemmis & McTaggart, 2000). With the exception of Schultze, these authors all made some modifications to the poles of the original Burrell and Morgan framework. For example, the poles of subjectivity/objectivity were replaced by voluntaristic/deterministic, political/problem-solving, or empowered / imposed. Similarly, the original poles of radical change/ regulation were replaced by notions of individual/social, action/order, or micro/ macro levels. These differences are presented in Table VI.

**Table VI: Modifications of poles in Burrell & Morgan model in subsequent adaptations**

Publication	Correspondence of poles between Burrell & Morgan model and subsequent adaptations			
	Subjective vs. Objective		Radical change vs. Regulation	
Burrell & Morgan, 1979				
Alexander, 1982	Subjectivity Voluntarism	Objectivity Constraint	Action	Order
Astley & Van de Ven, 1983	Voluntaristic	Deterministic	Micro level	Macro level
Waters, 1994	Subjective	Objective	Individualistic	Holistic
Miller, 2000	Political	Problem-solving	Chaos	Order
Armistead & Meakins, 2002	Empowered	Imposed	Individual	Organization
Kemmis & McTaggart, 2000	Subjective	Objective	Individual	Social



The various applications of this model indicate that it highlights real differences in theoretical approaches and that it can be a useful tool in many areas. However, they also suggest some limitations of using simple dichotomies. Similar to making changes in the poles of the models, many of these authors have given different names to the four quadrants of the original model (radical humanism, radical structuralism, interpretivism, and functionalism), but there is little correspondence among them.

The Burrell and Morgan framework has been criticized on many levels (Flynn; 2003). For example, the subjective-objective dichotomy is seen as being too extreme, due to the fact that most individuals adopt positions that are intermediate on this scale. The division of all theories and approaches into four mutually exclusive paradigms makes inclusion and acceptance of all theories impossible; therefore more categories may be needed. These criticisms can be taken into account by going beyond dichotomies (i.e. subjective/objective), for example by adding additional intermediate categories between the poles. An open continuum between poles (rather than separate compartments) can also be used, which allows individual theorists or streams of theories to be situated in specific regions between the various poles (Miller et al., 2000).

Despite its limitations, this framework can situate various debates and contradictions of various approaches. For example, should we consider organizations to be rational, technically constructed systems or rather socially constructed entities reflecting vested interests and the power structure of society (Astley & Van de Ven, 1983)? Are decision-makers rational or subjective individuals and is their behavior guided by goals valued by society or rather by political concerns and the acquisition of power? It seems reasonable that most situations involve a blend of these various opposites, depending on the situation. In this vein, from the perspective of

organizational analysis, a flexible 'contingency model' has been proposed, recognizing that the applicability of each model for the understanding a change varies in terms of the organization in question (Denis & Champagne, 1990).

In the area of knowledge management, research has observed various approaches and classified them using the fourfold framework of Burrell and Morgan. Many different approaches were used, however objective approaches on the level of the individual or the organization (referred to 'prescribed' and 'compliance' approaches) were dominant (Armistead & Meakins, 2002). It is difficult to balance the four approaches in this framework due to key trade-offs between imposed or empowered approaches, focus on the individual or organization, concern with explicit or tacit knowledge, or technological versus 'people solutions' (Armistead & Meakins, 2002). Despite these challenges, an integrative approach is often recommended in recent literature (i.e. Schultze, 1999; Nutley et al., 2003; Hildebrand, 1999). Overall, this illustrates many different representations of two useful poles in social research: the subjective versus the objective and individual versus the system. It is important to consider these aspects as non-exclusive and complementary to develop an appropriate framework for this intervention.

### ***Proposed Adaptation of Integrative Framework***

The incompleteness of knowledge-driven, problem-solving, and other theories and the need to integrate them must be recognized. It is therefore useful to explore potential application of more comprehensive classification systems proposed in the literature to encourage a more complete analysis of this type of intervention. For this particular project, a compromise between Miller's (2000) open graph approach and the four quadrant approach presented by other authors is proposed, which allows for intermediate

categories between the poles of subjective/voluntaristic and objective/deterministic perspectives (Figure 6).

Figure 6: Proposed Revised Analytical Framework for Project

Perspective / conception of actors					
Knowledge- Constitutive Interests	<i>Critical</i>				
	<i>Practical</i>				<i>Integrated reflexive dialectical view</i>
	<i>Technical</i>				
Level of analysis	<b>DETERMINISTIC</b> Imposed Objective Constraint rational	Intermediate - Cognitive, evidence-based, problem-solving approaches	Intermediate - Situated knowledge, Situated cognition, Social learning approaches	<b>VOLUNTARISTIC</b> Empowered Subjective political	
<b>MACRO</b> holistic order coherence					
<b>MESO</b> intermediate					
<b>MICRO</b> Individual Action chaos					

Adapted from Kemmis & McTaggart (2000)

A total of four categories can be identified in this proposed model from the objective to subjective poles: rational /objective, cognitive, situated, and political. We can consider the *rational/objective* category to correspond to objective scientific facts similar to positivist approaches. The *cognitive* category considers the perspective of the individual, their frames of reference, and processing of information. The *situated* perspective is similar to the cognitive perspective but pays even more attention to the use of information and the relation of the user to a particular context. Finally, the *political* model considers the factors of negotiation, power struggles, and

other factors which form a background and influence the overall situation. This model emerged from multiple comparisons of observations with theory during this project.

The category 'MESO' was also added between macro (social ) and micro (individual) categories to allow for intermediate categories between these two poles. While this is only one possible structure and representation, this particular framework is a starting point and should allow different types of approaches and interventions to be positioned more clearly, and the presence and importance of each category in the context of this project to be evaluated. The resulting adaptation results in an expanded 4x3 table.

For analysis of this project, various approaches in knowledge management will first be situated in this classification system. Secondly, results of the project on the development of the analytical framework and related activities will be analyzed and classified using this system. This type of approach should have the benefit of making the nature of a given knowledge management approach more explicit and therefore promoting understanding of similarities and differences between different interventions in knowledge management.

### ***Correspondence between framework and theoretical approaches to research utilization***

As an initial exercise, one can consider the groupings of research utilisation approaches in recent literature and how they can be approximately situated within this system of classification (Figure 7).

**Figure 7: Interpretation of correspondence of Theories of Research Utilization to Classification Framework**

Level of analysis	Perspective / conception of actors			
	<b>DETERMINISTIC Objective</b> Imposed Objective Constraint rational	<b>Intermediate - Cognitive</b> evidence-based, problem-solving approaches	<b>Intermediate - Situated</b> Situated knowledge, Situated cognition, Social learning- approaches	<b>VOLUNTARISTIC Political</b> Empowered Subjective
<b>MACRO</b> holistic, order coherence	<b>Knowledge-driven/ 'push' model</b>			
<b>MESO</b> intermediate	<b>Enlightenment or diffusion model</b>		↖ <b>Interactive Models</b> ↘	<b>Political/ Strategic Models</b> ↑ ↓
<b>MICRO</b> Individualistic Action Chaos		<b>Problem-solving / 'pull' model</b>		

- the traditional knowledge-driven or 'push' model could be placed on the deterministic and macro/holistic ends of the spectrum (Figure 6), due to the fact that it ignores subjective, interactive and other factors.
- The problem-solving model, because of its consideration of a decision-maker who seeks information for resolution of problems, is more action and process oriented, but still considers the decision-maker as being a largely rational being in need of information to make decisions.
- Interactive models due to their consideration of exchange, action, and different 'cultures of groups, can be situated in a central position of the grid. This position can be shifted towards any of the poles if different variants of these theories are considered.
- The enlightenment model could perhaps be placed as an objective approach at a meso level because of its consideration of the process of diffusion of information. This tends towards an action perspective perhaps more than the 'push' model.
- Political and Strategic Models: because of the non-logical nature of interactions in this model, they can be placed at the objective end of the spectrum.

This placing of groups of theories on a classification is necessarily arbitrary,

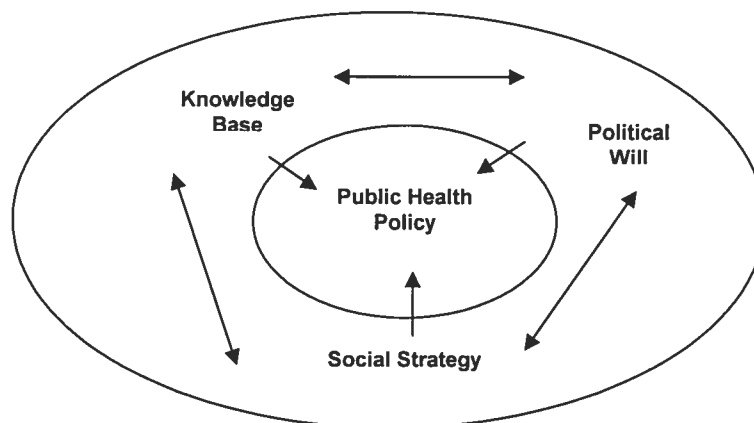
imprecise, and open to debate, especially because these classifications of theories are also imprecise and open to debate. Some variants of these theories may also cover a larger area rather than a given point. Detailed discussion of the exact nature or position of each group of theories is beyond the scope of this thesis. However, an important and useful observation of this simple exercise is that the various theories are dispersed along the spectrum, covering various areas. This indicates the potential usefulness of this type of approach in being able to integrate most approaches, observations, and situations in research utilization and the knowledge management area.

We will consider the results of the project in terms of this classification system to attempt to understand the various elements of the intervention and test the relevance of this type of classification system for interventions in knowledge management. Given that the context of this intervention is in the public health policy sector, specifically in the area of immunization, some theoretical models specific to this area will also be considered in the following sections.

### **The Public Health Policy Context**

When considering decision-making in the context of public health, it is important to recognize the importance of factors other than scientific knowledge from the outset. In addition to evidence, context must be considered, and evidence-based policy-making is seen as a successful balance between these two factors (Dobrow et al., 2004; forthcoming). Another useful representation of various factors which combine in the determination of public health policy is proposed by Richmond and Kotelchuck (1983), who contend that the knowledge base interacts with political will and a larger social strategy to produce public health policy (Figure 8).

Figure 8: The Richmond and Kotelchuck Model for the Development of Public Health Policy



Source: Richmond & Kotelchuck, 1983

Applying this model to the current situation in immunization program planning in Canada produces the following corresponding elements:

- **Knowledge Base:** knowledge on vaccines and potential immunization programs,
- **Social Strategy:** the National Immunization Strategy and various provincial and territorial strategies including immunization,
- **Political will:** openness of politicians in various jurisdictions to funding and support of immunization programs, and the willingness of provinces and territories to engage fully in F/P/T collaboration,
- **Public health policy:** decisions regarding financing, timelines, scope etc. of publicly funded immunization programs in Canada.

This type of systemic vision of public health policy aids to recognize the limits of knowledge in determining public policy. However, it also illustrates that the knowledge base can influence political will and social strategies, which in turn can contribute to the elaboration of public policies. Studies which integrate the mechanisms of interaction of knowledge, political will,

### ***Frameworks for Decision-Making***

Many frameworks exist to assist planning in public health, which go beyond the parameters of disease burden to address factors such as the social context, and economic concerns. These tools vary in complexity and their use. Consider the following two examples:

- a comprehensive framework for technology assessment proposed by BCOHTA (the British Columbia Office of Health Technology Assessment) which includes 5 elements: **population impact, economic concerns, effectiveness evidence, social context, and population at risk** (BCOHTA, 2000).
- the OVCD (Overview of Communicable Diseases) project in the UK, which employs the criteria of **burden of ill-health, social/economic impact, potential threat, health gain opportunity, and public concern**, and also asks users about priorities for further research (PHLS, 1999). (see Appendix for example)

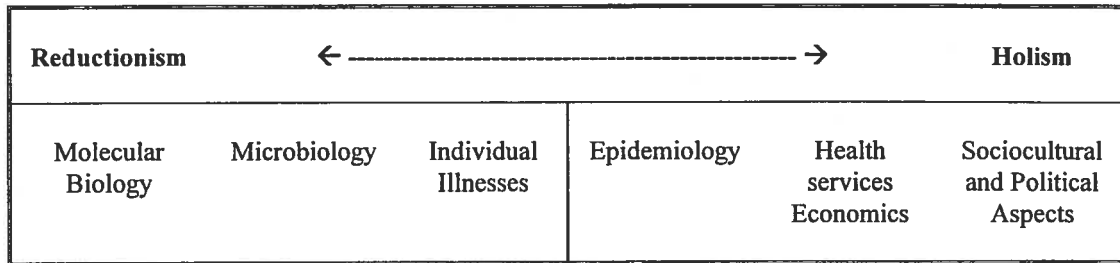
These models are examples of efforts to include all factors from the science to the broader social context in the area of public health. There are also some examples specific to immunization.

### **Models specific to immunization**

When considering immunization programs, there are many factors to consider. Firstly, there are factors that are 'micro' in nature, such as the molecular biology of the disease and the vaccine. At the other end of the scale are factors that are rather 'macro' in nature, such as political and organizational aspects. This is represented in Figure 9.



**Figure 9: Decision-making in Immunization**



Source: Duval, 2000

To be complete, examination of potential immunization programs must address all of these considerations, from the reductionist or micro level to the holistic or macro level. This distinction is important in situating theories and interventions to improve decision-making in the area of immunization as well as in the area of knowledge transfer in general (this will be discussed in following sections of this document).

### ***General Framework for decision-making in the area of immunization***

Harris (1975) stated that immunization programs should always be based on « profit and loss » analysis, with profit being determined by the degree of risk of the target disease, and loss being determined by the hazard of the immunization itself combined with the failure to protect those who are immunized. More generally, decision-making for a therapeutic intervention aimed at a group has been described as containing the following elements (Jenicek & Cleroux, 1985):

- the **disease or health problem** in question
- the proposed **therapeutic intervention**
- potential **intervention strategies**
- **feasibility** of possible strategies
- **evaluation** of the proposed intervention

This model is a simplified adaptation based on a normative scheme for the planning and evaluation of immunization programs in Canada, devised by White and Mathias (1982). White and Mathias' model has the same five criteria, but is much more detailed, having multiple questions to be addressed within each criterion, and the addition of a sixth: *Proposals for Acquisition for Further Evidence*. This section addresses whether further evidence is needed from the preceding points before making a decision (see Figure 10). Models of this type can be classified as *Multiple Criteria Decision Models* (MCDMs), and have already been implemented in the health care setting, for example for hospital resource allocation decisions (Durand-Zaleski, et al., 1996). At the provincial level, similar multiple-criteria models have also been examined informally in Quebec and British Columbia for vaccination program planning (King & De Wals, 1999). This model will provide a basis for development of the analytical framework in this project and the criteria contained within will be combined with criteria identified from data collection and consultation of key persons in the area of immunization in Canada.

**Figure 10: Framework for Planning and Evaluation of Immunization Programs (White & Mathias, 1982)**

- A. Definition of the Problem**
1. What disease is to be prevented or controlled?
  2. What is the evidence concerning the incidence of infection, disease, and complications by age, sex, and regional distribution ?
  3. What is the quality of that evidence ?
  4. What is the economic and social impact of the disease ?
- B. Assessment of the Immunizing Agent**
1. What are the characteristics of the immunizing agent? (e.g. live attenuated, killed, absorbed/non-absorbed, viral or bacterial product, etc.
  2. What is the evidence of short term and long term efficacy ?
  3. What is the evidence of vaccine safety ? (e.g. in the laboratory, in field trials, under wide-spread use, short term, long term, minor and major reactions, etc.)
- C. Identification of Strategies**
1. What are the alternative objectives ? (Options)
  2. What are the alternative strategies available for meeting alternative objectives ?
  3. What are the alternative target groups ?
  4. What is the evidence concerning the short term and long term effectiveness of alternative strategies ?
  5. What is the quality of that evidence ?
  6. What are the underlying assumptions (e.g. probable life time immunity, probable need for booster immunizations, effect on duration of maternal antibody, etc.)
- D. Assessment of Feasibility of Strategy**
1. How acceptable will the chosen alternative be to the target group, and to the population at large ? What levels of compliance are expected ?
  2. What would be the costs (vaccine and administration) of implementing and maintaining each strategy at various levels of compliance ?
  3. What is the availability of the vaccine, or desired vaccine combinations, in Canada ?
  4. What are the opportunity costs of alternative strategies ?
  5. What are the results of benefit : cost analysis for each strategy, and how rigorous were those analyses ?
  6. Are the resources available ?
- E. Evaluability**
1. Is evaluation an important component of the proposed program ?
  2. What tools are available for monitoring incidence of infection, disease and complications by age, sex, and geographic distribution ?
  3. How reliable are those tools ?
  4. Is baseline data currently available, and, if not, can it be developed ?
  5. If implemented, can a reliable evaluation component be built into the program ?
- F. Proposals for Acquisition for Further Evidence**
- Is further evidence relating to any of the above planning components necessary prior to making a decision?
- |                 |                 |
|-----------------|-----------------|
| A. The Problem  | D. Feasibility  |
| B. The Vaccine  | E. Evaluability |
| C. The Strategy |                 |

## **Combining Theory and Practice via Participative Inquiry Approaches**

What types of research approaches can successfully combine multiple theoretical perspectives in a single project? One proposed stream of research is that of participative inquiry or action research. In contrast to orthodox scientific method, participative inquiry involves working with and for groups as co-researchers (Reason, 1994; Reason & Rowan, 1981). This type of research method, also referred to as 'action research', is more of a style of research than a specific method, and can be traced back to work of Lewin (1951). Most definitions also mention its democratic nature, and its simultaneous contribution to social science and social change (Carr & Kemmis, 1986).

Due to the various definitions and forms of action research that exist, there has been a recent attempt to develop embracing definitions of action research. One such example the following definition proposed by Waterman et al (2001):

"Action research is a period of inquiry, which describes, interprets and explains social situations while executing a change intervention aimed at improvement and involvement. It is problem-focused, context-specific and future-oriented. Action research is a group activity with an explicit critical value basis and is founded on a partnership between action researchers and participants, all of whom are involved in the change process. The participatory process is educative and empowering, involving a dynamic approach in which problem identification, planning, action and evaluation are interlinked. Knowledge may be advanced through reflection and research, and qualitative and quantitative research methods may be employed to collect data. Different types of knowledge may be produced by action research, including practical and propositional. Theory may be generated and refined, and its general application explored through the cycles of the action research process." (Waterman et al., 2001).

This definition does not specify a particular philosophical perspective, in order to encompass the variety of approaches in health care action research.

Action research can be classified according to whether it is more scientific or empowering in nature (Hart & Bond, 1995). These types can also be classified into the three categories proposed by Habermas: *scientific-technical*, *practical-deliberative*, and *critical-emancipatory* action research (McKernan, 1991). The experimental end of the continuum (like Lewin's approach) has the researcher in the role of an external expert who designs the study (Whyte, 1991), and research components generally dominate action, improvement is considered as "socially engineered consensus" (Hart et al., 1996). At the other end of the scale, action components dominate the study, and there is a more pluralistic view of improvement (Rolfe, 1996; Hart et al., 1996). A similar classification has been proposed which mentions technical, practical and critical approaches

Action research is generally reflexive, involving a cycle of development/planning, implementation, reflection, observation and evaluation/planning (Schon, 1983; Waterman et al., 2001). Consider for example *co-operative inquiry*, a type of action research in which small groups of professionals who wish to systematically explore and develop their practice (Reason, 1994; Ebbutt, 1985). This method attempts to break down barriers between practitioner and researcher, allowing contribution to the action that is the subject of the research (Reason, 1988; Rolfe, 1996). Like in action research in general, there are four major phases in collaborative inquiry (Reason, 1994):

- 1) Collaborative determination of study theme
- 2) Application of ideas and procedures in practice
- 3) Immersion and new awareness of practice

It has been suggested that an advantage of this method is that each of these phases builds different kinds of knowledge (respectively: propositional, practical, experiential, and propositional; Heron, 1981).

Research findings from action research have a tendency to be practical and relevant in specific contexts rather than generalizable, but when combined with other types of research methodology can produce more generalizable results (Gibbins, 1993). Other challenges in this method include the increased complexity and workload of combining the traditional research tasks of data collection and analysis with the role of being a change facilitator (Hart et al., 1996). However, the overall goal of unraveling the complex organizational, personal and professional changes required for practice improvement to provide a map to practitioners of processes involved and strategies to achieve desired changes (Titchen & Binnie, 1993) is unquestionably a pertinent, and desirable goal of utmost importance in today's society.

Action research is increasingly being used in health settings (Meyer, 2000) particularly nursing (Rolfe, 1996), and is appropriate for development of solutions to improve practice (Meyer, 2000; Hart & Bond, 1995) and close the theory-practice gap (Webb, 1990), formalizing tacit, expert knowledge (Schon, 1987), and allowing learning which can lead to long term changes (Meyer & Bridges, 1998). In the U.K., there are multiple initiatives such as the NHS Research and Development Strategy, the NHS Center for Reviews and Dissemination, the Centers for Evidence Based Practice which emphasize practitioner-based research approaches such as reflexive action research (Meyer, 2000; Rolfe 1998; Titchen & Binnie, 1993).

### ***Comparing Action Research to Case Study Research***

There is some debate in the literature regarding to what extent these two similar research methodologies are related. There is no standard definition of case study research, however the following definition compiled from various sources highlights some key features of case study research:

*'A case study examines a phenomenon in its natural setting, employing multiple methods of data collection to gather information from one or a few entities (people, groups or organizations). The boundaries of the phenomenon are not clearly evident at the outset of the research and no experimental control or manipulation is used.'*

(Stone, 1978; Benbasat, 1984; Yin, 1984; Bonoma, 1985; Kaplan, 1985; in Benbasat et al., 1987)

The key factor in this definition which differentiates action research from case study research is the fact that no experimental control or manipulation is used. Despite this difference, the research element of action research projects is similar to a case study, and certain aspects of case study design and methodology can be applicable to action research projects. However, some consider that action research may contain 'cases' which may be studied with a case study approach (Davison, 1998), while others consider action research to be a subset of case study research (Benbasat et al., 1987; Galiers, 1991). Despite, these differences in opinion, some differences can be noted between case study research and action research (Table VII).

Table VII: Case Studies Compared to Action Research

<b>Case Studies</b>	<b>Action Research</b>
Researcher is observer	Researcher is active participant
Exploratory, explanatory or descriptive	Prescriptive, intervening
Focus on 'how?' and 'why?'	Additional focus on 'how to?'
May be positivist or interpretivist	Usually interpretivist

Source: Davison, 1998; adapted from De Vreede, 1995

Despite these various differences, action research can often be presented in writing in a case study format (Meyer, 2001), and the case study strategy can support action research in understanding the chain of events, despite the fact that the researcher has been a participant and co-producer of these events. This will be particularly important in the consideration of measures to ensure the validity of this study, in which some criteria specific to case study research will be considered along with general criteria for qualitative research and criteria specific to action research.



## **CHAPTER III: METHODS**

### ***Research Questions***

This project conducted and analyzed the development and implementation of an innovation and a new organizational structure in the area of immunization in Canada, using an action research methodology guided by an integrative analytical framework for knowledge transfer. Firstly, this allowed desired changes to be identified, implemented and tested in this area, which can serve as the basis of further change in the area of immunization in Canada, and eventually guide improvement of coordination and knowledge transfer in other areas of health care. Secondly, this allowed examination of an action research methodology to implement innovations and organizational change. Thirdly, this allowed the development and testing of an integrative framework for knowledge transfer to guide further work in this area. Specifically, the five following questions are central to this thesis:

1. What are the major important criteria in decisions regarding immunization programs in Canada, and how can these be developed into a practical analytical framework to aid knowledge transfer and decision-making in this area across Canada?
2. Using an action research approach, to what extent can this framework be tested and implemented in various contexts, and what is the appreciation of users?
3. What organizational changes are desirable and feasible in the area of immunization program planning in Canada?
4. To what extent is the action research approach successful in implementing changes, integrating various approaches and generating ideas, and to what extent is the approach potentially useful in other initiatives in the area of interjurisdictional coordination and knowledge transfer in health care in Canada?
5. To what extent does the integrative analytical framework based on work by Kemmis & McTaggart and Habermas apply to observed results, and to what extent is this theoretical framework potentially useful in other knowledge transfer initiatives?

The first three questions specific to immunization in Canada will be answered directly by data collected and interventions conducted in the context of this study, however this is not a final answer as implementation of the framework and organizational change are ongoing. The success and future potential of the action research approach in the area of knowledge transfer will be evaluated by examining the results obtained by this method in this intervention. Finally, the integrative framework will be evaluated by examining to what extent the various elements of this framework were present in observed results. Overall, the responses to these questions should be useful in generating practical and theoretical knowledge and guiding future research and intervention in the area of knowledge transfer and interjurisdictional coordination in health care in Canada.

### ***Research strategy- action research***

Overall, this project follows the pattern the form of action research, in which the starting point is the lived experience of people, in which observation, analysis, development of new tools and structures and their experimentation mingle, with the aim to produce knowledge and action directly useful to the group of people and leading to empowerment (Reason, 1994). In the spirit of generative thinking, design and creation of positive changes (De Bono, 1995), action research goes beyond the traditional boundaries of description and theory generation about 'here and now' to consider and realize, potentially, 'what ought to be'. (Waterman et al., 2001).

The intervention chosen for this project was the development of an analytical framework for decision-making and knowledge transfer in the area of immunization program planning in Canada. Considering that the goal is to bridge theory and practice while generating useful research, a balance between sound research and relevant action was sought. An updated

version of the White & Mathias (1982) model for immunization program planning was utilized as a starting point for construction of a multi-criteria framework for systematic evaluation of vaccines for publicly funded vaccination programs. This model was designed specifically for the Canadian context and has a broad perspective, considering not only characteristics of the disease and of the vaccine, but also strategies for intervention, feasibility, and available evidence for decision-making. This model is also has the advantage of having been developed in the Canadian context. Data collection from key persons in immunization in Canada was then collected to identify additional important criteria which were combined to form a prototype framework for testing.

This type of research has been used successfully to operationalize a conceptual framework to improve practice in the area of advanced nursing (Manley, 1997), so therefore seems to be a logical choice for implementation of this framework. More specifically, the project followed the structure of co-operative inquiry, as this method is recommended for use with small groups of professionals (Reason 1994). The use of participatory action research is proposed to enable study of the social world in a more encompassing perspective including subjective and objective elements, on the level of individuals (action) and organizations (structure) (Kemmis & McTaggart, 2000). This intervention represented an exploratory effort to integrate these different perspectives, and to contribute to development of more balanced methods of inquiry and intervention. The three levels of knowledge-constitutive interests proposed by Habermas (1972, 1974)- *technical*, *practical* and *critical* were also examined in this study to see to what extent they were related and also to examine their relationship to one another.

### ***Elements of a case study approach***

This project also has some elements similar to a single case study approach with embedded units of analysis (Yin, 1994). Strictly speaking, action research should not be considered a case study due to the fact that the researcher has some control over observed events (Yin, 1994), however the research component of this action-research project can be considered to be a type of case study. The case examined includes all interventions related to this project from August 1999 to December 2003, starting from, but not limited to the development, introduction, testing and implementation of an analytical framework for program planning in immunization in Canada. A major part of the project/case is the development of an innovation, as expected in the original research proposal. However, after developing the project in collaboration with stakeholders, much of the process involved a larger examination, discussion, questioning and proposed reform of organizational structures and processes in this area. Therefore, the appropriate level of analysis (considering the group dynamics involved and the overall research questions) is the ensemble of activities related to this project (Yin, 1994). The timeframe for analysis is from the beginning of the project in August 1999 to include events for which information was available until writing in December of 2003. Multiple levels of analysis were used, specifically considering interventions on the national and provincial (Québec ) levels. The 12 other provinces and territories can in the long term be considered as other units of analysis, however they did not receive direct intervention as in Québec. The indirect exposure to the project from the federal level was however considered in this analysis.

### ***Selection of context for study and intervention***

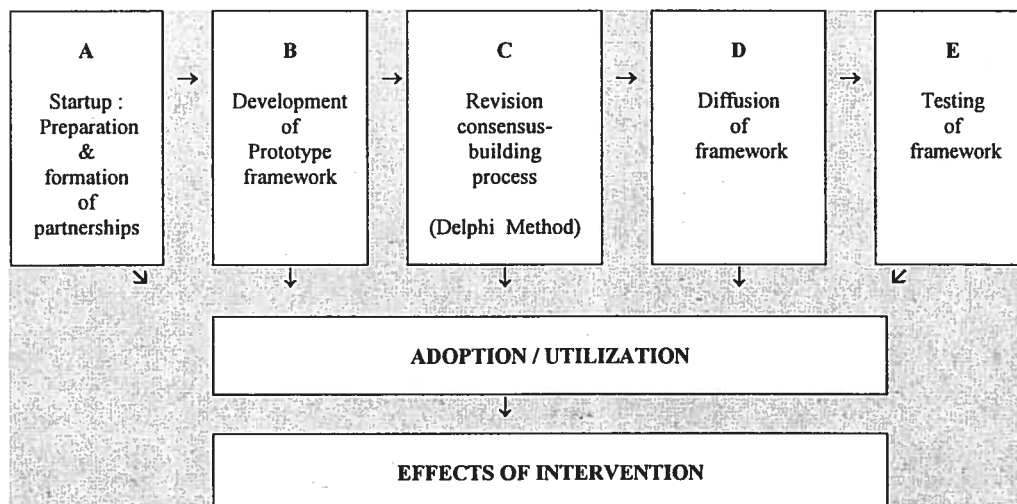
The context of immunization planning in Canada was selected for many reasons. Previous experience in this area as well as contact with key persons in other research projects facilitated identification of current developments and needs in this area. The increasing demand for timely evidence to support policy making and the realization that the current situation is suboptimal were also important in making this an appropriate context of intervention. The possibility to intervene and study on two major levels, in Québec and on the federal level with the limited resources available to conduct this study was also an important factor. The challenges in knowledge transfer and coordination in this area similar to those in other areas of health care in Canada, such as technology assessment. Finally, the choice of intervention for this study was also appropriate and timely as it was chosen for grant support by the NHRDP/CIHR Training Awards Program and also by Health Canada in the development of the National Immunization Strategy.

### ***Model of intervention***

The project model as originally conceived had one cycle of research and action, and involved the following major steps (Figure 11):

- A: Startup, Preparation, and Formation of Partnerships
- B: Development of Prototype Framework
- C: Revision and Consensus-Building Process
- D: Diffusion of Framework
- E: Testing of Framework

Figure 11: Original Model of Intervention



In **Phase A**, an effort would be made to enroll a maximum of stakeholders in this project, in the spirit of encouraging 'sustained interactivity' as mentioned by Huberman (1989) and increasing impact of this project. In the spirit of action research, efforts in this phase changed the nature of the planned project, had some unexpected results in terms of impact on the decision-making context, and ultimately increased the complexity and interactive nature of this project and its impacts.

**Phase B**, which involved the development of the analytical framework, would use identify criteria from multi-criteria decisional models in the area of immunization from the literature (White & Mathias, 1981), expert opinion (De Wals, 1999), and a Canada-wide questionnaire that identified important criteria in decision-making in immunization. All criteria identified would be grouped into one comprehensive list organized around broad categories, which would be submitted to experts for validation.

**Phase C** would involve revision of the developed framework, and a consensus-building process, preferably in face-to-face meetings. The proposed approach was the Delphi method (Adler & Ziglio, 1996; Duffield, 1993; Duffield, 1989; Nadeau, 1988; Sackman, 1975; Weaver, 1971). Experts would express their opinions on the inclusion of each point, followed by feedback of results until reaching a pre-defined level of consensus. This would produce the 'final' framework, which would have a structure and content agreed upon by the group of experts from across Canada.

**Phase D** would involve diffusion of the framework across Canada via key persons, presentations in conferences, and an eventual publication.

**Phase E** would involve testing of the framework with vaccines currently being evaluated, according to the available opportunities.

Because of the action research approach and the formation of partnerships in Phase A, a certain flexibility and iterative approach was expected in the project. For example, after testing of the framework in Phase E, information collected could be used to initiate another revision process followed by diffusion of the revised version of the framework. The flexibility of this approach allowed the project to benefit from opportunities in the context of application, and increased the scope and impact of the intervention, as will be seen in later sections. Overall, the five phases of the research project aimed to contribute to adoption and utilization of the framework and to improve the efficiency and quality of planning decisions regarding immunization planning and ultimately, to increase the effectiveness of immunization programs in Canada.

### ***Data Sources***

The overall strategy was to collect data from multiple sources over the period of the study, with feedback to participants in multiple iterations to validate, update and revise this data. This contributes to the richness and validity of this study (Yin, 1994; Waterman et al., 2001; Silverman, 1993; Contandriopoulos et al., 1990; Janesick, 2000; Miles & Huberman, 1994; Meyer, 2001; Guba & Lincoln, 1989; Lessard-Hébert et al., 1994; Murphy et al., 1998). Data collection occurred from August of 1999 to December of 2003.

### **Federal/National Level**

Multiple sources of data were used in the national component of this project, as presented in Table VIII. The fact that this project was part of a much larger initiative of Health Canada, namely the National Immunization Strategy, had an impact on the data collection process. For example, the data collection was associated with the ongoing consultations between the federal government and the provincial and territorial jurisdictions regarding possible mechanisms to increase collaboration, a very political process.

Table VIII: Data Sources for Project- Federal Level

Data Source	Details
1. List of Chief Medical Officers of Health (CMOH) in 14 Canadian provinces and territories	Obtained from the Immunization Subcommittee, Public Health Used for questionnaire mailout to identify key persons in immunization in each jurisdiction Working Group
2. Questionnaire #1: to CMOHs to identify key persons	Sent by e-mail, follow-up by fax if no response.
3. Questionnaire #2: to key persons identified in Questionnaire #1	Sent by e-mail, follow-up by fax if no response.
4. First Consultation with members of ISC to validate and revise questionnaire results	Preliminary report was circulated before ISC meeting, Nov 2000, discussed at meeting, participants were asked to circulate in their respective jurisdictions for comments and return these comments
5. Written Record of Decisions following ISC meeting	When available- was available for November 2000, meeting
6. Request for additional information on decision-making structures and processes in each jurisdiction	Representatives from each jurisdiction in the ISC were required to comment on the decision-making process as described in their jurisdiction in report
7. Second Consultation with members of ISC to validate and revise questionnaire 1 results	Draft report was circulated before ISC meeting, April 2001, discussed at meeting, participants were asked to circulate in their respective jurisdictions for comments and return these comments
8. Questionnaire #3: Goals and objectives for immunization programs	Sent out by Health Canada to each jurisdiction via representatives of the Immunization Subcommittee,
9. Consultation regarding Goals and Objectives for Immunization	Preliminary report was circulated before ISC meeting, April 2001, discussed at meeting, participants were asked to circulate in their respective jurisdictions for comments and return these comments
10. Worksheet to compare candidate immunization programs- federal level	Utilized in ISC meeting, Feb 2002 to compare expert evaluations of candidate programs. Administered as part of the meeting to test the framework and new national immunization committee
11. Questionnaire #4: follow-up on use of framework	Questionnaire to examine awareness and use of framework in all jurisdictions.
12. General: notes from meetings and telephone conferences	Various informal notes for verbal or otherwise undocumented data.

The elements of the data collection process indicated in Table –5 can now be considered individually (results will be presented in later sections of this report):

- 1) **List of Chief Medical Officers of Health:** Item #1 was simply a list of the Chief Medical Officers of Health from each jurisdiction to identify individuals who would receive the first questionnaire. The names and addresses of the Chief Medical Officers of Health were obtained for Canada's 13 provinces and territories from the Subcommittee on Immunization of the Public Health Working Group.



**2) Questionnaire #1 to identify key persons:** This initial questionnaire (#1) was administered to CMOHs of individual jurisdictions to identify key persons in immunization in their jurisdiction. CMOHs identified in (1) were then contacted by e-mail with a cover letter inviting them to complete a short questionnaire requesting that they identify key persons having an advisory role to their government in decisions regarding publicly funded immunization programs (see Questionnaire #1, Appendix 1). If no response was received within a week, the questionnaire was sent by fax. If no response was received after another week, individuals were contacted by telephone. The list of key persons identified was distributed to members of the Immunization Subcommittee, and certain changes and additions were made in terms of persons to be contacted. The resulting list of key persons in immunization across Canada would be used in the next steps of data collection (Appendix 3)

**3) Questionnaire #2 for key persons in immunization:**

This questionnaire was sent out to the key scientific and public health experts involved in the planning of immunization programs across Canada identified in (2), using the same process for mailout and follow-up of non-responders as in (2). This questionnaire (Appendix 3) collected a wide range of information from key persons on immunization planning in their jurisdiction. Firstly, key persons were asked to identify goals and objectives for immunization programs in their jurisdiction, structures and processes for decision-making in immunization, and whether a framework was used for decision-making in their jurisdiction. They were also asked to identify their general role in immunization program planning, and their specific role in immunization program planning for recent programs (such as measles 2<sup>nd</sup> dose, varicella, pneumococcal polysaccharide programs, pneumococcal conjugate vaccine or other

programs). The names of other key persons in their jurisdiction were also requested. Responders were asked to identify important criteria in recent decisions to identify appropriate criteria for the analytical framework. Finally, key persons were asked what criteria should be included in an analytical framework, what type of framework would be most helpful, what the major needs and problems in immunization program planning were in their jurisdiction, and finally what decision-making structures and processes should be in place to facilitate immunization program planning in Canada. Preliminary results of this questionnaire would be presented in a report and summarized in a presentation to members of the Immunization Subcommittee in November, 2000 for validation and following revision.

4) **First consultation with ISC members to validate questionnaire results:**

This first consultation with members of the ISC was another data source, as the preliminary report was circulated to each jurisdiction for corrections, revisions and comments, and then returned to the researchers for integration in the report. Some comments were given in person at the meeting, and additional comments were sent to the researchers by e-mail or fax.

5) **Written Record of Decisions, November 2000 ISC meeting:**

The written record of decisions document for this meeting simply was a record of details of this meeting (Appendix 14). This type of document was rarely available for meetings conducted during this project.

6) **Additional Data Collection on decision-making structures and processes:**

It was agreed in the ISC meeting that the researchers should contact individuals from each jurisdiction to collect more information on decision-making structures and processes in their jurisdiction. Therefore, the information on each jurisdiction was sent to a

representative from the ISC for each jurisdiction, who either responded personally to add more detail to the information, referred the request to another individual in their jurisdiction, or completed the information in collaboration with colleagues in their jurisdiction. This information was used to add more detail and revise the information on this section (Appendix 4).

7) **Second consultation with ISC members to validate and revise questionnaire results and report:** After completion of the report, the updated version was presented to the ISC in April 2001 for another round of consultations, using the same process as in (4). This allowed further completion, updating and revision of data in the report.

8) **Questionnaire #3 on Goals and Objectives for immunization programs:** At the request of Health Canada, an additional questionnaire was developed to collect detailed information on goals and objectives for all publicly funded immunization programs in Canadian jurisdictions. This questionnaire (Appendix 5) was developed and pre-tested with two experts in immunization. It was sent out by Health Canada to representatives designated by the ISC. Health Canada also ensured follow-up and that all jurisdictions responded.

9) **Consultation with ISC regarding Goals and Objectives Report:**

A preliminary report was circulated to ISC members before the April 2001 meeting, in which a summary of results was presented. As in (3), (4) and (7), this consultation allowed the collection of additional data, and the updating and revision of the report.

10) **Worksheet to compare candidate programs- federal level:**

This worksheet (Appendix 6) was used to structure an activity on evaluation and discussion of potential new programs with the ISC in

present at the meeting after presentations by experts on the three potential programs (meningococcal conjugate, pneumococcal conjugate, and varicella) structured around the 8 categories of the analytical framework. They were asked to indicate a response on a five-level Likert scale as to their appreciation of the desirability of each candidate program. Results of this exercise were summarized and presented to participants the next day of the meeting for discussion. Participants then divided into two breakout groups, and discussed the potential usefulness and applications of the framework, and also recommendations regarding structures and processes for immunization program planning in Canada to submit to the Advisory Committee on Population Health.

- 11) **Questionnaire #4- Follow-up on use of framework:** A follow-up questionnaire was sent out nationally to re-examine knowledge and use of the framework (Appendix 9). The SARS crisis occurred at the same time as the questionnaire, which interfered with data collection. However it was decided to distribute the questionnaire despite this major factor that was expected to reduce the response rate.

12) **General- notes from meetings and telephone conferences**

Finally, several informal notes were used to complete data which was not necessarily noted in written materials from meetings. This could involve the conclusions of discussions, proposals, etc, and served to validate the other formal data collection sources. The variety of notes and informal observation from participation in meetings, telephone conferences which were used are not all summarized in this thesis, and serve to confirm certain details of the various discussions on key issues during this process. They confirm certain events that do not have a written record elsewhere. One example was the proposal to use the framework in a National Consensus Conference on Pertussis held in May 2002 (NACI, 2003). Another example is the reaction of the National

Advisory Committee on Immunization to a presentation on potential uses of the framework in October- 2003. Verbally in this meeting, the members agreed to consider an expanded role for NACI in considering program considerations and working with the new Canadian Immunization Committee (CIC), testing the analytical framework for evaluation of potential new immunization programs. However, this did not imply any official changes in the mandate of NACI (yet), and these comments were expressed in anticipation of results of a meeting of experts to brainstorm options for NACI and the CIC in October 2003, followed by the inaugural meeting of the CIC in November 2003.

The structure of the contract with Health Canada facilitated the verification and validation of data collected in an iterative process which involved submission of preliminary reports, followed by distribution to all members of the ISC representing the 13 Canadian jurisdictions. Multiple face-to-face meetings of the ISC were preceded by distribution of reports. During the meetings, presentations were given to summarize results. ISC members were then invited to in turn circulate the results in their own jurisdictions, and return comments afterwards. This iterative, consensus-building process encouraged input from all jurisdictions and multiple occasions to validate, update, correct and revise data, legitimizing and greatly facilitating the data collection for this project.

Members of the Immunization Subcommittee were also involved in completing and validating additional information on decision-making structures and processes in their jurisdiction for submission in the report submitted in April 2001. In addition, they were responsible for completing or coordinating the responses to the additional questionnaire on goals and objectives for immunization programs for their respective jurisdictions.

## Provincial Level- Quebec

Like the intervention on the federal level, multiple sources and types of information were used during the interventions in the province of Quebec related to this project. While the steps of the intervention were less systematic than in the research contract with Health Canada, similar instruments were used, and in addition, two working group reports have been published, providing concrete examples of adoption of the analytical framework. These various sources are presented in Table IX.

**Table IX: Data Sources for Project- Province of Quebec**

1. Worksheet to compare candidate immunization programs- provincial level- Quebec	Utilized in CIQ meeting, March 2003 to compare expert evaluations of candidate programs Administered as part of the meeting to test the framework for use in the CIQ to all meeting participants. Similar to federal worksheet
2. Follow-up questionnaire to evaluate framework and related activities	Utilized in CIQ meeting, March 2003 to compare expert evaluations of candidate programs
3. Publication: report on meningococcal conjugate vaccine	Framework was used to structure report Published on website of the INSPQ
4. Participation in meetings of Pneumococcal conjugate vaccine working group	Presentation of framework to group followed by discussions of potential use in report.
5. Publication: report on pneumococcal conjugate vaccine	Framework was used to structure report. Published on website of the INSPQ
6. General: notes from meetings and telephone conferences	

### ***(1) Worksheet on vaccine evaluation***

As on the federal level, this sheet involved an pilot exercise to test the framework in March 2003. This instrument had been tested in the federal context, and revised to include 13 instead of 8 categories following comments, and was also translated into French. At the request of the CIQ,

a fourth potential program was added to the activity (acellular pertussis vaccine for adults and adolescents). The worksheet was pre-tested for the adequacy of the translation and readability with an expert (PDW). The worksheet and questionnaire used in the Quebec meeting is presented in Appendix 12 and Appendix 15.

As in the activity in the federal meeting, this unvalidated, subjective instrument was administered primarily an educational activity to demonstrate potential uses of the framework and stimulate discussion among experts. This was followed by a questionnaire, which aimed to evaluate the activity, and guide further uses of this framework with the CIQ and elsewhere.

### ***(2) Follow-up questionnaire on use of framework***

This tool (Appendix 13) was administered to gauge the appreciation of members of the CIQ of the activity with the framework in the meeting and their opinions on potential future uses. Like the activity, this information was collected to allow participants to voice their opinions about the specific activity and about methods for immunization program planning in general in Québec, and therefore have an impact on future uses of the framework.

### ***(3), (4),(5) Publications and participation in vaccine-specific working groups***

The reports published by the INSPQ on the pertinence of immunization programs in Québec using the meningococcal conjugate vaccine (De Wals et al., 2003) the pneumococcal conjugate vaccine (Guay et al., 2003), and the acellular pertussis vaccine (De Serres et al., in press) are important sources of data as they represent a concrete result of use of the framework resulting from multiple presentations to the CIQ and sometimes to individual

working groups to promote use of the framework. The concrete result is seen in the structure of these reports. For the meningococcal and pertussis working groups, approval to use the framework was obtained by proposing this use in general CIQ meetings. For the pneumococcal conjugate vaccine working group, a presentation was given during one of their meetings followed by discussion of use of the framework to structure the report of this working group.

#### ***6. General: notes from telephone conferences and meetings***

Notes from various meetings during this process were used to complete information on pertinent events in the project in Quebec. For example, in November, 2003, a meeting was held at AETMIS to discuss possible partnerships for evaluation of potential hepatitis A and B programs in Quebec between AETMIS, the INSPQ, and the CIQ. It was also proposed to examine the possibility of a national coordinated effort (for example in the economic evaluation of potential programs) with the Canadian Immunization Committee, NACI and Health Canada in 2004.

#### ***Sampling Strategy- Quebec***

The sampling strategy included those present at meetings of the CIQ during the multiple presentations and the activity using the framework. This is an appropriate sample in Quebec as the CIQ is the expert group mandated to examine scientific issues and make policy recommendations related to immunization in this province. The framework was applied to three immunization programs for which working groups made reports: the pneumococcal conjugate vaccine group, the meningococcal conjugate vaccine working group, and the pertussis vaccine working group.



## ***Strategies for Data Collection: Sampling, Validation, Revision and Triangulation of Data***

### ***Federal Level***

Within available time and resources, every effort was made to ensure that data collected was accurate, and that it represented the community of scientific experts across Canada having a role in the policy process for publicly funded immunization programs. The iterative and systematic process in which data was collected, summarized and presented to representatives from all jurisdictions allowed for the accurateness of factual data to be verified, and for data to be updated if necessary. This extensive feedback to stakeholders was a definite strength of data collection in this part of the study. This was a form of triangulation in that data collected from a jurisdiction was presented to ISC members who could then confirm this data in their jurisdiction. This also helped to complete missing data because of non-response or poor response rates. For example, the ISC member from the Yukon was able to provide information on decision-making structures and processes in that jurisdiction following this request at an ISC meeting.

For data collection and identification of key persons, it was deemed appropriate to follow the hierarchy or 'chain of command' in identifying key persons for the questionnaire. This was firstly to increase awareness of the project and involvement by CMOHs of provinces and territories, and secondly to avoid potential problems if experts in a given region participated in the project by completing the questionnaire without the knowledge of the CMOH. This was admittedly subjective and produced a variety of responses according to each region. There is potentially a bias according to the length of time that a CMOH has been in their jurisdiction, with newer CMOHs having less experience perhaps. In the Yukon, the identified CMOH was absent initially, and there was question of a change of staff for this position, therefore, key persons could not be identified for this jurisdiction, causing

therefore, key persons could not be identified for this jurisdiction, causing results for this step to be incomplete.

After key persons were contacted, some regions had a coordinated response, however there were no details on the nature or extent of this coordination. Therefore, we can assume that each jurisdiction used its own method in compiling the responses. Also, in some regions, large groups of individuals on provincial advisory committees on communicable diseases (not necessarily experts in immunization) were contacted, with only few responding, before a coordinated response was given (Alberta and Ontario, for example). When regions had one responder to the questionnaire, it was unclear to what extent responses accurately represented a summary of the responses for that jurisdiction.

Overall, the impacts of the subjectivity of the choices of responders for this questionnaire and the non-response rate are minimized by two factors: Firstly, the multiple opportunities to validate, revise, and update the information in the questionnaire by multiple steps of presentation of the results to the ISC followed by circulation and comments on revisions, which allowed for the information in the questionnaire to be completed, and revised where necessary.

The second factor which minimizes the impact of this potentially biased group of responders is the nature of the data collected. Much of the data was qualitative in nature, and served to explore the diversity of possible responses, such as the section on criteria for decision-making. Other sections asked for factual information on each jurisdiction, which was later verified. Finally, other sections asked for personal opinions on mechanisms to improve immunization program planning. While more responders would provide potentially more diversity of ideas, in general the amount of questionnaires received was adequate in generating a large variety of

considering to what extent they were validated and revised, and also the potential impacts in sampling or other biases. These points will be examined in the discussion section of this report.

Finally, when Questionnaire #4 was to be administered, the SARS crisis was occurring across Canada. This caused public health authorities involved with infectious disease to be very busy with either outbreak management or preventive measures. Despite this problem, the questionnaires were distributed with the hopes of obtaining at least partial responses, considering that the additional, while incomplete, information obtained in this manner would be preferable to no information at all. Taking into account the previous response rates to other questionnaires, contributions by participation the ISC from each jurisdiction, and the success of grouped responses, the individual from each jurisdiction considered as being most likely to be able to respond for was selected each jurisdiction to receive this questionnaire.

### **Meeting Notes, informal observation, participation in meetings, discussions**

The validity of these observations is not a problem if they are interpreted appropriately. This is often limited to the reporting of events, opinions or concerns at a specific meeting or data. This type of informal observation increases the validity of the project by adding additional data sources, enabling triangulation with other data sources, and enabling relevant events to be included which are not necessarily documented elsewhere. Informal events are often important in the political arena, however, much discussion is of a sensitive nature and is not diffused in the public arena. This often leaves the analyst with a 'black box' in terms of processes of decision-making, in which only some of the inputs and outputs are known. An example is the functioning of the ACPH and its submissions to the

Conference of Deputy Ministers, which lead to the approval of \$45 million for the National Immunization Strategy over the next five years. This is a very important decision which had much impact on the establishment of the CIC and the advancement of the project, but no information on how this decision was taken is available for further analysis.

### ***Project in Quebec***

For data collection in Quebec, one major event was the activity using the analytical framework to examine four potential programs. The goal of this activity was to test the framework and to examine methods for the CIQ to arrive at a consensus on the order of introduction of new immunization programs in Quebec in the next few years. Part of this data collection was designed to compare the degree of consensus and divergence among CIQ members regarding various potential programs. However, this data involved evaluation of vaccines according to subjective criteria. Therefore, members could interpret each question differently, which could add artificially to observed variation. However, despite the difference in the amount of time reserved for this activity, and the number of vaccines considered (4 in Quebec versus 3 in the federal meeting), similar response distributions were observed. The importance in biases due to interpretation of questions is reduced by the fact that responses were simply used in an exploratory nature and as a starting point to guide discussion. Should further exercises be desired, with more formal outputs, they should be accompanied by a more formalized process followed by ample time for clarification, revision and discussion both of the tools used derived from the framework and the resulting recommendations regarding priorities for individual immunization programs. Repetition of similar exercises with the framework would enable this process to be further refined and evaluated.

Concerning the follow-up questionnaire, the goal was simply to examine the appreciation of CIQ members for the activity using the framework and to collect their opinions regarding future uses of this tool and other improvements to the process of evaluation and planning of immunization programs in Quebec. A summary of general responses was returned to the CIQ for further discussion, therefore this instrument also served to further discussion and reflection regarding improvement of existing decision-making structures and processes in the CIQ. Potential biases could occur if a single member of the CIQ having a radically different opinion than other members was absent, or if members gave 'politically desirable' responses due to their knowledge that the president of the CIQ was a promoter of use of the framework. Despite these concerns, comments from this questionnaire were combined with comments from other uses of the framework in the CIQ working groups to examine similarities and differences. The reports published to date for meningococcal conjugate vaccine and pneumococcal conjugate vaccine programs in Quebec represent concrete examples of adaptation of the framework (as seen by the sections used to structure these reports), Therefore validity or triangulation are not concerns for these concrete, verifiable events.

This study can be considered to be exploratory in that it aims to examine the process of development and implementation of an innovation, and develop new ways of conceiving knowledge transfer approaches, combining existing theories, and developing new ones. There is also a certain explanatory element in that the contribution of an action-research approach to adoption of an innovation, and the applicability of the integrative model based on the adaptation of work by Burrell & Morgan (1979) and Habermas (1972;1974) by Kemmis & McTaggart (2000) are examined. The model for policy-making in public health proposed by Richmond & Kotelchuck (1983) is also examined in this context.

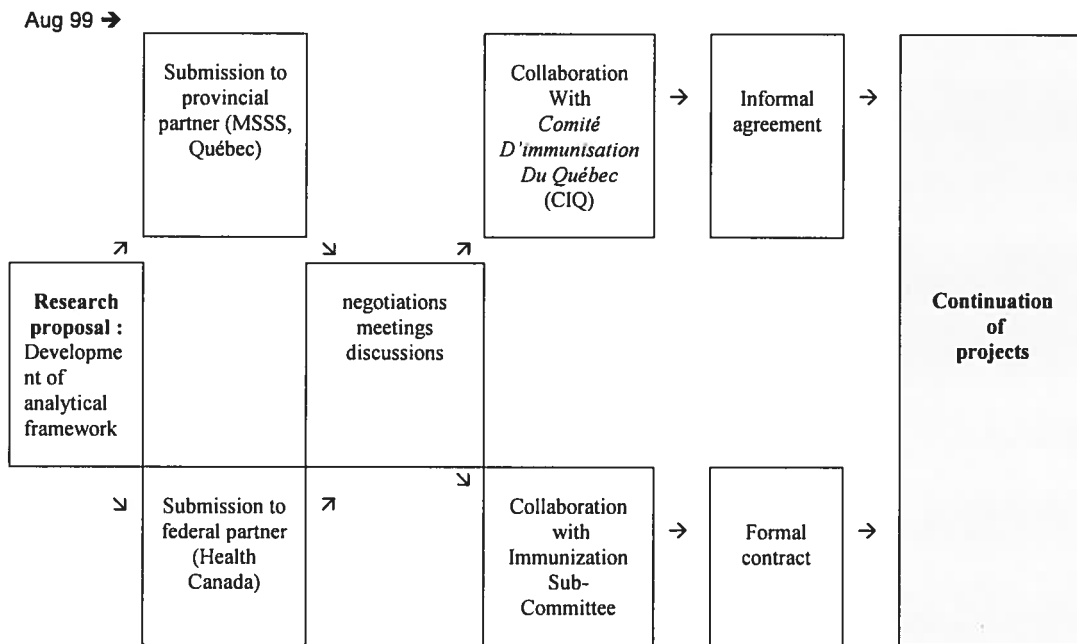
## **CHAPTER IV: ACTUAL INTERVENTION & RESULTS**

In the presentation of the results of this study, we must consider the specific context of action research, which includes not only observation but planning and implementation of concrete changes over the course of a study, in partnership with participants. Some elements of the methods, data collection and intervention can be specified in advance, however they must be modified to respond to constraints and opportunities during the project in a sequence of events which is not known in advance, and is only under partial control of the researcher.

### **Phase A: Preparation and formation of partnerships**

In September, 1999, letters were written to authorities at Health Canada and in the Quebec Ministry of Health to seek partnerships and support for this project. This led to collaborative project with a formal contract on the national level with Health Canada, and an informal agreement to work with the *comité d'immunisation du Québec* on the level of the province of Quebec (Figure 12).

Figure 12: Actual Phase A- Project Startup and Formation of Partnerships



### **Provincial Level- Québec**

In Québec, a letter was addressed to Dr Richard Massé, the Associate Deputy Minister of Health and Social Services to propose the development of an analytical framework for systematic evaluation of vaccines in Québec. A favorable response was received in a letter written in November 1999 which mentioned a possible collaboration with the *Institut national de santé publique du Québec* (INSPQ) and the *Agence d'évaluation des technologies et des modes d'intervention en santé du Québec* (AETMIS). Despite this favorable response, no formal contract or project was established, however several activities were conducted on an ad hoc basis with the *Comité d'immunisation du Québec* (CIQ). This committee was established in 1990 to give scientific advice on the use of vaccines and implementation of immunization programs to the Québec Ministry of Health and health professionals. This committee served as an experimental ground for testing the framework, starting in 1999. Several presentations were given on the framework and the possible prioritization exercises which could be conducted in the CIQ meetings in 2001-2002.

## **Federal Level- Health Canada**

On the federal level, Dr Arlene King, Director of the Division of Immunization of Health Canada was contacted by letter proposing the development of an analytical framework for immunization program planning in Canada. After several telephone conferences, discussions, and meetings, an iterative project was proposed to develop the analytical framework. The proposed project for developing the framework was grouped into the following phases:

**Phase I:** Formation of partnerships with Health Canada and provincial authorities to obtain approval and facilitate the project (already begun). In collaboration with provincial and territorial governmental authorities responsible for immunization program policy, identification of scientific experts having an advisory role in the policy-making process.

**Phase II:** study of the vaccine evaluation process by scientific experts in Canadian provinces & territories to identify criteria important in this process and variation between provinces/territories and individuals.

**Phase III:** Consensus-building process to adapt the important factors identified in part (2) into a prototype framework for Canadian immunization program planning.

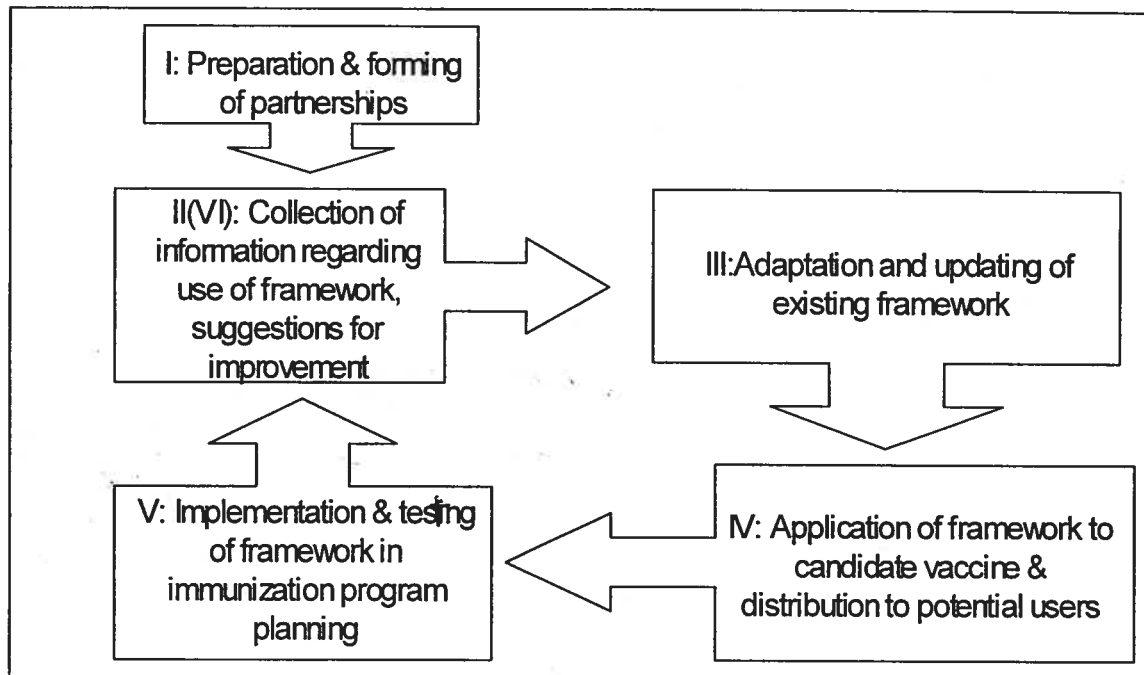
**Phase IV:** Completion of the framework developed in step (3) followed by distribution to potential users in Canadian provinces and territories for use in planning programs for this vaccine.

**Phase V:** Testing of the framework developed in step (3) in a national context. Revision.

These proposed phases, following the structure of action research, are illustrated in Figure 13.



Figure 13: Research Strategy as presented to Health Canada



### ***Specific Research Questions for Contract***

1. Who are the scientific experts who give advice to provincial policy makers in the area of immunization programs?
2. According a sample of identified scientific experts involved in the decision-making process for Canadian immunization programs (at the provincial and territorial levels):
  - a) What were the major events and considerations in the policy-making process for recent immunization programs?
  - b) How do these criteria compare to those presented in the White and Mathias model and what are all of the important criteria identified?
  - c) What is the usefulness of this framework, and in general, what should be done to facilitate evaluation of candidate vaccines for publicly funded immunization programs in Canada? How can the framework be improved and how should it best be used?
3. What is the usefulness of this analytical framework, and to what extent has it been diffused and used across Canada? What is the appreciation of this approach?
4. What lessons can we learn from this exercise about developing and implementing analytical frameworks for decision-making?

***Additional Questions (added to contract):***

In addition, another aspect was added following negotiations with Health Canada and members of the Subcommittee on Immunization. This involved adding study and evaluation of structures and processes for decision-making in immunization in Canada to the project, and would have a major impact on further developments and impact of the project, as will be illustrated in the following sections.

5. What are the formal and informal structures for evaluating vaccines for potential publicly funded vaccination programs in Canadian provinces and territories?
6. What other changes in structures and processes would be feasible and beneficial to improve immunization program planning in Canada?

***Details of Contract with Health Canada***

After several discussions, meetings and telephone conferences, an official contract was agreed upon, with the following objectives:

- a) 'Describe the decision-making structures, processes and frameworks pertaining to publicly funded immunization programs in Canada; and
- b) recommend a prototype framework, structures(s) and process(es) to improve the coordination /harmonization of publicly funded federal/provincial/ territorial immunization programs.

This project was to be conducted in collaboration with the Subcommittee on Immunization of the National Advisory Committee on Population Health, co chaired by Dr. Arlene King of Health Canada, and Dr André Corriveau, Ministry of Health, Northwest Territories. Project deliverables were interim and final research reports as well as presentations at meetings of the National Subcommittee on Immunization of the Public Health Working Group, (which responds to the Advisory Committee on Population Health). , The contract followed the five proposed phases in the project (Table X)

Table X: Phases in Project With Health Canada, (July 2000)

Project Phase	Deliverable	Date
I	Development of Project Outline Description	March 2000
II	Detailed research protocol development 30 page report	April 2000
III	i. interview study participants	September 2000
	ii. prepare 1 <sup>st</sup> draft of report on current frameworks and decision making structures and processes in place in Canada, identification of similarities and differences in these and recommendations	
	iii. submit 1 <sup>st</sup> draft report to co-chairs for comments	October 31, 2000
	iv. Submit 2 <sup>nd</sup> draft report and present to Immunization Sub-Committee (ISC) meeting in Toronto	November 14, 2000
	v. Submit 3 <sup>rd</sup> draft report (which includes input from ISC)	November 24, 2000
IV	i. Distribute 3 <sup>rd</sup> draft report to study participants to obtain input	November 2000
	ii. Prepare 4 <sup>th</sup> draft report which includes input from study participants	December 15, 2000
	iii. Distribute 4 <sup>th</sup> draft report to study participants to obtain views on others comments	December 20, 2000
	iv. Prepare and submit 5 <sup>th</sup> draft report to co-chairs	January 31, 2001
	v. Submit 6 <sup>th</sup> draft (which includes co-chairs and ISC input)	
V	i. Prepare and submit final draft report to co-chairs on testing of prototype framework	March 2001
	ii. Prepare and submit final report to co-chairs	End April 2001
	iii. Presentation to ISC of final report	

This formal contract was important to the success of the project as it gave structure and legitimacy to the project and integrated it into federal efforts related to the development of the National Immunization Strategy. An additional contract was added later to examine goals and objective for immunization in Canada, another of the five components of the National Immunization Strategy (Table XI). This component of the project addresses many of the same issues of structures and processes for national coordination of immunization programs.

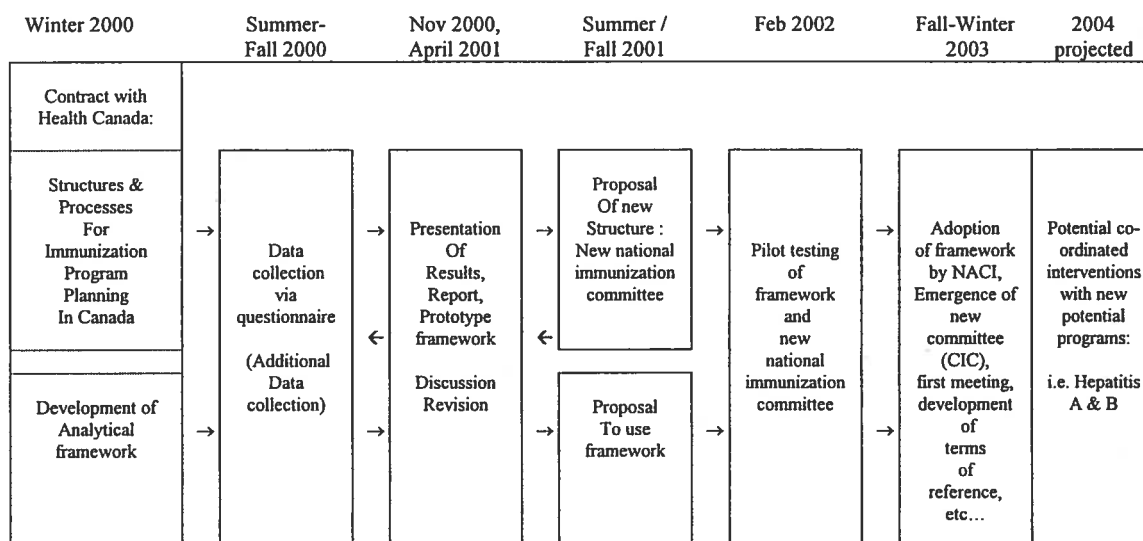
**Table XI: Phases in 2nd contract with Health Canada- Goals and Objectives for Immunization Programs**

Project Phase	Deliverable	Date
I	i. Report of current information on goals and objectives for immunization programs in Canada	September 2001
	ii. Development of a questionnaire on goals and objectives for Canadian provinces and territories	October 2001
II	i. Distribution of questionnaire	
	ii. Analysis of results	
	iii. Submission of report to NIS directors	November 22, 2001
	iv. Revision of report	
	v. Submission of final report	December 2001

### ***Other phases of Actual Intervention- National Level***

Overall, the actual intervention on the national level can be summarized in the following figure (Figure 14).

**Figure 14: Actual Intervention on National Level**



### **Data Collection**

The next phase was conducted with the intention of collecting data on real decisions for publicly funded immunization programs directly from key persons involved in the 13 Canadian jurisdictions. However, after discussion with collaborators at Health Canada from the outset, it was stated in the questionnaire that in addition to the analytical framework, the aim was to create structures and processes to facilitate immunization program planning in Canada, a significant broadening of the goals of the project. Participants were aware that this project was being conducted as part of the development of the National Immunization Strategy. In addition to the sections of the questionnaire designed to collect data for development of the framework, other information was collected on structures and processes for decision-making in each jurisdiction, goals and objectives for immunization programs, needs and problems in immunization program planning, and proposed frameworks, decision-making structures and processes should be in place. This data collection step was identified as the first step of an iterative process, including a consensus-building process.

### **Results**

As described in the section on data sources, key individuals were identified in each jurisdiction by the CMOH of that region in Questionnaire #1. A total of 75 individuals were identified (Table XII). Response rate for this step was 13/14 jurisdictions. In the Yukon, there was originally no response due to the absence of the CMOH, afterwards there seemed to be some uncertainty about a personnel change in this jurisdiction. Therefore no information on scientific experts was obtained for the Yukon. However, participants in the Immunization Subcommittee from the Yukon at a later date would receive the preliminary reports at multiple steps and had an opportunity to complete and validate the data.

**Table XII: Number of Scientific Experts in Immunization identified by Chief Medical Officers in Canadian Jurisdictions**

<b>Jurisdiction</b>	<b># of scientific experts identified by CMOHs</b>	<b>comments</b>
<b>Newfoundland (NF)</b>	8	
<b>Nova Scotia (NS)</b>	2	
<b>New Brunswick (NB)</b>	5	
<b>Prince Edward Island (PEI)</b>	2	
<b>Quebec (QC)</b>	6	
<b>Ontario (ON)</b>	19	The entire Advisory Committee on Communicable Disease was designated
<b>Manitoba (MN)</b>	1	One expert designated to respond to questionnaire
<b>Saskatchewan (SK)</b>	7	
<b>Alberta (AB)</b>	13	
<b>British Columbia (BC)</b>	6	
<b>Yukon (YT)</b>	0	No response due to absence of CMOH
<b>Northwest Territories (NWT)</b>	5	
<b>Nunavut (NV)</b>	1	The CMOH was the only expert identified
<b>TOTAL</b>	<b>75</b>	

It is already evident that there is a large degree of diversity between jurisdictions in terms of the number of scientific experts available to influence policy decisions on publicly funded immunization programs. This diversity was illustrated further in responses to the second questionnaire, addressed to the key persons identified in these jurisdictions. The key individuals identified by CMOHs in Questionnaire #1 were then sent a detailed questionnaire (#2, Appendix 3) to collect data on various aspects of immunization program planning in their jurisdiction. The responses from various jurisdictions are summarized in Table XIII.

Table XIII: Summary of Response Patterns to Questionnaire #2 by Jurisdiction

Jurisdiction	Number originally sent questionnaire	Number responding	Response rate	Coordinated response?	comments
NF	8	4	4/8	No	Mailout included regional CMOHs
NS	4	2	N/a	Some	Questionnaire was directed to 3 experts not mentioned in questionnaire #1.
NB	5	1	N/A	Yes	One person designated to respond for NB
PEI	1	1	N/A	Yes	CMOH responded
QC	6	3	3/6	No	
ON	19	7	N/A	Yes, after mass mailout to ACCD members	After partial response, chair of ACCD gave coordinated response
MN	1	1	N/A	Yes	One person designated to respond for MN
SK	7	2	2/7		
AB	12	1	N/a	Yes	One person designated to respond for AB
BC	6	1	N/a	Yes	One person designated to respond for BC
YT	0	0			No response from CMOH
NWT	5	1	1/5		
NV	1	(1)	N/A		e-mail response from CMOH
Total	75	24 including 6 group responses	10/26 individuals, 8/8 grouped responses per jurisdiction		

A total of 24 questionnaires were received. All provinces and territories except for the Yukon were represented. As the questionnaire was sent out by e-mail to the entire group of experts identified in each jurisdiction, there was some discussion and exchange following the original e-mail between the experts regarding who should respond. Some individuals asked for clarification of the origin and goals of the project before responding. Some provinces clearly designated an individual to combine responses for key persons in their region (Manitoba, New Brunswick, Alberta, British Columbia). Some non-responders commented that they did not feel qualified to respond and therefore would let other experts in their jurisdiction complete the questionnaire. Overall there was awareness of the potentially

political nature of this questionnaire, originating from a project with Health Canada and aiming to promote national coordination, which seemed to be a factor in discussions within jurisdictions regarding who should respond.

Therefore the response rate reflects the decision of several jurisdictions to group their responses. While this left the method of aggregating responses for each jurisdiction beyond control of researchers (and thus subject to variation), it facilitated responses from these jurisdictions. Responses were also partial when questionnaires were sent 'at large' to all key persons or communicable disease committee members identified in a given jurisdiction. There was a certain 'self-selection' in which individuals replied that they did not feel qualified to respond to the questionnaire (or certain sections).

Fortunately, this questionnaire was only the first step in a long iterative process of data collection and consultation which served to validate, update and refine the information collected.

## **Summary of Responses to Questionnaire #2**

The following sections summarize responses to sections of this questionnaire which was administered to key persons in immunization across Canada.

### **1. Goals and objectives for immunization programs in Canada**

The responses indicated that there was much diversity on goals and objectives for immunization programs in the various jurisdictions (Figure 19).



**Figure 15: Examples of Goals and Objectives for Immunization programs in Canada Identified in Questionnaire #1**

**Nova Scotia and Ontario** have detailed goals for immunization. These include many diseases (tetanus, measles, rubella, Hib, diphtheria, ...) and various objectives regarding continuing absence of indigenous diseases, elimination of certain diseases by specific dates, and increase of vaccine coverage in target groups.

In **Ontario**, annual targets have been developed for some vaccines (i.e. influenza).

**Nova Scotia** mentioned that in 1996 these goals were developed for each publicly funded vaccine developed based on national targets.

**New Brunswick:** coverage goals for routine childhood immunizations were 95% coverage at 2 years, 99.5% coverage at school entry, 100% at school leaving. The target value for influenza vaccine uptake is 80% in identified target groups.

**Alberta :** The following targets are mentioned in the Alberta provincial Business Plan. 4. Percentage of 2 year old children who have received the recommended immunizations:

Target (2002): 97% (diphtheria, pertussis, tetanus, haemophilus influenza b, polio)

Target (2002): 98% (measles, mumps, and rubella).

**Saskatchewan:** none in Saskatchewan Immunization Manual. However, immunization group within Public Health Services Project is working on possible goals.

**Newfoundland:** Strategy 5 to provide immunization programs to general public was mentioned, but does not appear to include specific coverage targets.

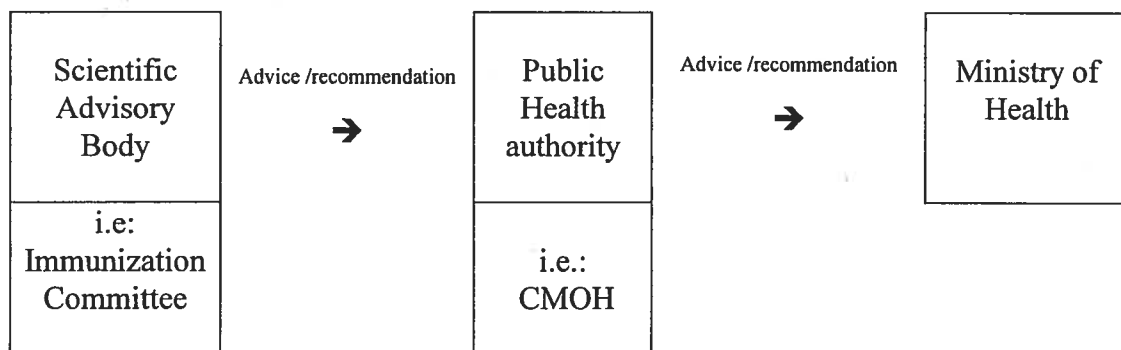
**Québec:** Coverage objectives exist in the *Priorities Nationales de Santé Publique*, and there are specific objectives for certain programs such as hepatitis B vaccination in schools and influenza programs.

While there was some impact of federal goals introduced in 1995, most jurisdictions had few resources to monitor attainment of goals, or to develop new ones. Due to the fact that goals and objectives for immunization programs was one important component of the National Immunization Strategy, this data collection in Questionnaire #2 was followed up by a specific questionnaire on Goals & Objectives (Questionnaire #3, Appendix 5).

## 2. Structures and Processes for Planning of Publicly Funded Immunization Programs

Overall, we can note three major elements in structures and processes for immunization program planning in Canada (Figure 16 ). There is a scientific advisory element, which transfers information to a public health authority. This public health authority advises in turn the Ministry of Health on the potential program.

**Figure 16: Common Overall Structure and Process for Immunization Program Planning in Canadian Jurisdictions**



Despite these common overall elements, there is significant variation in the structures and processes for immunization planning in different Canadian provinces and territories. The degree of formalization of the scientific advisory bodies and the processes by which they advise the public health authorities are quite variable. Some jurisdictions have formal Immunization Committees (such as Quebec), and working groups on specific immunization programs, whereas others have only Communicable Disease Committees, which are responsible for much more than simply immunization. Understandably, certain jurisdictions have much smaller populations and fewer resources and personnel for this planning process. Consider for example Prince Edward Island, where process can be limited to

the Communicable Disease Nurse and the CMOH examining available literature and discussing options to be submitted to the Ministry of Health. The type of advisory given can vary from written reports to simply informal discussions according to the individual jurisdiction. Considering the vast differences in population and resources available to each province and territory, it is not surprising that these structures and processes vary. Some examples are presented in Figure 17.

**Figure 17: Examples of Structures and Processes for Immunization Program Planning in Canadian Jurisdictions from Questionnaire #2**

**Ontario:**

Ministry of health staff receives advice regarding publicly-funded vaccine programs from the Advisory Committee on Communicable Diseases (ACCD), the Canadian pediatric society, NACI, working groups with Ministry. The ACCD has an Immunization Working Group. Sometimes working group or subcommittee is created for a vaccine to make recommendations (i.e regarding target groups), or to plan implementation or evaluation. Recommendations made by the Working Group will be considered in the elaboration of a proposal by ministry staff that considers cost, cost-effectiveness, and implementation issues.

**Québec:**

*Comité d'immunisation du Québec (CIQ)*, (affiliated with the *Institut national de santé publique du Québec (INSPQ)*) committees on specific vaccines (varicella and pneumococcal conjugate vaccines), implementation working groups, *comité de l'acte vaccinal*.

**Saskatchewan:**

Standing Committee on Immunization made up of representatives from Saskatchewan Health, representatives from the Medical Health Officers Council of Saskatchewan and the Nurse Managers Group. Committees for specific vaccines: i.e. pneumococcal vaccine

**Alberta:**

Advisory Committee on Communicable Diseases receives input from the Council of Medical Officers of Health, the Communicable Disease Nurses Working Group, the Pediatric Society and other sources and advises Alberta Health and Wellness.

**NFLD:**

Advisory committee on Infectious diseases, and Medical officers of Health Committee. Regional MOHs meet quarterly and make recommendations in consultation with provincial MOH. In addition to Medical Officers of Health, Communicable Disease Nurses and nursing managers may provide recommendations regarding new programs.

**NS:**

Committee with wide representation. Subcommittee usually formed to provide a discussion paper regarding feasibility of introduction of a new publicly funded vaccine. Paper is then reviewed by provincial CDC committee, and recommended option is submitted to public health working committee for approval. If approved by PHWC, submitted to senior staff in Dept. of Health for approval.

**PEI:**

Chief Health Officer and Communicable Disease public health nurse review available information on particular vaccines and make recommendations.

**NB:**

CMOH and project manager review scientific literature, NACI recommendations, discussions with regional MOH and consultation of infectious disease experts. Proposal to recommend new program is submitted to senior management for consideration and budgetary approval

In recent years there has been a tendency towards more formal and specific committees. For example, in addition to communicable disease committees, many regions have immunization committees and also specific working groups for new potential programs (i.e: varicella, pneumococcal conjugate, influenza). Of note is the fact that these committees in different regions have little contact with each other despite dealing with common issues. The following table summarizes the similarities and differences between regions (Table XIV).

**Table XIV: Summary of Provincial/Territorial Structures and Processes for Immunization Program Planning**

	QC	BC	ON	AB	MN	SK	NS	NF	NWT	PEI	NVT	N B	Y T
informal framework for vaccine evaluation - program planning		✓	✓		✓			✓					
formal framework for vaccine evaluation and program planning	✓					✓	✓						
Infectious/Communicable disease committee	✓	✓ <sup>1</sup>	✓	✓	✓		✓	✓					
Immunization committee	✓	✓	✓	✓	✓	✓		✓	✓				
Working groups for specific vaccines:													
varicella	✓	✓	✓	✓									
pneumococcal conjugate	✓												
influenza (regular program)	✓	✓	✓		✓								

Notes: 1. In BC there is a "Communicable Disease Policy Committee".

More detailed descriptions by province/territory are presented in Appendix 4. This confirms the wide degree of variation in structures and processes for immunization program planning between different Canadian jurisdictions. This also identifies that there is a large degree of duplication between different jurisdictions. For example, four provinces indicated having working groups for varicella. While experts in this area undoubtedly have some informal exchanges, there is no formal forum in which these groups can address the same evaluation questions for a particular vaccine. Coordination of these working groups was seen as desirable, but would require additional resources to support exchanges between these groups or organizational change in the area of immunization in Canada. These concerns were voiced in other sections of the questionnaire and would be important in many following phases of this project.

### **3. Existing frameworks for new publicly funded immunization programs**

Nova Scotia, Saskatchewan, and Ontario mentioned using a type of framework or structured approach for immunization program planning. Nova Scotia and Saskatchewan have a stepwise framework which identifies *prerequisite criteria*, *absolute criteria* (which are both necessary for a publicly funded program) and also *relative criteria* which are desirable but not essential for the program to be approved. This tool is presented in Figure 18.

**Figure 18: Framework for the Introduction of a new publicly funded vaccine use in Nova Scotia and Saskatchewan**

The following framework is developed as a guide to facilitate decision-making for the introduction of a new vaccine in the Publicly Funded Vaccine Program.

This framework has three basic levels of consideration:

1. ***Pre requisites of primary factors***- result of vaccine studies/research that indicate:
  - 1.1. vaccine is licensed by the Health Protection Branch (determined to be safe and effective)
  - 1.2. vaccine is beneficial to the individual
  - 1.3. burden of disease justifies the introduction of the vaccine (mortality and morbidity, incidence/prevalence, cost-benefit analysis)
2. ***Absolute factors***- factors that must be in place within the province in order to consider a vaccine for inclusion in the immunization schedule
  - 2.1 NACI recommends the vaccine
  - 2.2 Equitable and effective ways to deliver the vaccine to over 90% of the intended group are established
  - 2.3 adequate funding is secured
  - 2.4 adequate human resources available to deliver the program
  - 2.5 Regional Health Services were consulted
  - 2.6 resources available to provide education/information to those implementing the program
  - 2.7 the provincial medical society was consulted
  - 2.8 delivery options/models were examined.
3. ***Relative factors***- factors that are 'nice' to have, or considered but not necessary.
  - 3.1 WHO and national goals established
  - 3.2 impact on the current immunization schedule
  - 3.3 political impact of action or inaction (public fear)
  - 3.4 accessibility to 100% of target population
  - 3.5 cost of the vaccine is comparable to other vaccines in the current schedule
  - 3.6 material resources required for the vaccine are similar to those vaccines currently in the schedule
  - 3.7 vaccine may be delivered during one of the regular visits or on the current immunization schedule

**Non Publicly funded vaccines**- these are vaccines that the Department of Health will support but not fund. To support a vaccine, prerequisite factors identified above must be met.

Ontario mentioned having an informal list of about 10 issues for consideration, which is in some ways similar to criteria for considering whether a disease should be made reportable to public health authorities.

(This includes criteria such as disease incidence, mortality and morbidity, preventability by other measures, efficacy and effectiveness of the vaccine, vaccine safety, implementation issues such as cold chain stability, method of administration, public versus private delivery, schedule and its integration into existing immunization schedule, cost-effectiveness compared to other preventive interventions, etc...). Despite the existence of and publication of the White and Mathias framework in 1981, these were the only decision-making or planning frameworks that were identified to be in use in Canada.

#### **4. Identified roles of key persons:**

Responses of key persons indicated a diverse variety of roles in the immunization planning process. This question produced an impressive variety of roles. The following major categories were mentioned:

- educating, communicating and advocacy regarding programs
- scientific advisory role, literature reviews, assessing evidence
- membership in various committees and/ or working groups
- disease monitoring
- monitoring of vaccine adverse events
- monitoring and evaluating implementation
- determination of priorities
- consultation of other provinces

This diversity of roles suggests that many different situations may exist across Canadian jurisdictions. It is also interesting to note that these individuals may be involved in disease monitoring or other related public health activities, which may limit the time and energy available for immunization programs.

#### **5,6. Major factors and criteria used in decisions regarding immunization program planning**

Many criteria from existing frameworks were mentioned, such as burden of

disease, effectiveness of vaccine and vaccine cost. Many additional factors, mostly broader context-related concerns, were also mentioned and proposed for inclusion in the analytical framework such as the following:

- accessibility of target population
- antibiotic resistance
- requirement to be cost-neutral
- whether other provinces provide a vaccine
- if pressure is likely to vaccinate
- international thrusts or targets
- impacts on other sectors (physicians, long term care facilities, occupational settings)
- ease of fit with existing programs
- anticipation of public pressure for vaccine
- public perception of risks of disease
- public perception of risks of vaccine
- cost of vaccine similar to other vaccines on the current schedule
- material resources required for the vaccine similar to those vaccines currently on the schedule
- avoided costs of outbreak control
- human resources

These criteria indicate that many factors beyond the basic scientific evaluation of effectiveness are important in the consideration of immunization programs in Canada, and should be included in an analytical framework which aims to be comprehensive and include all important criteria in actual decisions in this area in Canada.

### **7. Type of framework which would be most helpful in immunization program planning**

This question aimed to collect opinions about the preferred type of analytical framework. Some major comments concerned the need for long-term planning considering all aspects of immunization programs, from monitoring to implementation:



- provincial leadership/ national guidelines
- quick access to registration information /other studies
- involvement of laboratories from the beginning to ensure data standards and integrity, as these data will be used to judge needs for a program and also to assess post vaccine program successes
- capture of scientific evidence, cost benefit analysis
- NACI guidelines
- should reestablish the Advisory Committee on Epidemiology (ACE)
- use of objective/weighted criteria which can be scored, which can allow comparison of an intervention to accepted and already implemented interventions within and outside of the public health sector.
- must address logistics of delivery, timing human resources of vaccine administration which can often fall upon regions without adequate planning for resources
- long range plan considering other potential new programs

It is interesting to note that many responses to this question did not seem to concern specifically the analytical framework, but however addressed broader concerns such as leadership, guidelines, and potential organizational changes in Canada (i.e. reestablishing the Advisory Committee on Epidemiology).

#### **8. What elements should be included in IPP framework?**

This question was added to complement questions 5 and 6 to identify criteria for inclusion in the analytical framework. Some notable responses include the following :

- vaccine effectiveness, efficacy, cost, supply, safety, stability...
- value for money
- prioritization among available vaccines
- acceptability to health care system
- acceptability to parents
- additional resources required to deliver vaccine
- resource impact/ savings
- communications
- documentation required and supported

- information to consumers and providers
- time frame for introduction of new vaccines and what's expected in the next 5-10 years
- appropriate budgeting process for administration of vaccine as well as purchase price
- very thoughtful health economics arguments as new vaccines increasingly prevent morbidity more than mortality

Again, the expected factors of vaccine effectiveness and cost were mentioned. However, a host of broader context-based factors were identified, again confirming the importance that the analytical framework be broad in scope to include these important factors.

### **9. Major needs and problems in immunization program planning:**

This question aimed to explore the broader issues and needs in various jurisdictions. Again, the responses touched a variety of areas:

- lack of personnel and fiscal resources (many responses)
- no specific operating budget for program evaluation and program support, including public information
- concern about anti-vaccination movement
- workload issues : where will staff come from and how will they get paid ?
- how to prioritize vaccines, competition for resources of catch-up programs and new vaccines
- complicated delivery system (particular physicians) with unknown, uncontrollable delivery costs. Delivery by public health could facilitate coldchain management and record-keeping
- lack of a vaccine registry makes it difficult to report on coverage
- lack of financing for resources to vaccinate given the current pressure on the system
- operationalization of programs by regions without proper planning/resources
- impression that we have reached saturation in terms of the number of vaccines which can be given
- lack of harmony in provincial programs
- people who choose not to immunize
- need of funding for varicella vaccine
- streamlined schedules for infants and adolescents

One response referred to information systems, noting the lack of a vaccine registry. Another response mentioned the lack of a method for prioritization of vaccines. The other responses revolved around issues of funding, and practical aspects such as delivery, resources, personnel, public attitudes and the growing number of vaccines in the immunization schedule. As in the other questions, these responses indicate the importance of broader factors in the planning of immunization programs.

#### **10. Frameworks, structures and processes which should be in place in Canada:**

This question aimed to examine ideas of key persons regarding optimal structures and processes for immunization program planning in Canada, and produced many proposals for major changes:

- continue to support NACI
- reestablish ACE (forum for planning and discussion at the provincial epidemiologist level)
- a committee of provincial/territorial staff, perhaps reporting to the PHWG, would be instrumental in developing such frameworks for decision-making and assisting P/T programs in becoming more uniform, which has been a stated goal of a number of supports for many years (i.e. the immunization schedule, immunization registries, etc.)
- consideration of which level of government should provide funding for purchase of vaccines should also be considered, and there may be a role for the federal government in this area.
- the Health Canada Population and Public Health Branch should have funding to support the federal immunization program support initiatives such as coverage surveys among 2-year olds, cold chain surveys, active surveillance for vaccine preventable diseases, and targeted studies required to elucidate policy recommendations related to issues such as appropriate immunization schedules and vaccine immunogenicity.
- criteria for introduction of new programs need to be developed and approved at the minister of health level to facilitate decision-making following vaccine licensure.
- interprovincial committee to review and discuss new vaccines and make recommendations for provincial consideration.

- tactic to convince those with budget authority of the costs/benefits associated with recommended program changes
- standard approach across Canada to avoid inequities between provinces, including standard resource base and standard array of publicly funded vaccines.
- increased resources to accompany increased program activities
- independent scientific analyses (vaccine efficacy, international experience, study of epidemiological impact, modeling, economic evaluation)
- prioritization among available vaccines
- operational feasibility (i.e. frozen varicella vaccine)
- clear implementation and follow-up process
- need for a group to operationalize NACI guidelines
- consensus meetings to standardize immunization programs across Canada
- universal immunization program in Canada, with deviation only for special circumstances (i.e. high-risk communities)
- understanding of epidemiology in certain communities (i.e. First Nations, Inuit)
- consideration of vaccines by conference of deputy ministers. Their awareness of the importance of the vaccine will facilitate funding for introduction at the provincial level.
- F/P/T decision-making process to facilitate standardized decision-making process across the provinces. Some agreement probably required at the DM or ministerial level.
- NACI needs to be more than a yes/no body to support whether a vaccine is indicated or not. Considerations mentioned in consensus conferences such as program costs, population impact and delivery problems need to be incorporated into decision-making.

These responses indicate a desire for increased federal funding of vaccines, and support development of national committees to help evaluate and make recommendations on potential programs. Broadening the role of NACI was also mentioned. The development of standard approaches for evaluation of programs and more standardized programs was also seen as important. Overall, the responses indicate that there is much interest and support for change.

Globally, these responses indicate many factors that are important other than the basic science and costs of vaccines. A very clear pattern in the responses is also the desire for more federal support in this area, with increased coordination and funding, perhaps including a universal immunization program in Canada. This proposed change is major in that it would change the freedom of the provinces and territories with regard to their health care system and spending. However, smaller provinces and territories often were more enthusiastic in supporting this increased federal role than the largest provinces.

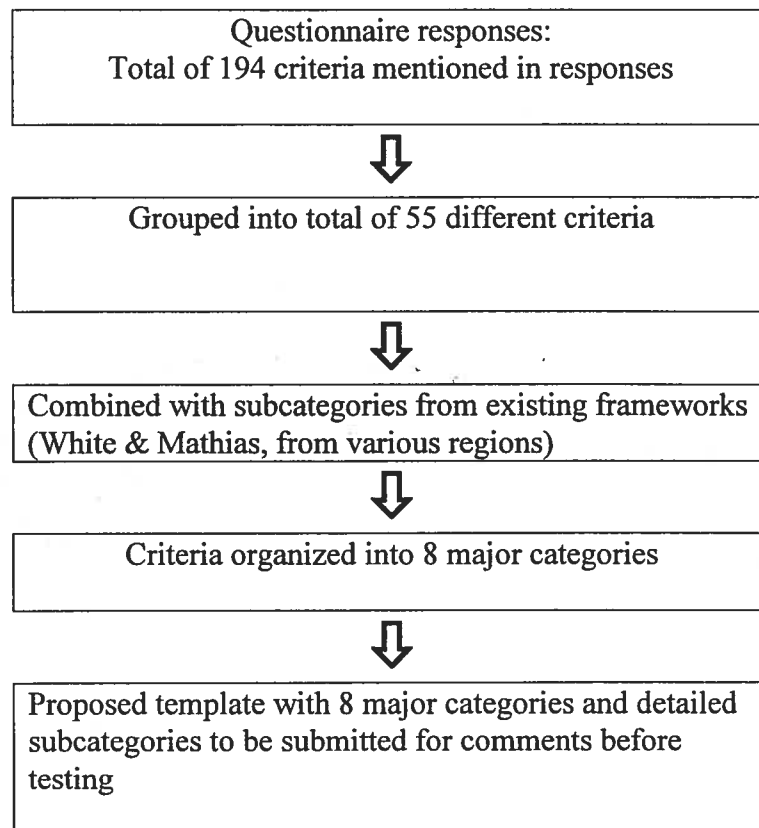
Overall, the results of this questionnaire provided important information as planned regarding criteria in decision-making as originally planned in the project. Due to the inclusion of broader questions regarding organizational structures and processes in this area in Canada, this questionnaire also collected numerous proposals for major organizational changes. This represented a major broadening of scope of the project and potential impact well beyond the simple development of the analytical framework for decision-making. These responses were used to create the analytical framework and a preliminary report and a presentation for the Immunization Subcommittee Meeting in November, 2000.

### ***Creation of the Analytical Framework***

This step aimed to use all available sources to identify important criteria for inclusion in the analytical framework. A total of 194 questionnaire responses representing potential decision-making criteria were entered in to an Excel database (Figure 19). For completeness, criteria included in known provincial frameworks and the White and Mathias model (White & Mathias, 1982) were also added.

A clustering process was utilized to reduce the list of questionnaire responses into unique criteria, using the dendrogram method to group conceptually similar responses into criteria (described in Miles & Huberman, 1994) representing groups of responses. Multiple mentions of the same criteria (i.e vaccine cost) were eliminated as were different wordings representing the same concept (i.e. vaccine price and vaccine cost).

For clarity and inspired generally by categories mentioned in existing provincial frameworks and the White and Mathias model, the list was arbitrarily grouped into 8 sections to create the sections of the template. This produced a total of 55 criteria classified into 8 categories, including the burden of disease, vaccine characteristics, immunization strategy, cost-effectiveness, acceptability and feasibility, evaluability of program, research questions, and other considerations (equity, ethical, legal and political). The framework was returned to participants for validation and tested in expert committee meetings.

**Figure 19: Process for Creation of Analytical Framework**

The overall result is a comprehensive list that captures the variety of different factors expressed from various sources regarding important criteria in immunization program planning in Canada and makes a comprehensive tool that including all important factors to be addressed. The questionnaire results and existing criteria generally show convergence in terms of overall content. This analytical framework for Immunization Program Planning in Canada, developed as a result of this questionnaire and the process of grouping of identified criteria, is presented in Figure 20.

Figure 20: Analytical Framework for Immunization Program Planning in Canada

**General Categories: (references will be included for each point)**

- 1. Disease Characteristics and Burden**
- 2. Vaccine Characteristics**
- 3. Alternative Immunization Strategies and Programs**
- 4. Social and Economic Costs and Benefits of Alternative Programs**
- 5. Feasibility and Acceptability of Alternative Programs**
- 6. Ability to Evaluate Programs**
- 7. Research Questions**
- 8. Other considerations**

**Detailed Points for Each Category:**

**1. Disease Characteristics and Burden**

- 1.1 Nature and characteristics of the infective agents, including reservoirs, mode of transmission, and pathogenic mechanisms.
- 1.2. Clinical manifestations and complications.
- 1.3. Epidemiology of the disease, including incidence, clustering, time trends, seasonal and geographic variations, fatality rate, sequelae rate, and loss of life years.
- 1.4. Specific populations affected and risk factors.
- 1.5. Current disease treatment and preventability by measures other than immunization.
- 1.6. Social impact of the disease, including reduction of quality of life of affected individuals, and loss of quality-adjusted life years, long-term disability, impact on families/ caregivers, fear of disease, stress on communities.
- 1.7. Economic impact of the disease, including direct and indirect costs to patients and families, productivity losses, health service utilization and costs to health system.



## **2. Vaccine Characteristics**

- 2.1. Nature and characteristics of immunizing agent (i.e. live, attenuated, killed, absorbed/non-absorbed, viral or bacterial product).
- 2.2. Characteristics of the commercial products (i.e preparation, stabilizing agents and preservatives, dosage, combination, conservation).
- 2.3. Storage, handling, product format (frozen, etc).
- 2.4. Vaccine manufactures, production capacity, and supply to Canada.
- 2.5. Administration schedule, number of doses, combination with other vaccines.
- 2.6. Nature and characteristics of immune response.
- 2.7. Immunogenicity in different population groups.
- 2.8. Efficacy: short and long-term, including direct and indirect protection (herd immunity).
- 2.9. Effectiveness: expected impact on reduction of burden of disease (morbidity, mortality, etc...).
- 2.10. Safety: rates and severity adverse events, contraindications, precautions.
- 2.11. Potential interaction with other vaccines.
- 2.12. Potential impacts on antibiotic resistance.

## **3. Alternative Immunization Strategies and Programs**

- 3.1. Existing recommendations/guidelines for use of the vaccine (i.e. NACI, consensus conferences, ACIP, AAP).
- 3.2. Objectives of disease control/elimination/eradication at international (i.e. PAHO, WHO etc..), national, and/or provincial/territorial levels.
- 3.3. Alternative immunization strategies for meeting objectives (i.e. selective vs universal immunization programs, catch-up programs).
- 3.4. Specific objectives in terms of reduction of incidence, complications, sequelae and mortality.
- 3.5. Specific objectives in terms of vaccination coverage for different target groups.
- 3.6. Delivery strategy/system: nurses versus physicians, different locations (i.e schools, private clinics, public health clinics).

3.5. Specific objectives in terms of vaccination coverage for different target groups.

3.6. Delivery strategy/system: nurses versus physicians, different locations (i.e schools, private clinics, public health clinics).

#### **4. Social and Economic Costs and Benefits of Alternative Programs**

4.1. Total and opportunity costs of program in a societal perspective, including direct and indirect costs for families and the health system.

4.2. Evidence regarding the short and long-term effectiveness, including reduction in disease incidence, complications, sequelae and mortality.

4.3. Evidence regarding social and economic benefits including reduction in health care costs, improvement in life expectancy, in quality of life for individuals, families, caregivers and communities, productivity gains.

4.4. Other benefits (i.e reduced microbial resistance, reduced emergency room overcrowding).

4.5. Economic evaluation : Net present costs and cost-benefit ratios (from health care and societal perspectives) of alternative strategies (per life saved, case prevented, life year gained, quality-adjusted life year gained), discussion of underlying assumptions, evaluation of robustness of economic model using sensitivity analyses, comparison with other studies, pertinence for local settings, and comparison to other vaccines and other health care interventions.

#### **5. Acceptability and Feasibility of Program**

5.1. Public perception of disease risk, severity, fear, need for disease control.

5.2. Demand for/ acceptability of immunization program to target groups, population at large, professionals (nurses, MDs, public health personnel) and political authorities.

5.3. Priority for new program with respect to other potential/approved programs.

5.4. Expected dates of licensure or current use of vaccine (i.e. by the private sector).

5.5. Integration of new program with existing immunization programs and schedules.

5.6. Impacts of program (including catch-up) on existing immunization services and other health care sectors (physicians, long-term care facilities, hospitals, occupational settings...).

5.7. Accessibility of target population, and expected levels of uptake/coverage for target groups.

5.8. Availability of vaccine supply.

5.9. Availability of funding for vaccine purchase.

5.10. Availability of human, technical and financial resources for distribution, conservation (cold chain stability), and administration of vaccines, including implementation of the new program and catch-up.

5.11. Availability of appropriate documentation/consent forms for the population and health care providers.

5.12. Availability of system for recording/registering vaccine administration.

5.13. Availability of resources for marketing and communication to the public, information and training of health professionals.

5.14. Existence of operational planning and implementation committee.

## **6. Ability to Evaluate Programs**

6.1. Desirability of evaluation to families, professionals (nurses, MDs, public health personnel) and political authorities.

6.2. Availability of information systems to measure coverage (including immunization registries) and vaccine utilization, quality of vaccination services.

6.3. Availability of information systems for monitoring reduction of disease incidence, complications, sequelae, and mortality.

6.4. Availability of information systems for monitoring adverse events associated with vaccine administration.

6.5. Availability of systems for linking health outcomes databases, immunization registries and population registries.

## **7. Research Questions**

7.1. Ongoing and planned research projects in the fields of vaccine development, immunogenicity, efficacy and safety.

7.2. Identification of areas in previous sections in which research is needed to assist evaluation, planning and decision-making regarding this particular program and proposals to meet these needs in a timely manner.

## **8. Other considerations**

8.1. Equity of new program including universality, accessibility and gratuity of services for the most vulnerable population groups.

8.2. Ethical considerations, including informed consent, and protection of confidentiality of medical information.

8.3. Conformity of new program with planned or existing programs in other jurisdictions and countries.

8.4. Possible political benefits and risks associated with implementation of new program.

## **Explanation of Categories in the Analytical Framework**

We will now consider in detail some examples of important factors for each of the categories of the framework identified from the questionnaire, the scientific literature in Canada, and consultation with experts:

### **1. Disease Characteristics and Burden**

In a public health perspective, the **burden of disease** is an important factor to set priorities. Vaccines were first developed to prevent frequent and deadly diseases such as smallpox, diphtheria, tetanus, infant pertussis, poliomyelitis, or measles, and the relevance of the programs implemented during the 20<sup>th</sup> century cannot be questioned. However, new vaccines developed during the last ten years are targeting less frequent or less severe conditions, and investments for their prevention have to be weighted

against other competing health priorities. The need to justify new programs led to epidemiological studies aiming to assess precisely the health and economic impact of vaccine preventable diseases in Canada, including varicella (Law et al. 1999a; Law et al. 1999b, Getsios et al. 2002), pneumococcal infections in children (Scheifele et al. 2000; Petit et al., 2003 in press), meningococcal disease (Erickson & De Wals, 1998), and adolescent pertussis (Senzilet et al. 2001, Skowronski et al. 2002, De Serres et al. 2000). The high frequency of invasive and non-invasive pneumococcal infections in children coupled with the increasing resistance of the bacteria to antibiotics was determinant in assigning the 7-valent conjugate vaccine as a top priority, while the rarity of severe complications and absence of permanent sequelae from whooping cough (pertussis) in adolescents determined the low priority given to an adolescent pertussis program (De Wals P, personal communication).

## **2. Vaccine characteristics**

Efficacy and safety of vaccines are the main criteria in the initial evaluation process. When the decision was made in Quebec to use the new serogroup C meningococcal vaccine instead of the polysaccharide vaccine to control an outbreak in 2001, the high effectiveness in young children of the former and its capacity to induce long-term memory were critical arguments (NACI, 2002). When acellular pertussis vaccines were introduced in Canada, safety above all other considerations was decisive for their immediate adoption (NACI, 2000). The introduction of a refrigerator-stable varicella vaccine was a definite improvement over the previous frozen vaccine, an important factor encouraging the use of this new vaccine.

All immunization programs must be evaluated in terms of their safety and population effectiveness. In addition, public health authorities must be accountable to taxpayers. In Quebec, there is a well-established tradition of

including an evaluative component in all new immunization programs. The usefulness of this type of investment was demonstrated after the mass serogroup C meningococcal immunization campaign in Quebec (using the polysaccharide vaccine) in 1992-1993, in which post-implantation studies alerted of the poor performance of this vaccine in young children and the short duration of protection (De Wals et al., 2001).

### **3. Alternative Immunization Strategies and Programs**

Sometimes, public health objectives can be attained via different immunization strategies, and the control of influenza is a good example. A universal vaccination program was implemented in Ontario, in 2000, while a « high-risk » approach is still used in the other provinces (Schabas 2001). Unfortunately, the relative cost-effectiveness of the two strategies has not yet been evaluated. Another example is the new meningococcal conjugate vaccine, which can be given in a one-dose universal program (as in Quebec), or in a three-dose universal program (as in Alberta).

### **4. Social and Economic Costs and Benefits of Programs**

With the increasing cost of vaccine products, cost-effectiveness analyses are needed to justify new programs, especially because long-term, recurrent expenditures are involved (BCG and smallpox being exceptions). In Canada, the first economic analysis was performed for the influenza vaccination of health care workers in 1991 (Yassi et al., 1991). Presently, this type of information is systematically requested and cost-effectiveness analyses have been produced for the two-dose measles program (Pelletier et al. 1998), the adult pneumococcal program (CETS, 1998), the varicella

program (Brisson et al., 2002; Getsios et al. 2002), the infant pneumococcal (Lebel et al., 2003; De Wals et al., 2003) and serogroup C meningococcal programs (CIQ 2002; De Wals et al., 2003, in press). Although not always cost-saving, immunization programs generally compare well with other health interventions (Tengs et al. 1995; Stone et al. 2000). It seems, however, that the absolute cost of a program is perceived to be more important than the predicted marginal cost-effectiveness ratios in the short-term perspective of some decision-makers. In addition, little is known about the actual impact of economic evaluation on decision-making (Contandriopoulos, 1999) and this issue warrants further study.

### **5. Feasibility and Acceptability of Alternative Programs**

The best immunization strategies have no value if they are impossible to carry out in practice. Past experience has shown that it is always easier to implement a new vaccine if it is combined with an existing vaccine or if it may be administered in the same visit as another vaccine. This was indeed the case for the replacement of the live oral polio vaccine with the inactivated combined injectable polio vaccine. In certain cases, practical aspects require vaccine doses to be given which are not strictly necessary. An example is the second dose of the mumps vaccine at the same time as the indispensable second dose of measles vaccine and the less indispensable second dose of rubella vaccine.

The demand for a new program is a very powerful argument for decision-makers at the political level. Consider for example the case of serogroup C meningococcal disease, which generates a lot of anxiety in the population and attracts enormous media attention, due to the unpredictable, rapid onset of this disease and its serious consequences (Erickson et al., 1998). A survey in Quebec in 2002 found that 86% of respondents felt that the conjugate vaccine should be included in the routine childhood immunization

series. Support for a vaccine against (pneumococcal) pneumonia was 60%, and only 41% for a vaccine against chickenpox (De Wals et al., 2002). Despite the fact that the varicella program is the most favorable program from an economic point of view (Brisson et al. 2002; Getsios et al. 2002), and also that the greatest disease reduction can be achieved from a program using the 7-valent pneumococcal conjugate vaccine (De Wals et al. 2003), a routine one-dose meningococcal program was introduced in Quebec in 2002. No decision has yet been made for the other two vaccines. While Canadians may be generally favorable towards immunization, general lack of knowledge by the public about vaccines may hamper the feasibility of new programs (Ritvo et al., 2003)

## **6. Ability to Evaluate Programs**

This section involves the availability of resources and information systems to evaluate immunization programs. Often there are no resources devoted to measuring immunization coverage, therefore making evaluation of impact of the program difficult. This was the case for the universal immunization program for influenza in Ontario, where little information was available to determine vaccine uptake and coverage. This also involves planned research projects, and implementation of immunization registries.

## **7. Research Questions**

New immunization programs are often implemented before important **research questions** can be resolved. A current example is the fact that the duration of protection given by the type C meningococcal conjugate vaccine given at 12 months of age is not yet known (Richmond et al., 2002), while this program aims to prevent invasive meningococcal infections until adulthood. In contrast, for certain programs uncertainty about certain scientific questions may block adoption of the program. For example,



uncertainty about the impact of a varicella immunization program and impact on the incidence of zoster in the adult population (Brisson et al. 2002) are factors which have delayed implementation of this program in several provinces.

## 8. Other Considerations

Applying principles of equity applied to immunization in Canada should mean that vaccines are freely accessible to populations that can benefit from them. The supposedly universal nature of Canadian health care is often cited as an example to follow for other countries.

Problems of access to vaccines occurred with the original varicella vaccine in Canada which had to be stored frozen. This caused several problems for the distribution network, particularly in outlying regions. During the Canadian Varicella Consensus Conference in 1999, availability of a refrigerator-stable vaccine was considered as a *sine qua non* criterion for adoption of a universal program (LCDC, 1999). Fortunately, the pharmaceutical companies involved rapidly met this challenge and refrigerator-stable varicella vaccines were quickly developed and commercialized in Canada.

In Canada, there are no mandatory immunizations, and regulations regarding immunization in schools or workplaces allow exemptions in certain cases, or are challenged if no exemptions are allowed. Important measures have been taken by public health authorities to supply the best possible information on vaccine products and to ensure informed choices by the populations, via publications, Internet sites, or information sheets given during visits for vaccinations. A practice guide for vaccinators has also been distributed. Multiple efforts are thus undertaken to avoid any ethical or deontological problems in the area of vaccination.

In the practice of curative medicine, certain medications are often used in a manner different than that originally recommended by the manufacturer and defined in the original licensure of the product. The principle of freedom of practice in treatment is harder to apply in the areas of prevention and publicly funded immunization programs than in other areas. For example, mounting evidence indicates that a single dose of the hepatitis A vaccine gives good long-term protection and that the marginal effectiveness of the second dose is quite low. Therefore, implementation of a one-dose hepatitis A vaccination program for half the cost of the original two-dose program (following the manufacturer's recommendations) can be considered for evaluation as a program option. With resources saved by this program, it would theoretically be possible to invest in other programs to maximize health benefits for the population. However, this type of approach has the potential problem of legal action in the case of vaccine failures.

Also, it is important to consider political aspects of immunization programs which can involve political benefits or risks. Mass meningococcal immunization programs had political benefit in Quebec as they responded to demands from the public and also attenuated much negative media coverage of disease outbreaks (De Wals et al., 2002). Political risks and problems are present in the case of pre-exposure smallpox vaccination in the United States for certain workers, which has caused much disagreement and debate, while in Canada discussions in this area are quite laborious, especially given our political structure.

### ***Transformation of the analytical framework into a practical tool***

Overall, the effort to identify all criteria which are important in planning decisions for immunization programs in Canada has identified an impressive list of factors which may be important. However, questionnaire results and

recent examples of decisions have indicated that different criteria are important in each case. Even non-experts recognize the differences between for example varicella and meningococcal programs. This variation was important to consider in the design of the framework to be adopted for testing in the next stages of the project. Because of these factors and the research-action approach of the project, a flexible 'template' approach was adopted for the framework. A template is defined as a gauge, pattern or mold used as a guide to the form of another object being created (Collins, 1988). Similarly this 'template' was considered to be a guide to be transformed by users for various applications of the analytical framework. The decision was made to include the maximum number of potentially pertinent subpoints in each section as the template should be modified to 'fit' each particular case. For example, more or less detail can be used in specific categories depending on pertinence to each potential program and application of the framework. This tool was presented to the Immunization Subcommittee in the next step of the project for consultation, discussion and revision.

### ***Testing of the Analytical Framework***

#### **Meeting of PHWG ISC, Toronto, November, 2000**

This meeting of the Immunization Subcommittee of the Public Health Working Group had representatives from Canadian provinces and territories and was held to update efforts on the National Immunization Strategy. The presentation and following discussion by participants is summarized in the Draft Record of Decisions summarizing this meeting (PHWG, 2001), presented in Appendix 14.

The results of the questionnaire and preliminary consultation process were

presented in two forms, a 22-page report entitled 'Development of an Analytical Framework for Immunization Program planning in Canada: Preliminary Results, Phases I & II' (circulated prior to the meeting) and also a presentation which summarized results of the questionnaire and gave preliminary recommendations, followed by a discussion. The presentation summarized questionnaire results and the development of the framework, as well as presenting existing frameworks in certain jurisdictions such as Nova Scotia and Saskatchewan. (Figure 18). The desire of various jurisdictions (expressed in the questionnaire responses) that mechanisms be developed to address implementation concerns, human resources, public perception and cost-benefit issues was highlighted. Members agreed that a systematic framework is required at a national level to effectively evaluate immunization program planning, which addresses social and political considerations.

As indicated in the contract with Health Canada, the project went beyond the simple development of the analytical framework, considering also organizational structures and processes in this area in Canada and making proposals for change. In addition to supporting the framework, members indicated that it was necessary to look at structures and processes for immunization program planning in Canada, particularly those which '*can withstand political change*'. It was noted that while the National Advisory Committee on Immunization (NACI) provides recommendations to the federal government on the optimal use of vaccines:

*'it does not effectively address the issues of immunization programs and the delivery of vaccines so some additional mechanism is required to take the scientific recommendations to an implementation phase'* (PHWG, 2001)

The members agreed to a stepwise, collaborative approach to development of a national '*framework, structure and process*'. This was a confirmation of a key development in the project to broaden its scope. It was suggested to

use a current potential program as a concrete pilot project for testing the framework, such as the pneumococcal conjugate vaccine. A potential role for the framework in an expected national consensus conference on the pneumococcal conjugate vaccine was also discussed, as members agreed upon the significant value of this type of conference in the immunization planning process in Canada.

The following actions were agreed upon as the next steps in the project, now referred to as 'Program Planning in Immunization in Canada (PPIC):

- Validation and circulation of report
- Completion of draft analytical framework in March 2001 for presentation to ISC and approval
- Discussion of NACI statement on pneumococcal conjugate vaccine in February/ March 2001.
- Testing of framework and development of recommendations for pneumococcal conjugate vaccine at April 2001 ISC meeting.

These actions were indeed completed, except for the last one regarding the pneumococcal conjugate vaccine. While there was indeed some work conducted with the pneumococcal conjugate vaccine working group in Quebec, there was no formal work done in this specific area on the federal level. There would simply be an informal discussion at the next ISC meeting in April 2001.

#### **April 2001 Meeting of the Immunization Subcommittee of the Public Health Working Group**

This meeting was a continuation of from the November 2000 meeting. In a similar manner, a 34-page report entitled *Program Planning in Immunization in Canada* was submitted to participants before the meeting, and a

presentation was given summarizing the results, and proposed continuation of the process. This was followed by a plenary discussion to ratify the report.

The 34-page report gave detailed summaries of questionnaire responses and was divided into the following 5 sections:

1. Goals and objectives for immunization in Canadian provinces & territories (presented in previous section)
2. Detailed structures and processes for decision-making in Canadian provinces & territories (Appendix 4)
3. Presentation of the analytical framework for evaluation of candidate programs (presented in previous section)
4. International examples of structures and processes for immunization planning and proposed structures for Canada (part of which was presented earlier in this report-section in immunization)
5. Conclusion.

The report and presentation differed from those presented at the November 2000 ISC meeting in that the results were more complete. In addition, structures for national coordination of health care planning in Canada were presented, such as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), the National Transplantation Strategy, and the Social Union Framework, to help examine the pertinence of such models for immunization. Testing of the framework was proposed with the pneumococcal conjugate, meningococcal conjugate and influenza vaccination programs in various national activities. For example, an activity with the framework was proposed for a national influenza conference to be held in May of 2001. This finally did not occur because the planning process for this meeting was already too far advanced for this meeting to include activities with the framework. Finally, in addition to proposing testing of the framework with various potential programs, the presentation concluded by recommending the establishment of a new national committee

for immunization program planning to complement the current activities of NACI.

The subcommittee ratified the analytical framework and agreed that it be tested in current cases. In addition, they discussed the possibility of a national committee on immunization programs, which could be an expansion of NACI or a stand-alone committee. The function and mandate of this committee would be to address immunization program issues that are not currently addressed by NACI. This would support and complement the work that is currently carried out by provincial/territorial committees, consensus conferences, and ad hoc committees and avoid duplication of efforts. This would also promote better coordination between regions. National representation in the committee would be expected, and the link to federal/provincial and territorial governments could be similar to some of the examples mentioned previously in this report.

This meeting also included some work in smaller breakout groups which was to establish key messages to be given to the PHWG and the ACPH in a meeting in May 2001 as part of a preparation of submissions to the Deputy Ministers meeting in June 2001. The messages developed in these breakout sessions included the following:

- Immunization is a very cost-effective intervention, saving lives and avoiding much illness and suffering.
- Inter-jurisdictional differences are causing inequitable access to vaccines in Canada
- Immunization is an essential foundation of the system of public health in Canada
- The status of immunization in Canada is threatened by the lack of coordination which exists and the lack of a National Immunization Strategy.

The primary recommendation was that inter-governmental partnerships are needed to support a consistent national immunization strategy, as is a re-

investment in the immunization program as part of a commitment to the renewal of the public health system in Canada. These statements express recognition of these key persons in immunization of the need for change in this area in Canada.

While this meeting continued the process of development of the framework and discussion of its potential use, the larger questions of possible organizational changes in the area of immunization were also being further discussed. As previously mentioned one potential change involved the establishment of a new immunization planning committee, for which there was a large degree of consensus. A more controversial proposal, which was simply discussed at the informal level, was that the federal government fund the purchase of certain vaccines on a national level. Representatives from certain provinces and territories (especially the less populated ones) were very supportive of such a plan to allow them to fund some of the new candidate programs with vaccines which are much more expensive per dose than traditional vaccines.

However, the attitude from some of the other jurisdictions, particularly the larger and more populous ones, were less open to what was considered as federal infringement on the provincial / territorial jurisdiction of health care spending. Some individual provinces would wish to opt out of such a program and request simply that the federal government transfer the funds to the province or territory so that it could decide on how to spend it in their particular jurisdiction. This situation has occurred often in the past with provinces, especially Quebec, wishing to opt out of federal initiatives. An example is the establishment of Canadian Blood Services, in which the province of Quebec decided to establish its own agency, Hema-Quebec. This illustrates some of the uniquely Canadian and very complex issues involved in any efforts of national coordination in the area of health care. Despite the support of members of the ISC for organizational changes, a



long process of federal / provincial / territorial consultation would be required to officially approve and implement such changes.

***Meeting with Health Canada officials, June 1<sup>st</sup>, 2001***

The purpose of this meeting was to present the proposed components of the National Immunization Strategy to senior officials at Health Canada, including the Deputy Minister of Health, and help to develop a federal position on proposed organizational changes. The meeting included a presentation followed by a discussion. The Deputy Minister was unfortunately unable to attend the meeting, however, other key officials from the office of the Deputy Minister and Health Canada were present. While the discussion was useful, little formal written agreements or other documentation were produced from the meeting, and its impact is difficult to measure. However, this meeting was certainly an important step in the political negotiation process, and helped to develop the proposals which would be submitted to the conference of the provincial and territorial Deputy Ministers of Health in summer 2001. A submission was made at this meeting regarding the National Immunization Strategy, but no documentation is available regarding the precise nature of this submission, and the related specific discussion and decisions at this meeting.

***National Immunization Strategy Meeting, Feb 2002***

This meeting was a culmination of the research contracts conducted in collaboration with the Subcommittee on Immunization of the Public Health Working Group of the Advisory Committee on Population Health. Originally, work was conducted on two components of the National Immunization Strategy, namely:

- Goals, objectives and monitoring of immunization programs
- Mechanisms to ensure that vaccines are available and used in a cost-effective manner across Canada

However, this work also included examination of immunization planning structures and processes in Canada and concluded that a new national committee to study immunization programs would be desirable to support the individual provinces and territories in planning their immunization programs. The analytical framework was proposed as a tool to support work of this committee. This meeting of representatives from the 13 Canadian jurisdictions was conducted on a pilot basis to test this tool and the possible functioning of such a committee on three real candidate programs in Canada.

There was a systematic effort involved in planning the meeting with Dr Philippe De Wals, the co-chairs of the Subcommittee on Immunization, Arlene King (Director, Division of Immunization, Health Canada) and Greg Hammond (Director, Department of Communicable Disease, Manitoba Ministry of Health). Given the fact that many jurisdictions were considering new programs with the conjugate pneumococcal vaccine, the conjugate meningococcal vaccine and the varicella vaccine, it was deemed pertinent to discuss these programs in particular, using the analytical framework as a tool to structure these activities. The meeting was conducted as follows:

- 1) Experts were invited to give short presentations on each potential program: varicella, meningococcal conjugate, and pneumococcal conjugate. They were allotted 20 minutes to give a presentation on each potential program. In addition, they were required to structure their presentations around the 8 categories of the analytical framework (of which they were given a copy in advance). They were not required to address each of the sub-points of each category, but rather to give an overview in their expert opinion on each category.
- 2) Experts present at the meeting were requested to rank the candidate vaccines in terms of their relative desirability for a publicly funded program in Canada. This worksheet was based on the 8 major categories of the analytical framework, and asked experts to rank the desirability of each potential program on a Likert scale from 1 (not desirable) to 5 (most desirable). This worksheet is presented in ,

#### Appendix 6.

- 3) This was followed by presentation of the response profiles to experts, and discussion.
- 4) Finally, there was an informal discussion evaluating this activity and the pilot committee.

This exercise allowed examination of the degree of consensus or divergence among experts in terms of their evaluation of each candidate program. For example, by tabulating the frequency of responses in each category, and the distribution of responses in the various categories, points in which there is a need for more discussion or explanations of divergent opinions can be identified. Table XV presents the frequency of responses of experts present at the National Immunization Meeting on the worksheet in Appendix 6.

Table XV: Number of Responses per Category, Worksheet for Vaccine Comparison, February 2002 National Immunization Meeting

	Type C Meningococcal	Varicella	Heptavalent Pneumococcal Conjugate
<i>Ranking scale/order:</i>	<i>(Not desirable).....1 2 3 4 5..... (Very desirable)</i>		
Disease Characteristics and Burden	1 3 0 <u>10</u> 7	0 0 1 <u>8</u> <u>10</u>	<b>0 0 0 5 <u>13</u></b> (ex.1)
Vaccine Characteristics	0 1 1 3 <u>4</u>	2 0 4 <u>8</u> 6	0 0 3 7 <u>8</u>
Immunization Strategies	0 0 2 8 <u>9</u>	0 0 5 <u>8</u> 6	0 0 <u>8</u> 3 5
Social and Economic Costs and Benefits	<b>0 4 <u>6</u> 5 4</b> (ex.2)	1 1 2 <u>10</u> 6	0 2 3 <u>8</u> 6
Feasibility and Acceptability	0 0 1 6 <u>11</u>	<b>0 3 5 <u>8</u> 3</b> (ex.3)	0 0 2 <u>9</u> 7
Ability to Evaluate Programs	0 0 5 6 <u>8</u>	0 0 <u>7</u> <u>7</u> 4	0 1 <u>6</u> 6 4
Research Questions	0 2 <u>8</u> 5 4	1 2 5 <u>9</u> 2	0 2 6 <u>7</u> 3
Other Considerations	0 1 5 <u>7</u> 4	0 1 <u>8</u> 6 1	0 0 5 <u>6</u> 3
Overall-this vaccine should be publicly funded	0 1 4 <u>6</u> 4	0 0 1 <u>7</u> <u>7</u>	0 0 1 <u>7</u> 6
Comparisons across vaccine types- ranking	0 6 <u>7</u>	5 1 <u>6</u>	5 <u>8</u> 0
<i>Ranking scale /order</i>	<i>1<sup>st</sup> 2<sup>nd</sup> 3<sup>rd</sup></i>		

Each number represents the number of responses per category. The mode (most frequent response) is underlined in each category, examples are in bold figures

We can consider some examples of response distributions of experts to individual questions on the worksheet for this activity:

- Example 1: We see for example that there is strong consensus among Canadian experts as to the important burden of pneumococcal disease (column 3, row 1 of Table XV), with 13 experts checking box #5 on the Likert scale (most desirable), and 5 checking box #4 (the second to most desirable of the 5 response options), and no experts choosing the other choices. This strong consensus indicates that there is no need to debate or further study this area to examine current consensus among Canadian experts. Identification of this type of consensus has the advantage of conserving time to address the more contentious issues where there is more divergence among experts about potential programs.

- Example 2: consider social and economic costs and benefits for potential programs with meningococcal conjugate vaccine (column 1, row 4 of Table XV). Here in contrast, responses of experts are almost equally distributed among four response categories, reflecting a great deal of divergence of opinion. This differing assessment of costs and benefits of meningococcal immunization programs probably reflects different opinions by experts on the value of calming the media and the public in the context of a meningitis outbreak.
  
- Example 3: regarding feasibility and acceptability of potential varicella programs (column 2, row 5 of Table XV), the response distribution is an intermediate between strong consensus and strong divergence. The identified factors here were a balance between the advantages of this program requiring only 1-2 doses versus the perception of certain parents and caregivers that varicella ('chicken pox') is a normal, innocuous part of childhood which will reduce uptake of varicella vaccine in potential programs.

While the overall profile of responses can present certain advantages in giving a detailed presentation of individual responses of experts in this activity, it makes global interpretation more difficult. For this reason, responses were also converted to a single index score which represented the percentage of a maximal (most favorable) score possible obtained for each section (Table XVI).

**Table XVI: Indexed Responses from Activity using Analytical Framework, Immunization Subcommittee Meeting, February 2002**

	Type C Meningo	Varicella	Pneumococcal Conjugate
1. Disease Characteristics and Burden	73%	87%	93%
2. Vaccine Characteristics	78%	70%	82%
3. Immunization Strategies	84%	76%	66%
4. Social and Economic Costs and Benefits	61%	74%	74%
5. Feasibility and Acceptability	90%	51%	82%
6. Ability to Evaluate Programs	79%	71%	69%
7. Research Questions	64%	62%	65%
8. Other Considerations	68%	61%	71%
Overall-this vaccine should be publicly funded	72%	85%	84%

Comparisons across vaccine types- ranking	3rd	2nd	1st
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\*Conversion method : % of maximal score=  

$$\left[ \frac{(0 \times \# \text{ of response } 1 + 1 \times \# \text{ of response } 2 + 2 \times \# \text{ of response } 3 + 3 \times \# \text{ of response } 4 + 4 \times \# \text{ of response } 5)}{4 \times \# \text{ of responders}} \right] \times 100\%$$

Example: The response profile for row 1, column 2 in Appendix — was the following:

Response:	1	2	3	4	5
Points:	0	1	2	3	4
# of responses:	1	3	0	10	7

% of maximal score=  $(0 \times 1) + (1 \times 3) + (2 \times 0) + (3 \times 10) + (4 \times 7) / (4 \times 21) = 61/84 = 73\%$

These results were presented to experts at the February meeting to guide a follow-up discussion. The first part of this discussion involved examination of areas in which there was little consensus among experts, and helped to clarify which areas regarding each potential program were clear versus other areas which required more discussion and/or targeted research to guide decisions.

Participants were in agreement to the usefulness of such an approach, but also identified the lack of a Canadian forum in which to have this type of discussion. The meeting concluded with the recommendation that Canada establish a body to coordinate national immunization planning, using exercises such as this one with the analytical framework to support Canadian jurisdictions in vaccine evaluation. While coordination and harmonization of immunization programs is a stated goal of the National Immunization Strategy, the jurisdiction of the provinces and territories in health care was not brought into question. However, the possibility of eventual federal programs to purchase vaccines for new provincial/territorial programs was considered as desirable by most participants.

This exercise, developed in collaboration with organizers of the meeting and some expert participants, illustrates another use of the framework. After considering comments of participants, the framework was revised and its structure of categories was modified. The changes involved dividing the categories of Feasibility and Acceptability into two separate categories of Feasibility and Acceptability. In addition, the original category 8, 'Other Considerations' was divided into 5 categories: equity/accessibility, ethical considerations, legal considerations, conformity of program, and political considerations. This gave a total of 13 categories in the revised framework (Table XVII). This revised framework was tested in a similar experience with the CIQ in Québec in March of 2003.

**Table XVII: Revisions to Categories of Analytical Framework**

Original Categories	Revised Categories
1. Burden of Disease	1. Burden of Disease
2. Vaccine Characteristics	2. Vaccine Characteristics
3. Alternative Immunization Strategies and Programs	3. Alternative Immunization Strategies and Programs
4. Social and Economic Costs and Benefits	4. Social and Economic Costs and Benefits
5. Feasibility and Acceptability	5. Feasibility
	6. Acceptability
6. Ability to Evaluate Programs	7. Ability to Evaluate Programs
7. Research Questions	8. Research Questions
8. Other considerations	9. Equity/ accessibility
	10. Ethical considerations
	11. Legal considerations
	12. Conformity of program
	13. Political considerations

#### ***Questionnaire #4: Follow-up on Use of Framework***

In February 2003, a follow-up questionnaire (Appendix 9) was sent to key persons in Canadian provinces and territories (except Quebec). The goal of the questionnaire was to collect additional information to examine to what extent the framework was known across the country, to what extent it had been used, and in what manner, to what extent key persons in immunization found it to be useful and in which manners and contexts. In addition, the



questionnaire collected information about recent and expected changes in immunization planning in each jurisdiction.

Considering responses to previous questionnaires and participation in ISC meetings, one key person was contacted from each jurisdiction to respond to the questionnaire or refer it to other persons in their jurisdiction qualified to respond (Appendix 10). As expected, considering that this was the fourth questionnaire to be administered in this project and that it was distributed during the SARS crisis, response to the questionnaire was quite limited. However, information was obtained from five jurisdictions. This was valuable due to the fact that little new information had been received about use of the framework in jurisdictions other than Quebec.

### ***Summary of Responses to Questionnaire #4 by province/territory***

#### **British Columbia**

One key person responded to the questionnaire after consultation with colleagues. The analytical framework was noted to be similar to that used in Ontario and B.C. for the preparation of budget submissions, treasury board submissions, or briefing notes related to obtaining new funding for vaccine programs. While the framework had not yet been used, it was seen as providing a good structure for future submissions. It was also mentioned that the framework must be individualized for specific vaccines with some parameters carrying more weight than others depending on the context. The framework was seen as potentially useful in providing a template for funding requests for new programs, serving as a reminder of key issues to be

included. In Canada in general, it was proposed that the framework could be used by Health Canada, or a working group under the new National Immunization Strategy, to 'fill in the blanks', assisting many provinces and territories in this process in completing the identical or similar components of their submissions to their respective governments. The framework was considered to be a good approach to detailing the considerations undertaken in preparing a justification for a new vaccine program for policy-makers and politicians. Standardized pharmacoeconomic analyses were seen to be of increasing importance as vaccines become generally more expensive (and less cost-effective). A major challenge in B.C. was stated as having insufficient resources to deal with current challenges /competing priorities such as West Nile Virus, SARS, and new vaccine programs. However, a process underway to develop 'core programs' for public health was seen as a potential solution in articulating clear goals/objectives for immunization programs. Challenges in obtaining funding for new immunization programs include convincing decision-makers that diseases are worth preventing, and that programs will actually be as cost-effective as predicted. Varicella was an example of a program with these two concerns, as well as concerns about potential harm from insufficient coverage.

In terms of solutions to deal with these challenges, more resources from the NIS for example, could help. In addition, standardized approaches to pharmacoeconomic analyses and Canadian-based research into the determinants and deterrents of immunization uptake or acceptance including at the political level. In the future, it was considered likely that a wider variety of participants would be involved in the planning process for new vaccines, and that more information would be collected on various aspects of pre-marketing of vaccines such as acceptability to health care providers and the public.

While in British Columbia not enough time has passed since introduction of

the framework for it to be used in planning activities, this response corresponds with many themes previously identified in the project, such as the desire for support from Health Canada, the approval of the framework as a useful tool, the desire for coordinated planning, and the need to broaden the research base to include factors such as acceptability of programs.

### **Saskatchewan**

A verbal response by telephone indicated that in Saskatchewan there had not been sufficient immunization planning activities to test the framework. The framework and immunization planning issues were to be discussed with the Saskatchewan Immunization Committee.

### **Manitoba**

Two responders were designated for Manitoba. While several of the components of the framework had been used in planning decisions, there was an interest in using the framework as a checklist for funding proposals for new vaccines. The framework was also seen as being useful in planning decisions, should the federal government eventually fund immunization programs. Another unanticipated use of the framework was in educating health care professionals and the public about the various important aspects of immunization programs. This framework was seen as beneficial in addressing all areas of concern for health care providers, the public, and politicians. It was seen as a tool that could avoid duplication of efforts between provinces and territories for evaluation of potential programs. Another advantage of the framework was to make specific differences between programs and key 'stumbling blocks' to funding or implementation more explicit, aiding understanding of all relevant issues. This could also increase transparency in justifying the basis for public spending decisions by Ministries of Health and governments.

In terms of desired changes to immunization planning in Canada, targeted research on questions of national interest (i.e. efficacy of acellular pertussis vaccines in adolescents) was mentioned as well as cost-effectiveness studies which could be included in NACI recommendations. An increased interest in cost-effectiveness analyses, as well as coordinated planning was mentioned. The Manitoba immunization committee requested additional information on the framework, to study possibilities for integration into their planning process. Finally, this type of effort was seen as potentially assisting immunization and other areas of prevention in attaining a higher profile and a justified increase in funding in Canada.

### **Nova Scotia**

A response was given by telephone, which indicated that appropriate persons were aware of the framework in Nova Scotia, and appreciated its usefulness. However, it was mentioned that they did not have current programs under consideration and therefore had not tested the framework.

### **Northwest Territories:**

It was indicated that the framework had been used in discussion of pneumococcal and meningococcal vaccine position statements in the NWT. The framework was seen as being useful in bringing more variables for consideration and broadening the scope of the evaluation process for new programs, helping the planner organize a logical argument and providing guidelines for putting forward policy options. Major challenges in NWT mentioned were vaccination coverage, funding for new programs, and education of health care personnel.

The framework was seen as an 'excellent tool', which was adopted in the NWT. In fact, an article on the framework and criteria for evaluating

immunization programs was published in the issue of *Epi-North* a publication on public health by the NWT Department of Health and Social Services (Bell, 2002). The author of this article was the representative for the NWT at meetings of the Immunization Subcommittee.

While these responses from several jurisdictions were partial and did not represent all jurisdictions, they confirmed data collected in other steps of the project. The challenges facing various jurisdictions in terms of funding for new programs, and the interest in cost-effectiveness analysis were confirmed, as were the desire to avoid duplication of efforts and for better coordination of planning. Despite the relatively short time frame in terms of observable impacts on public health planning decisions, the framework was welcomed as a useful tool and part of eventual, broader changes in this area. Multiple examples of unexpected adoption or use of the framework (educational uses, journal article, ongoing discussions) suggest that this tool was useful to those involved in immunization planning. These general tendencies are encouraging in that they are quite similar to data collected in numerous other steps of the project in various jurisdictions. Ongoing and future events in 2004 and beyond will certainly provide more occasions to further examine the adoption and potential impacts of this project.

### **National Advisory Committee on Immunization Meeting (October 2003)**

As a key organization in the area of immunization in Canada, The National Advisory Committee on Immunization (NACI) is an important player in any proposed organizational changes in this area. NACI was asked to consider the use of this framework in an expanded role for current programs under consideration by Health Canada. In October 2003 a presentation was given at the NACI meeting explaining how the framework has been used to date,

and commenting on how it could be potential used by NACI to coordinate national immunization program planning. This demand came in the context of organizational changes in immunization program planning in Canada, such as the emergence of a new national immunization committee the 'Canadian Immunization Committee', made up of Chief Medical Officers of Health from the 13 Canadian jurisdictions. This committee's first meeting occurred in November 2003.

### **Canadian Immunization Committee Meeting (November 2003)**

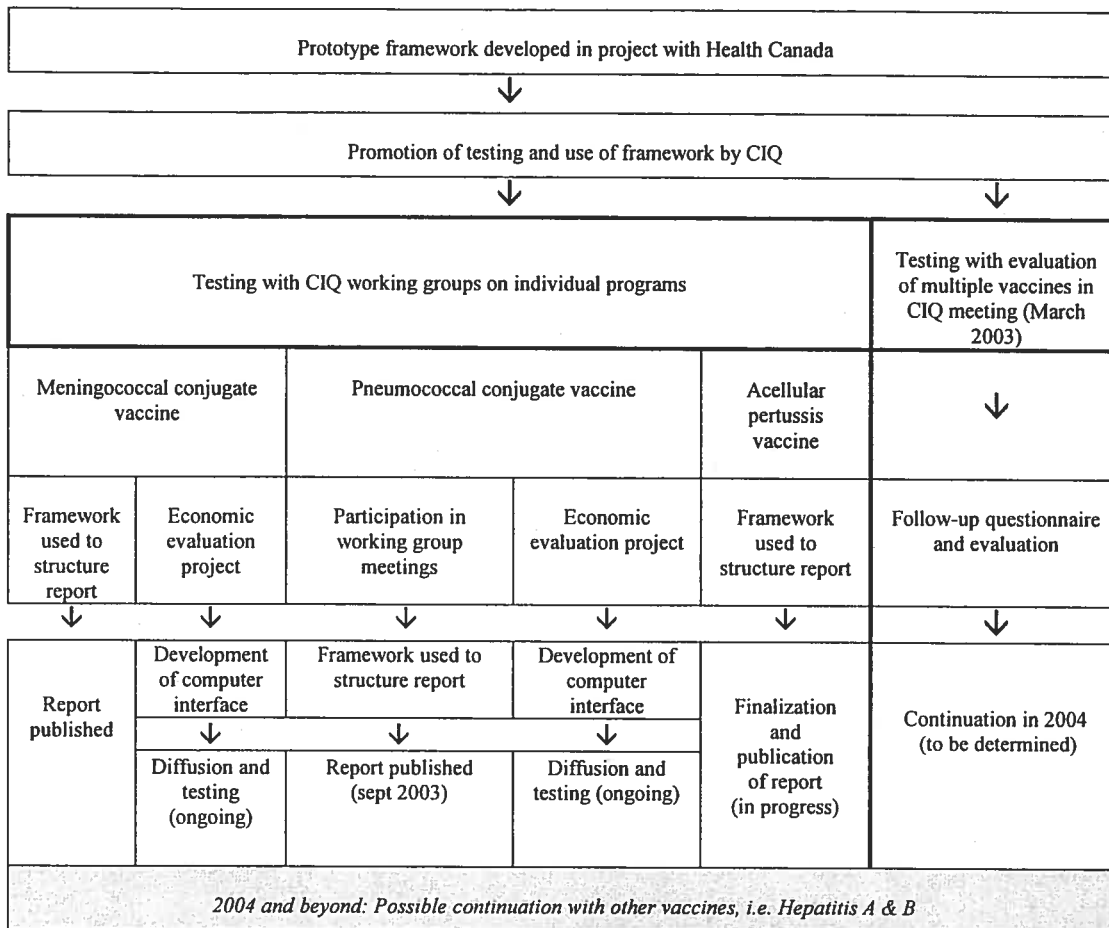
Following presentation of the framework to NACI in October 2003, and a meeting of key persons on possible structures and processes for immunization program planning in Canada (October, 2003), the analytical framework was presented to the Canadian Immunization Committee at its inaugural meeting in November 2003. While the exact functioning of this group is under discussion, the framework is one potential tool to help this group develop methods for harmonizing publicly funded immunization programs in Canada. More official information on the functioning of this committee and their planned use of the analytical framework is expected to be published or otherwise made available in 2004.

## Provincial Level- Québec

In phase A, it was proposed that this project be conducted in collaboration with the *Institut national de santé publique du Québec* (INSPQ) and /or the *Agence d'évaluation des technologies médicales et des interventions en santé du Québec* (AETMIS). Finally, it was decided that this project would be conducted in collaboration with the CIQ on an *ad hoc* basis, (the details of the collaboration were to be determined later). This collaboration was greatly facilitated by the fact that one of the main researchers on our project (Dr P De Wals) is also the president of the CIQ. Unlike the federal project, the actual intervention was less well defined in terms of timing, steps and scope. Initially, two presentations were given to present the potential uses of the framework and also to inform the CIQ of the advancement of the federal project.

Once the prototype framework (or template) had been developed in the federal project (as described in previous sections) the details of the framework were presented to the CIQ. However, no immediate dates were determined for such an exercise, therefore much time passed and this item was often pushed back to later meetings of the CIQ. In spite of this, the framework was integrated into vaccine specific working groups of the CIQ at an early stage, for programs such as meningococcal conjugate vaccine and pneumococcal conjugate vaccine. The overall structure of the Quebec intervention and results to date is presented in Figure 21.

**Figure 21: Actual Project Interventions in Quebec (until December 2003)**



**Testing with individual vaccine working groups**

**Meningococcal Conjugate Vaccine Report**

This report, completed by members of the CIQ, used the framework to as its structure (CIQ, 2002). This can be seen by comparing the framework categories to the table of contents of this report (Table XVIII)



Table XVIII: Comparison of sections of report on Meningococcal Conjugate Vaccine and the Analytical Framework

Sections of Report	Corresponding Categories of Analytical Framework
Introduction	-
Disease Characteristics	Disease Characteristics
Vaccine Characteristics	Vaccine Characteristics
Vaccination Strategy	Vaccination Strategy
Cost-Effectiveness Indexes	Social & Economic Costs and Benefits
Acceptability of Program	Feasibility & Acceptability of Program
Feasibility of Program	Program
Evaluation of Program	Evaluation of Program
Research Questions	Research Questions
Other Considerations	Other Considerations
Conclusions	
Recommendations	
References	

### ***Pneumococcal Conjugate Vaccine Working Group (Québec)***

In October 1999, the *Comité d'immunisation du Québec (CIQ)* created a working group to study the pertinence of introducing the new heptavalent conjugate pneumococcal vaccine (known as Prevnar® or PCV-7) into the regular infant immunization schedule in Quebec. This mandate included the production of a report including consideration of the burden of pneumococcal disease in children, vaccine characteristics, costs and benefits of a program, feasibility and acceptability of this potential immunization program. This report would aim to assist public health authorities in making an informed decision regarding the use of PCV-7 in Québec.

Meetings of the PCV-7 working group were attended to discuss economic evaluation of the program and also to explain the potential use of the analytical framework by this working group. Due to the strong concordance

between the mandate of the PCV-7 working group and the elements of the analytical framework, it was suggested that the working group use the framework to structure their work and the final report. This was accepted, and the sections of the analytical framework indeed correspond to the table of contents of the group's final report (Guay et al., 2003) as presented in Table XIX.

**Table XIX: Comparison of sections of report on Pneumococcal Conjugate Vaccine and the Analytical Framework**

<b>Sections of Report</b>	<b>Corresponding Categories of Analytical Framework</b>
Introduction	-
Disease Characteristics	Disease Characteristics
Vaccine Characteristics	Vaccine Characteristics
Potential Programs and Strategies	Potential Programs and Strategies
Social & Economic Costs and Benefits	Social & Economic Costs and Benefits
Feasibility & Acceptability of Program	Feasibility & Acceptability of Program
Evaluation of Program	Evaluation of Program
Research Questions	Research Questions
Other Considerations	Other Considerations
Recommendations	-
References	-

This report was officially made public by the *Institut de santé publique du Québec* (INSPQ) and posted on their website ([www.inspq.qc.ca](http://www.inspq.qc.ca)) in September 2003. Like the meningococcal conjugate vaccine working group report, this report followed very closely the categories of the framework. This type of common structure between evaluation efforts for different programs is a concrete example of adoption and impact of the analytical framework in Quebec.

### ***Pertussis Vaccine Working Group (Québec)***

The working group on pertussis is also in the process of writing a report on the pertinence of potential immunization programs using the acellular pertussis vaccine in Quebec for adolescents and adults. This committee is also utilizing the framework to structure their report, which is currently being written (De Serres G, personal communication). The framework was proposed for use in a national consensus conference on pertussis in 2002. Initial planning discussions were held but the proposed activity did not occur at this meeting. This could have been due to the fact that this proposal arrived too late in the planning process for the meeting, however the exact reason is uncertain.

### ***Hepatitis A and B programs***

In addition, there is currently the possibility of using the framework with a working group and a potential coordinated national effort regarding new hepatitis A and B immunization programs in Canada. Discussions were held in November 2003 with the INSPQ, the CIQ and AETMIS regarding potential joint efforts in evaluation of these potential programs. As of December, 2003, A project submission to Health Canada as part of the National Immunization Strategy is being prepared. A second possibility is submission to CCOHTA for funding as part of current technology assessment initiatives of national importance in Canada. Concrete developments in this area are expected in early 2004.

### ***Testing with evaluation of multiple vaccines***

At the CIQ meeting in March 2003, a prioritization exercise similar to that conducted in February 2002 was conducted using the framework to

compare the following potential programs:

- Meningococcal conjugate vaccine
- Heptavalent pneumococcal vaccine
- Varicella vaccine
- Acellular pertussis vaccine (for adolescents and adults)

A worksheet on the framework was circulated to participants in the meeting (Figure 22). The worksheet used was based on that used in the February 2002 National Immunization Meeting except for the addition of the fourth candidate program, acellular pertussis for adolescents and adults. Following comments on revision of the framework from testing at the February 2002 meeting, the 8 categories were revised to 13 categories.

Figure 22: Worksheet for exercise with analytical framework in CIQ meeting- with responses  
 Distribution of responses, CIQ members, meeting on March 14, 2003. n = # of responses.

Catégorie	Vaccin conjugué contre le méningo. de type C					Vaccin contre la varicelle					Vaccin heptavalent conjugué contre la pneumocoque					Vaccin acellulaire contre la coqueluche pour adolescents				
	En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....		
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
1. Fardeau de la maladie	0	1	1	5	0	0	2	2	3	1	0	0	0	3	5	2	0	3	2	1
2. Caractéristiques du vaccin	0	0	2	1	4	0	0	2	6	0	0	1	0	4	3	0	2	0	2	4
3. Stratégies/programmes d'immunisation potentiels	0	0	2	2	3	0	0	2	5	1	0	0	0	4	4	0	0	2	3	2
4. Coûts et bénéfices sociaux et économiques	1	1	2	2	1	0	1	5	2	0	0	5	3	0	0	1	2	5	0	0
5. Acceptabilité du programme	0	0	1	0	6	0	2	3	3	0	0	0	1	4	2	1	3	4	0	0
6. Faisabilité du programme	0	0	2	2	3	0	1	2	1	4	0	2	1	2	2	1	1	4	1	1
7. Capacité à évaluer des programmes	0	0	0	2	5	0	0	0	4	4	0	0	1	2	4	0	1	3	3	1
8. Questions de recherche	0	0	2	5	0	0	2	3	2	1	0	0	2	3	2	0	1	4	1	2
9. Équité/ accessibilité	0	0	1	3	3	0	0	1	4	3	0	1	0	3	3	0	1	1	4	2
10. Considérations éthiques	0	0	1	3	3	0	0	3	2	2	0	0	2	2	3	0	1	2	2	2
11. Considérations légales	0	0	2	2	3	0	0	5	1	2	0	0	3	3	1	0	0	3	3	2
12. Conformité du programme	1	0	4	2	0	0	1	3	4	0	0	0	4	2	2	1	2	5	0	0
13. Considérations politiques	0	0	0	1	6	0	3	5	0	0	0	0	3	5	0	2	4	2	0	0
Évaluation globale- ce vaccin devrait-il être ajouté au programme public d'immunisation au Québec?	En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....			En défaveur du programme.....		En faveur du programme.....		
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
	0	0	2	2	3	0	0	2	3	3	0	0	0	2	6	0	1	2	3	0
Rang (desirabilité versus les 3 autres vaccins candidats)	plus désirable		désirable			plus désirable		désirable			plus désirable		désirable			plus désirable		désirable		
	1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>		1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>		1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>		1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>	
	1	1	3	2		2	1	4	0		4	3	□	□		□	2	□	□	5

As in the previous exercise, participants were asked to evaluate the potential programs based on their current knowledge and taking into account the expert presentations which had occurred in the CIQ meetings. As in the federal exercise previously presented, these responses can be indexed to facilitate comparison (Table XX).

**Table XX: Indexed Responses from Activity using Analytical Framework, CIQ Meeting, March 2003**

% of maximal (most favorable) score for each category\*

	Type C Meningo	Varicella	Pneumococcal Conjugate	Acellular Pertussis for adolescents/adults
1. Disease Characteristics and Burden	64%	59%	91%	50%
2. Vaccine Characteristics	82%	69%	78%	75%
3. Immunization Strategies	79%	72%	88%	75%
4. Social and Economic Costs and Benefits	54%	56%	34%	38%
5. Acceptability	93%	53%	79%	34%
6. Feasibility	79%	75%	64%	50%
7. Ability to Evaluate Programs	93%	88%	86%	63%
8. Research Questions	68%	56%	75%	81%
9. Equity/ Accessibility	79%	81%	79%	72%
10. Ethical Considerations	82%	71%	79%	68%
11. Legal Considerations	79%	66%	68%	72%
12. Conformity of Program	50%	59%	69%	38%
13. Political Considerations	96%	47%	66%	25%
Overall-this vaccine should be publicly funded	79%	78%	94%	71%

Comparisons across vaccine types-ranking	3 <sup>rd</sup>	2 <sup>nd</sup>	1 <sup>st</sup>	4 <sup>th</sup>
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\*Conversion method was the same as for Table XVI)

Like the exercise on the federal level, certain patterns emerge, such as the recognition of the burden of pneumococcal disease, and the very political nature of meningococcal programs. With the addition of the acellular pertussis program, we see that it is not supported as much as the other potential programs by experts in Quebec. This exercise should be repeated on the national level to verify agreement of responses. These responses

provide many areas to target discussion to examine areas of divergence and consensus among Quebec experts regarding these immunization programs

***Comparison of Vaccine Ranking Exercises: National Meeting versus CIQ meeting.***

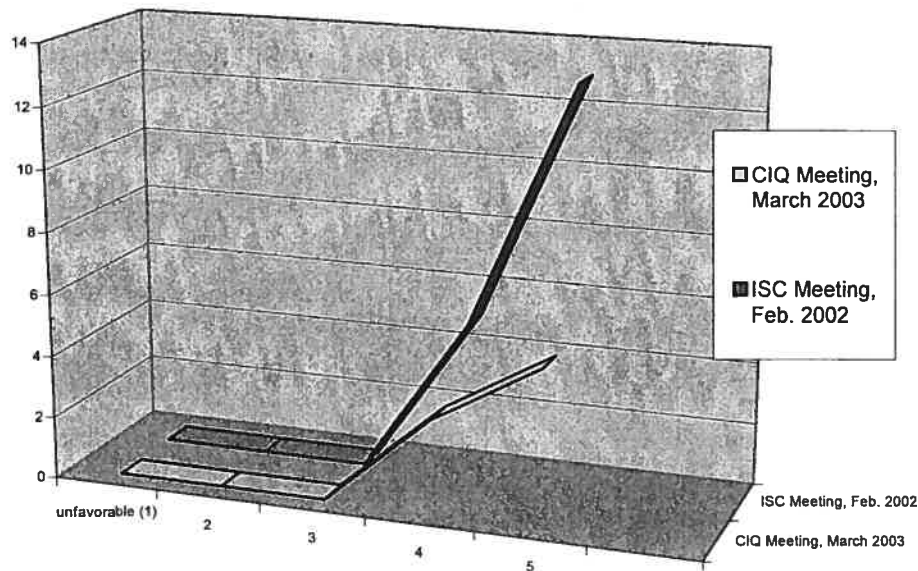
The two similar activities using the framework worksheet to evaluate programs and guide discussion among experts on federal and provincial (Quebec) levels can be compared. There are several significant differences between the National Immunization Program planning meeting in February 2002 and the *Comité d'immunisation du Québec* (CIQ) meeting in March 2003 in which the framework was formally tested. First of all, an additional vaccine was added to the worksheet, the acellular pertussis vaccine for adolescents and adults. Secondly, the framework categories were expanded from 8 to 13. However, for the categories which did not change, it is interesting to compare response profiles in the two contexts. Consider for example Category #1: disease burden and characteristics applied to the heptavalent pneumococcal program (Table XXI, Figure 23). The response profile at the CIQ meeting, like the Canadian meeting, had a relatively strong consensus as is seen in the concentration of responses in the last two categories of the Likert scale (on the favorable end of the response scale).

**Table XXI: Comparison of Response Distributions on Provincial and Federal Levels: Burden of Disease, Pnemococcal Conjugate Vaccine**

Response	Number of responders per category, evaluation of Burden of Disease	
	CIQ meeting, March 2003	ISC meeting, Feb 2002
Unfavorable (1)	0	0
(2)	0	0
(3)	0	0
(4)	3	5
(5) Favorable	5	13

Alternatively, these results can be presented graphically (Figure 23).

Figure 23: Comparison of Responses for Burden of Pneumococcal Disease



It is important to indicate that these comparisons are made on a purely exploratory basis. While the exercises were similar in nature in asking the experts to make a certain judgment using the framework about the candidate vaccines, there were important differences such as the context (national versus provincial meeting), the framework used (8 vs. 13 categories), the timing (Feb 2002 vs. March 2003), and also the time given to complete the responses. In the CIQ meeting, less time was available for the activity, and expert presentations were only given on one of the potential programs (acellular pertussis vaccine for adults and adolescents).

Another example is category 4, social and economic costs and benefits for meningococcal conjugate vaccine (Table XXII). In the CIQ meeting, while there was a smaller number of responders, the responses are fairly widely



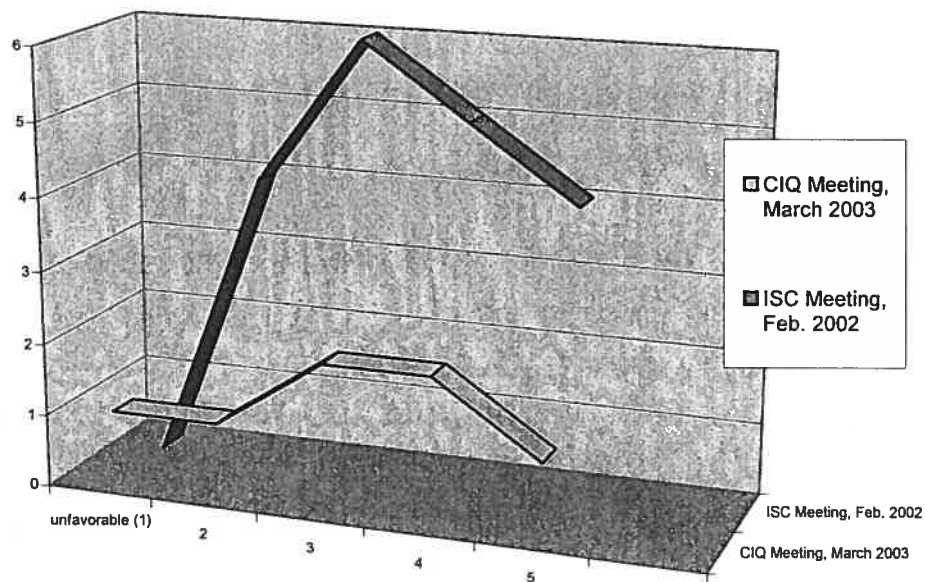
distributed, indicating a lack of consensus, with most experts in the central area of the scale.

**Table XXII: Comparison of Responses on National and Provincial Levels: Meningococcal Conjugate Vaccine**

Response	Number of responders per category, evaluation of Social and Economic Benefits	
	CIQ meeting, March 2003	ISC meeting, Feb 2002
Unfavorable		
(1)	1	0
(2)	1	4
(3)	2	6
(4)	2	5
(5)		
Favorable	1	4

As in the previous example, these responses can also be presented graphically (Figure 24).

**Figure 24 : Comparison of Responses at National and Quebec meetings: Social and Economic Costs and Benefits of Meningococcal Conjugate Vaccine**



This particular application of the framework with the CIQ differed from the application at the national meeting in February 2002 in various ways, other than the addition of another (fourth) candidate program to the exercise. These differences are summarized in Table XXIII. Contrary to the previous exercise on the federal level, planning for the CIQ meeting was ad hoc, at the last minute, and poorly structured. When the activity was finally performed in March 2003, this was only following multiple and sometimes repetitious presentations at the CIQ meetings, over the previous year, after which the exercise was pushed off the agenda and delayed until the next CIQ meeting. The fact that four potential programs were considered increased the demands of this exercise considerably, especially considering the fact that there was only a presentation on one of the candidate programs during the meeting. The fact that the framework had expanded from 8 to 13 categories also increased the number of responses required of participants 52 in the CIQ meeting versus 24 in the federal meeting. This produced somewhat of a 'cognitive overload' for participants, who often commented that the number of categories was too high, and the time was too limited, a comment which was absent from the federal meeting.

**Table XXIII: Differences in the exercise with the Analytical Framework Exercise with the CIQ (March 2003) and in the federal meeting (Feb 2002)**

Aspect	CIQ meeting	Federal meeting	comments
Planning of activity	Ad hoc, often delayed, unstructured, role of researcher unclear.	Systematic, multiple meetings, and telephone conferences, role of researcher clear and defined by formal contract.	This could explain the superior functioning and evaluation of this activity at the federal level.
Number of vaccines considered	4: as in federal meeting with addition of acellular pertussis for adults and adolescents	3: varicella vaccine, pneumococcal conjugate vaccine, meningococcal conjugate vaccine.	This was due to timing of the meeting and advancement of the evaluation process for these vaccines
Number of categories in the framework	13: revised version	8	Nuber of categories was increased after comments at federal meeting, however, this does not seem to have been an improvement.
Time for meeting	Part of an afternoon	Most of a day	There was not enough time available in the CIQ meeting to optimally perform the activity.
Expert presentations	One given on same day, following the framework categories	Presentations on all three programs given at same meeting, structured with framework	For the other candidate programs, CIQ members were asked to consider previous presentations, not necessarily structured around the framework.
Time for discussion	Limited	Ample time given in meeting	Discussion in federal meeting also revolved around possible organizational changes.
Follow-up or next actions	Unclear- possibly for hepatitis programs	Discussions underway with NACI, and CIC, possibly for hepatitis programs	Possible in early 2004

### ***Questionnaire on appreciation of framework***

A questionnaire was circulated to members of the CIQ regarding their appreciation and suggestions for use of the analytical framework, specifically in this activity as well as in general. The full questionnaire and responses (in French) are presented in Appendix 9. The questions and variety of responses can be summarized as follows:

#### **1. Appreciation of activity with framework:**

The activity was generally seen as useful. However, participants noted that there were too many categories in the framework, there was not enough time to correctly complete the worksheet, and that criteria were not well-defined enough to evaluate for each potential program. It was also seen as important to define the precise program strategy before evaluation. Participants felt that not all categories should have the same importance. For example, one responder felt that too much emphasis was placed on political, legal and ethical considerations and not enough on vaccine efficacy and short and long term benefits of immunization. Overall, responses indicate that while members of the CIQ appreciated this type of activity, many improvements could be made. This would require time and effort to plan a structured discussion by CIQ members to determine how they could best use this framework.

#### **2. Which tools or other processes should be used with the CIQ in the future?**

Members suggested having better structured meetings, with use of the framework with standardized criteria and responses, and evaluation of specific immunization strategies. It was proposed to use the framework to

structure future written documents produced by the CIQ.

### **3. Have you used the framework in other contexts?**

Some members mentioned having used the framework on several occasions with medical students or medical residents in community health to inform them of the complexity of decision-making in immunization, and prepare for their licensing examinations.

### **4. What other applications of this tool should be considered in the future?**

Members suggested using the framework to plan a pre-decision research program, as a tool for directors of public health and other decision-makers, to communicate between various actors in the health system (nurses, M.D.s, CLSCs, etc.), and also for educating students in medicine and nursing. It was also mentioned that this tool should be proposed to Health Canada and NACI.

### **5. Considering expected changes in the next 10 years, what actions should be taken to support immunization planning in Quebec?**

Members had numerous suggestions for this question, including better links with the media and better promotional efforts for vaccination. The need to address the notion of opportunity cost, increase research capacity in economic evaluation and to have specialists in this area on a permanent basis was highlighted. A general effort to inform decision-makers and the public of important criteria for decisions in this area was also mentioned. Finally, better monitoring systems for vaccine-preventable diseases, a

vaccination registry, and a national immunization strategy were also noted.

## **2. Other comments:**

Previous comments on the format of the framework were again mentioned—that there were too many categories and that there were possibilities of different interpretations of sub-categories. However, it was mentioned that this process was essential, and could have a positive impact on the public health system at the provincial and federal level. Overall, this questionnaire indicates that the CIQ members had many ideas of how to improve this particular activity. More systematic planning of this activity, more time for the actual activity and more consultation of CIQ members beforehand to tailor the activity to the needs of this committee would have perhaps avoided these problems.

However, CIQ members appreciated the framework and had many ideas for improving the immunization planning process in Quebec and in Canada. Overall, their desire for increased coordination and more systematic planning including resources for economic evaluation of potential programs confirmed the comments collected in various other steps of the programs from various key persons in other Canadian jurisdictions.

### **Targeted intervention on one category of framework: Social and Economic Costs and Benefits**

In conjunction with the immunization program planning project with Health Canada, the specific area of category 4 of the framework, 'Social and Economic Costs and Benefits', was targeted for study and intervention. The goal was to illustrate how specific categories of the framework could be examined to develop national coordinated efforts in research and planning. This focused effort at national coordination on a specific area of the analytical framework aimed to facilitate the development of other coordinated efforts in other categories of the framework (i.e.: acceptability and feasibility of programs).

Researchers in this project had previously been involved in numerous economic evaluations in the area of immunization, for example the meningococcal polysaccharide mass immunization campaign (De Wals & Erickson; 2002), meningococcal vaccination of college students in the U.S. (Scott et al, 2002), use of the pneumococcal conjugate vaccine in Canada (De Wals et al, 2003a), and the meningococcal conjugate vaccine (De Wals et al., 2003b), and economic evaluations of influenza vaccination programs (presentation at Influenza Conference, Montreal). This experience and observation of the actual use (or non-use) of the results of these studies, involvement with Health Canada in an effort to improve use of and timeliness of economic evaluations as well as the expressed demand for better coordination of economic studies motivated this project, which aimed to improve coordination of economic evaluations of vaccines in Canada. The original means chosen was to develop a flexible computer interface for economic evaluation of programs which could be modified and updated by users. Therefore, all jurisdictions could adapt economic evaluations of potential programs easily to their jurisdiction by changing parameters such

as population, epidemiology of disease, vaccine price and number of doses. This program could also be used as an educational tool. Two economic evaluations were selected for intervention: the pneumococcal conjugate vaccine and the meningococcal conjugate vaccine.

### ***Pneumococcal Conjugate Vaccine***

The vaccine manufacturer, Wyeth-Ayerst Canada, and Health Canada, financed an economic evaluation under the direction of Dr De Wals. To ensure impartiality, the project was conducted in collaboration with the *Agence d'évaluation des technologies et des modes d'intervention en santé du Québec* (AETMIS). The output of this project was a report (AETMIS, in press) and a journal article. However, in addition to this, a computer interface was developed in collaboration with AETMIS. This computer interface allows users to modify the assumptions of the economic model and change parameters such as the population vaccinated, which is useful for individual provinces and territories to estimate budgetary impact of a potential program in their jurisdiction. This interface was presented at the Quebec *Journées annuelles de santé publique (JASP)* in Quebec City in November 2002, and also at the Canadian National Immunization Conference in Victoria, British Columbia in December 2002. In addition, the program is available for testing to representatives from all Canadian provinces and territories.

### ***Meningococcal Conjugate Vaccine***

The concept of a computer interface was taken further for the economic evaluation of the conjugate type C meningococcal vaccine, in collaboration with the population and public health branch of Health Canada. A more user-friendly computer interface was developed, *MeninGo Solution*, downloadable in a CD-ROM format or from a website, with an information



booklet, protected by copyright. The *MeninGo Solution* CD is currently being distributed to key persons in immunization program planning in Canada for testing. When outbreaks of meningococcal disease next occur, key persons should have this computer program on hand, which can be readily modified or updated to reflect the current epidemiological and vaccine cost data. This should provide valuable information regarding the use of economic evaluations by scientific experts and key decision-makers in Canada.

Data collected in this project have indicated an interest in the development of coordinated and standardized methods in this area. Despite the fact that there are many questions about the interpretation and use of economic evaluations and their actual impact on decision-making (Contandriopoulos, 1999; Salkeld et al., 1995), factors such as the timing and the manipulability of research have been mentioned to increase impact (i.e.: Beyer and Trice, 1982), therefore this type of interactive form of economic evaluation should be studied as a first step in better understanding and improving this process. It is important to examine, particularly for programs with intense political pressures such as meningococcal vaccination, the actual role economic considerations and specific research evidence play in program decisions. This sector of the project is ongoing and hopefully will provide useful information on use of economic evaluations and improvement in this area.

### **Other diffusion/ communication efforts for project**

In addition to the efforts previously mentioned during this project, there were numerous occasions in which the framework and /or the project including proposed organizational changes in immunization in Canada was diffused publicly. These events were important as they increased awareness of the project with key persons in immunization in the Quebec and Canadian contexts. Here are the key events in conferences, publications, and

information on web sites:

### **Presentations at Conferences:**

The framework and the project were presented on numerous occasions at conferences on the federal and provincial levels. This allowed experts in the area to be aware of the project and to link it to other activity in the area of immunization on the federal and provincial levels.

- **National Immunization Conference, Halifax, December 2000:** The development of the framework and the project on immunization planning was presented at a plenary presentation on the National Immunization Strategy (Arlene King, Joel Kettner).
- **8e Colloque provincial en maladies infectieuses, Hull, Québec, 11-12 mai 2000 :** The project on development of the framework was presented in a plenary presentation (Philippe De Wals)
- **Colloque provincial de maladies infectieuses, Québec City, (18-19 avril, 2002) :** The immunization planning and decision-making processes in Quebec were presented as well as the framework and compared to current work in technology assessment ( Philippe De Wals, Lonny Erickson, Van Hung Nguyen).
- **Journées Annuelles de santé publique (JASP), Québec City, (Nov, 2002) :** The analytical framework was presented in a seminar on technology assessment and immunization (Lonny Erickson, Renaldo Battista, Philippe De Wals). A computer interface developed for the pneumococcal conjugate vaccine in collaboration with AETMIS was also presented at their kiosk at this conference (Lonny Erickson).
- **Canadian National Immunization Conference, Victoria BC, (December 2002):** The project examining structures and processes for immunization planning and the framework was mentioned in a plenary presentation (Arlene King). The computer interface developed for the meningococcal conjugate program was presented at a kiosk at the conference (Lonny Erickson)
- **Réunion de la Direction Scientifique, AETMIS, (Feb., 2003) :** The project on the development of the analytical framework was presented with potential applications to health technology assessment (Lonny Erickson).

- **Conférences-midi, DSPPÉ Montérégie (Jan 2004):**  
Presentation will be given on development and testing of the analytical framework (Lonny Erickson).

#### **Web Sites**

- A copy of the Power point presentation given at the Journées Annuelles de Santé Publique (JASP) is available on the site of the INSPQ. ( [www.inspq.qc.ca](http://www.inspq.qc.ca) )
- This presentation was posted on the site of AETMIS ( [www.aetmis.gouv.qc.ca](http://www.aetmis.gouv.qc.ca) ) in English and French in May, 2003.
- The reports on meningococcal and pneumococcal programs are available in the publications section of the INSPQ site ([www.inspq.qc.ca](http://www.inspq.qc.ca) )
- Summary of presentation given at the Canadian National Immunization Conference, December, 2002 entitled 'Working Together Better: Program Planning and Equitable Access to Immunization in Canada' ([http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/03vol29/29s4/29s4\\_2e.html](http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/03vol29/29s4/29s4_2e.html) ) on Health Canada's website (also published in CDR)
- The Canadian Institutes of Health Research (CIHR) Institute for Infection and Immunity mentions the need for and advancement of the National Immunization Strategy, including 'collaborative program planning for equitable access' at: <http://www.cihr-irsc.gc.ca/e/institutes/iii/17777.shtml?>

The importance of the internet as a means of diffusion of this project is hard to quantify exactly, however some statistics are available concerning the number of downloads of the presentations on the analytical framework from the site of AETMIS since May, 2003 (Table XXIV):

**Table XXIV: Statistics on number of downloads of presentation on Analytical Framework from AETMIS web site, May-September 2003**

Month	French version	English Version
May 2003	6	2
June 2003	6	11
July 2003	2	7
August 2003	5	15
September 2003	18	19
<b>Total</b>	<b>37</b>	<b>54</b>

Source : Service des communications, AETMIS, November 2003

Combined with the INSPQ site, the posting of this information on the internet is another effective diffusing information about the framework and this project.

### ***Publications***

- The two reports from the CIQ working groups on the meningococcal and pneumococcal conjugate vaccines.
- An article on the development of the framework is being prepared for submission to the Canadian Journal of Public Health in early 2004.
- Summary of presentation given at the Canadian National Immunization Conference in December 2002 was published in CCDR (Canada Communicable Disease Report, 2003)

## CHAPTER V: DISCUSSION

Discussion of results must be conducted considering the action research approach of this project. In analyzing the results, we see the representation of certain types of phenomena mentioned in the literature. *Objective, cognitive, situated* and *political* aspects are all present. In addition using the three types of knowledge constitutive interests proposed by Habermas (1972, 1974), what was originally a project involving only *technical* and *practical* levels was expanded to include a *critical* element, due to the action research approach.

### **Analysis: Looking with Several Eyes**

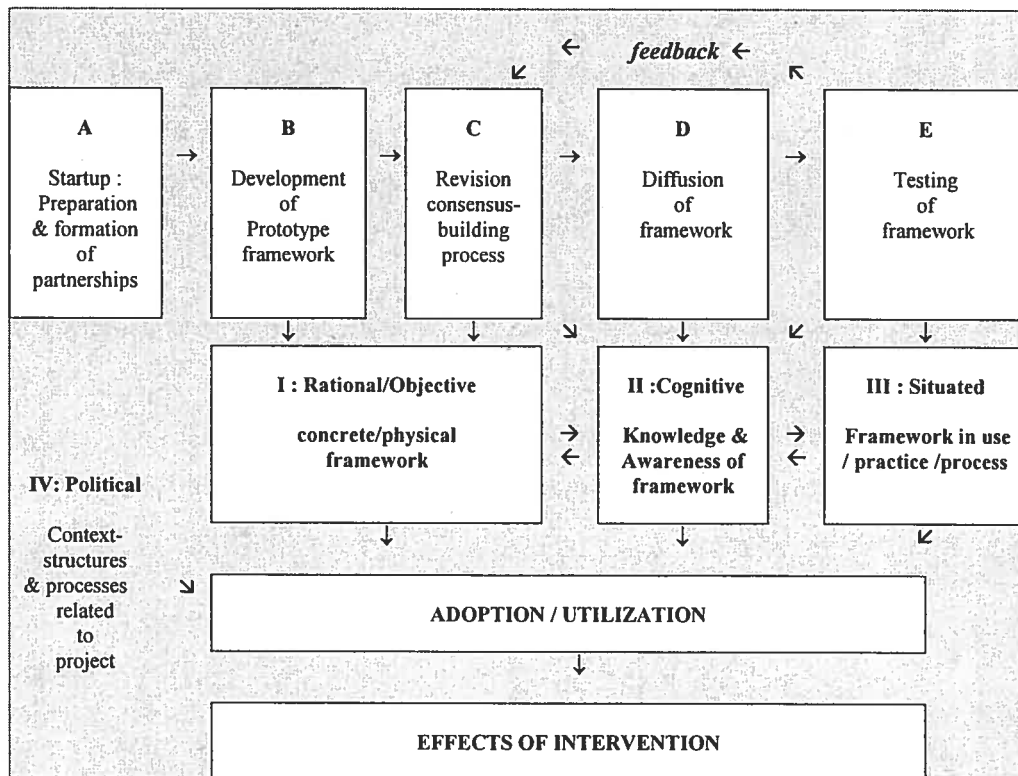
Following a broad theoretically inclusive approach similar to that proposed by many authors (Huberman, 1989; Astley & Van de Ven, 1983; Armistead & Meakins, 2002; Nutley et al, 2003, Hildebrand, 1999; Kemmis & McTaggart, 2000; Schultze, 1999) in an effort to more fully understand the various levels of this intervention, a four-level theoretical model was adopted for analysis of this particular intervention. However, this model was refined as previously presented (Figure 6) to include four levels on the subjective to objective poles:

- *Rational/Objective*
- *Cognitive*
- *Situated*
- *Political*

After preliminary analysis of results of this intervention, correspondences between these four levels were found with various aspects of the intervention. We can therefore add these components to our original model of the intervention, applying them specifically to the creation of the analytical

framework (Figure 25). This allows us to consider the various steps of the intervention in relation to their influence on the four levels of impact leading to adoption/utilization of the framework and the ultimate effects of the intervention, and explore the suitability of this emergent model.

Figure 25: Emergent Model of Intervention with 4-Level Theoretical Model for Analysis



The presence of rational, cognitive, situated and political factors in this project will be considered in terms of specific aspects of the project. However, it is important to first consider the broader scope of how the overall intervention compared to the original planned project.

### ***Actual versus Planned Intervention***

The results indicate that this project went beyond the simple development of an analytical framework, examining organizational structures and proposing organizational changes in Canada. The actual intervention did not include all elements of the original planned intervention. For example, the development of a single, universal framework and its revision using the Delphi method did not occur. This was in part due to a lack of interest in continuing the refinement of the framework, instead using a flexible 'template' which could be modified according to different uses. Another reason was the interest in discussing and exploring possible organizational changes in Canada. The flexibility of the action research approach allowed the project to be expanded in scope to better respond to needs of stakeholders and ultimately have broader impact. These changes in the project made it difficult to have a high methodological complexity in data collection in this project. However, this was compensated by a gain in relevance, adoption of the innovation, and long-term impact of the project. The first major events in planning the actual intervention will be considered in the next section.

### ***Phase A: Startup of project***

The project was developed in close collaboration with Dr De Wals, an expert on immunization very active in research on the provincial, Canadian and international levels. This certainly provided much expert experience in designing a tool and means of intervention not available to an outsider to this context, and promoting the innovation from within this context. This corresponds to the notion of the important role and contribution of a 'champion' of an innovation noted in the literature (Schön, 1963; Rogers 1995). Also, there was careful consideration of similar efforts in the area of

immunization such as the Vaccines for the 21<sup>st</sup> Century project. The initial proposal was to perform the same type of exercise as in this project, however adapted for Canada. After reflection and discussion, it was decided to pursue another approach. This was in part due to knowledge of the needs of the decision-making context in immunization in Canada, and also of the limits of the approach of Vaccines for the 21<sup>st</sup> Century, which was based on prioritizing new vaccines in the next 10 years based on cost-effectiveness models. From the outset, the approach of the framework was based on a more flexible, interactive approach. In terms of Habermas, this project began with a *technical* approach in the development of the framework, but was also *practical* in that it sought involvement of stakeholders and active testing of this tool from the outset.

This flexible, interactive approach allowed the project to be tailored to best integrate with the two major contexts of application- the national level and the provincial level in Quebec. The intervention on the two levels was quite different, and depended on the individual agenda and timelines of partners at each level. One major difference which existed between the two levels of intervention was the fact that there was a formal contract at the national level, while in Quebec, there was simply an informal agreement to examine the potential uses of the framework (with no written contract). This formalization of the intervention on the national level had many advantages such as clarifying and legitimizing the role of the researcher and the project, providing a clear and defined timeline for the project, and defining specific deliverables for each phase of the project. At the federal level, there were systematic iterations of data collection, feedback, revision, reflection and action in the true nature of action research. This helped increase the richness of the data and confirmed its validity, and was a definite strength of the project on this level. In contrast, on the provincial level in Quebec, with the absence of a defined project and contract, the delays were much longer and the proposed activities could be easily pushed back on the agenda to



later meetings. Therefore there were fewer iterations and systematic feedback on this level of the project, which limited the planning of certain interventions and perhaps also the scope of the project.

Overall, both levels of this project (federal and provincial), we note the crucial importance of forming partnerships in the startup phases of such a project, and allowing structures and process of the context of application to influence the project to aid in adapting it to the particular setting in a process, which is more political than scientific in nature. This was an essential step that assisted the project enormously and allowed many opportunities, contexts, and interventions that would not have been possible otherwise.

### ***Federal Level***

On the federal level, submission of the original project proposal was crucial to the success of the project, as it began a process of discussion and negotiation which led to the agreement of a formal contractual collaboration with Health Canada. This allowed the development of the framework to play a role in the larger effort of developing a National Immunization Strategy, specifically one of the five components, which was to help ensure that vaccines in Canada are accessible and utilized in a cost-effective manner. A second component, goals and objectives for immunization programs, was added later to the project. The support and involvement of Health Canada gave legitimacy to the project and facilitated data collection by relating the project to the National Immunization Strategy. Consider simply the considerable resources required to finance, schedule and organize multiple face-to-face meetings with representatives from all 14 Canadian jurisdictions in the area of immunization, a unique opportunity for the researcher to present the project to key persons from across Canada, observe, interact,

and actively participate in the discussion and consultation process of meetings of the Subcommittee on Immunization.

These observations correspond with certain observations from the literature on the political or contextual level regarding the importance of factors such as personal contact between researchers and decision-makers, participation of users, and relevance to the policy agenda. This initial stage was indeed very political, involving a rich process of discussion and communication with the Division of Immunization at Health Canada to explain the project and its potential benefits, followed by more discussion and negotiation to establish a very detailed and structured contract including deliverables and precise deadlines (Table X). For Health Canada and the Immunization Subcommittee, the framework was of interest because it represented a practical means to pursue an important component of the National Immunization Strategy.

A very interesting and unexpected benefit of this initial negotiation process with Health Canada was that some additional components were added to the intervention, namely the study and evaluation of structures and processes for immunization program planning in Canada. This key addition allowed the project and its eventual impacts to be much larger in scope than originally expected. The new analytical framework was not only being proposed as an innovative way to evaluate immunization programs, it was part of a broader proposal to change structures and processes for this evaluation and planning process in Canada. The resulting emergence of a new Canadian Immunization Committee and an expanded role for the National Advisory Committee on Immunization, with future possibilities of a federal program for immunization, are all new forums in which the framework can be employed and have a significant impact.

The interactive nature of this project also helped the project to attain its'

action research orientation, in which researchers and participants work to seek and enact solutions to problems of a current situation and bring a concrete solution (Greenwood & Levin, 2000). This type of intensive consultation at the beginning of a participatory research project is important to success. Another factor is the existence of a detailed written agreement that defines the roles, expectations, timeline and deliverables of the researcher and the participants. Without this structure, there is less of a clear mandate for the researcher to interact with participants, and this lack of structure can cause delays and problems with data collection and advancement of the project, as was seen in Quebec. Part of the approach of the project, which included data collection on decision-making processes in Canada in an effort to improve them, can be seen to be a rather functional, technical or rational approach. However, there is a practical aspect in examining the pilot testing of the new committee in February 2002 (as described in the results section). This is contrasted however, with the extremely political federal committee meetings and processes of consultation, discussion, negotiation and consensus-building regarding immunization program planning in Canada.

In the particular Canadian context of federal-provincial-territorial relations in Canada, the interest of provinces and territories for federal support in areas of public health is balanced by their resistance to federal infringement on their jurisdiction of health spending. Therefore, these federal/ provincial/ territorial initiatives have a uniquely Canadian jurisdictional tension (similar to meetings on the constitution) that affects their content and functioning. Again, in terms of knowledge management, this component of the project is in the realm of negotiation, and political endeavors, and voluntaristic (*subjective*) in terms of the collaborative nature of the consultation and development process for the framework.

## Development and Testing of the Framework

The data collection regarding criteria for decision-making produced an impressive array of criteria that are important in decision-making in immunization in Canada. However, a similar, yet less detailed list had been existence and had been published over 20 years ago, but was not in use (White & Mathias, 1982). The important question was therefore how this framework could be used and how it should be modified for potential uses. While there was question initially of developing a more formal framework with a scoring system, this idea was not practical for several reasons. Firstly, this would require enough interest in the development of such an instrument nationally and also enough resources to complete such an exercise. Secondly, the growing awareness that the importance of various factors was not constant between potential programs made the development of such a rigid quantitative instrument less desirable and practical. Therefore an approach in which the framework was distributed and used in various activities was adopted. This had the advantages of enabling this tool to be adapted to various contexts and needs at the time of application. By involving the target users and allowing them to have a role in the use of and revision of the framework, they became active in the project, promoting adoption and usefulness of this tool.

Use of the framework in a vaccine ranking exercise was a success. For example the meeting in February 2002 including presentations by experts followed by evaluation and discussion was an important learning exercise. In addition, responses allowed identification of issues on which there was a consensus among experts versus those for which responses were divergent. This allowed targeted discussions to examine further important points. This type of activity is important in consensus building and can help to identify research priorities and areas for further study at an early stage. Another important benefit of this type of activity is to be more efficient among

jurisdictions, avoiding the repetition of efforts that has occurred in recent cases. Use of the framework on the national level allowed key persons from various jurisdictions to distribute it in their jurisdiction, and use it in their immunization planning activities, or have it ready for use when the next potential programs are considered, as indicated in responses to Questionnaire #4.

The spontaneous uptake of the framework to be used in educational settings was an unexpected application of this tool, and added an area in which this project can have an impact. If this new physicians and nurses are exposed to this tool, there could be a positive impact on understanding of the rationale for decisions regarding immunization programs. This is especially important if these individuals receive documentation about potential programs that follows the format of the framework, which will be perceived differently if they have already been exposed to this tool. Finally, an important event was that the exercise to develop the framework highlighted the absence of a national forum in which to use it. This was part of the justification for proposed organizational changes that are in the process of implementation on the federal level. Overall it seems that the specific details of the framework are less important than the process of building awareness about current decision-making processes and generating ideas about how to improve them with key stakeholders in Canada.

## **Examination of structures and processes for Immunization Planning in Canada**

The addition of this aspect of the project was a key element on the federal level of the project, which had a certain synergy with the development of the framework. Originally, the object of studying these processes was simply to better understand how to use the framework, but early in the project this expanded to a critique of existing processes and proposals for change on the federal level. This is a major shift, and adds a *critical* aspect (in the sense proposed by Habermas) in questioning current arrangements.

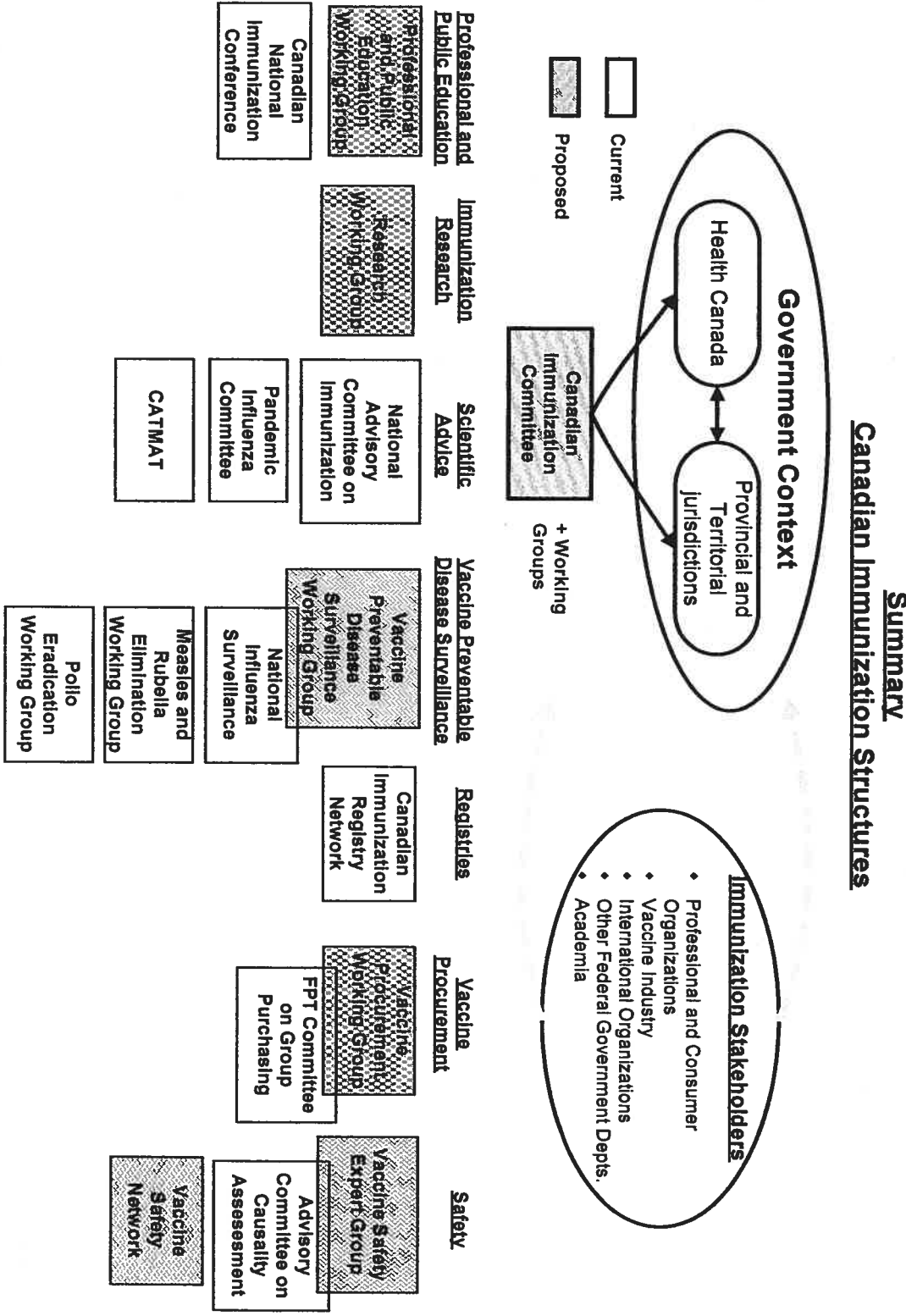
The action research methodology began with reflection on the current situation. This was supported by collection of detailed information in questionnaire #2 which was then returned to key persons from all jurisdictions and distributed via ISC members. This raised awareness and allowed various parties to identify problems in the current situation and participate by proposing changes to the current situation. The recognition of the duplication of efforts in various jurisdictions was highlighted, for example working groups on individual programs which have little informal or formal contact. This led to the proposal of a national working group on a specific program as a test case, which would require resources from Health Canada to occur. This has not yet occurred, but is being proposed with Hepatitis A and B programs (December, 2003), in the context of the National Immunization Strategy, or in with CCOHTA.

A new national immunization planning committee that considers potential new immunization programs was also formally proposed and tested. The pilot testing exercise testing February 2002 examined how the analytical framework could be used and also how such a new committee would function. This confirmed to parties from all jurisdictions that a national

committee evaluating immunization programs using the analytical framework was a desirable and feasible change.

In fact, this activity led to official acceptance of these proposals, and major changes are underway in Canada. This includes the emergence of the new Canadian Immunization Committee (CIC), which had its first meeting in November 2003. This committee will deal with issues regarding the planning of immunization programs and will have the Chief Medical Officers of Health or their delegates as members. The emergence of this committee is of great importance and potential impact. Further changes have been proposed recently in the broader national context. Over the course of this project, the National Immunization Strategy received funding of \$45 million over several years to further development of this strategy. Many other new structures have been proposed in Canada. The overall nature of the planned organizational changes are illustrated in Figure 26.

Figure 26: Current and Proposed Structures for Immunization Planning in Canada, 2003



Source: Health Canada, Population and Public Health Branch, 2003



In considering these results, we note that the aspect of the project involving the framework produced concrete results and resulted in successful adoption of this tool. In addition, the broadening of the project started a more profound process of organizational change, which led to implementation of a new structure for federal /provincial /territorial coordination in immunization planning in Canada. While the advancement of these organizational changes is relatively slow, their potential impact is great. The flexibility of the action research approach of this project allowed it to capitalize on these opportunities and increase the long-term impact of this project.

As is presented in Figure 26, the CIC is a new structure that aims to facilitate coordination between Health Canada and the 13 jurisdictions. This is a major addition to NACI, which has been historically the most important structure in this area in Canada. However, the role of NACI is also changing, as it must determine to what extent it will officially address program issues and recommend which new vaccines should be adopted. The extent and impact of these ongoing changes will certainly be major and will be observed in the coming years in Canada. More profound changes are also possible, particularly following the SARS crisis in Canada in 2002-3, and the following report released in October, 2003 (National Advisory Committee on SARS, 2003), which proposed that the federal government provide \$100 million in funding for vaccine purchase of 'agreed upon vaccines' in all Canadian jurisdictions. This confirms the desire for such a program expressed multiple times throughout this project, and would increase the importance of these new structures and the analytical framework in reaching decisions on which vaccines and programs to fund nationally.

### ***Provincial Component of Project- Quebec***

As previously mentioned, intervention on the Quebec provincial level was quite different from the federal project. Firstly, there was no formal contract defining the intervention and the various steps to follow. However, the role of one of the co-researchers (Dr. De Wals) as the president of the CIQ was very important in identifying opportunities for intervention. Unlike the federal project, there was little broader questioning of the decision-making processes in Quebec, other than potential uses of the framework and suggestions collected from the follow-up questionnaire on use of the framework. While the vaccine evaluation exercise using the analytical framework to evaluate several vaccines was less successful than in the national meeting, this was perhaps due to lack of planning and time for this exercise, as indicated in the follow-up questionnaire. CIQ members are now aware of the potential uses of this tool, and can easily integrate into future activities involving the entire committee if desired.

However, the vaccine-specific working groups in Quebec were an important setting in which to apply the framework. Three groups to date have used the framework to structure their reports, and a fourth has been proposed for the future. These examples have been presented on the federal level, and may lead to similar types of groups being formed either on a pilot or on a systematic basis. As on the federal level, the flexible, action research approach enabled this project to interact with key persons in the context and adapt the project to harmonize it with other initiatives and also to respond to user's needs. However, the lack of a formal contract and systematic discussion, feedback, and iterative steps made this interaction less intense than on the federal level. This could be in result due to a lack of resources in Quebec to specifically support such a project.

### ***Potential biases and their impacts***

We can now consider potential biases in the data collection and their possible impacts. When evaluating action research, care must be taken not to apply inappropriate arguments from a different paradigm of research (Meyer, 2001; Guba & Lincoln, 1989; Kemmis & McTaggart, 2000; Waterman et al., 2001). As in qualitative research in general, the principles of *triangulation*, *reflexivity*, and *respondent validation* (or member checks), are seen as particularly important (Silverman, 1993; Guba & Lincoln, 1989; Janesick, 2000; Yin, 1994). In general, we can also consider *plausibility* and *credibility* of qualitative research (Hammersley, 1990). Recently, the term *crystallization* has been proposed as a more complete alternative to triangulation, which considers multiple dimensions and perspectives of a single reality (Richardson, 1994). Taking into account these various general factors which apply to qualitative research and specifically action research, we can consider the potential biases in data collection in various stages of this project and their potential impacts (Table XXV). More general considerations of validity and quality will be discussed in later sections).

Consider first of all the data collection on the federal level. As previously mentioned, the choice of key persons was subjective and determined by CMOHs of each jurisdiction. This was done in part because CMOHs were in a good position to identify key persons having an impact on the policy process in their jurisdiction, and also to follow the hierarchy of power in each area in terms of making the project known and building support. The persons identified by CMOHs were validated by representatives from each jurisdiction to the ISC, and some changes were then made. Therefore overall, while it cannot be considered that the totality of persons who may have an impact on immunization programs in Canada responded to the questionnaire, a significant amount of data from many key persons in nearly

all 13 Canadian jurisdictions was collected and afterwards validated to begin the research/action process.

**Table XXV: Potential Impacts of sampling and other biases in Questionnaire #2**

<i>Category of information collected</i>	<i>Potential problems</i>	<i>Actions to reduce potential problems</i>	<i>Potential impact on results</i>
Q1: Goals and Objectives for Immunization Programs	Lack of detail, lack of information for certain jurisdictions	Consultation, follow up. Additional project with detailed questionnaire on goals and objectives	Minimal, due to follow-up with Goals and Objectives Project
Q2: Structures and Processes for Immunization Planning	Lack of detail, lack of information for certain jurisdictions	Multiple consultations and submissions for revision. Additional data collection specifically on structures and processes for decision-making in each jurisdiction conducted for each jurisdiction via ISC representatives.	Minimal, as information was eventually obtained from all jurisdictions.
Q3: Use of a framework for immunization planning	Omission of frameworks in use.	Framework was diffused as broadly as possible in many channels as possible across Canada, however no other frameworks were identified (other than those mentioned in questionnaire responses)	Minimal, as existing frameworks were identified.
Q4, Q5: roles of responder	Omission of roles of those not responding to questionnaire	Original questionnaire requested identification of key persons with general and specific questions.	Some loss of information, probably of minimal impact on project, as roles of individuals were simply collected as background information.
Q6-8: important criteria in decisions, type of framework decided	Omission of important criteria in decisions or types of useful frameworks due to non-responders	Comprehensive list of criteria was created from combination of questionnaire responses, literature and expert consultation. Framework was also revised after broad multiple consultations to add points considered relevant if requested by users.	Potentially some loss of information if non-responders had important points which were omitted. However, multiple consultations and opportunities were available to update the framework, minimizing the chance of this occurring. Also, this was designed as a flexible template to be transformed by users according to desired use.
Q9-11: Major needs, problems in immunization planning, solutions, general comments	Omission of useful information due to non-responders.  Responses influenced by political factors	Multiple consultations, discussions, revision, follow-up. ISC members were asked to consult key persons from their jurisdictions at all levels of their project. This question was included to start a discussion that was continued at multiple levels with the PHWG, ACPH, and the conference of Deputy Ministers in the development of the National Immunization Strategy and new organizational structures for immunization planning.	Potentially some loss of information if non-responders had important points which were omitted. However, multiple forums allowed for and actively sought out expression of major needs and problems in immunization planning, potential solutions in a consensus-building process in the ISC and elsewhere, therefore most important points should have been mentioned at some point during the project.

We can consider the Questionnaire #2 for key persons in particular in terms of the nature of the data collected, efforts to reduce potential problems, and potential impact on results of possible biases, considering this questionnaire in the context of ongoing consultations and interventions to follow in this project (Table XXV). A lower number of responders and incomplete coverage may have impacted the data in terms of omission of some responses which were not emitted elsewhere. However, due to the iterative nature of the project and data collection and revision, and the minimal nature of expected impacts on results, the impact on this collaborative project is expected to be minimal. The nature of the multiple and sustained contacts with stakeholders enables the data collected to be validated and very 'grounded' in the real-life context of immunization program planning in Canada, over a long and recent time span.

#### ***Goals and Objectives Questionnaire***

Regarding the following questionnaire on goals and objectives for immunization programs in each jurisdiction, an enormous amount of data was collected, with responses being received from all jurisdictions via the ISC. As this data was more objective and simply aimed to describe these official policies in each jurisdiction, there was no need for a larger consultation, and there were few concerns about validity of this data. In addition, the use of this data was simply to start a discussion on mechanisms to develop and monitor goals and objectives for immunization programs in the future in Canada, therefore consequences of minor omissions or errors on certain programs in certain jurisdictions cannot reasonably be imagined to have a major impact on the overall diversity in this area in Canada nor on the resulting discussions.

### ***Worksheet on vaccine evaluation***

This sheet involved a pilot exercise to test the framework, in which categories of responses corresponded to those in expert presentations. This was not a validated scientific instrument, the categories were not specifically operationally defined, and the ranking methods were subjective, therefore responses can be considered to be affected by potential differences in interpretation. However, the goal of this exercise must be considered, which was not to produce a global score for each vaccine with the diverse responses for each category, but rather to compare profiles of responses of experts in terms of the degree of consensus or divergence. This could guide further discussions into points for which there was much divergence to explore the underlying issues and potentially provoke further research or systematic study. The overall aim was to make the expert knowledge of participants more explicit, as well as the important points in the evaluation of particular candidate vaccines. Comments were collected on this activity to make revisions before applying a similar worksheet in the provincial context in a similar activity.

### ***Action research approach***

By allowing the project to be transformed and revised in an iterative process, the action research or co-operative inquiry approach allowed the project to benefit from consideration of needs of stakeholders and be appropriately adapted to needs in the context at the time of application. This allowed the researcher and the project to be broadened in scope, going beyond the objective area of scientific knowledge to explore the cognitive factors of decision-makers, situated in their specific context and influenced by political factors. Therefore, action research has the benefits of bridging theory and practice, being reflexive, and producing change relevant to participants in

the context.

However, this intense involvement or 'sustained interactivity' with the context which is actively sought out to improve the links between research and practice also limits the methodological complexity and 'objective' scientific rigor of the research aspect of the project. For example, there was no formal coding of some types of data for analysis. Factual data (i.e. on immunization structures and processes) was systematically compiled and verified. Data on important criteria for decision-making for the analytical framework were systematically clustered to form the criteria for the framework. However, data regarding opinions of key persons was not formally coded, due to the fact that this data was to be summarized and returned to key persons for discussion and debate. The method for summarizing this type of data was simply to present the variety of responses expressed to contribute to the collaborative intervention. No further formal coding was seen as necessary after the intervention was completed.

In this intervention, the action research approach worked exceptionally well to develop a decision-making tool and begin a process of organizational change in a broad interjurisdictional setting, with objective, measurable events that occurred as an impact of this intervention as tangible results. While the action research approach did permit an integration of multiple elements and perspectives of this phenomenon, it is unclear to what extent these could be studied in depth without having more resources for this project. Therefore, from a perspective of trying to bridge research and practice, implement change or try to better understand methods to strengthen this link and/or improve practice, the action research approach is a definite success in this case. This approach enabled not only the creation of an analytical framework by key persons in the target context, but also began a wider process of organizational change that is continuing. The action research approach enabled not only the effective and broad

implementation of this tool, but also a generative process of reflection, expression of ideas, and consensus-building, leading to major changes in this context.

This approach also enabled integration of objective and subjective elements, at the individual and system level. Multiple, sustained, long term interactions and collaborations with the context, particularly on the federal level where there was a formal contract, allowed the project to be responsive and pertinent to the context. Opposed to these benefits, the action research approach presents some limitations. The generalizability of these results, highly influenced by the context, can be questioned, and must be confirmed by other studies or cases. Due to the unpredictable nature of the project and the intervention, which were at the mercy of the context, there was little control over time frames and data collection by the researcher. All planned interventions and data collected needed to be presented to partners in the context of application for approval. While this resulted in several successful interventions (described in the results section) and was in some aspects a strength of the project, it also resulted in delays and some lost opportunities. Consider for example that the vaccine ranking exercise with the CIQ was delayed for a year, perhaps making it less pertinent as some programs were already being approved (i.e the meningococcal conjugate program).

It must be considered that collaborative research is a two-sided coin with advantages and corresponding disadvantages. The formal collaboration with Health Canada allowed the project to be structured and connected to the context, giving the researcher a clear mandate and opportunities to interact with the context. However, priorities of the research partners were sometimes not the same. For example, at one point in the project, establishment of a pilot national working group on a specific vaccine such as pneumococcal conjugate vaccine was proposed, which would provide



another opportunity for diffusion and testing of the framework and national collaborative structures for immunization planning. However, at this time there was a need for action on the element of the National Immunization Strategy concerning goals and objectives for immunization programs. Therefore a questionnaire (#3) and lengthy data collection was performed. While results in this area confirmed results of questionnaire #2 in terms of the need for national coordination and long-range planning, this did not specifically advance research or action on the framework. In addition, administration of this additional questionnaire may have reduced response rates on the following questionnaire (#4).

The specific context of this research project as a PhD thesis must also be mentioned. While the goal was to test existing theories, explore and develop new ones, and test a mode of intervention to implement a change to improve knowledge transfer, this all had to be done satisfying a certain degree of methodological complexity and rigor of scientific research, beyond the success or practicality of this particular intervention. The strength of being grounded in the actual context and validated by multiple iterations and actual observable changes is balanced by the weaknesses of the lack of a predetermined, objective, validated and structured data collection and analysis method. These tradeoffs are central to many current debates on action research and qualitative research. Further study should focus on how these tradeoffs or potential shortcomings can be minimized.

## **How do results compare to literature and theories of knowledge transfer?**

First of all these results can be compared to the five categories of knowledge transfer (i.e. knowledge-driven) commonly identified in the literature. As expected, no single theory could account for the range of observations in this project, and 'knowledge' or 'evidence' was but one factor in a very complex process of decision-making (Woodward et al., 1997). The introduction of an innovation was a complex, multistep process as described in the literature (Rogers, 1995). In particular, this project was conducted in a complex interjurisdictional setting in which much political negotiation and discussion were present in addition to the knowledge or science components. The innovation was designed to be flexible to encourage appropriation and use by target users, and was indeed transformed, reinvented and sometimes simplified according to the time and context of application.

Many factors which have been seen to optimize impact on decision-making in the literature were observed in this project. For example, personal contact or 'sustained interactivity' between researchers and policy-makers helped tailor the project to the current policy agenda, make it timely, encourage user participation, and encourage focus on concerns of the specific context (i.e. Beyer & Trice, 1982). This leads us to consider the observations of this project as compared to various categories of models for knowledge transfer. Firstly let us consider in turn the five groupings of knowledge transfer approaches (previously presented in Table V) as applied to observations in this project and context:

### **1. Knowledge-driven and 2. Enlightenment models:**

It is not surprising that these models cannot account for the complexity of interactions and events observed. However, it would be an error to reject this model, as much of the base of public health and indeed vaccines and immunization programs involves scientific knowledge with a rational component. In terms of the analytical framework, these components correspond especially to the first four categories, namely *burden of disease* and *vaccine characteristics*; and also to the third and fourth categories, *alternative immunization strategies and programs*, and *social and economic costs and benefits*. A recent example of scientific knowledge having an impact on decisions was the high frequency of pneumococcal infections in children being determinant in assigning this vaccine as a top priority, while the rarity of complications from pertussis contributed to its being assigned a low priority (Erickson & De Wals, 2003).

Another observation during the development of the analytical framework was the spontaneous uptake and use of the framework as an educational tool in multiple settings in Quebec and Manitoba. This was discovered in questionnaire responses and also requests to obtain copies of the framework, without any active promotion of this type of use. Therefore, as in the agricultural extension model (Rogers, 1988), innovations can simply be adopted without any active effort at diffusion. However one must admit that some sort of exposure (active or not) is required for users to learn of the innovation. Indeed, knowledge does not diffuse without mechanisms (such as publications or conferences), and this can be passive as illustrated in the cases mentioned. However, this ignores more active processes that were observed and can be accounted for by other models.

### ***3. Information-seeking or 'pull' model***

Certain aspects of this model can be observed in the context of immunization program planning in Canada. Corresponding to this model, the identified need for which information is sought is a potential new immunization program, which must be evaluated. This can originate from scientific experts, ministries of health, public demand or a combination of these. When an advisory body in a given jurisdiction is given the mandate to produce advice on a given program, they gather and review data about this subject and present their assessment to the decision-makers (in this case the Ministry of Health). Consider for example the working groups in the province of Québec mandated by the CIQ to make recommendations on potential new programs such as the pneumococcal conjugate vaccine. The need for information about this potential program was sufficiently important that specific research projects were funded (such as an economic evaluation of a routine immunization program with this vaccine). Therefore, like the knowledge-driven model, the information-seeking model describes part of the multiple and complex events in this case but only provides a partial or incomplete view of the overall situation.

### ***4. Interactive model***

This model applies to many observations in this project, which involved numerous interactions between key persons in the development of the analytical framework and the negotiation and approval of organizational change. There are multiple interactions, formal and informal networks in the area of immunization in Canada, which had an important role in the adoption of the framework and the emergence of organizational change in Canada. The emergence of a new Canadian Immunization Committee is an opportunity to create new interactions in a new community of practice in this

area that can influence policy. Therefore, this model seems to address one aspect of knowledge transfer quite well. However, it is not clear to what extent this model includes considerations such as a problem-solving approach or simple use of information as in the other two models.

### ***5. Political models***

These models are totally appropriate for the context of this intervention, in particular the federal context in which constant negotiation between the federal government and the 13 provinces and territories was present. Any attempts at national coordination were made in the context of sometimes divergent interests by provinces and territories. It has often been observed that the larger provinces are more independent in terms of resources from Ottawa and therefore aim to preserve and increase their power. Smaller provinces and territories on the other hand are in need of resources to assist them in their planning activities and therefore have more to gain by collaboration with the federal government and national coordination.

It must be noted that while decisions on immunization programs may have a scientific base, a favourable decision regarding a new immunization program has many political implications, such as negotiating and approving new spending by the government, and having the resources and support of of involved partners in the health system to implement the program.

The decision to provide mass immunization against meningococcal disease in the province of Québec was highly political both times it occurred, with public pressure and dramatic media coverage putting pressure on the Ministry of Health to adopt a program. Other examples in which programs have been implemented at least in part to political pressures have been noted in Canada. For example, the province of Prince Edward Island

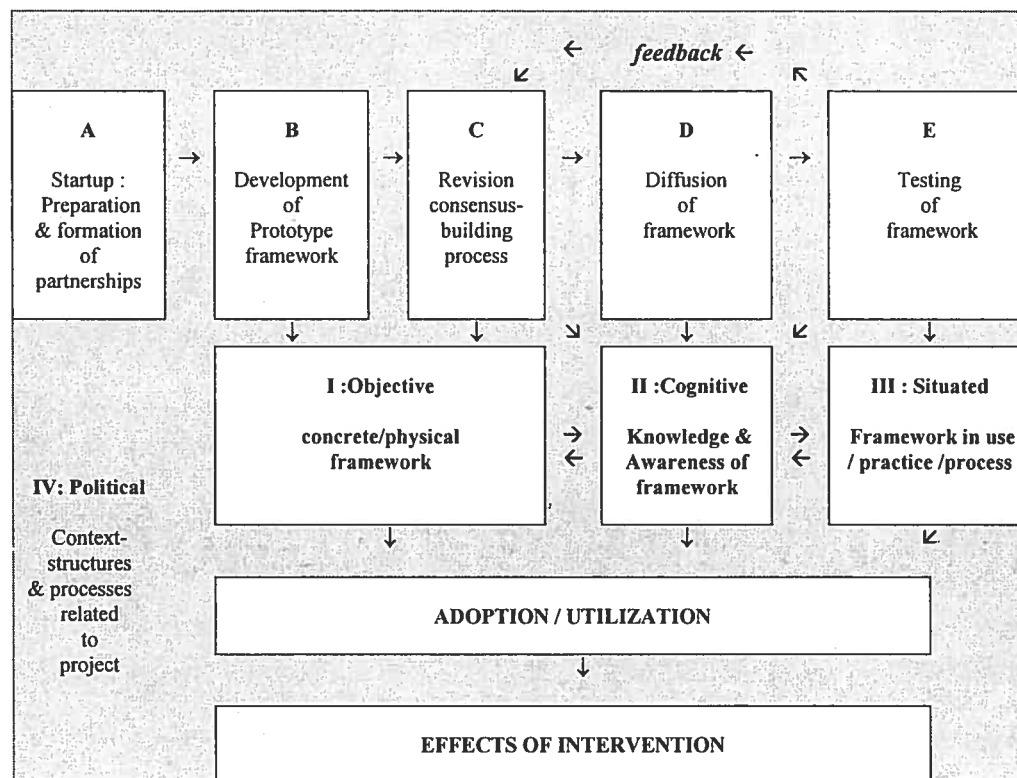
implemented a varicella program at least in part due to pressure on government officials by a parent of a child with sequelae of varicella. Some have suggested that the decision of the province of Ontario to provide free influenza vaccine to all residents occurred as a result of a desire to reduce emergency room overcrowding, which can be interpreted as a largely political consideration.

Overall, observations in this project indicate that each model has something to offer in terms of describing the observed events, however, no single approach can account for the overall picture. We see particularly that the frames of reference of the decision-maker are important, as is the application of research or an innovation to their particular context. Therefore, cognitive, situated learning and reflexive approaches can help to better understand these areas which are not specifically covered in broader theories. By adopting the four-category model (proposed in figure 5) which includes objective, cognitive, situated and political levels, we will attempt to perform a more complete analysis.

### ***By four levels of analysis***

We can also analyze the overall project in terms of the four levels previously mentioned which were proposed for this particular project: *objective/rational, cognitive, situated* and *political* (Figure 27).

Figure 27: Project model with four levels of analysis



### I Objective/Rational Level:

We can consider which elements contributed to the actual physical framework in this project and how this contributed to adoption and utilization of the framework. The development phase employed a questionnaire to collect information on important criteria for decision-making in immunization, which increased the pertinence of the instrument, allowing the content of the to include elements from the actual context in Canada. The elaborate revision and consensus building process also allowed the framework to be revised and modified, again according to comments from stakeholders/ participants in the context. After testing, there was also revision of the instrument. Subsequent steps allowed the instrument to be revised according to the desired application also. Therefore globally, the actual framework evolved over time as a consequence of interaction with the

context. This allowed it to be tailored to the actual context, increased its pertinence, and ultimately facilitated its adoption and utilization. Overall, objective characteristics of the physical framework developed are important in determining its pertinence and degree of adoption and utilization. However, the objective approach does not take into account how individuals perceive or understand the framework, how they use the framework, or the political factors in the context of application. Therefore, the other approaches can complement an overall understanding of the intervention.

## **II Cognitive Level:**

Many steps of the project contributed to knowledge and awareness of the framework. In the initial development phase, a national questionnaire made key persons in immunization aware of the development of the framework. Also, presentations to ISC and discussions, and circulation of reports allowed individuals to know about the framework. Several presentations at important meetings for those involved in immunization also referred to or discussed the analytical framework and initiatives to improve immunization program planning on the federal level. This included presentations at national immunization conferences, Quebec provincial immunization conferences (twice), and the *Journées Annuelles de Santé publique (JASP)* in Québec. Therefore, we can consider that the objective framework existed also on another level in terms of knowledge by potential users, which was influenced by their contact with and understanding of this framework in various contexts.



### **III Situated Level:**

The situated level involved going beyond simple knowledge about and familiarity with the framework to actually test this tool in specific activities, such as evaluation of vaccines, or structuring reports or presentations. By testing the framework in different contexts, its use and integration passed to another level than simple knowledge of the tool. This allowed the instrument to be integrated into actual processes. These could be artificial processes such as the vaccine evaluation activities, or actual use of the framework in preparing a report, or conducting an actual committee meeting on a particular program. This can be considered to build on knowledge of this tool and demonstrate to potential users how this tool can be used in their particular context.

### **IV Political Level:**

By considering the particular political context(s), structures and processes related to the project, we can interpret the intervention at a more global level. These factors were present in and affected all aspects of this project. Because the implementation of new immunization programs requires new government funding, obtaining of this funding is necessarily embedded in a political process. In this project, political factors were present in all aspects and had impacts on the various stages of the project. Interestingly, the intervention on the federal level acted on these structures and processes as part of a process of organizational change that is ongoing. These organizational changes impacted the framework and the project on the objective, cognitive, and situated levels.

### ***Relationships between four levels of analysis***

How then are these four levels of analysis related to one another? Overall, we can compare the objective, cognitive, situated and political approaches in terms of their increasing scope and consideration of contextual factors. With the specific project to develop the framework, these stages were interdependent, with existence of the *objective* physical tool required to allow it to be known by users in the *cognitive* phase. The cognitive knowledge of this tool was in turn required for users to test this framework in various contexts and develop a *situated* level of integration of this tool. The *political* aspect was omnipresent, especially due to the participative and interjurisdictional nature of this project. Consider for example that the objective/rational level is concerned with the concrete aspects of the framework: format, content, etc. This first step of creation of the framework was necessary to develop the cognitive aspect, in which this tool was known, observed, and understood after diffusion in various contexts. This in turn is necessary for a situated level of application of the framework- actually using the tool in various contexts. This testing can surely develop and enhance the cognitive level (knowledge of the framework), which can also influence the objective form of the framework by allowing feedback to improve this tool. This was observed in the modification of the number of categories of the framework after initial testing.

While this emerging four-category model is quite preliminary, it provides a first step in integrating the various types of models to explain knowledge transfer. Further study of intermediate cognitive and situated approaches will help to more clearly define each type of approach. Other categories may be added also if further distinctions are required. The use of this type of categorization would also have the benefit of making the actual type of knowledge transfer studied in a particular context more explicit, as well as

the importance of each factor in that specific context or intervention. Further testing of this model in other contexts would be beneficial in evaluating and revising the model, and most importantly developing theories which integrate the various, yet often isolated approaches which currently exist. These four levels of classification were useful in this project. However, less attention was paid to the differences between the macro, meso and micro levels. Further research could focus particularly on the differences between these levels. In addition to the integrative framework, the three-category classification system of knowledge-constitutive interests proposed by Habermas can also be examined in relation to the four categories (objective, cognitive, situated, political) and the observed results.

#### ***Correspondence to three levels of knowledge proposed by Habermas***

The three levels of knowledge-constitutive interests proposed by Habermas (1974, 1972), namely *technical*, *practical*, and *critical*, were clearly observed in this project. Firstly, the *technical* level is very similar to the objective/rational level, which was concerned with developing a framework that included all important criteria. In this project, the original approach which involved identification of important criteria in decisions regarding vaccines corresponds to a technical approach. A project involving solely the determination of these criteria and the development of a comprehensive model to be more efficient at reaching decisions can be seen to be technical in nature. However, from the outset, this project strove to develop a tool which was more than simply an interesting theoretical device, and would actually be implemented and used in immunization program planning in Canada.

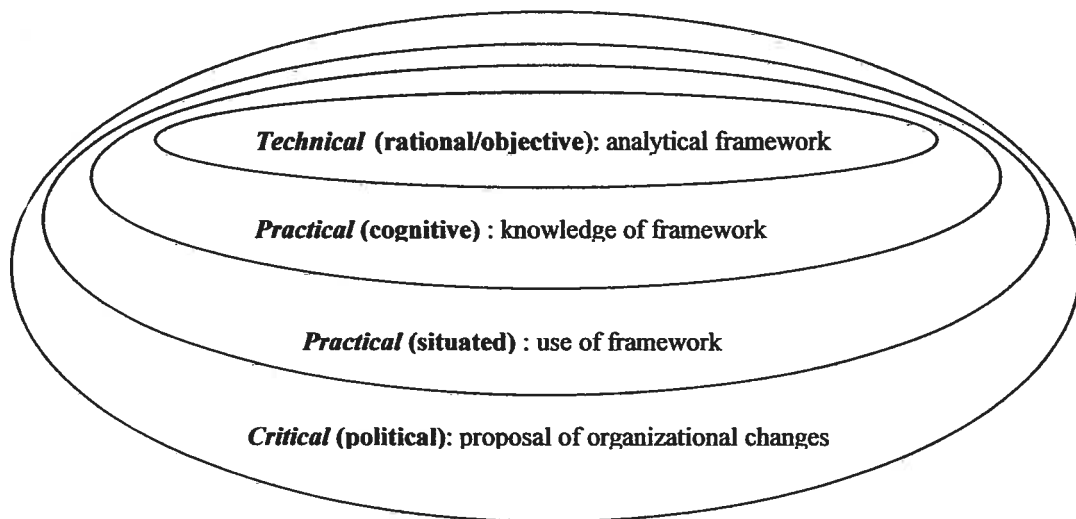
Therefore, the *practical* level was also included in this project. This corresponds to *cognitive* and *situated* levels, which involved the potential

users and allowed them to modify, and comment on the intervention. This recognized the importance of the users as subjects having a specific perspective and specific needs, who are required to make complex choices in changing contexts. This implies efforts to educate actors or practitioners to help them understand more fully the consequences of their actions, thus assisting them in choosing the optimal course of action (Kemmis & McTaggart, 2000). This corresponds to the analytical framework allowing actors to more explicitly examine all relevant criteria regarding a potential immunization program to more accurately assess potential impacts and guide the decision about this specific program. The practical approach is further seen by allowing users to test, evaluate and revise the framework following use in various contexts. Examination of the overall context of the intervention by users on a broader level leads to the third perspective suggested by Habermas.

The *critical* perspective extends beyond both technical and practical reason, considering limits of the current situation on actors and how it could be changed. This is similar to the *political* perspective of negotiation and power struggles, but goes beyond the current situation to consider and propose change. This was clearly observed in the project on the federal level, which examined current structures and processes for decision-making in immunization and proposed changes. There was also some discussion of federal funding for vaccine purchase, which also relates to this critical perspective as it implies a change in relationships between the federal and provincial /territorial governments regarding the responsibility for vaccine purchase. On the provincial level in Quebec, there was also some presence of a critical perspective when CIQ members were questioned regarding potential changes to immunization planning in Quebec. It seems that the action research perspective allowed the project to transcend the technical and practical perspectives and take a critical perspective towards broader organizational changes. As suggested in the literature (Varey et al, 2003;

Ulrich, 2001; Kemmis & McTaggart, 2000), each of the three levels suggested by Habermas represented a broader perspective, integrating the previous levels (Figure 3). In addition to confirming this relationship, the results can allow us to adapt the relationship presented in Figure 3 to include the four levels proposed by the framework developed in this project : *rational, cognitive, situated* and *political* (Figure 28).

**Figure 28: Proposed relationship between various levels of knowledge and analysis\***



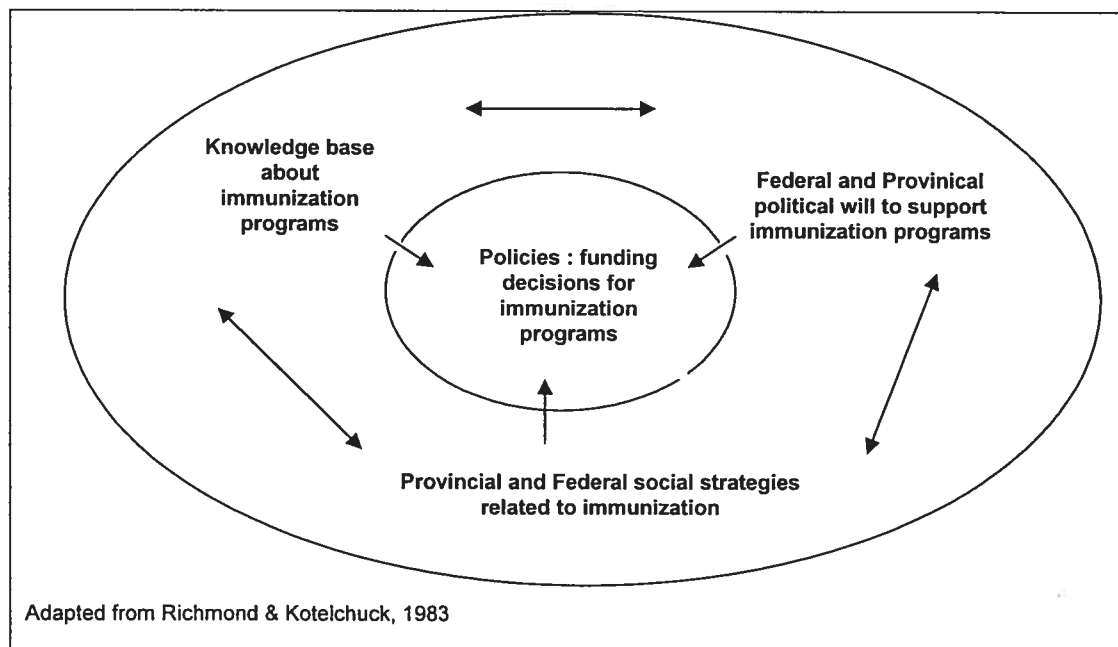
\*Adapted from Figure 3

We can consider these levels in relation to recent observations stating that technical information or 'evidence' constitutes the rational core of an innovation, which is encircled by a series of practical problems when applied to a given context (Denis et al., 2001). This approach can be useful in being more specific at the outset regarding knowledge transfer projects in stating their scope. What technical, cognitive, situated, and political aspects will be addressed? This emergent model represents an important refinement of these categories that can help future research and interventions to go beyond research /policy or evidence /context dichotomies to a more encompassing, global view.

## The Richmond & Kotelchuck Model for Public Health Policy

We can also consider this model in light of observations in this project, particularly how the components of the **knowledge base**, **political will** and **social strategy** combine to produce **public health policy**, adapting it for immunization in Canada (Figure 29). This project originally focused on the knowledge base and the transfer and organization of research information, aiming to improve and facilitate this via the analytical framework. However, on the federal level, the project was coupled with the development of a new social strategy, namely the emergent National Immunization Strategy.

Figure 29: Revised Richmond and Kotelchuck Model for the Development of Public Health Policy in Immunization in Canada



Considering political will, it was observed that this factor can be influenced by external pressures, such as the media and public in the case of meningococcal immunization campaigns. The variation in public policy in terms of currently funded immunization programs previously presented in

Table I (Sibbald, 2003) illustrates the importance of other factors than simply the knowledge base in the determination of these public policies. While there are certainly some variations in the knowledge base between jurisdictions, these are insufficient to account for the wide variation in programs. Linking efforts at improving the knowledge base to an interjurisdictional social strategy such as the National Immunization Strategy can help to create more links and similar pathways to influence public health policy in terms of publicly funded immunization programs in a similar direction. The type of systemic, multidimensional analysis proposed by this model is beneficial to understanding the complexity of knowledge transfer and policy-making in this area.

### **Validity**

As mentioned in previous sections, action research should be judged from a slightly different perspective than traditional research. Sacrifices in methodological complexity are expected to be balanced by gains in 'face validity', which refers to what extent the change developed is implemented, successful, and makes sense to participants (Kemmis & Mc Taggart, 2000). This is indeed indicative of some of the tradeoffs and different priorities of action research as compared to more traditional forms of research. However, despite certain particularities, action or qualitative research does not escape from concerns about validity (Silverman, 1994), which need to be addressed. Due to similarities of action research to case study research, four tests proposed to examine the validity of empirical social research can be considered as an initial exercise (Yin, 1994), presented in Table XXVI.

Table XXVI: Case Study Tactics for Four Quality Tests in Social Research

tests	Case study tactic	Phase of research in which tactic occurs
Construct Validity	-use multiple sources of evidence -establish chain of evidence -have key informants review draft case study report	Data collection  Data collection Composition
Internal Validity	-do pattern-matching -do explanation-building -do time-series analysis	Data analysis
External Validity	-use replication logic in multiple case studies	Research design
Reliability	-use case-study protocol -develop case study data base	Data collection

Adapted from Yin, 1994

Using this framework, we can now consider these types of validity in turn.

### Construct Validity

This involves establishing correct operational measures for the concepts being studied (Yin, 1994). According to Yin, use of multiple sources of evidence, establishment of a chain of evidence, and having key informants review the draft report can increase this. This project certainly used multiple sources of evidence in a broad consultation covering a period of years across Canada, to the extent of available resources for the intervention and data collection. Another key advantage was that results were systematically returned to key persons for validation, commentary, updating and correction as much as possible during the project. This was especially structured in activities with the ISC, which systematically required circulation of a draft



report, presentation of a summary at meetings, circulation in individual jurisdictions. Finally a chain of evidence could be established, as the methods section described how data was collected and the context of the project from which observations were made and conclusions drawn in detail. One area in which construct validity was not specifically addressed was in the categories of the framework, which were not given specific operational definitions. This was in part due to the fact that exercises with the framework involved its use as an informal tool to guide discussion rather than a formal quantitative tool to prioritize programs. On a practical level, there were no resources available federally, nor a sufficient interest at this phase of the project to further develop and define categories of the framework. In the Quebec level of the project, an interest was expressed in this type of exercise by members of the CIQ. This type of initiative may indeed occur if the CIQ, NACI, CIC or other committees using the framework wish to develop it into a more formal and explicit tool.

### **Internal Validity**

This involves inferences of causality in explanatory aspects of a study, particularly regarding events not directly observed. In this particular intervention, relevant questions could include the following:

- Did the action research approach improve the scope, quality and long-term impact of the intervention?
- To what extent do the theoretical framework, various theories of knowledge transfer, and the three levels of knowledge proposed by Habermas apply to results?
- To what extent does the Richmond & Kotelchuck model of public health policy apply to results?

Yin mentions pattern-matching, which is the comparison of results to multiple predicted patterns, explanation-building, which aims to explain a chain of events, and time-series analysis which compares chronological evolution of independent and dependent variables. These efforts aim to

examine convergence of evidence and identify rival explanations or confounding factors. Proving causality is a complex endeavor. This action-research study was largely exploratory in nature; however, some aspects of these strategies were employed. For example in consideration of the impact of action research approach on the implementation of the study, there is an observable chain of events that led to implementation of the framework and organizational changes in various contexts. This chain of events stems from the initial documented interventions to develop the framework, and propose the new national immunization committee. It is therefore warranted to consider that a causal role, while unproven, is plausible, especially in the absence of rival explanations. The considerations of how well various theories apply to results is more of an exploration of to what extent they may be useful in explaining observed phenomena rather than accepting or rejecting these theories. This was principally undertaken to demonstrate the partial application of all theories and promote a more inclusive approach.

### **External Validity**

The question of generalizability to other cases and contexts was not addressed in this single case study. Implementation of the framework occurred in several different contexts (provincial and federal), however these were not independent cases but rather different levels of the larger overall case (immunization planning in Canada). However, there was some question of multiple contexts if the 13 Canadian jurisdictions were considered, which all seemed to have a similar reaction to the framework and the proposed organizational change despite variations in their specific contexts. This could be further examined by repeating the exercise in another country. Also, additional similar approaches using an action research orientation, exploring the applicability of various theoretical models

could also be tested in other areas in which interjurisdictional coordination in health care planning is desired in Canada (i.e. technology assessment). Similar results in this type of project would address external validity of this exploratory project.

### **Reliability**

This involves demonstration that the procedures of the study could be repeated with the same results. In this project, this is achieved by documenting the data collection process and actual interventions in detail. Some aspects of the research-action project, such as the reports or presentations would certainly have been different, and there would probably be minor differences in the summary of collected data as no clear algorithm was followed. However if the qualitative approach of representing the diversity of different responses in data summaries were respected, another researcher would probably arrive at a very similar result. Because this project was very context-dependent, one could not expect to replicate the exact variety of persons involved in particular meetings, nor the external factors in individual jurisdictions which change over time. However, more general factors related to the context and the intervention would be expected to be constant; the intervention should be repeated in a project that uses multiple data collections and sustained interaction with the stakeholders to develop a global picture of the situation in this area in Canada.

### **Quality**

Miles and Huberman (1994) discuss five main issues related to the quality of studies. It is also useful to consider this project following these five main themes:

## **1. Objectivity / Confirmability**

This concerns whether conclusions depend on the subjects and conditions of the inquiry, rather than on the inquirer (Guba & Lincoln, 1981), has neutrality and freedom from researcher biases been reached? This can be demonstrated by detailed description of the study's general procedures, data treatment and transformation. In this case there was much objectifiable data in terms of concrete interventions. Outside of events, the researcher also depended on data collected and verified from multiple data sources. Therefore if certain biases were present in representing non-factual data, such as opinions, there were ample opportunities for responders to correct these. This strong connection with the context and multiple verifications and public circulation of reports including detailed primary data ensured the objectivity of the researcher in this project. On the level of inferences regarding the application of theories, the increased level of abstraction allows for greater subjectivity in analysis. However, overall patterns are fairly evident and have been based on observations from the study, which tends to limit the degree of potential bias by the researcher.

## **2. Reliability / Dependability / Auditability**

In terms of observations and data collection regarding interventions in this project, there was much congruence between informants, contexts and through time. No data was available for certain jurisdictions at certain stages of the project, which may have enriched the data. However, multiple iterations of data collection enabled compensation for this by completing missing data. This frequent review by stakeholders of data collected, analysis and conclusions and convergence of interpretations was in itself an ongoing audit of the products of this study, and was a form of quality control. In terms of theoretical explorations, these were emergent and not based on pre-defined criteria but general observations, and therefore should be considered as preliminary.

### **3. Internal Validity / Credibility /Authenticity**

This involves whether the findings make sense, give an accurate portrait of reality, and are credible to the people studied and to readers (Miles & Huberman, 1994). This study was definitely 'context rich', reflecting the studied contexts. Triangulation of data from different sources strengthened and converged on the same general conclusions. Areas of uncertainty identified include the actual higher-level decisions processed in provincial/territorial governments, however the other aspects of the decision-making process outside this 'black box' were studied in detail. Participants ratified conclusions at various steps of the intervention. Certain predictions were indeed accurate, such as the effectiveness of an action research approach to bridge theory and practice. While observations can be associated to theories by pattern-matching, this was general, exploratory and limited in scope due to the absence of specific constructs of these theories.

### **4. External Validity / Transferability / Fittingness**

This considers to what extent findings can be generalized. This intervention was largely exploratory and examined a single case. Therefore to a certain extent, findings are unique to the context of immunization in Canada, however it is plausible that they may be applicable to other areas in which interjurisdictional collaboration in health care is desired in Canada (i.e. coordination of health technology assessment). This must be verified by similar interventions in different contexts. The effectiveness of the action research approach to implement changes and bridge the theory-practice gap corresponds to multiple observations and general conclusions in the literature.

## **5. Utilization/ Application/ Action Orientation**

This level considers what the study does for its participants. This is also called 'pragmatic validity' (Kvale, 1989), and is increasingly important as we address the use and short-term practical applications of research. This is parallel to the debate in evaluation studies that considers in addition to methodological rigor, the impact of a study on decision-makers and policy. As previously mentioned in considerations of quality in action research, this is often considered as the dominant criteria for evaluation. In this area, the current study has been extremely successful, which is perhaps not surprising due to its action orientation from its conception in aiming to implement a useful innovation in collaboration with stakeholders in a given context. In terms of evaluation reports, Patton mentions that the ultimate test of credibility is the response of decision-makers and users to the report (Patton, 1990). In this action-research approach, the response has already started to occur and is continuing based on various interventions before the final global report, in terms of continuing implementation and use of the innovation and implementation of organizational change.

One can also judge 'good' qualitative research as enhancing levels of understanding and sophistication and the ability of participants and stakeholders to take action during and after an inquiry. In this project, findings were intellectually and physically accessible to users, and stimulated working hypotheses as a guide for further actions. Many levels of usable knowledge were produced, ranging from consciousness-raising about decision-making processes to development of a consensus regarding organizational change and processes to guide decision-making. The intervention and findings did have a catalyzing effect leading to changes, which is a first step towards solving the identified problems. In terms of

empowerment, we can speak of increasing involvement and participation leading to increased control of developments in the context of participants. This project involved learning by participants as they examined decision-making processes, learned about new programs, and tested the analytical tool in evaluating and discussing these programs with other experts. Some value-based concerns were addressed in aspiring to the principle of equitable access to health care in Canada.

Therefore we see the trade-off that often occurs between methodologically complex and practical research. Ideally, we would like research to succeed on both levels, but this is a challenge given the limited resources for conducting projects. This can perhaps be better defined by more explicit examination at the outset of research projects in defining the research questions and how they refer to adding to knowledge or improving practice.

### ***Specific criteria for assessing action research projects***

A list of twenty specific questions have recently been proposed for assessing action research projects in a recent systematic literature review on action research (Waterman et al., 2001) This list is presented in Appendix 16. In general, this project responded well to these assessment questions. Briefly, we can consider in some detail how this project responds to these key considerations. Firstly, the objectives of this study were clear, and the results were useful to users. Concrete and major changes were implemented in the area of immunization planning in Canada and are continuing. Further research is appropriate to examine mechanisms for interjurisdictional collaboration, the development of integrative theoretical frameworks for knowledge transfer, and the potential uses of action research to bridge the research-policy gap in Canada. The research process was clearly outlined and the choices for study were justified. Local contexts

were considered when implementing changes, and the role of the researcher was clearly defined. The project was managed appropriately, involving key competent persons and responding to events and participants. There was an underlying ethical consideration that was the encouragement of equitable access to vaccines and disease prevention across Canadian jurisdictions. While the study could have been increased in scope with more funding and data collection and interventions could have occurred in additional jurisdictions, data collection was appropriate and the study design was flexible and responsive to the context. The intervention was explicitly described and findings were linked to existing knowledge and theories in this area. The findings of this study may be transferable to other settings, but further research is required for this. Finally various specific and general issues regarding the evaluation of this study addressed by the author in various sections of this report. These guidelines should be useful in developing more structured methods of conducting and evaluating action research in the area of health services in the future.

### **Limits of Study**

Action research is admittedly 'low tech', as researchers in this area often make concessions in methodological and technical complexity in exchange for more immediate gains in face validity. This is done to generate timely evidence that can be used and developed in a process of transformation of practices, practitioners, and practice settings (Kemmis & McTaggart, 2000), concentrating on generation of ideas and implementation of changes. The focus is on determining and working towards 'what can/ should be' rather than analyzing 'what is' (Waterman et al., 2001). However, as is often the case with interventions in the context of public health, some levels of the actual impact of the intervention are difficult to evaluate.



In this study in particular, the intervention has succeeded in implementing a decisional tool in various jurisdictions and on the federal level, and also an organizational change at the federal level. However, we do not yet know if and how the intervention will actually change decisions regarding immunization programs in Canada. One problem is the relatively long cycle of decisions and emergence of new potential programs in immunization. While many new programs are being considered, the 4 years from the start of the project to its current stage of implementation have not included a very large number of decisions which have been exposed to the framework and the new organizational structures in Canada implemented in November 2003. The process of adoption of new programs and differences between Canadian jurisdictions in the long term will allow some of the impact of the framework and the new Canadian Immunization Committee to be estimated.

Another important limitation is the general lack of study of the impact of evidence on the policy-making process in public health in Canada. The actual decisional processes in individual Ministries of Health can be considered as similar to 'black boxes' in which only some of the inputs and the final output are known. A decision that follows the recommendation of a particular report or economic evaluation may not have been caused by that evidence but rather may be simply a coincidence. Finally, while this single intervention in a specific context has been successful and is encouraging to guide efforts in other similar areas, the observations of this study must be confirmed in other contexts. This justifies that resources be contributed to further study and development of more integrated methods for knowledge transfer and better decisions in health care planning in Canada.

## ***Contribution of thesis project***

### ***i) Theoretical Level***

The results of this thesis make several theoretical contributions. Firstly in the area of immunization, the model originally proposed by White and Mathias has been confirmed in its applicability to immunization, however many additional factors have been added. This is perhaps in part due to the fact that this framework was developed over 20 years ago. The Richmond and Kotelchuck model for public health policy reflects the interaction of knowledge with political will and social strategies in determining public health policy, and can help us to understand the limits of knowledge in policy-making in public health.

Regarding models commonly used for knowledge transfer, such as the 'push' model, the 'pull' model, interactive, enlightenment, and political models, these results indicate that aspects of each model can be observed, but no single model can represent the variety of observations in reality. In addition, some additional factors related to cognitive and situated learning aspects need to be addressed to develop an appropriate theory. Therefore, a more global model that integrates these approaches is appropriate. The adaptation of the model proposed by Kemmis & McTaggart developed for this project is useful in that the objective, cognitive, situated and political aspects were observed and give a more complete view of reality, and comprehension of the knowledge transfer process. These theoretical levels can be further developed and explored in further empirical research on decision-making, and further operationalized in terms of concrete approaches to knowledge transfer and management.

The technical, practical and critical categories of knowledge-constitutive

interests suggested by Habermas could also be linked to the four levels of the emergent theoretical model in this project, which suggests their usefulness in better understanding the various aspects of knowledge use and transfer. This can help to better classify and explain observed phenomena in the area of knowledge transfer, and also to better define the scope of interventions- will they be technical in nature, or also practical? Is it desirable to go as far as a critical approach, questioning current arrangements and proposing new ones? This can help to advance the current conception of the relation of evidence to context, and research to policy-making that is being given much attention in recent literature.

Finally, the action research approach does seem to enable reaching of a reflexive-dialectical view as suggested by Kemmis & McTaggart. In addition to producing practical solutions to real problems, projects using this approach can help in theory building and theory development, and ties in to recent considerations of new models of knowledge production and collaboration between researchers and decision-makers in recent literature. Overall, this development of theory is a small but important first step in meeting a need for integrative theories in this area, which can translate into improved understanding and interventions to improve health services planning and their ultimate quality.

*ii) Practical Level*

This project has contributed in many specific and general ways on the practical level. Firstly, much information has been collected and circulated regarding decision-making and planning of immunization programs in Canada. The general criteria used have been identified and combined to make an analytical tool that is being used in various contexts in various jurisdictions and should continue to be developed and used in the future. Wide diffusion of the tool by various media and eventual publication should

allow the instrument to be known and perhaps adopted internationally. Other new tools for economic evaluation have been developed and a new organizational structure has just been implemented in Canada. This is expected to lead to new ways of collaborating on various specific themes between jurisdictions. These contributions represent numerous concrete steps towards improved knowledge management, planning and coordination in the area of immunization in Canada.

In the area of health care in Canada, the success of this approach can be used to guide other interventions to coordinate and improve knowledge transfer, decision-making and health care planning. The area of coordination of technology assessment in Canada is one possible application. This is especially practical in the current context in Canada in which these themes are being given much attention by national bodies such as the CIHR, and the CHRSF. In addition, new federal bodies mandated to improve coordination in health care have been recently established, such as the Council of the Federation and the National Council on Health Care.

In terms of action research, this project helps to further illustrate the advantages and potential pitfalls of such a methodology to guide future interventions. The success of this method in developing and implementing tools for decision-making, and even catalyzing broader organizational changes within a limited time period is truly impressive and can have multiple applications in the area of public health. Perhaps the most important contribution that can be noted by this project is to indicate that it is indeed possible and desirable to combine theory and practice, and despite certain challenges and limits, to produce research which is valid and makes significant contributions to these two fields that we are currently striving to bring together.

## CHAPTER VI: CONCLUSIONS

This project is in accordance with a general broadening of public health research to include more subjective and context-based concerns. By proposing a global classification scheme for various approaches and theories of knowledge transfer in the literature, this project aimed firstly to clarify and make explicit the often unclear differences in the underlying structure of these approaches. This permitted examination of the relative roles of various approaches in this specific intervention in the area of immunization and to note the presence of observations corresponding to the four categories. The proposed integrative model for knowledge transfer allows approaches to be explicitly linked to major streams of social theory. In the future, these links can be further refined and developed to guide specific interventions in various contexts.

While the successful sustained interactivity with stakeholders in this project increased its impact, adoption and success of the project, this represented a loss of a certain degree of control, and additional challenges in timelines and data collection in the PhD project, which were only partially controlled by the researcher. However, with limited resources this project succeeded in developing a new tool collaboratively with key persons from across Canada, diffusing it widely and testing it in multiple contexts, leading to multiple settings and types of adoption. In addition, this project played a key role in a process leading to proposal and approval of organizational changes in immunization in Canada. These changes may provide the foundation for major changes if federal purchase of vaccines is implemented in the future.

The data collected and interventions occurring during this project cannot be explained solely by one type of theory on knowledge management, but can

rather be understood by a variety of approaches addressing both objective and subjective levels of analysis, as well as those related to large-scale structure and individual actions. Finally, it is important to consider these events using intermediate approaches that are mixture of the subjective and the objective, and the system/structure versus the individual/action. It is perhaps not surprising that theories other than positivist, objective approaches have increased in importance as researchers have moved outside controlled laboratory-type settings to real-world settings. While decision-makers are often considered as being illogical and not aware of scientific knowledge that supposedly can be easily applied to rational decisions, there is a growing awareness of a different logic in the real-world decision-making arena. This should force researchers to admit that much research can be criticized by decision-makers as being context-poor, or irrelevant to their specific situations.

Therefore, as has been widely discussed in recent years in Canada, both researchers and decision-makers can benefit from increased interactions in many contexts. Projects that are conducted or funded in collaboration with researchers and the decision-makers, as currently practiced with the Canadian Health Services Research Foundation (CHSRF), provide a clear structure and mandate in which to achieve this balance and exchange. There are certainly multiple areas in which there are common interests and benefits to be gained in the area of health services research in Canada. A broad, inclusive theoretical framework such as the one proposed in this project, combined with an interactive, collaborative approach can be rich in advancing and improving knowledge transfer and its understanding in Canada and elsewhere.

### ***Key Implications***

To summarize, and return to the various themes of this study, here are some key implications of this study:

- The collaborative or action research approach seemed to be a key factor in the success of the implementation of an innovative tool and an organizational change in immunization, and merits study in other areas;
- The technical, practical and critical levels of interest proposed by Habermas were observed and useful in understanding this intervention, and an action research approach allowed the project to go beyond technical and practical considerations to reach a critical perspective and catalyze organizational change;
- Typical categories of knowledge transfer were all represented in results, but no single theory could account for all observations. Therefore broader, more integrative theories should be examined, tested and developed to better design, guide and understand knowledge transfer and management activities in a systematic fashion.
- While the dichotomies of subjective versus objective and system/structure versus individual/action are useful in understanding different approaches, they can be further broken down into intermediate categories. The exploratory example of using the four categories of rational/objective, cognitive, situated, and political approaches on the subjective to objective continuum corresponds to the levels of knowledge proposed by Habermas, captures complementary levels of reality and warrants further development and testing in the future.

### ***Future Directions***

Presently in the area of immunization in Canada, a new Canadian Immunization Committee has just had its first meeting, and the National Immunization Strategy is part of a \$45 million, multiyear initiative. The next step related to this project may be ongoing testing of the analytical framework and the new committee with coordinated evaluation and planning of new hepatitis A and B immunization programs. Following the Naylor Report on SARS, \$ 100 million has been proposed for purchase of agreed-upon vaccines by the federal government. If this recommendation is implemented, the new committee and the framework should have an important role in evaluating and reaching decisions on potential programs. A similar initiative in which interjurisdictional collaboration in Canada is important is in the area of technology assessment, and CCOHTA has recently received \$45 million to improve and develop coordination mechanisms across Canada. However, it is uncertain which structures and processes will enable different jurisdictions to optimally work together. The Council of the Federation has just been formed to increase coordination between provinces and territories (Dougherty, 2003). The establishment of a new National Health Council, based on recommendations in the Romanow Report, has just been formally announced (CBC news, 2003).

Given the numerous technological advances and budgetary restraints in health care, there is currently much interest in developing mechanisms for interjurisdictional and intersectorial collaboration in health care in Europe and Canada. To effectively strengthen our research capacity in Canada, we should continue to build and strengthen links between researchers and decision-makers to be able to address rational and political concerns and increase chances of success. Models similar to those used in this project,



which integrate diverse perspectives, such as subjective and objective approaches and those based on the individual (action) and the organization (structure) should allow for more complete and effective interventions and better understanding in this area, and to situate the targets and approaches of interventions aiming to improve knowledge transfer. Consideration of technical, practical and critical types of research and knowledge should help to situate and define the scope of individual knowledge transfer initiatives. This project has been an interesting and useful exploratory first step in this area. However, this type of intervention and analytical model should be further tested and developed by application in other contexts of knowledge transfer and interjurisdictional collaboration in health care in Canada.

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## APPENDICIES

### Appendix 1 : Cover letter and Questionnaire #1 for CMOHs- Identification of Key Scientific Experts in Immunization

From: [REDACTED]

Date: Mon, 10 Jul 2000 18:58:19 -0400

To: [REDACTED]

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TO: Provincial & Territorial Chief Medical Officers of Health

FROM: Lonny James Erickson, Program Planning in Immunization in Canada Project

SUBJECT: Identification of key Scientific Experts in Immunization Program Planning

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July 10, 2000

Dear CCMOH Members,

As part of the current National Immunization Strategy, the Subcommittee on Immunization of the Public Health Working Group has commissioned this project to develop an analytical framework to facilitate decision-making across Canada regarding publicly funded immunization programs.

This 'Program Planning in Immunization in Canada' (PPIC) framework project includes a research team of Dr. Arlene King (Health Canada), Dr. Philippe De Wals (Univ. de Sherbrooke), Dr. Lambert Farand (Univ de Montréal), and myself (Université de Montréal) as part of my Ph.D project in Public Health.

We will solicit collaboration from scientific experts in all Canadian provinces and territories to develop a framework that addresses common and regional needs in this area. Your collaboration is essential to identify these experts in your jurisdiction.

In the attached document, please fill in the names of the key scientific advisors to your Ministry of Health regarding publicly funded immunization programs and respond to me via fax or e-mail. If no response has been received by Monday, July 17th, I will be recontacting you by fax. Please do not hesitate to contact me at (450) 928-6777, extension 4060 or at (514) 813-6100 should you have problems opening the document, or for further information.

Thank you for your participation in this project.

Sincerely,

Lonny James Erickson, M.Sc,  
PPIC Framework Project  
for the Public Health Working Group Subcommittee on Immunization

NB: Document is attached in 2 different formats (Word, and RTF).  
(See attached file: CMOH Word form.doc) (See attached file: CMOH RTF form.rtf)

*This is the first step in a collaborative project in which all Canadian provinces and territories will be consulted and called to participate in the development of an analytical framework to facilitate program planning regarding publicly funded immunization programs (documentation available upon request- call for more information). These individuals will then be contacted regarding how to develop structures & processes to facilitate their evaluation of candidate vaccines for publicly funded programs.*

*Please answer the following two questions (copy or add additional pages if necessary).*

- 1) Please name the scientific experts having a key advisory role in recent policy decisions regarding publicly funded immunization programs in your jurisdiction ('key role' means that this person has sufficient input to potentially change policy decisions in your jurisdiction).

**NB: add rows to table if necessary**

Name of Expert	Organization	Phone #

- 2) Please name scientific experts who have played (&/or will play) a key advisory role in determination of policy regarding the following specific vaccines/programs:

Vaccine/program	Name of expert(s)	Organization	Phone #
a) measles second dose program			
b) pneumococcal polysaccharide programs for adults			
c) varicella vaccine for children			
d) adult pertussis vaccine			
e) adult influenza vaccination program (current and next season)			
f) pneumococcal conjugate vaccine for children			

*Please return by FAX to LJ Erickson at (450) 928-3078 or (450) 679-6443. Thank you!*

## Appendix 2: Scientific Experts Identified, Contacted and Responding to Questionnaire

Province/ Territory	Name (s)	affiliation(s)	Id'd in Cmoh Q?	Q sent	Q received
NFLD (8)	Medical Officers of Health in Regions (6)				
	1 Dr David Allison Medical Officer of Health	Health & Community Services-St John's	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	2 Dr Jane Pickersgill Medical Officer of Health	Health & Community Services-Central Gander NF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	3 Dr Floyd Harris Medical Officer of Health	Grenfell Regional Health Services St Anthony, NF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	4 Dr Catherine Donovan Medical Officer of Health	Health & Community Services- Eastern Holyrood	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	5 Dr Minnie Wasmeier Medical Officer of Health	Health & Community Services- Western Corner Brook, NF	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	6 Dr Ian Feltham Medical Officer of Health	Health Labrador Corporation PO Box 7000, Happy Valley, Goose Bay, LB	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	7 Dr Rick Cooper	St John's Health Care Corporation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	8 Dr Faith Stratton	Dept of Health & Community Services	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
NS (2)	Dr Scott Halpern	IWQH-Grace Health Centre	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr Wallie Schlech	QEII Health Care Complex	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr Mahnaz Farang Mehr			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Dr Jeff Scott			<input checked="" type="checkbox"/>	
	Dr Maureen Baikie			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
NB (5)	Dr Wayne McDonald	A/CMOH, Dept. of Health & Wellness	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> NB elected to have one coordinated response from Lyne Cochrane compiled from Dr Assaf and Kim Blinco
	Dr David Assaf	Regional MOH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Lynn Cochrane	Immunization Project Manager, Dept of Health & Wellness	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr Denis Allard	Former CMOH- no longer working with NB	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Kim Blinco	Immunization Project Manager	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
PEI (2)		Communicable Disease Public Health Nurse		<input checked="" type="checkbox"/>	
	Lamont Sweet	Chief Health Officer		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
QC (6)	Bernard Duval	INSPQ, CSP Qc	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Yves Robert	LSPQ, INSPQ	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Monique Landry	RRSSS Laval	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Gisèle Trudeau	MSSS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Horacio Arruda	MSSS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Gaston De Serres	INSPQ, CSP	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	



ONT (19)	Cmoh only identified himself therefore all members of ACCD were contacted	Some coordination of responses from ACCD
	members of Advisory Committee on Communicable Diseases :	
	Dr Lee Ford-Jones                      Dept. of Pediatrics, The Hospital for Sick Children Toronto ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Ian Gemmill                      Kingston, Frontenac, Lennox & Addington Health Unit Kingston ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Michael John                      London Health Science Centre 800 Comissioners Road East London ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Allison McGeer                      Mount Sinai Hospital Toronto	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Marg McReynolds                      Kingston, Frontenac, Lennox & Addington Health Unit Kingston	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Ms. Susan Plewes                      Ontario Hospital Association Toronto ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Graham Swanson                      Ontario College of Family Physicians of Canada Burlington ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Susan Tamblyn (chair)                      Perth District Health Unit Stratford ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Mary Vearncombe                      76 Grenville Street Toronto ON	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Barbara Yaffe Director of Communicable Diseases & AMOH	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Colin D'Cunha Director, Public Health Branch and Chief Medical Officer of Health	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Barbara Kawa Senior Medical Consultant Vaccine Preventable Diseases & TB Control	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Chuck Leber Senior Veterinary Consultant Zoonoses and Food-Borne Diseases	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Monika Naus Physician Manager & Provincial Epidemiologist, Communicable Diseases	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Evelyn Wallace Senior Medical Consultant Sexually Transmitted Diseases and HIV/AIDS Disease Control Service	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Laboratories Branch Dr. Margaret Fearon Medical Virologist	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Dr. Fran Jamieson Medical Microbiologist	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
	Ms. Dawn Ogram                      Laboratories Branch	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>

	Director Monitoring and Quality Improvement (Specialty Services) Unit Dr. James Edney	Toronto ON Medical Consultant Toronto ON M7A 1G2	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
MAN (1)	1) Dr Digby Horne	Immunization Medical Officer of Health, Communicable Disease Control Unit, Public Health Branch, Winnipeg, Manitoba		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> group coordinated response
SASK (7)	Mary Scott	consultant, public health nursing population hlth branch Saskatchewan Health Regina Sask	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr. Tania Diener	CMHO, Regina Health District, Regina SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Donna Stockdale	Nurse Epidemiologist, Population Health Unit, Keewatin Yathé Health District, La Ronge, SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Laraine Tremblay	Communicable Disease Nurse South Central Health District, Wayburn SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr Mark Vooght	Medical Health Officier Mosse Jaw Health District Moose Jaw, SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Nida Wurtz	Manager, Communicable Diseases & Aids coordinator, Population Health Branch, Sask Health Regina SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	Dr Eric Young	Deputy CMHO Saskatchewan Health Regina SK	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Alberta (13)	1. Dr Hillary Winters	Med officer of Hlth Mistahia Hlth Region	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	2. Dr. James Talbot	Prov Lab Pub Hlth, North	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	3. Dr. Geoff Taylor	Div Inf Dis U of Alberta	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	4. Ms Donna Koch	Mistahia Hlth Region	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	5. Mr Dan Richen	Hlth Authority 5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	6. Dr. Joan Robinson	Pediatric/infectious diseases U of Alberta	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	7. Dr Paul Hasselback	Med Off of Hlth Chinook Hlth Region	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	8. Dr Tav Jadavji u of Calgary	Head Inf Dis Alberta Children's Hospital	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	9. Dr Michele Ovenden	Alberta Pediatric Society	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	10. Dr Shaunalee McIver	Summit Centre Med Centre	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	11 Ms Agnes Honish	Alberta Hlth & Wellness	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	12. Ms Elaine Sartison	Capital Health Region, Edmonton	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	13. Dr. John Waters	Prov Hlth Officer Alberta Hlth & Wellness	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> co- ordinated response from Dr J. Waters office
BC (6)	1. Dr Danuta Skowronski	BCCDC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	2. Dr. Mark Bigham	BCCDC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Coordinated response
	3. Dr David Patrick	BCCDC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	from Dr.

	4. Dr. Perry Kendall	BC MOH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Patrick from BC
	5. Dr. Shawn Peck	BC MOH	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	BC
	6. Dr David Schiefele	UBC	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
YT	<u>Sent to Dr Timmermans</u>	<u>e mail sent august 4, fax also called no answer ?</u>		<input checked="" type="checkbox"/>	<u>No response-staff change?</u>
NWT (5)	1 Ms Marnie Bell,	Chairperson, NWT Advisory Committee on Immunization DHSS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	2 Ms Wanda White	Consultant, Communicable Disease Control, DHSS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	3 Dr Nicole Chatel	Pediatrician, Stanton Regional Hospital	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	4 Dr André Corriveau, CMHO	DHSS	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
	5 Glenn Whiteway	Regional Pharmacist, Stanton Regional Hospital	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
NUNV'T (1)	Dre Anne Roberts	CMOH Nunavut		<input checked="" type="checkbox"/>	e-mail response
TOTAL :					
75					

### Appendix 3: Questionnaire #2 for Key persons in immunization in Canada

Dear \_\_\_\_\_,

On behalf of the Immunization Subcommittee of the Public Health Working Group, I invite you to participate in this project, which aims to create a framework, structures and processes to facilitate immunization program planning in Canada. One objective is the development of an analytical framework for publicly funded immunization programs, which can be used to provide a “report card” on any potential or existing immunization program in Canada. This is one of a number of initiatives contained in the Canadian National Immunization Strategy.

The first step is collection of information regarding your role in immunization program planning, the way in which immunization program planning is performed in your jurisdiction, and identification of other scientific experts active in immunization program planning in your jurisdiction. In addition, we would like your suggestions or ideas on what could facilitate immunization program planning in Canada.

Your responses are strictly confidential, and will be aggregated with those of other participants to create a recommended framework, structures and processes which will be submitted to a consensus-building process with yourself and other participants before testing. Please respond by Friday, September xx, 2000 by [REDACTED]

This project has the potential to improve the way immunization is planned, delivered and evaluated in Canada, and will ultimately maximize the benefits of immunization for our citizens.

Thank you in advance for your valuable participation.

LJ Erickson, PPIC project  
for the Immunization Subcommittee of the Public Health Working Group

*Please answer the following questions. Use additional pages if necessary.*

1. Does your province/territory have goals and objectives for immunization programs?

*(If so, please describe them below)*

2. What structures and processes are in place for considering and making decisions on (new) publicly funded immunization programs? *(i.e general committees, working groups for specific vaccines or specific issues, etc...)*

3. Does your province/territory use a framework for considering new publicly funded immunization programs?

*(if so, please describe the framework used)*

4. Please describe your general role/involvement in immunization program planning:

5. Did you have a specific role in immunization program planning for the following recent candidate vaccines?

*(If so, please describe your role for each vaccine and also indicate the current stage of the planning process for this vaccine in your jurisdiction.)*

measles 2<sup>nd</sup> dose :

• varicella :

• pneumococcal polysaccharide vaccine for adults :

• pneumococcal conjugate vaccine for children :

• other specific recent programs (specify : \_\_\_\_\_) :

6. For each of the specific immunization programs identified in 5), please identify the following :

Name of vaccine: \_\_\_\_\_

a) Which (if any) other scientific experts were involved in evaluating that particular vaccine/potential immunization program in your jurisdiction ?

Name	Vaccine	Comments
------	---------	----------

b) What major criteria/factors came into play in the decision ? (i.e price)

Factor/Criteria	comments	Importance Ranking 1 <sup>st</sup> , 2 <sup>nd</sup> , 3 <sup>rd</sup> ...
-----------------	----------	---

c) Please rank the relative importance of the criteria mentioned above

*Please complete a copy of this page for each specific vaccine mentioned.  
(NB: 3 copies will be included)*

7. What type of framework would most help you in immunization program planning?

8. Considering your previous responses, what elements/factors/criteria should be included in a framework to assist you in immunization program planning?

9. Currently, what are your major needs/ problems in immunization program planning ?

10. What frameworks, decision-making structures and processes should be in place to facilitate immunization program planning in Canada?

11. Other comments :

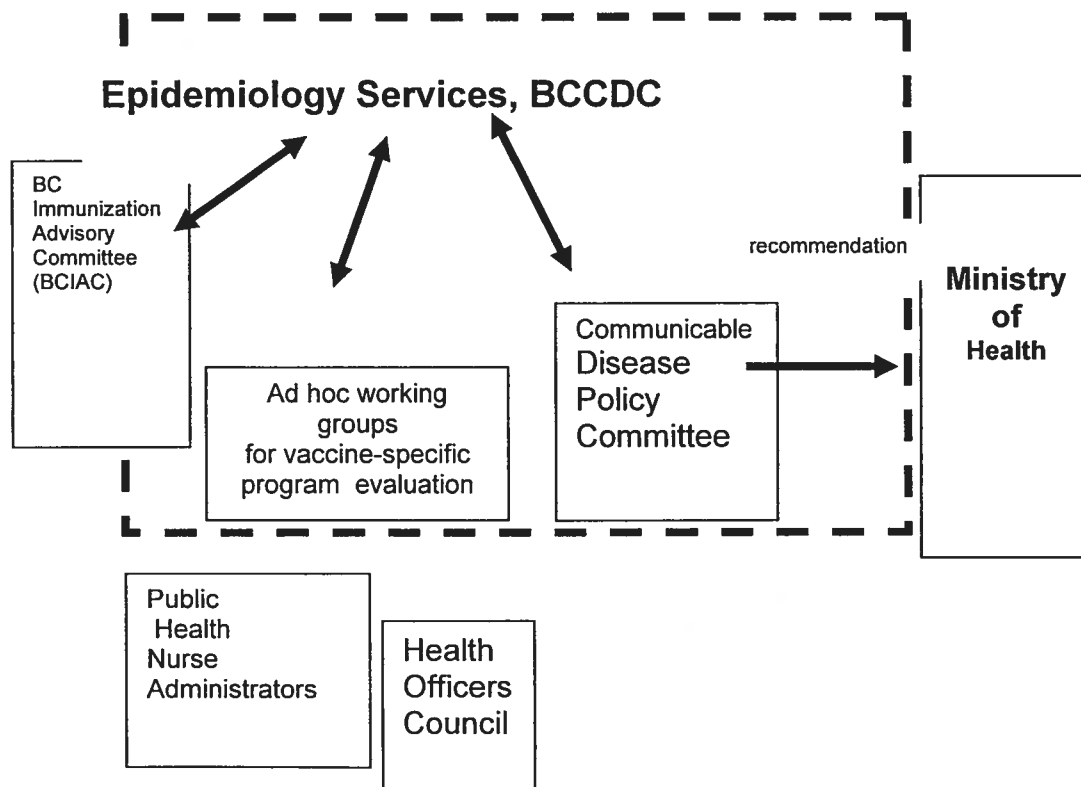
***Thank you for your participation. You will soon receive a summary of the results of this consultation and an invitation to participate in the consensus building process.***



## Appendix 4 : Structures and Processes for Immunization Program Planning in Canadian Provinces and Territories

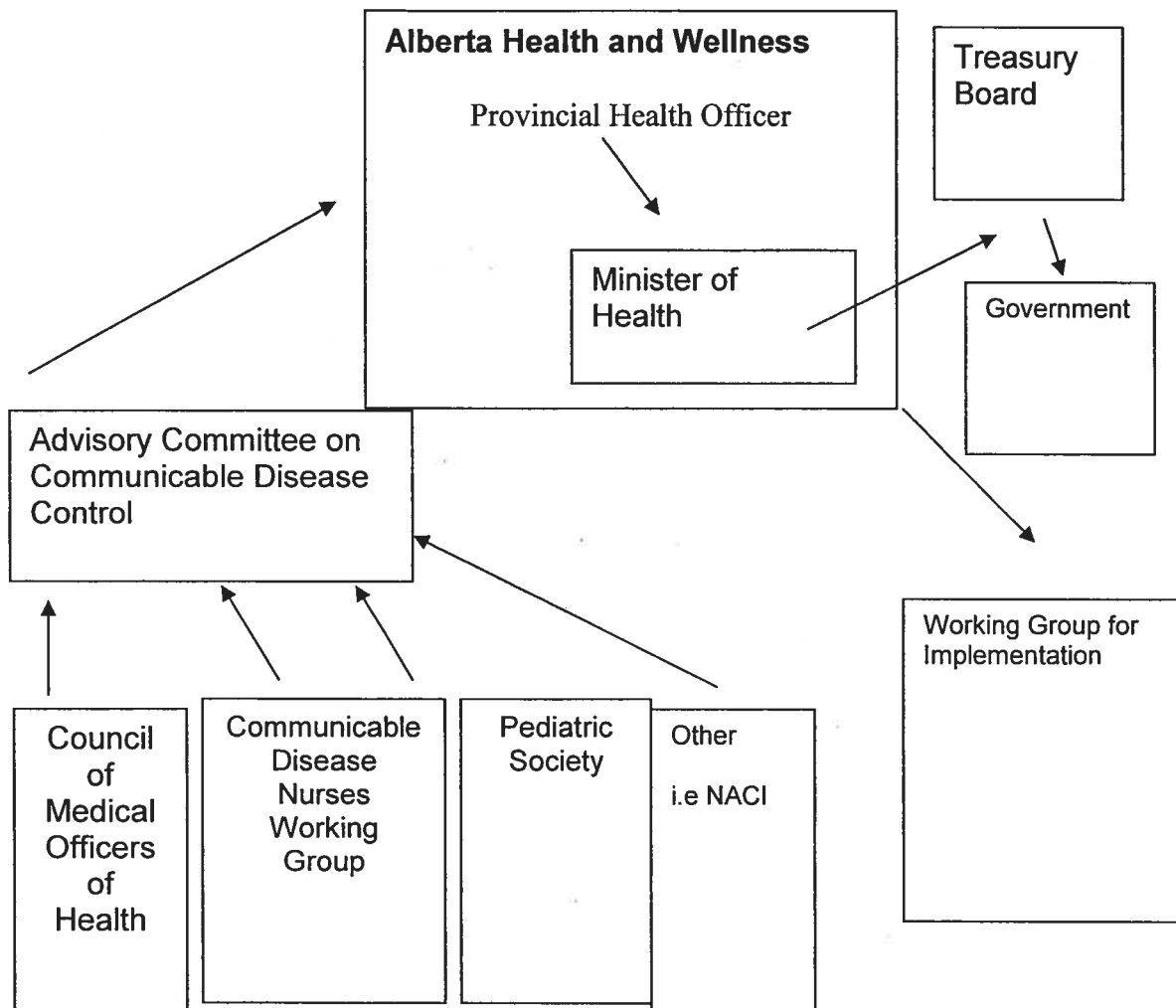
### British Columbia

Dedicated staff (medical and nursing) to assess immunization programming. An expert Provincial immunization advisory committee, the 'BC Immunization Advisory Committee' (BCIAC) gives scientific advice. Epidemiology Services of the BC Centre for Disease Control (BCCDC) has a coordinating role in preparing submissions to the Communicable Disease Policy Committee, which makes recommendations on Programs to the Ministry of Health. Health Officers Council and Public Health Nurse Administrators provide input and occasionally advocacy. Provincial ad hoc working groups for vaccine-specific program evaluation.



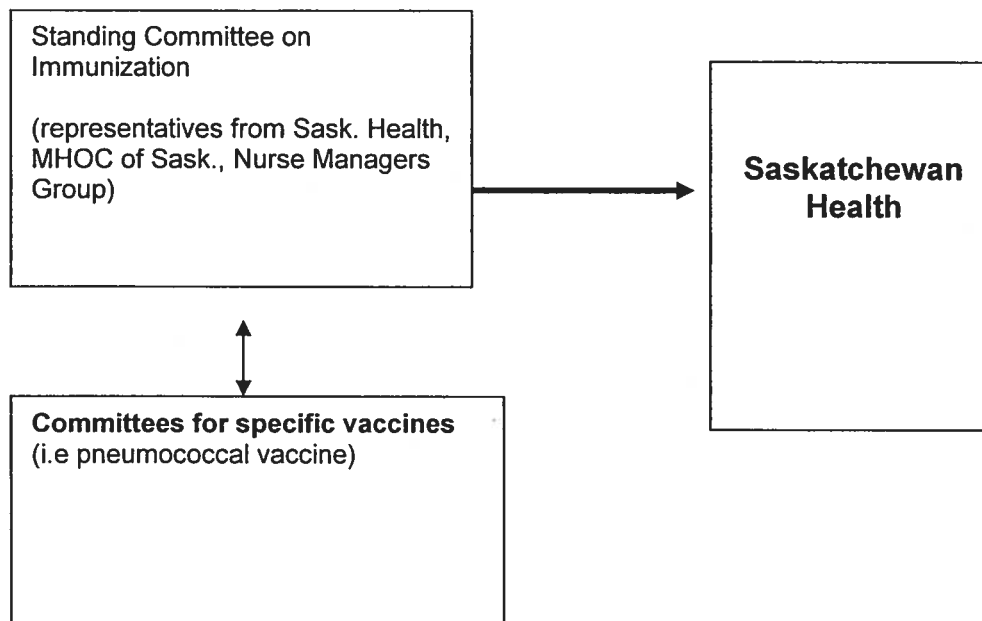
## Alberta

Advisory Committee on Communicable Diseases receives input from the Council of Medical Officers of Health, the Communicable Disease Nurses Working Group, the Pediatric Society and other sources and advises Alberta Health and Wellness.

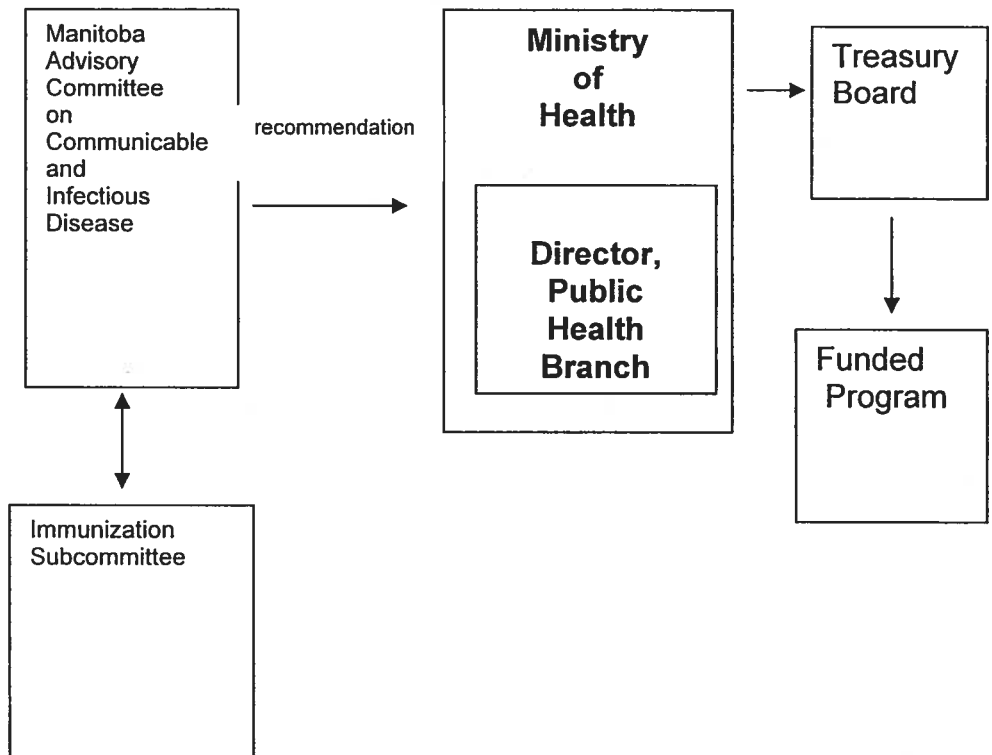


## Saskatchewan

Standing Committee on Immunization made up of representatives from Saskatchewan Health, representatives from the Medical Health Officers Council of Saskatchewan and the Nurse Managers Group. Committees for specific vaccines: i.e. pneumococcal vaccine.

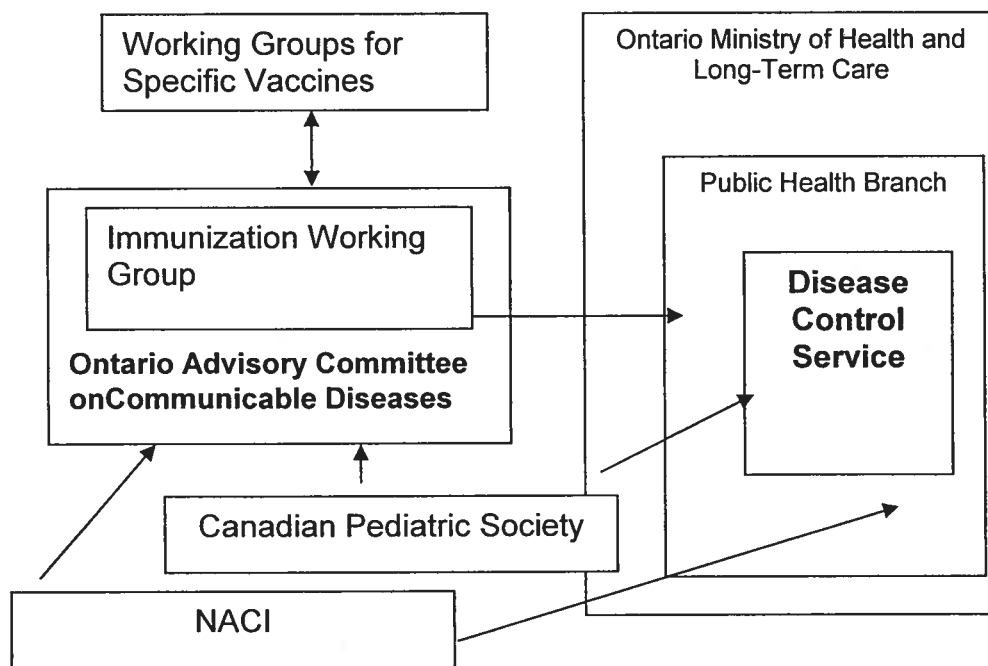


# Manitoba



## Ontario

Staff at the Ministry of Health and Long-Term Care receive advice from the Advisory Committee on Communicable Diseases (ACCD), the Canadian Paediatric Society, NACI, as well as working groups within the ministry. The ACCD has an Immunization Working Group. The ACCD makes recommendations to ministry regarding publicly-funded vaccine programs. Sometimes a working group or a subcommittee is created for a special vaccine either to make recommendations (i.e. regarding target groups), or to plan implementation or evaluation. Recommendations made by the working group will be considered in the elaboration of a proposal by ministry staff which considers cost, cost-effectiveness, and implementation issues. Sometimes ministry acts by its own mechanism, external to the ACCD (i.e. universal influenza vaccination program, to avoid emergency room overcrowding).



Notes: 1) The Ontario Ministry of Health has a 'business planning and allocation process' in its annual budget cycle. 2) Within the ministry and the government, appropriate policy approvals have to be obtained for any new program proposals.

## Québec

### STRUCTURES AND PROCESSES FOR DECISION-MAKING REGARDING IMMUNIZATION PROGRAMS IN QUEBEC

#### 1. STRUCTURES

##### 1.1. *Ministère de la santé et des services sociaux du Québec / Quebec Ministry of Health*

The *Ministère de la santé et des services sociaux (MSSS)* of Quebec is responsible for publicly funded immunization, including the decision to implement any new programs, purchase and distribution of vaccines, information to the public and health care professionals, organization and funding of vaccination activities, measurement of progress in reaching objectives for vaccine coverage, as well as evaluation of positive and negative health impacts of programs. Immunization programs are the responsibility of the *Directeur de la protection de la santé publique* (Director of Protection of Public Health) who reports to the *sous-ministre adjoint à la santé publique* (Deputy Minister of Public Health). To determine the pertinence of introducing a new vaccine in the program or the modification of an existing program, the MSSS asks for recommendations from the *Comité sur l'immunisation du Québec (CIQ)*, which is affiliated with the *Institut national de santé publique du Québec (INSPQ)*. When a new immunization program is implemented, the MSSS creates an *ad hoc* implementation committee composed of members from the MSSS and health care professionals.

##### 1.2. *Institut national de santé publique du Québec (INSPQ- Quebec Institute of Public Health)*

The *INSPQ* was established in 1998 has the mandate of supporting and advising the MSSS and the *régies régionales de la santé et des services sociaux (RRSSS- regional health boards)* in their mission with regards to public health, notably regarding immunization programs. The *INSPQ* regroups laboratories and scientific experts in a network. Experts from various regions make up the *Groupe scientifique en immunisation (GSI- scientific group on immunization)* which addresses questions regarding immunization and which responds to the *Directeur de la protection de la santé publique*. Most GSI members are also members of the *CIQ* and also are also affiliated with a university and are members of a university research center.

##### 1.3. *Comité sur l'immunisation du Québec (CIQ- Quebec Immunization Committee)*

This permanent expert committee has existed since 1990 and is responsible for making recommendations and giving recommendations regarding optimal use of immunizing agents in Québec. More specifically, this committee advises the *Directeur de la santé publique* (Director of Public Health) regarding the application

of immunization programs, objectives, strategies, choice of products, and practice guidelines. The comité is composed of active members chosen for their expertise in the area of immunization and from educational, research and public health settings, invited members representing organizations and associations, as well as *membres d'office* representing the (MSSS). This committee originally reported directly to the *Directeur de la protection de la santé publique* of the MSSS. In 1999, it was affiliated with the *Institut national de santé publique du Québec (INSPQ)* and also reports to *Directeur de la protection de la santé publique*. To study each new vaccine and the pertinence of a new immunization program, *ad hoc* committees are formed, composed of members of the CIQ and invited experts.

#### **1.4. Régies régionales de la santé et des services sociaux (RRSSS- regional health boards)**

The *Régies régionales de la santé and des services sociaux (RRSSS)* are responsible for planning, organization, co-ordination and evaluation of health services in the 18 sociosanitary regions of the province of Quebec. In the area of immunization, the RRSSS mainly distribute vaccines supplied by the MSSS, participate in promotion of programs, organise and co-ordinate publics and private services to make vaccination accessible in the entire territory. Administration of public immunization programs is the responsibility of the *Directeur de la santé publique* who gives this mandate to a *Coordonnateur en maladies transmissibles* (Co-ordinator in infectious Disease)

#### **1.5. Table de coordination nationale en santé publique (TCNSP)**

The *Table de coordination nationale en santé publique (TCNSP)* is a tripartite committee (MSSS-INSPQ-RRSSS) which coordinates public health activities, notable immunization. It regroups the Directors of public health of the 18 health boards (RRSSS), the director of the INSPQ and is presided by the *Vice-Ministre adjoint à la santé publique* of the MSSS. This table has the mandate of co-ordinating implementation of immunization programs in different regions.

#### **1.6. Table nationale de concertation en maladies transmissibles (TNCMI)**

The *Table nationale de concertation en maladies transmissibles (TNCMI)* is a consultative tripartite assembly, composed of Infectious Disease Co-ordinators from each RRSSS, the *Directeur de la protection de la santé publique* of the MSSS and the *Director de la protection de la santé publique* of the INSPQ. This group is a subcommittee of the TCNSP and coordinates operational aspects of immunization programs.

## **2. DECISION-MAKING PROCESS**

The initiative to evaluate the pertinence of a new public immunization program

generally comes from the *GIS*, whose members are informed of licensing of new products by the Bureau of Biological products of Health Canada, as well as representatives from pharmaceutical companies which produce vaccines. In concert with the *MSSS*, a formal request is addressed to the *CIQ* which establishes an *ad hoc* working group. Specifically, the working group must conduct a study on the pertinence of an immunization program including sections on the burden of disease, vaccine characteristics (immunogenicity, efficacy, security), potential effectiveness of an immunization program, associated costs and risks, as well as program feasibility. Rather than a single recommendation, the document must describe different advantages and consequences of possible vaccination strategies, including total absence of immunization.

Once completed, the study is brought to the *CIQ* for discussion and approval. To study the subject in depth, representatives from vaccine manufacturers are invited to present their produce and present available published and unpublished data. When the study has been finalized, the report is transmitted for critique and validation to the Infectious Disease Coordinators of each regional health board (*RRSSS*), to professional associations (i.e. pediatric and family physician associations) and public and private organizations (*CLSC* and hospital associations, for example). Feedback is then discussed by the *CIQ* and a final document is prepared and transmitted to the *Directeur RBEO* of the *INSPQ* after which the *INSPQ* makes official recommendations.

The recommendation is then transmitted to the *Directeur de la protection de la santé publique* of the *MSSS* who must decide upon the optimal strategy, evaluate feasibility of the proposed programme and possibilities for funding. The opportunity for a new program is decided by the *Sous-ministre adjoint à la santé publique* (Deputy Minister of Public Health) after consultation of regional directors of public health in boards (*RRSSS*) reunited at the *Table nationale de coordination en santé publique (TCNSP)*, as well as the Public Health Co-ordonators en santé publiques reunited at the *Table de concertation nationale en maladies infectieuses (TCNMI)*. A ministerial dossier is then prepared, including budgetary estimations. In the case of a new program with a significant budget requirement, the dossier is transmitted to the *Sous-ministre à la santé publique* and to the Minister of Health who makes the final decision and announcement.

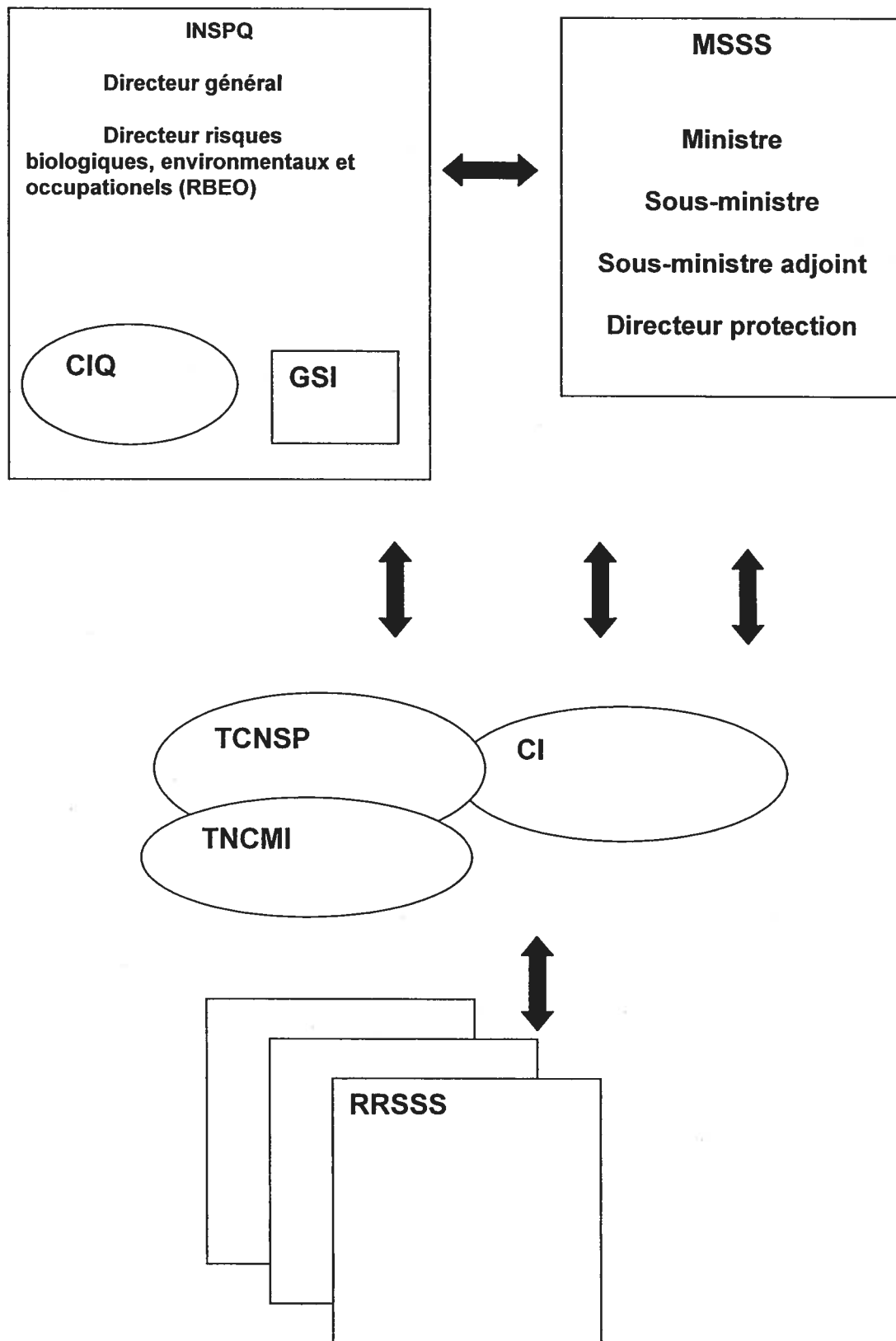
Once a decision is taken, the *MSSS* forms an ad hoc committee, which is in charge of planning implementation of a new programme. At this stage, Infectious Disease Co-ordinators are consulted, as well as representatives from main groups of vaccinators (*CLSCs*, pediatricians and family physicians, for example).

During the entire process, external influences can be present. For example, vaccine manufacturers may interact with members of the *CIQ*, *GIS* and the *MSSS*. Professional associations and parent associations can also be active and the media also inform decision-makers. Consensus conferences organized by Health Canada and to which the *Directeur de la protection de la santé publique* is invited a certain



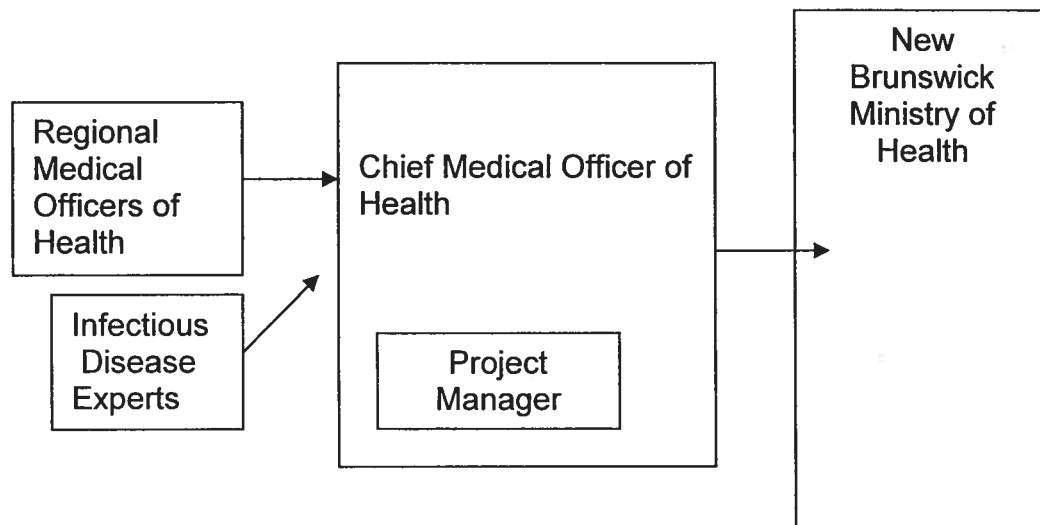
amount of inter-provincial program harmonisation as to principles, yet little regarding timing. Decisions announced by other provinces also influence that of Québec. This is despite the fact that there is no formal structure for inter-provincial co-ordination other than the preparation of the plan for an influenza pandemic.  
*12-02-2001*

Figure 1 : Decision-making and Functional Structures in Quebec



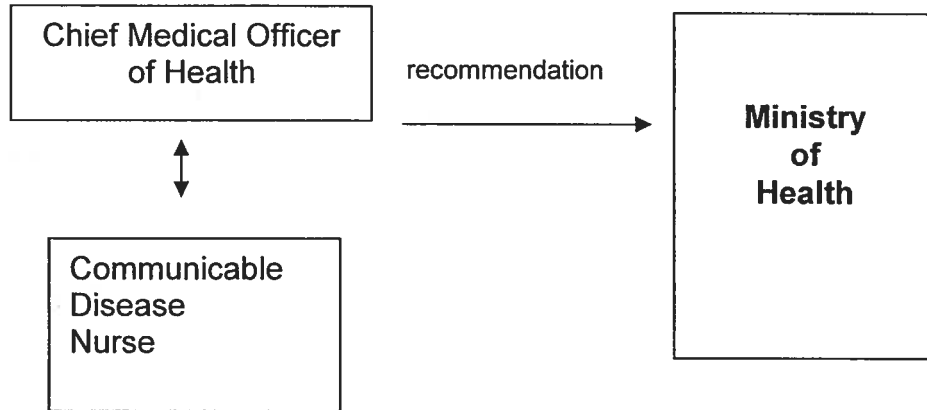
## New Brunswick

The CMOH and project manager review scientific literature, NACI recommendations, discussions with regional MOH and consultation of infectious disease experts. Proposal to recommend new program is submitted to senior management for consideration and budgetary approval



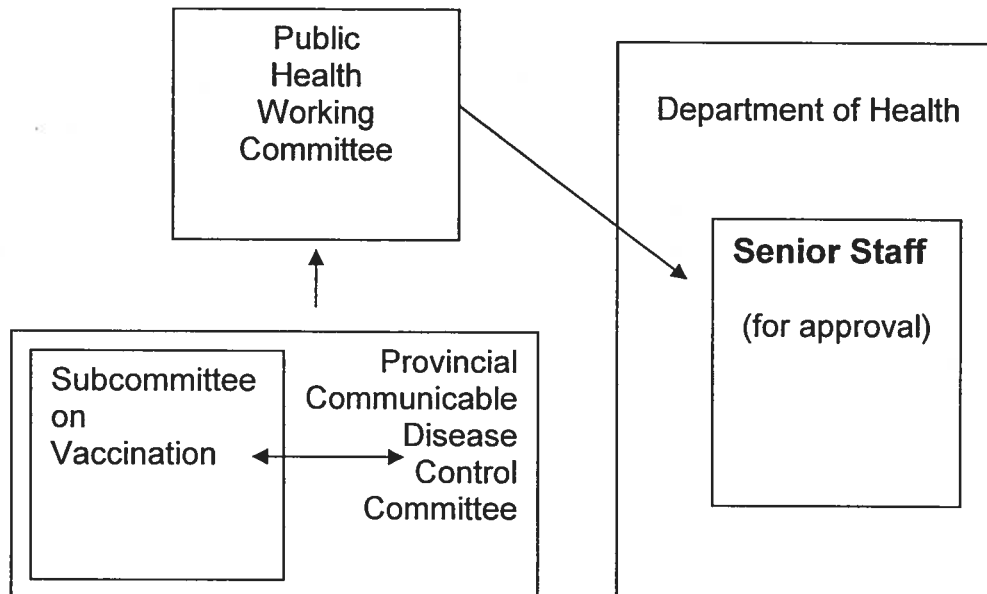
## Prince Edward Island

Chief Health Officer and Communicable Disease public health nurse review available information on particular vaccines and make recommendations.



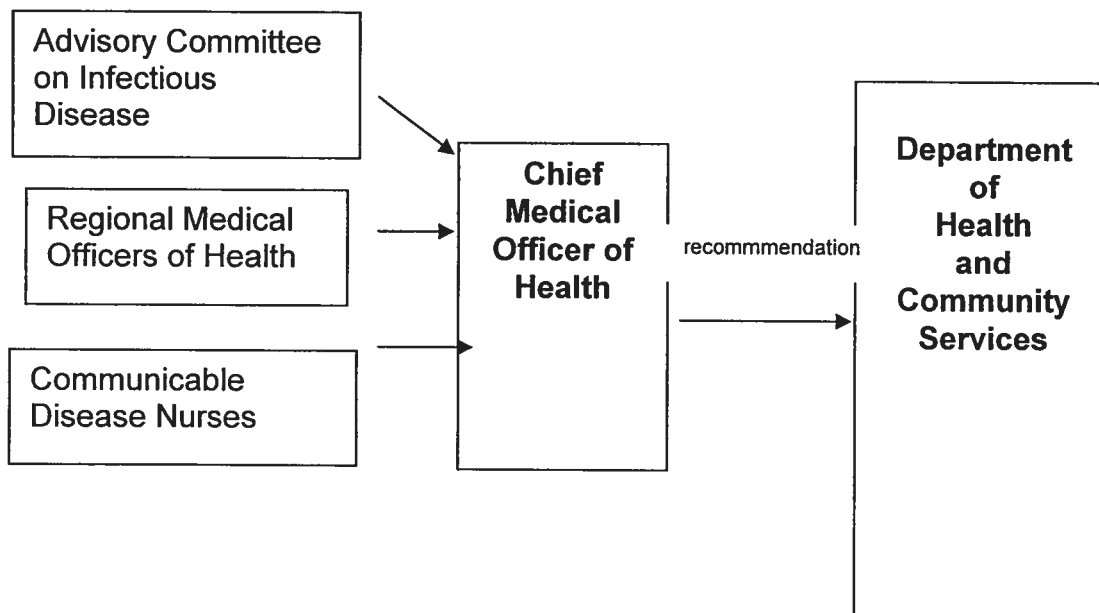
## Nova Scotia

Committee with wide representation. Subcommittee usually formed to provide a discussion paper regarding feasibility of introduction of a new publicly funded vaccine. Paper is then reviewed by provincial CDC committee, and recommended option is submitted to public health working committee for approval. If approved by PHWC, submitted to senior staff in Dept. of Health for approval.



### Newfoundland and Labrador

Advisory Committee on Infectious Diseases, and Medical officers of Health Committee . Regional MOHs meet quarterly and make recommendations in consultation with provincial MOH. In addition to Medical Officers of Health, Communicable Disease Nurses and nursing managers may provide recommendations regarding new programs.

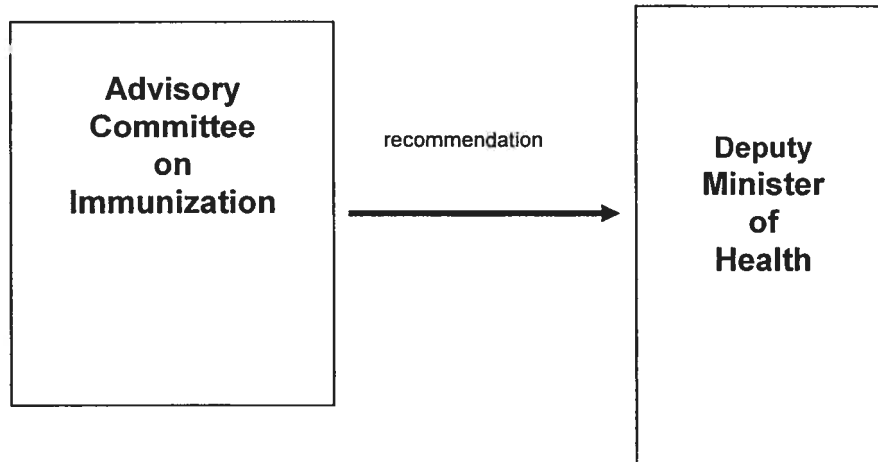


## **Yukon Territory**

Largely informal process following NACI guidelines

## **The Northwest Territories**

The Northwest Territories Advisory Committee on Immunization (NWTACI) has wide representation and is mandated to provide timely advice to the Department of Health and Social Services and to health and social services boards on all issues related to immunization and specific immunization practices. A subcommittee of NWTACI researches new vaccines, epidemiology of vaccine preventable disease in Canada and the NWT, economic, social and health impacts and prepares a discussion paper on the options, feasibility, and acceptability of introducing a new vaccine into the NWT schedule. The paper is reviewed by the full NWTACI, discussed, and recommendations put forward to the Deputy Minister for approval.



## **Nunavut**

Little information is currently available, except that there are not a large number of personnel available to work in this area. The fact that this territory has only recently come into existence as an independent jurisdictional entity must also be taken into account.

## **Appendix 5 : Questionnaire on Goals and Objectives for Canadian Immunization Programs**

### **QUESTIONNAIRE GOALS AND OBJECTIVES FOR PUBLICLY FUNDED IMMUNIZATION PROGRAMS IN CANADA**

#### **INSTRUCTIONS FOR COMPLETING QUESTIONNAIRE:**

Please complete the questionnaire regarding goals and objectives for all of your publicly funded vaccination programs.

For each program, please fill out one table per program. Make additional copies if necessary.

Should you require clarification to complete the questionnaire, please contact Lonny Erickson at (450 )928-6777, ext. 3087.

Please submit the completed questionnaire electronically or by fax no later than NOVEMBER 15<sup>TH</sup>, 2001 to:

Julie Pigeon, PHWG Secretariat  
F/P/T Officer / Agente f/p/t  
Population and Public Health Branch /  
Dir. générale de la santé de la population et de la santé publique  
Health Canada / Santé Canada

████████████████████  
Tel: (613) 941-3448  
Fax/Télec.: (613) 952-7223

**In addition, please transmit any relevant documentation on goals and objectives from your jurisdiction (i.e. annual reports, etc) to Julie Pigeon.**

Thank you for your collaboration.



***N.B.: Please complete the following table(s) for all publicly funded immunization programs.  
(make additional copies if necessary)***

Vaccine (generic name):

Province/Territory:

Target group (complete one table for each target group)	(specify)
Strategy	<input type="checkbox"/> Control <input type="checkbox"/> Elimination <input type="checkbox"/> Eradication <input type="checkbox"/> other
Vaccine schedule (number of doses, time interval)	
Disease reduction objectives	<input type="checkbox"/> not stated <input type="checkbox"/> stated >(specify below)
Data sources for measuring disease reduction	<input type="checkbox"/> none <input type="checkbox"/> yes (specify below)
Achievements in disease reduction	<input type="checkbox"/> unknown <input type="checkbox"/> other (specify below)
Vaccine coverage objectives i.e x % by _____ (date)	<input type="checkbox"/> none <input type="checkbox"/> yes (specify below) _____ % by _____ (date)
Data sources for measuring vaccine coverage objectives *(i.e manufacturer, survey, etc.)	<input type="checkbox"/> none <input type="checkbox"/> yes (specify below)
Achievements in vaccine coverage to date (i.e x % in _____ year)	<input type="checkbox"/> unknown <input type="checkbox"/> other (specify below)
Comments	

--	--

Additional questions

<p>1. What new programs are being implemented currently (or in the near future) in your jurisdiction? (specify)</p>
<p>2. What are the goals and objectives for these new programs? (specify below)</p>
<p>3. Do you intend to establish additional goals and objectives for immunization programs in your jurisdiction in the coming year? (if so, specify).</p>

--

4. If you will be developing new goals and objectives for immunization in your jurisdiction, please describe how they will be developed (i.e. consultation of experts, working group, meeting of provincial/territorial infectious disease/immunization committee, etc.)

5. How do you measure goals and objectives for your programs? What are some of the challenges in monitoring goals and objectives in your jurisdiction? How could these be overcome?

6. What specific actions on a national level (i.e. as part of the National Immunization Strategy) would best support the development and monitoring of goals and objectives for immunization programs in your jurisdiction? (i.e. national meetings, working group, other...)

## Appendix 6: Worksheet February 2002 National Meeting – Using the Analytical Framework

Instructions: As you listen to the presentations from the experts on each vaccine, please assess the desirability of this publicly funded program for each category of information listed below from the perspective of your province.

	Type C Meningococcal Conjugate Vaccine					Varicella Vaccine					Heptavalent Pneumococcal Conjugate Vaccine									
	Not Desirable 1	2	3	4	Very Desirable 5	Not Desirable 1	2	3	4	Very Desirable 5	Not Desirable 1	2	3	4	Very Desirable 5	Not Desirable 1	2	3	4	Very Desirable 5
Disease Characteristics and Burden	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vaccine Characteristics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Alternative Immunization Strategies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Social and Economic Costs and Benefits	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feasibility and Acceptability	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to Evaluate Programs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Research Questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other Considerations	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Overall - this vaccine should be publicly funded.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comparisons across vaccine types - Ranking	1		2		3	1		2		3	1		2		3	1		2		3

### **Disease Characteristics and Burden**

- Nature and characteristics of the infective agents
- Clinical manifestations and complications
- Epidemiology of the disease
- Specific populations affected and risk factors
- Current disease treatment and preventability
- Social impact of the disease
- Economic impact of the disease

### **Vaccine Characteristics**

- Nature and characteristics of immunizing agent
- Characteristics of commercial products
- Storage, handling, product format
- Vaccine manufacturers, production capacity and supply
- Administration schedule, number of doses, combination with other vaccines
- Nature and characteristics of the immune response
- Immunogenicity in different population groups
- Short and long-term direct and indirect protection
- Impact on reduction of burden of disease
- Safety: rates and severity of adverse effects, contra-indications, precautions
- Potential interaction with other vaccines
- Potential impacts on antibiotic resistance

### **Alternative Immunization Strategies and Programs**

- Existing recommendations/guidelines for use of the vaccine
- Objectives of disease control/elimination/eradication at international, national, and/or provincial/territorial levels
- Alternative immunization strategies for meeting objectives
- Specific objectives in terms of reduction of incidence, complications, sequelae and mortality
- Specific objectives re: coverage of specific groups
- Delivery strategy/system

### **Social and Economic Costs and Benefits**

- Total and opportunity costs of program for families and the health system
- Evidence regarding short-and long-term effectiveness
- Evidence regarding social and economic benefits
- Other benefits
- Economic Evaluation: net present costs and cost-benefit ratios

### **Feasibility and Acceptability of Alternative Programs**

- Public perception of disease risk, severity, fear, need for control
- Demand for/acceptability of immunization for target groups
- Priority for approved program compared to other programs
- Expected date of licensure or current use of vaccine
- Integration of new program with existing programs and schedules
- Impacts on existing immunizations services and the health care sector
- Accessibility of target population/expected levels of uptake
- Availability of vaccine supply
- Availability of funding for disease purchase
- Availability of human, technical and financial resources
- Availability of appropriate documentation/consent forms
- Availability of system for recording/registering vaccine administration
- Availability of resources for marketing and communication
- Existence of operational planning and implementation committee

### **Ability to Evaluate Questions**

- Desirability of evaluation to families, professionals
- Availability of information systems to measure coverage, utilization, quality
- Availability of information systems for monitoring reduction of disease incidence, complications, sequelae, mortality
- Availability of system for monitoring adverse events associated with vaccine administration
- Availability of systems for linking health outcomes databases, immunization registries and population registries

### **Research Questions**

- Ongoing and planned research projects in the fields of vaccine development, immunogenicity, efficacy and safety
- Identification of areas in previous sections in which research is needed to assist planning evaluation and decision-making

### **Other Considerations**

- Equity of new program, including universality, accessibility and gratuity of services for the most vulnerable population groups
- Ethical considerations, including informed consent, and protection of confidentiality of medical information
- Conformity of new program with planned or existing programs in other jurisdictions and countries
- Possible political benefits and risks associated with implementation of the new program

**Appendix 7: Worksheet from February 2002 National Meeting – With frequency of each response**

For each question, the number of participants responding for each choice is indicated (some participants chose not to respond to certain questions).

	Type C Meningococcal Conjugate Vaccine				Varicella Vaccine				Heptavalent Pneumococcal Conjugate Vaccine						
	Not Desirable 1	Desirable 2	Very Desirable 3 4 5		Not Desirable 1	Desirable 2	Very Desirable 3 4 5		Not Desirable 1	Desirable 2	Very Desirable 3 4 5				
Disease Characteristics and Burden	1	3	0	10	7	0	0	1	8	10	0	0	0	5	13
Vaccine Characteristics	0	1	1	3	4	2	0	4	8	6	0	0	0	3	7
Alternative Immunization Strategies	0	0	2	8	9	0	0	5	8	6	0	0	0	8	3
Social and Economic Costs & Benefits	0	4	6	5	4	1	1	2	10	6	0	2	3	8	6
Feasibility and Acceptability	0	0	1	6	11	0	3	5	8	3	0	0	2	9	7
Ability to Evaluate Programs	0	0	5	6	8	0	0	7	7	4	0	1	6	6	4
Research Questions	0	2	8	5	4	1	2	5	9	2	0	2	6	7	3
Other Considerations	0	1	5	7	4	0	1	8	6	1	0	0	5	6	3
Overall - this vaccine should be publicly funded.	0	1	4	6	4	0	0	1	7	7	0	0	1	7	6
<b>Possible responses</b>	Not Desirable 1	Desirable 2	Very Desirable 3 4 5		Not Desirable 1	Desirable 2	Very Desirable 3 4 5		Not Desirable 1	Desirable 2	Very Desirable 3 4 5		Not Desirable 1	Desirable 2	Very Desirable 3 4 5
Comparisons across vaccine types - Ranking	1st 0	2nd 6	3rd 7		1st 5	2nd 1	3rd 6		1st 5	2nd 8	3rd 0		1st 5	2nd 8	3rd 0

**Appendix 8: The OVCD instrument for priority-setting in communicable diseases**  
(PHLS,1999)

Example: Response for rabies

Index	Criteria for assessing importance Score from 1 to 5 (1= low importance, 5=high)					Areas where further work is required tick one or more column(s)				
	Burden of ill-health	Social/Economic Impact	Potential Threat	Health Gain Opportunity	Public Concern	Diagnostic & specialist microbiology	Surveillance	Guidelines	Evaluation of interventions	Other
Rabies	1	1	3	1	4			✓		

**Criteria for assessing importance**

**Present burden of ill-health**, assessed according to age and sex-related morbidity and mortality; and data on Quality Adjusted Life Years.

**Social and economic impact**, assessed by considering the costs of infections to individuals and organisations and to health care providers.

**Potential threats (next 5-10 years)**, assessed by considering extrapolations of current trends including antibiotic resistance; known, suspected or predicted gaps in vaccine coverage; changes in animal husbandry and food/water provision, changes in environment; developments overseas; and demographic changes and population movements.

**Health gain opportunity**. Is there an opportunity to affect present and future burden of ill-health through specific activities such as those listed below?

**Public concern and confidence**, assessed by considering media and public interest, and numbers and types of parliamentary questions relating to infection(s).

## Appendix 9: Follow-up Questionnaire on Analytical Framework

Dear \_\_\_\_\_,

We have recently been studying structures and processes for planning of publicly funded immunization programs in Canada, to develop ways to support and improve this process. One aspect of this project is the development and testing of an analytical framework for immunization program planning (funded by Health Canada and CIHR). The resulting tool aims to make the evaluation process for potential new immunization programs more efficient and systematic by identifying all criteria that may be important when considering new programs, and can be adapted according to the needs of users in various contexts.

The current version of the framework has the following 13 categories:

1. Disease Burden
2. Vaccine Characteristics
3. Potential Programs and Vaccination Strategies
4. Social & Economic Costs and Benefits
5. Acceptability of Program
6. Feasibility of Program
7. Capacity to Evaluate Program
8. Research Questions
9. Equity of Program
10. Ethical Considerations
11. Legal Considerations
12. Conformity of Program (with other jurisdictions and countries)
13. Political Considerations

Each category has several sub-points (see attached document for full version).

It is important to examine how this instrument can be useful in immunization program planning in Canada, specifically in your jurisdiction. The following questions will help us evaluate this.

If you wish to receive a summary of questionnaire responses, please check the box at the end of the questionnaire. If you have any questions or comments, you may contact Lonny Erickson at (514) 813-6100 or at [lonny.erickson@aetmis.gouv.qc.ca](mailto:lonny.erickson@aetmis.gouv.qc.ca)

You may complete the questionnaire directly in the Word document and return it by e-mail. If you prefer, you may also print it out and return it to me by fax at (514) 873-1369.

If you prefer, we could also complete the questionnaire by telephone. If I don't receive your response, I'll contact you by phone.

Thank you for your collaboration.

Sincerely,

Lonny Erickson



*(N.B.: page layout reduced for presentation)*

**CONFIDENTIAL WHEN COMPLETED (this page will be removed)**

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

e-mail: \_\_\_\_\_

province/territory: \_\_\_\_\_

*If there are additional persons in your province/territory who should be contacted to complete this questionnaire, please list them below:*

Name	Institution

*If you have any questions, please contact Lonny Erickson at (514) 813-6100. You may now begin the questionnaire.*



### Section I: Exposure to Analytical Framework

We would like to know to what extent you have been exposed to this framework since its development.

1. Have you heard of this framework before?

NO

YES ⇒ *specify when & where:*

2. Have you seen this framework before?

NO

YES ⇒ *specify when & where:*

3. Have you personally used this framework before?

NO

YES ⇒ *specify when, where and how:*

4. To your knowledge, has this been used in your province/territory framework before?

NO

YES ⇒ *specify when & where:*

5. To your knowledge, have other tools for immunization program planning been used in your province/territory?

NO

YES ⇒ *specify which tools, and how they were used:*

## Section II: Evaluation of Analytical Framework

We would like your evaluation of the usefulness of the framework since its development.

Please specify your experience with the use of this instrument by indicating the context in which it was used and your evaluation of its usefulness. Add additional pages if necessary.

5 i) Context in which framework was used:

Evaluation of usefulness of framework in this context:

5 ii) Context in which framework was used:

Evaluation of usefulness of framework in this context:

b) We would like your general evaluation of the usefulness and potential applications of this framework

6. How could this instrument be used in the immunization planning process in your jurisdiction ?

7. How could this instrument be used in the immunization planning process in Canada?

8. Is this a good approach to improving and supporting immunization program planning in Canada ?

Why or why not?

9. What other approaches could be beneficial to support and improve immunization program planning in Canada?

10. What are currently the main issues/challenges in immunization program planning in your jurisdiction?

What would help you to better deal with these issues/challenges?

11. Have there been any recent changes in the immunization program planning process in your province/territory ? *(if yes, specify)*

12. What changes in the immunization program planning process in your province/territory do you anticipate in the future?

13. General or additional comments:

*Please return to Lonny Erickson: By e-mail at: [lonny.Erickson@aetmis.gouv.qc.ca](mailto:lonny.Erickson@aetmis.gouv.qc.ca)  
Or by fax at: (514) 873 1369. Thank you for your collaboration!*

### Appendix 10: Experts receiving and responding to Questionnaire #4

Province/ Territory	Expert contacted	Responders	
BC	Monika Naus	Monika Naus	
AB	Agnes Honish		
SK	Rosalie Tuscherer	By telephone	
MN	Greg Hammond	Digby Horne Barbara Law	
ON	Barbara Kawa		
NB	Lynn Cochrane		
NS	Mahnaz Farang Mehr	By telephone	
PEI	Lamont Sweet, CMOH		
NF	Faith Stratton		
YT	Donna Marshall		
NWT	Wanda White	Wanda White	
NVT	Ann Roberts		

## **Appendix 11: Goals and Objectives for Immunization Programs in Canada**

### **I. Goals and Objectives for Immunization**

Regarding goals and objectives for immunization, we see that only the objective for measles has been adopted nationally. However, national goals published in 1995 have been the basis for goals adopted in many regions, often with slight modifications. There has been some formal review of the extent to which these goals have been met (i.e. in B.C. and Québec), and this has also been conducted informally in other regions (i.e. Alberta). These goals and objectives should be reviewed and updated. In addition, efforts to monitor to what extent they have been reached should be expanded to allow evaluation of the field effectiveness of immunization programs in Canada.

At the April 2001 meeting of the Subcommittee on Immunization of the Public Health Working Group, participants were invited to check the completeness and accuracy of information pertaining to their jurisdiction, to provide a qualitative evaluation of the adequacy of the existing structures and processes, and to envisage possible change and improvement in light of experience in other provinces and countries. A second objective of the meeting was to discuss the nature and the performance of the structures and processes existing at federal and interprovincial/territorial levels and to propose developments which would be acceptable from political and financial points of view. The final objective of the meeting was to agree on how this consensus-building exercise should be continued.

#### **1. Provincial and Territorial Goals for Immunization**

Following a series of consensus conferences, national goals and objectives for immunization were created and published (LCDC, 1995). Many provinces have also publicly stated goals for immunization. In the fall of 2000, provinces and territories were questioned to identify goals and objectives for immunization in their jurisdictions. The results are summarized in the following table. Some details follow for individual provinces, and when available detailed texts on these goals are included in the appendices. Note that some regions have general goals for immunization which could be interpreted to integrate these specific goals.

#### **National and Identified Provincial/Territorial Goals for Immunization in**

## Provinces and Territories<sup>1</sup>

National Goal	BC	AB <sup>2</sup>	SK <sup>3</sup>	MN	ON	QC	NB	PEI	NS	NF <sup>4</sup>	YT	NWT	N U
97 % coverage for vaccines in schedule	✓	✓		✓ (95%)	✓ (95%)	✓ (95%)	✓		✓	✓			
Diphtheria elimination	✓			✓	✓	✓			✓	✓			
Hib type b: absence of prev cases	✓			✓	✓	✓			✓	✓			
Hepatitis B Coverage for adolescents				✓	✓	✓				✓			
Hepatitis B Reduction of incidence	✓			✓	✓	✓			✓	✓			
Measles Eradication	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Mumps	✓			✓	✓	✓				✓			
Pertussis	✓			✓	✓	✓				✓			
Polio	✓			✓	✓	✓			✓	✓			
Rubella	✓			✓	✓	✓			✓	✓			
Tetanus	✓			✓	✓				✓	✓			
<b>Other Goals</b>	BC	AB	SK	MN	ON	QC	NB	PEI	NS	NF	YT	NWT	N U
Influenza				✓	✓	✓	✓		✓	✓			
Hepatitis A-reduction of incidence						✓							
Pneumococcal coverage				✓	✓					✓			
Improvement of Cold Chain					✓	✓				✓			
Reduction of vaccine wastage					✓	✓				✓			

<sup>1</sup>Subject to verification. Provincial Goals often differ slightly from national goals. Detailed discussion is beyond the scope of this report

<sup>2</sup> Alberta: more comprehensive goals are stated in the Alberta Immunization Manual (to be obtained).

<sup>3</sup> Saskatchewan: Goals are being developed

<sup>4</sup> based on *activities* stated in Strategies 5 and 6(a), *Community Core Programs*.

**British Columbia** has detailed goals based on the national goals, and has examined to what extent these goals have been reached (see following section)- one goal has been achieved, 6 are 'partially achieved or on track', 2 have not yet been achieved, and there is no information for 3 goals (BC Ministry of Health, 1999).

**Alberta:** The following targets are mentioned in the Alberta provincial Business

**Plan.**

Percentage of 2 year old children who have received the recommended immunizations.

Target (2002): 97% (diphtheria, pertussis, tetanus, haemophilus influenza b, polio)

Target (2002): 98% (measles, mumps, and rubella).

In addition, there are more comprehensive goals in the Alberta Immunization Manual (a copy will be obtained and reviewed).

**Saskatchewan:** none in Saskatchewan Immunization Manual. However, immunization group within Public Health Services Project is working on possible goals.

**Manitoba** has adopted goals following closely the nationally developed goals. There are also goals for influenza and pneumococcal vaccine coverage.

**Ontario** has detailed goals for immunization (available online at [http://www.gov.on.ca/health/english/pub/pubhealth/manprog/mhp\\_5.html#prevdis](http://www.gov.on.ca/health/english/pub/pubhealth/manprog/mhp_5.html#prevdis)). These include many diseases (tetanus, measles, rubella, Hib, diphtheria, ...) and various objectives regarding continuing absence of indigenous diseases, elimination of certain diseases by specific dates, and increase of vaccine coverage in target groups.

**Québec:** Coverage objectives exist in the *Priorities Nationales de Santé Publique*, (see appendix) and there are specific objectives for certain programs such as hepatitis B vaccination in schools and influenza programs.

Targets by the year 2002:

- 95% of 2 yr. olds vaccinated according to the immunization schedule
- 95% of 15-yr. olds vaccinated against hepatitis B (including booster shots)
- eradicate measles, rubella, diphtheria, mumps and poliomyelitis through immunization programs
- reduce incidence of the following diseases to the following levels:
  - invasive H. influenzae type b disease: <50 cases per year
  - whooping cough: 50% reduction in # of cases
  - hepatitis B: 50% reduction in # of cases in people becoming sexually active (young people under 25)
  - hepatitis A: 50% reduction in number of cases
- at least 80% of institutionalised elderly people vaccinated against influenza each year



- 60% of people over 65 living at home vaccinated against influenza
- reduce the percentage of unused vaccines from 10% (annual percentage) to 5%
- reduce the percentage of vaccines stored at unsafe temperatures from 5% (1996 figure) to 2%.

**New Brunswick:** coverage goals for routine childhood immunizations were 95% coverage at 2 years, 99.5% coverage at school entry, 100% at school leaving. The target value for influenza vaccine uptake is 80% in identified target groups.

**Nova Scotia** mentioned that in 1996 goals were developed for each publicly funded vaccine developed based on national targets.

**Newfoundland:** Strategies 5 and 6 a) of the Community Health Core Programs mention monitoring and evaluation of immunization programs. While the copy obtained of this document does not specifically refer to targets for individual diseases, provincial health officials have indicated that goals exist for the specific diseases indicated in Table 1.

### **To what extent have goals been reached?**

In 1997, a survey was conducted examining to what extent National Goals had been reached (Health Canada, 1998b). While coverage levels for the first dose of MMR appear to be near targeted levels, coverage rates for diphtheria, pertussis, and tetanus were much below target. Other problem areas such as lack of data and non-standardization of reporting were identified. . Of note is the fact that there are no consistent methods of measurement of to what extent goals are actually reached.

#### ***Examples of Provincial Follow-up on Goals:***

To date, some information on formal monitoring has been obtained from BC and Québec. Data on immunization status (% with completed DPT-Polio, MMR, HIB) as of school entry is also monitored (i.e Newfoundland).

#### **British Columbia**

In 1999, overall provincial coverage for MMR at the second birthday was estimated at over 80%, with much variation by region, and some estimates were available for influenza vaccine coverage for seniors (BC Ministry of Health, 1999). The following table summarizes progress for specific diseases in the national goals:

Table --: Progress in Achieving National Goals, British Columbia (1999)

Disease	Goal/Target	Status in BC*
Diphtheria	Eliminate indigenous cases by 1997	▶
Invasive Hib infections	Achieve and maintain absence of preventable cases in children by 1997	▶
Hepatitis B	Reduce prevalence of indigenously acquired chronic infections in children & young adults by 90% by 2015	?
Measles	Achieve incidence of <1 per 100 000 by 2000	▶
	Eliminate indigenous cases by 2005	▶
Mumps	Maintain active prevention program to minimize serious effects	?
Pertussis	Reduce illness and deaths related to pertussis	×
	Have all reported cases managed appropriately	?
	Reduce intensive care admissions 50% by 1997	×
Polio	Maintain elimination of wild indigenous cases	✓
	prevent future imported cases	▶
Rubella	Eliminate congenital rubella syndrome by 2000	▶
Tetanus	Maintain elimination of tetanus in newborns and children	✓

Legend: ✓= achieved, ▶ partially achieved or on track, ×= not achieved,

?= no information

\*Source: BC Provincial Health Officer's Report, 1999, page 126.

## Québec

As part of follow-up on implementation of the 1997-2002 public health priorities in Québec, summaries are issued (MSSS 2000; MSSS 2001). The 3<sup>rd</sup> summary (*3e bilan*) is in press and gives estimates for vaccine coverage, elimination of measles, mumps, diphtheria, rubella and polio; reduction of incidence of Hib type b infections, pertussis, and type A and B hepatitis; coverage for influenza vaccination for elderly (institutionalized & non-institutionalized); and finally reduction of vaccine wastage and loss due to breaks in the cold chain.

Continued work is necessary in this area to examine development of provincial goals and targets and to what extent these are being reached in practice. Monitoring of program implementation is a key element in a successful National Immunization Strategy

## **Appendix 12: Worksheet for Analytical Framework, Meeting of the comité d'immunisation du Québec, March 2003**

### **Questions concernant l'opportunité d'implanter un nouveau programme de vaccination**

1. Le fardeau de la maladie justifie-t-il un programme de contrôle/élimination/éradication?
2. Les caractéristiques du vaccin vont-elles permettre la mise en œuvre d'un programme efficace et sécuritaire?
3. Existe-t-il une stratégie d'immunisation permettant d'atteindre le but visé par le programme de contrôle, les objectifs sanitaires et opérationnels?
4. Est-il possible de financer le programme et les indices coût-efficacité sont-ils comparables à ceux d'autres interventions de santé?
5. Un niveau élevé de demande ou d'acceptation existe-t-il pour le programme d'immunisation?
6. L'implantation du programme est-elle faisable compte tenu des ressources existantes?
7. Les différents aspects du programme seront-ils évaluables?
8. Existe-t-il d'importantes questions de recherche qui conditionnent la mise en œuvre du programme?
9. Le programme est-il équitable en terme d'accessibilité du vaccin pour l'ensemble des groupes cibles?
10. Existe-t-il des problèmes d'éthique qui conditionnent la mise en œuvre du programme?
11. Existe-t-il des problèmes juridiques qui conditionnent la mise en œuvre du programme?
12. Le programme planifié est-il conforme avec ceux planifiés ou implantés dans d'autres endroits?
13. Le programme risque-t-il de faire l'objet d'une controverse et son implantation présente-t-elle des bénéfices politiques immédiats?

## CADRE D'ANALYSE

### 1. Fardeau de la maladie

**Question 1: Le fardeau de la maladie justifie-t-il la mise en œuvre d'un programme de contrôle?**

Cochez une des cases suivantes:

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

1.1 Nature et caractéristiques de l'agent infectieux, incluant les réservoirs, les modes de transmission et les mécanismes pathogènes.

1.2. Manifestations cliniques et complications.

1.3.Épidémiologie de la maladie, incluant l'incidence, les tendances temporelles, les variations saisonnières et géographiques, l'agrégation des cas.

1.4. Les populations spécifiquement touchées et les facteurs de risque.

1.5. Traitement actuel de la maladie et prévention par des moyens autres que l'immunisation.

1.6. Impact sanitaire de la maladie dans la population, incluant la fréquence des cas, des décès et la perte d'années de vie.

1.7. Impact social de la maladie, incluant l'intensité des souffrances, la nature des séquelles chez les survivants, la diminution de qualité de vie chez les personnes affectées, ainsi que la perte d'années de vie ajustées pour la qualité, les invalidités et handicaps, l'impact sur les familles et le personnel soignant, la peur de la maladie, le stress pour les communautés.

1.8. Impact économique de la maladie, incluant les coûts directs et indirects pour les patients et les familles, les pertes de productivité, l'utilisation du service de santé et les coûts pour le système de santé.

### 2. Caractéristiques du vaccin

**Question 2 : Les caractéristiques du vaccin vont-elles permettre la mise en œuvre d'un programme d'immunisation efficace et sécuritaire?**

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 2.1. Nature et caractéristiques de l'agent immunitaire (ex: produit vivant ou non, atténué, absorbé ou non, viral ou bactérien)..
- 2.2. Caractéristiques des produits commerciaux (ex: préparation, agents stabilisateurs et de conservation, dosage, combinaison, entreposage, manipulation, conservation, format du produit).
- 2.3. Fabrication du vaccin, capacité de production et approvisionnement au Canada.
- 2.4. Délais d'administration, nombre de doses, association avec d'autres vaccins.
- 2.5. Nature et caractéristiques de la réponse immunitaire.
- 2.6. Immunogénicité dans différents groupes de population.
- 2.7. Efficacité du vaccin à court et à long terme, incluant la diminution de la maladie et les risques de décès.
- 2.8. Effet du vaccin sur la transmission des organismes pathogènes (ex: réduction du taux de portage, remplacement).
- 2.9. Efficacité à court et à long terme pour la population (ex: impact sur la réduction du fardeau de la maladie, incluant l'immunité de groupe).
- 2.10. Sécurité: taux et gravité des effets indésirables, contre-indications, précautions.
- 2.11. Possible interaction avec d'autres vaccins.
- 2.12. Possible impact du programme d'immunisation sur la résistance aux antibiotiques et antiviraux.

### 3. Stratégie et programme d'immunisation

*Question 3: Existe-t-il une stratégie d'immunisation permettant d'atteindre le but visé par le programme de contrôle, les objectifs sanitaires et opérationnels?*

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- 3.1. Recommandations et lignes directrices existantes pour l'utilisation du vaccin (ex: CCNI, conférences de consensus, ACIP, AAP, monographie du produit).
- 3.2. But de la prévention: contrôle, élimination, ou éradication de la maladie.
- 3.3. Autres stratégies et programmes d'immunisation alternatifs pour atteindre le but visé (ex: programmes d'immunisation sélectifs ou universels, programmes de rattrapage).
- 3.4. Stratégies et modes d'administration des vaccins: infirmières ou médecins, privé ou public, diversité des lieux de vaccination (ex: écoles, cliniques privées, centres de santé ).
- 3.5. Objectifs spécifiques du programme en termes de réduction de l'incidence, des complications, des séquelles et de la mortalité.

3.6. Objectifs spécifiques opérationnels en termes de couverture vaccinale pour différents groupes cibles et de perte de vaccin.

#### 4. Coût-efficacité du programme

Question 4: Les indices coût-efficacité du programme sont-ils comparables à ceux d'autres interventions de santé?

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4.1. Coût du vaccin qui est déterminé, entre autres, par le nombre de compagnies distribuant le vaccin au Canada et leur stratégie de marketing.

4.2. Coût du programme dans une perspective sociétale, incluant les coûts directs et indirects pour les familles et le système de santé, les coûts pour la mise en œuvre et le déroulement du programme.

4.3. Preuve de l'efficacité du programme à court et à long terme, incluant la diminution de l'incidence de la maladie, les complications, les séquelles et la mortalité.

4.4. Bénéfices sociaux et économiques associés au programme, incluant la diminution des coûts de soins de santé, l'amélioration de l'espérance de vie, de la qualité de vie des individus, des familles, du personnel soignant et des communautés, ainsi que des gains de productivité.

4.5. Autres bénéfices indirects (ex: diminution de la résistance microbienne, diminution de l'engorgement dans les salles d'urgence).

4.6. Évaluation économique: les coûts présents nets et les ratios coûts-bénéfices (dans une perspective sociétale et de celle du système de santé) du programme par rapport aux stratégies alternatives (en termes de vies sauvées, de cas prévenus, d'années de vie gagnées, d'années de vie gagnées ajustées pour la qualité), discussion des hypothèses sous-jacentes, évaluation de la robustesse du modèle économique utilisant les analyses de sensibilité, comparaison avec d'autres études, pertinence du modèle pour le contexte local et comparaison avec d'autres interventions de santé).

4.7. Comparaison des indices coût-efficacité du programme d'immunisation proposé avec ceux d'autres programmes d'immunisation et d'autres interventions de santé à visée curative ou préventive.

#### 5. Acceptabilité du programme

Question 5: Un niveau élevé de demande ou d'acceptation existe-t-il pour le programme d'immunisation?

Pas du tout	Plutôt non	Ni oui	Plutôt oui	Tout à fait
-------------	------------	--------	------------	-------------

ni non

5.1. Perception du public du risque de maladie et de sa gravité, l'appréhension d'une épidémie.

5.2. La demande pour un programme de contrôle de la maladie, l'acceptabilité d'un programme d'immunisation pour les groupes cibles, le grand public, les professionnels de la santé (infirmières, médecins, personnel de santé publique) et les autorités politiques.

5.3. Priorité pour un nouveau programme tout en respectant les autres programmes potentiels/approuvés.

**6. Faisabilité du programme**

**Question 6: L'implantation du programme est-elle réalisable compte tenu des ressources existantes?**

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.1. Disponibilité du vaccin et approvisionnement à long terme.

6.2. Disponibilité du financement pour l'achat du vaccin, incluant le rattrapage.

6.3. Opportunité de mise en œuvre d'un nouveau programme (ex: autre programme d'immunisation visant le même groupe).

6.4. Existence d'un plan opérationnel et d'un comité d'exécution.

6.5. Intégration d'un nouveau vaccin dans les programmes d'immunisation et les calendriers de vaccination existants.

6.6. Impacts du programme (incluant le rattrapage) sur les services d'immunisation existants et les autres secteurs de soins de santé (médecins, établissements de soins de longue durée, hôpitaux, établissements professionnels...).

6.7. Accessibilité de la population ciblée et niveaux attendus de couverture des groupes cibles.

6.8. Disponibilité des ressources humaines, techniques et financiers pour la distribution, la conservation (stabilité de la chaîne du froid) et l'administration des vaccins, incluant la mise en œuvre du nouveau programme et du rattrapage.

6.9. Disponibilité de la documentation appropriée et des formulaires de consentement pour la population et les fournisseurs de soins de santé.

6.10. Disponibilité d'un système d'enregistrement de l'administration du vaccin ou de son inscription

dans un registre .

6.11. Disponibilité des ressources pour la mise en marché et la communication avec le public, accès à l'information et formation des professionnels de la santé.

## 7. Capacité d'évaluation des programmes

**Question 7: Les différents aspects du programme seront-ils évaluables?**

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.1. Souhait d'évaluation pour les familles, les professionnels (infirmières, médecins, personnel de santé publique) et les autorités politiques.

7.2. Disponibilité de systèmes d'information afin de mesurer la couverture (y compris les registres de vaccination) et l'utilisation du vaccin, ainsi que la qualité des services de vaccination.

7.3. Disponibilité de systèmes d'information pour contrôler la réduction de l'incidence de la maladie, les complications, les séquelles et la mortalité.

7.4. Disponibilité de systèmes d'information pour évaluer les effets indésirables associés à l'administration du vaccin.

7.5. Disponibilité de systèmes de liaison entre les bases de données, les registres d'immunisation et les registres de population.

## 8. Questions de recherche

**Question 8: Existe-t-il d'importantes questions de recherche qui conditionnent la mise en œuvre du programme?**

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.1. Importantes incertitudes concernant les effets du vaccin et les impacts du programme

8.2. Projets de recherche en cours et en préparation dans le domaine du développement du vaccin, de l'immunogénicité, de l'efficacité et de la sécurité.

8.3. Besoins de recherche pour l'évaluation, la planification et la prise de décision concernant le programme et propositions pour répondre à ces besoins de manière appropriée.



8.4. Nécessité d'avoir un programme pilote d'immunisation.

### 9. Équité du programme

Question 9: Le programme est-il équitable en termes d'accessibilité du vaccin pour l'ensemble des groupes cibles?

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9.1. Équité d'un nouveau programme incluant universalité, accessibilité et gratuité des services pour la plupart des groupes de population vulnérables.

### 10. Considération éthique

*Question 10: Existe-t-il des problèmes d'éthique qui conditionnent la mise en œuvre du programme?*

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10.1. Les considérations éthiques, incluant le consentement avisé, et la protection de la confidentialité de l'information médicale.

### 11. Considérations légales

*Question 11: Existe-t-il des problèmes juridiques qui conditionnent la mise en œuvre du programme?*

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11.1. Les considérations légales concernant l'utilisation du vaccin (ex: à partir des recommandations

du fabricant).

## 12. Conformité du programme

Question 12: Le programme planifié est-il conforme avec ceux planifiés ou implantés dans d'autres endroits?

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

12.1. Conformité du nouveau programme avec les programmes planifiés ou existants dans d'autres juridictions et pays.

## 13. Considération politique

Question 13: L'implantation du programme présente-t-elle des bénéfices politiques immédiats?

Pas du tout	Plutôt non	Ni oui ni non	Plutôt oui	Tout à fait
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13.1. Bénéfices politiques possibles.

Controverses possibles et risques politiques associés à la mise en œuvre du nouveau programme.

## Appendix 13 : Questionnaire and Responses on Testing of Analytical Framework, CIQ meeting, March 2003

### Évaluation du cadre analytique pour les programmes d'immunisation

1. Quelle est votre appréciation de l'utilisation du cadre analytique qui a été fait pendant cette réunion du CIQ?

-excellente- je l'ai utilisé à plusieurs reprises avec des étudiants en médecine pour les sensibiliser aux difficultés de la prise de décision en immunisation

-aidant

-bon, mais beaucoup d'emphase sur le politique, éthique, légal, etc... et peu d'emphase sur l'efficacité, sécurité, et bénéfique de court terme versus long terme.

-certaines questions me paraissent avoir plus de poids que d'autres

-certaines catégories sont difficiles à évaluer.

-toutes les catégories ne devraient pas avoir le même poids.

-cela semble tout de même un bon outil de base mais ne devrait pas être le seul.

-le cadre est très utile pour systématiser. Il faut améliorer sa modalité d'utilisation.

-bien, mais trop de catégories et sous-catégories (2 fois)

-utile

-l'utilité serait plus grande après qu'une stratégie de programme est retenue car les réponses sur des éléments de faisabilité/acceptabilité/ éthique, etc... sont grandement dépendant de la stratégie.

-informations trop larges pour pouvoir répondre aux questions. Les questions devraient être en fonction de stratégies précises.

-pas utilisé systématiquement, un peu rapidement, +/- grande appréciation du processus.

-très bien- mieux préciser les catégories, en particulier 8 (questions de recherche), 9(équité/accessibilité), et 11 (considérations légales).

-C'est un outil intéressant qui aide à systématiser la démarche. Mais elle est lourde et comporte trop de sous-catégories

-très intéressant mais difficile d'y répondre sans préciser la stratégie proposée (i.e. questions sur stratégies, coûts/bénéfices, acceptabilité et faisabilité du programme, équité et accessibilité)

-manque de temps pour en faire une utilisation optimale

- stratégie d'immunisation non-précisée

- fort intéressant de faire cet exercice de façon systématique

- intéressant mais difficile de compléter la grille soumise pendant la réunion

- suggestion de fournir les définitions des catégories au verso de la grille.

- Prendre un peu plus de temps pour ré-expliquer les catégories avant de

- remplir la grille
- Difficultés d'interprétation risquent de diminuer la valeur des réponses

2. Quels outils (ou autres processus) serait-il souhaitable d'utiliser au sein du CIQ à l'avenir?

- animation des réunions mieux structurée
- cadre analytique avec standardisation des critères et des réponses possibles
- évaluer des stratégies précises
- la même mais + schématisés
- utiliser (dans la mesure du possible) le cadre analytique lors de la rédaction des documents futurs du CIQ.

3. Avez-vous utilisé cet outil dans d'autres contextes?

- non ( 3 fois)
- formation des résidents en santé communautaire
- avec des étudiants
- cadre de référence pour préparer questions d'examen de spécialité en médecine communautaire
- je l'ai utilisé à plusieurs reprises avec des étudiants en médecine pour les sensibiliser aux difficultés de la prise de décision en immunisation
- aidant

4. Quelles autres applications de cet outil seraient souhaitables à l'avenir? (i.e. formation des professionnels, discussions avec divers acteurs en santé publique, échange d'informations avec d'autres juridictions, etc...)

- préparer programme de recherche pré-décision
- outil pour les directeurs de santé publique, décideurs, etc (ceux qui auront à prendre des décisions sur l'ensemble de l'information)
- si le nombre de catégories est réduit, utile pour la formation/ discussion avec des acteurs de santé publique
- discussions avec divers acteurs en santé publique, échange d'informations avec d'autres juridictions.
- formation
- je pense aussi qu'au niveau des décideurs, cet outil est intéressant
- utilisation avec nos partenaires CLSC/MD lors de formation
- à utiliser avec nos directeurs de santé publique
- éducation des décideurs (directeurs de santé publique, ministre de la santé)
- formation des étudiants en médecine et en sciences infirmiers
- proposer cet outil à Santé Canada et au CCNI (NACI).

5. Tenant compte des changements anticipés dans les 10 prochaines années (nouveaux vaccins, modes d'administration, augmentation des prix), quelles actions devraient être entreprises pour soutenir la planification des nouveaux programmes d'immunisation publics au Québec?

- lien avec média
- promotion de la vaccination mieux structurée
- augmenter capacité de recherche pré-décision, en particulier sur le volet économique
- intégration des spécialistes en économie de la santé sur une base régulière et non pas ad hoc.
- informer plus les décideurs et le public, non seulement des effets bénéfiques potentiels des programmes, mais aussi de toutes les contraintes liées à ces choix (ex. : coûts d'opportunité).
- positionnement du CIQ par rapport à sa considération des aspects de faisabilité / acceptabilité p/r à 1 vaccin et p/r à une stratégie globale de promotion de vaccination
- production de recommandations bien étoffées comme il se fait actuellement
- meilleure connaissance des nouveaux vaccins qui sont plausibles avec d'une meilleure planification des activités de recherche et de connaissances préalables : les délais de priorisations et d'opérationnalisation sont trop courts actuellement.
- plus de données coût-bénéfice
- meilleur programme de surveillance des maladies évitables par la vaccination
- sensibilisation des directions de santé publique et autres décideurs
- développement de ce genre d'outil
- utilisation plus large
  - démarche plus systématisée
  - augmenter les ressources financières et humaines (agents de recherche, inromations, secrétariat allouées au CIQ
  - sensibiliser les décideurs concernant la vaccination (coûts-bénéfices) à titre de mesure préventive
  - assurer l'implantation d'un registre sur la vaccination
  - avoir une stratégie 'nationale' fédérale d'immunisation

6. autres commentaires :

- démarche essentielle à poursuivre, qui peut sûrement avoir une influence bénéfique sur le réseau de la santé publique au niveau provincial et fédéral.

-bon cadre, mais trop de catégories et sous catégories, et l'interprétation des questions principales peut varier d'un individu à un autre à moins qu'il prend le temps de lire les nombreuses sous-questions (et même là il pourrait y avoir des différences d'interprétation).

**Appendix 14 : Public Health Working Group (PHWG) Sub-Committee on Immunization Meeting, November 14<sup>th</sup>, 2000; Sheraton Gateway – Toronto; Record of Decisions**

**Participants:**

**Members**

Cathy O'Keefe (NF)  
Joanne MacDonald (PEI)  
Lynn Cochrane (NB)  
Mahnaz FarhangMehr (NS)  
Mary Scott (SK)  
André Corriveau (NWT)  
Digby Horne (MAN)  
Pat Mandl (YT, via teleconference)  
Danuta Skowronski (BC)  
John Waters (AB)  
Colin D'Cunha (ON)  
Greg Hammond (MN, co-chair)

**Health Canada**

Arlene King (co-chair)  
Susan Vent (Secretariat)

**Others**

Lonny Erickson (Université de Montréal)  
Laura Oster (Transpolar)

**1. Introduction (A. Corriveau, A. King)**

Andre Corriveau and Arlene King welcomed members to the first face to face meeting of the PHWG Sub-Committee on Immunization. André advised that since he has recently accepted to co-chair the PHWG he would be stepping down as co-chair of the Sub-Committee on Immunization; however he will remain as a Sub-Committee member. Greg Hammond was introduced and welcomed as the new provincial co-chair for the Sub-Committee on Immunization.

The Agenda was approved.

**2. Overview of National Immunization Strategy (A. Corriveau, A. King)**

André Corriveau advised that at the October 11th - 13<sup>th</sup>, 2000 PHWG and ACPH meetings it was agreed that Vaccine Safety would be added as a fifth component of the National Immunization Strategy.

Arlene King presented an overview of the National Immunization Strategy referencing the June 1999 background document which members had received when the Sub-committee was initiated. She spoke to the major issues regarding immunization that have been identified and suggested that members could embellish these issues at a later date. A brief overview of the national goals and each component of the strategy was provided. (A copy of the presentation was disseminated at the meeting)

Arlene introduced Lonny Erickson who has been contracted to complete the "Program Planning for Immunization in Canada" (PPIC) project and Laura Oster from Transpolar Technology who has been contracted to complete the "Vaccine Procurement Review".

Questions were raised with respect to the National Immunization Records Network Message and Arlene clarified that the "message" is in reference to the data to be transferred between jurisdictions. It was suggested that national legislation needs to be considered to effectively facilitate portability of data. Arlene advised that the opportunity does exist now to provide input in this area as the Federal Health Protection legislation is being reviewed.

...

#### **4. Program Planning in Immunization in Canada (Lonny Erickson)**

Lonny Erickson provided the background and objectives of the program planning in Immunization in Canada project. (Presentation was disseminated at the meeting)

Lonny reviewed the questions that were used in the project and elaborated on the findings as outlined in the presentation. Implementation concerns, human resource, public perception, cost-benefit issues all need to be addressed.

Nova Scotia and Saskatchewan submitted copies of their program planning framework which was forwarded to members. Other provinces have also submitted to Lonny copies of their frameworks. It was suggested that all existing P/T frameworks be shared with members. Members commented on their existing frameworks and how they work. It was agreed that at a national level a systematic framework is required to effectively evaluate program planning. It was questioned whether there are any fundamental differences between current frameworks being used.

#### **Members comments:**

The need to look at all aspects, such as social and political considerations, which influence decision making was also identified. Structures and processes which can withstand political change are required.

It was observed that the framework is one component and other aspects



need to be considered. Discussions ensued regarding advisory bodies such as NACI and consensus conferences and how they could contribute. It was suggested that the NACI statement on conjugate pneumococcal vaccine which will be available in February 2001 could be used for further discussions. NACI as a scientific body provides recommendations to the federal government on the optimal use of vaccines. NACI does not effectively address the issues of immunization programs and the delivery of vaccines so some additional mechanism is required to take the scientific recommendations to an implementation phase.

Members agreed that a stepwise, collaborative approach would be effective to develop a national framework, structure and process. It was suggested that a concrete pilot be used to test the framework and the conjugate pneumococcal vaccine could be considered.

It was also agreed that the Sub-committee will be responsible for identifying and developing the recommendations on the framework, processes and structures including funding requirements and implementation. It was suggested that consideration be given to presenting the draft framework at the proposed Pneumococcal Consensus Conference to have broad discussion on public health implications. The question was raised as to whether consensus conferences should be considered an integral part of the framework of the program planning process. FPT deputies need to be advised if consensus conferences are an integral part of the process which allow the science to become public policy. Members agreed that there was significant value of the consensus conferences.

#### **Next Steps**

Initial report (draft framework) will be validated and circulated to members and others as required.

Draft framework to be completed in March for presentation/approval to Sub-Committee.

NACI statement on conjugate pneumococcal vaccine to be obtained in February/March for discussion.

Suggest that next Sub-Committee meeting in late March be used to test draft framework and develop recommendations to bring forward to PHWG. Present and seek approval from PHWG/ACPH at their May meeting.

#### **Actions:**

Available P/T frameworks to be forwarded to members. **L. Erickson, S. Vent**

Approval from PHWG to use conjugate pneumococcal vaccine to test framework to be requested at the PHWG January meeting. **Co-chairs**

Draft framework to be presented to PHWG/ACPH May meeting for their approval.

**L. Erickson, Co-chairs**

NACI statement on conjugate pneumococcal vaccine to be forwarded to members for future discussion.

**Co-chairs, S. Vent**

5. ...

6. **Pneumococcal Conjugate Vaccines (T. Tam via teleconference)**

Theresa Tam provided an update on pneumococcal conjugate vaccines. It was suggested that the Sub-committee on Immunization could consider using this vaccine as a "test case" on decision making concerning vaccine programs in the P/Ts.

A detailed update is attached at the end of this document.

**Action:**

The possibility of using the new pneumococcal conjugate vaccines as a test case for PPIC is to be reviewed. **L. Erickson, Co-chairs**

6. **Workplan**

Considering the logistics to obtain the various levels of approval for all the components, it was suggested that the workplan timelines be reviewed by the co-chairs and then distributed to members. Members also requested an organizational chart which identifies ACPH/ PHWG.

**Actions:**

Workplan timelines to be developed and distributed to members. **Co-chairs, S. Vent**

Teleconference and meeting dates to be forwarded to members.

**S. Vent**

ACPH booklet to be forwarded to members. **S. Vent**

...

**Future Teleconferences and Meetings**

Teleconference: January 9<sup>th</sup>, 2001

Vaccine Procurement Review - Report

January 16<sup>th</sup>, 2001

PPIC - review of report

Vaccine Safety report

Meeting:

End of March beginning of April - to be determined

### Appendix 15: Worksheet for testing exercise for analytical framework CIQ meeting

Tenant compte de toutes les informations et expertise que vous possédez sur chacun des programmes potentiels, veuillez évaluer la désirabilité de chaque vaccin sur chacun des catégories dans le contexte d'un programme éventuel d'immunisation au Québec. Dans l'échelle employée, 1 indique que une évaluation pas favorable au vaccin, 3 indique une évaluation neutre, et 5 indique une évaluation très favorable du vaccin.

Catégorie	Vaccin conjugué contre le méningocoque de type C		Vaccin contre la varicelle		Vaccin 7-valent conjugué contre la pneumocoque		Vaccin acellulaire contre la coqueluche (adolesc. & adultes)			
	En défaveur du programme.....	En faveur du programme.....	En défaveur du programme.....	En faveur du programme.....	En défaveur du programme.....	En faveur du programme.....	En défaveur du programme.....	En faveur du programme.....		
1. Fardeau de la maladie	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
2. Caractéristiques du vaccin	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
3. Stratégies/programmes d'immunisation potentiels	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
4. Coûts et bénéfices sociaux et économiques	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
5. Acceptabilité du programme	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
6. Faisabilité du programme	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
7. Capacité à évaluer des programmes	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
8. Questions de recherche	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
9. Équité/ accessibilité	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
10. Considérations éthiques	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
11. Considérations légales	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
12. Conformité du programme	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
13. Considérations politiques	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>	5 <input type="checkbox"/>
Évaluation globale- ce vaccin devrait-il être ajouté au programme public au Québec?	En défaveur du programme.....		En faveur du programme.....		En défaveur du programme.....		En faveur du programme.....		En faveur du programme.....	
Rang (désirabilité versus les 3 autres vaccins candidats)	plus désirable 1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>	5	plus désirable 1 <sup>e</sup>	2 <sup>e</sup>	3 <sup>e</sup>	4 <sup>e</sup>	5

## **Appendix 16: Twenty Guidance Questions for assessing action research proposals and projects**

(Waterman et al., 2001)

1. Is there a clear statement of the aims and objectives of each stage of the research ?
2. Was the action research relevant to practitioners and/or users?
3. Were the phases of the project clearly identified?
4. Were the participants and stakeholders clearly identified and justified?
5. Was consideration given to the local context while implementing change?
6. Was the relationship between researchers and participants adequately considered?
7. Was the project managed appropriately?
8. Were ethical issues encountered and how were they dealt with?
9. Was the study adequately funded/supported?
10. Was the length and timetable of the project realistic?
11. Were data collected in a way that addressed the research issue?
12. Were steps taken to promote the rigour of the findings?
13. Were data analyses sufficiently rigorous?
14. Was the study design flexible and responsive?
15. Are there clear statements of the findings and outcomes for each phase of the study?
16. Do researchers link the data that are presented to their own commentary and interpretation?
17. Is the connection to an existing body of knowledge made clear?
18. Is the extent to which aims and objectives were achieved at each stage discussed?
19. Are the findings transferable?
20. Have the authors articulated the criteria on which their own work is to be read/judged?

## Appendix 17: Chronology of PhD project

Date	Event	Comments
Aug. 1999	Proposal for developing an analytical framework developed	
Sept 1999	Letters written to officials at Québec MSSS and Health Canada	Letters proposing participation in the development of an analytical framework for evaluating new immunization programs-
April 18, 2000	Examen de synthèse	
July 2000	Questionnaire mailout to CMOHs to identify key persons in immunization	
August 2000	Questionnaire mailout to key persons in immunization in Canada	
11-12 mai, 2000	8e Colloque provincial en maladies infectieuses, Hull, Québec	Presentation on immunization planning (P. De Wals) mentioning framework for immunization program planning
October 2000	Questionnaire mailout on structures and processes for immunization program planning	
Nov. 14, 2000	Meeting Subcommittee on Immunization, Toronto, Ontario	Presentation on Immunization Program planning in Canada and proposed analytical framework
Dec. 2000	National Immunization Conference, Halifax N.S.	Presentations on National Immunization Strategy with mention of analytical framework
January 2001	Teleconference with co-chairs of ISC	Suggested testing of framework with meningococcal and pneumococcal conjugate immunization programs
Feb 5, 2001	Meeting with Arlene King, Health Canada	Meeting to discuss advancement of project
Feb 2001	Contact of provincial /territorial representatives for additional information on structures and processes for immunization planning	Key persons were contacted by phone, e-mail or fax to collect more detailed information regarding the structures and processes for immunization program planning in their jurisdictions.
Mar 1, 2001	Submission of preliminary report for April meeting	Submitted for comments and discussion from ISC co-chairs
April 2 2001	Meeting, Subcommittee on Immunization, Toronto, Ontario	Presentation and highlights of report on program planning in immunization in Canada and framework
April		Collection of comments from participants and

2001		revision of report presented at April 2 meeting
May 1-2 2001	Conference on Influenza Control and Vaccines	Presentation on the economic impact of influenza in Canada. This conference addresses national coordination of influenza control measures
May 9, 2001	Public Health Working Group Meeting	Preparation of briefing notes for presentation of summary of activities on immunization program planning
May 22, 2001	Draft Report : Equitable Access to Vaccination	46 pages
June 2001	Meeting at Health Canada with senior staff  Presentation  Tunney's Pasture, Ottawa	Presentation of structures and processes for immunization planning in Canada and recommendations To Assistant deputy minister; Director, bureau of infectious disease ; Assistant director, centre for infectious disease prevention and control (Health Canada) and Chair, Advisory Committee on Population Health ; Chair National Advisory Committee on Immunization, co-chair, Public Health Working Group
July 2001	Meeting on National Immunization Strategy,  Centre de santé publique, Beauport, Québec	Meeting with Dr Arlene King, Division of Immunization, Health Canada, Dr Horracio Arruda, Direction Générale de la santé publique, MSSS, Dr. Greg Hammond, Dept of Infectious Disease, Manitoba, PHWG co-chair.
August 2001	ACPH Teleconference	To inform ACPH members of decisions made by the PHWG in June regarding the National Immunization Strategy.
August 24 2001	Meeting at Health Canada with senior staff  Tunney's Pasture, Ottawa	To discuss advancement of NIS Presentation on national goals and objectives for immunization programs and testing of analytical framework
Sept.- Dec. 2001		Contract on Goals and Objectives Survey and Report (followed by presentation)
Feb 5, 2002	Meeting with Arlene King, Health Canada, Tunney's Pasture, Ottawa, Ontario	Meeting to plan February meeting in Toronto
Feb 2002	Meeting of ISC Toronto, Ont	Presentation of goals and objectives project Activity for testing of framework
18-19 avril, 2002)	Colloque provincial en maladies infectieuses, Québec City, Québec	Presentation on decision-making structures and processes for immunization.
Nov ( ?) 2002	Journées Annuelles de Santé publique, Quebec City, Québec	Presentation of analytical framework as part of a seminar on technology assessment and decision- making in immunization