SPECIAL SERIES:
THE ROLE OF FEDERALISM IN PROTECTING THE PUBLIC'S HEALTH

Concurrency in Public Health Governance: The case of the National Immunization Strategy

Jennifer E. Keelan
Department of Medicine
University of Toronto

Institute of Intergovernmental Relations
School of Policy Studies, Queen's University

Public Health 2008(2)

Introduction

Immunization is an area of public health in which harmonization of policy across Canada is particularly critical. While individuals derive tangible benefits from being immunized, certain protective traits of most routine immunizations emerge when groups of individuals are immunized. This population or herd immunity, achieved by near universal immunization, can be undermined if pockets of susceptible individuals accumulate to a critical mass resulting in an outbreak of infectious disease upon exposure (Fine 1993). Since infectious diseases do not respect political borders, and immunizations do not provide perfect immunity, outbreaks in one jurisdiction increase the risk for infection along lines of contact. If, for example, one province does not immunize its citizens and these citizens migrate to another province, the effectiveness of the immunization program in the province of migration could be undermined.

While there is some ambiguity over the concurrency or overlap in public health governance, provinces and territories have largely retained jurisdiction over the determination and delivery of public health programs. Provinces and territories have therefore pursued their own immunization programs largely separate from the federal government and as a consequence, there has been a divergence in immunization policies across the country. In an effort to address this inconsistency Federal/Provincial/Territorial officials adopted a National Immunization Strategy at the 2003 Conference of Federal/Provincial/ Territorial Deputy Ministers of Health (Federal/Provincial/Territorial Advisory Committee on Population Health and Health Security (2003). The objectives of the Strategy were ultimately funded by the federal government through a dedicated trust. The long-term goal of the architects of the National Immunization Strategy was to institute a permanent body charged with implementing a broadly collaborative Federal/Provincial/Territorial policy process to negotiate comprehensive and harmonized immunization policies across the country. Core components of the strategy included setting national goals and objectives, ensuring collaboration on immunization program planning, research, and evaluation, securing the vaccine supply and setting up a national vaccine registry—each of these objectives are, in their own right, essential components of

rational immunization policy-making (Canadian Institute of Health Research Institute of Infection and Immunity III 2003; Federal/Provincial/Territorial Advisory Committee on Population Health and Health Security (Advisory Committee on Population Health and Health Security) 2003).

The development and implementation of the National Immunization Strategy provides some insights into how collaborative relationships and federal leadership can be effectively combined to achieve desired policy goals. This chapter will explore the effectiveness of this innovative Federal/Provincial/ Territorial collaborative approach to immunization policy-making and assesses its suitability for other public health areas in which there is large variability in provincial/territorial programs, where uniformity of programs is particularly important and where there is a reluctance or inability of the federal government to legislatively mandate the harmonization of programs. This chapter will first describe the roles and responsibilities of different orders of government in immunization policy and then describe the developments that lead to the creation of the National Immunization Strategy. Two provinces, Ontario and Alberta, two provinces with very different immunization delivery models, were chosen as case studies to explore how the implementation of the National Immunization Strategy has impacted Federal/Provincial/Territorial relationships.

Methods

To evaluate the effectiveness of a federally-funded inter-governmental bureaucracy, intending to stand in stead of outright federal regulation over provincial and territorial public health policies, it is necessary to delve deeper into the resulting relationships created between different orders of government and the impact that these relationships have on Canadian federalism. The framework used for this analysis is a modified version of the descriptive framework first developed by Harvey Lazar and Tom McIntosh (see the revised description this volume) and applied by Wilson, McCrae-Logie, and Lazar (2004) in their analysis of federalism in public health (Wilson et al. 2004). This study was informed by a documentary analysis, semi-structured interviews of key stakeholders and the use of the Lazar analytic framework described in detail in this volume (See also Wilson 2004a).

Federal Roles and Responsibilities in Immunization Policy

The federal responsibility for immunization policy is distributed over four government ministries, six separate government branches, two primary arms-length advisory agencies, and several national and international professional organizations (such as the Canadian Paediatric Society and the World Health Organization). The role played by the federal government can be quickly summarized in the areas where it has explicit constitutional jurisdiction to regulate immunization policy. Federal control over immunization policy has historically been tied to quarantine legislation that gives federal agents the power to detain, confine and if necessary forcibly treat those with infectious diseases (and immunize all contacts) at ports of entry (First enacted in 1871, see the Quarantine Act, [R.S. 1985, c. Q-1] >> 10). In addition, Health Canada maintains sole authority for the approval of all new drugs and therapeutic agents and is responsible for licensing new vaccines, and performing post-drug approval safety and adverse events surveillance: "Health Canada is the regulatory authority in Canada that is responsible for maximizing the safety, efficacy, and quality of drugs, including vaccines, for human use marketed in Canada"(Health Canada 2005). The licensing of new vaccines is governed by the *Food and Drugs Act* and regulations and these activities are carried out by the Directorate of Biologics and Genetic Therapies, part of the Health Products and Food Branch of Health Canada, who are directly responsible for reviewing the safety and claims of all new vaccines.

While the federal government maintains broad constitutional powers to monitor infectious diseases of national significance, and has certain powers to act unilaterally during a public health emergency involving multiple jurisdictions, immunization policies are generally preventative programs that involve the delivery of routine health services (Table 1). Thus, there is no precedent for the federal government to unilaterally impose routine immunization policies using any of the eligibility requirements for the provincial and territorial cash transfer payments (CHT) under the *Canada Health Act.* Scheduled immunizations are not considered medical treatment and thus arguably not strictly 'medically necessary'. Nor has the scope of Peace, Order and Good Government (section 91 of the *Constitution Act* describing the division of powers between the federal and

provincial/territorial legislatures) been traditionally interpreted to allow for federal regulation in the delivery of routine public health programming (Naylor 2003, 48-9). Such steps could be taken in cases of a threat with a national scope or in the event of an emergency but it is unlikely that the federal government could interpret the *Constitution Act* to enable them to routinely regulate policies under provincial and territorial jurisdiction without laying out these new powers. Outside federally-governed institutions and territories, the delivery of health care services, and public health programs such as immunization have, and are likely to, remain under the sole jurisdiction of the provinces and territories. This heavily circumscribes when the federal government can act unilaterally to regulate immunization policies at the provincial and territorial level.

There are also few instances where the federal and provincial/territorial governments engage in immunization policy-making of a purely collaborative character. One example is a voluntary bulk-purchasing program run by the federal department of Public Works (Public Health Agency of Canada 2006a). This federal purchasing agency can negotiate contracts for vaccine supplies on behalf of participants. Cost-savings for participants are achieved through joint negotiation, although jurisdictions with the smallest populations likely benefit the most from joint ventures. Participation in the program is completely voluntary, and up until 2005, less than ten per cent of vaccines (other than influenza) were purchased through this system. For example, in 2000/01 bulk purchasing through the federal program accounted for 1.5 million dollars versus the 114.8 million dollars spent on vaccine procurement by all jurisdictions excluding P. E. I. (Federal/Provincial/Territorial Advisory Committee on Population Health and Health Security (Advisory Committee on Population Health and Health Security) 2003, 11).

Table 1: Federal Roles and Activities in Immunization Governance

(last column optional)

Ministry	**Activities & Legislation (where the federal government has regulatory powers)**
Minister and Receiver General of Canada Department of Public Works	Vaccine Supply through the Bulk Purchasing Programme
Department of National Defence and Canadian Forces	Immunization of Special Population: Military Personnel *National Defences Act* *Constitution Act, [1867] 1982*
Correctional Services	Immunization of Special Populations (Federal Prisons) *Constitution Act, [1867] 1982*
Health Canada	
First Nations & Inuit Health Branch	Immunization of Special Populations (Immunizations on Reserves and Inuit Communities) *Constitution Act*
Biologics and Genetic Therapies Directorate	Vaccine Approval and Licensing-limited post-approval safety surveillance *Food and Drugs Act*
Marketed Health Products Directorate (Therapeutic Products Programme)	Drug Reactions Reporting System (regulations include vaccines but not reporting guidelines
Public Health Agency of Canada	*Public Health Agency of Canada Act*
Division of Immunization and Respiratory Diseases	National Immunization Strategy: National Agenda Setting, Programme Planning, Setting National Goals, Vaccine Research and Safety Provides Logistical Support for

	Federal/Provincial/Territorial Canadian Immunization Committee Funds National Advisory Committees (National Advisory Committee on Immunization), Working Groups and Task Groups National Security and Infectious Disease Control Quarantine at Ports of Entry / Airports Vaccine Safety and Surveillance, Vaccine Adverse Events Following Vaccination Database Coordinates Active Surveillance for Adverse Events through IMPACT Infectious Disease Surveillance (Vaccine-Preventable Diseases and other Reportable Diseases)
Office of Public Health Practice	Public Health Information System (iPHIS), National Immunization Registry. iPHIS adopted in select regions across the country. British Columbia, Manitoba(Winnipeg Regional Health Authority), Saskatchewan, Alberta (David Thompson Health District and Alberta Health and Wellness), Northwest Territories, Newfoundland and Labrador, Ontario, Yukon.Public Health Agency of Canada. 2006. Canadian Integrated Public Health Surveillance (CIPHS Public Health Agency of Canada, 2005-11-01 [cited 1 April 2006]. Available from http://www.phac-aspc.gc.ca/php-psp/ciphs_e.html#hwdoes.

Provincial/Territorial Roles and Responsibilities in Immunization Policy

Childhood and adult immunization schedules are set, delivered, and monitored under a patchwork of provincial and territorial legislation. All provinces and territories have developed a recommended infant and childhood immunization schedule. These vaccines are covered under the provincial and territorial health insurance and the ministries of health are responsible for procuring vaccine for the province and allocating funds for the delivery of immunization programs. Immunization is, by in large, delivered by local agencies including semi-autonomous municipal/regional public health offices under the direction of regional health authorities.

Only two provinces, Ontario and New Brunswick, have some form of mandatory immunization for school-aged children (Peppin 2005). In the absence of specific legislation requiring local agencies to provide all scheduled vaccines, local compliance to provincial standards is technically voluntary, although the reporting of infectious disease and local immunization statistics to the provinces and territories is frequently mandatory under the various pieces of legislation governing public health (Peppin 2005). The relationship between provinces/territories and their localities in setting immunization policy is however, generally provincial/territorial-hierarchal because provincial and territorial determine the set of insured vaccines. In addition, base-budget cash transfers to localities for program delivery frequently require some form of accountability to provincial and territorial immunization standards (Alberta regional health authorities Act, Sections 19-20). Finally, the mere existence of insured provincial/territorial vaccines means that localities must realistically find means to deliver these services to citizens in their jurisdiction. Examples of how the provincial/territorial-local relationship works for various aspects of immunization policy-making will be described further in the case study analysis.

While provinces and territories have the legislative authority over immunization policy, in practice, they do not have an unfettered freedom to act completely disentangled from the federal government. The case for an improved process for collaboration across jurisdictions has increased over the last few decades and pressure has come from many sources political, public and legal. In the Ontario Auditor's report for 2005, the auditor

argued that federal immunization recommendations should be immediately applied in Ontario unless specific scientific and medical arguments could be made that they would not apply to the Ontario population (Ontario Provincial Auditor Report 2003). Since 1964, national recommendations for routine immunization have been determined by an arms-length scientific advisory committee, the National Advisory Committee on Immunization who reports directly to the Chief Public Health Officer of the Public Health Agency of Canada. National Advisory Committee on Immunization makes its decisions through a process that includes a review of relevant scientific literature, assessment of the targeted disease's epidemiology, and a comparative risk and cost-effectiveness analysis for each new vaccine (National Advisory Committee on Immunization (National Advisory Committee on Immunization) 2005). National Advisory Committee on Immunization's mandate is restricted to determining the best practices to protect the population in Canada from vaccine-preventable diseases.[1] Their recommendations must then be translated into the provincial and territorial health policy arena, competing with a wide array of priorities for health care spending. Thus, the public administration, global health budgets, and spending priorities of each province and territory ultimately shape the feasibility of introducing new vaccines approved by National Advisory Committee on Immunization and the programs adopted.

An emerging policy problem

In the final report of the Royal Commission examining the future of health care in Canada, Roy Romonaw argued that the lack of national standards for immunization was emblematic of systemic problems with Canadian public health governance whereby each jurisdiction works largely in isolation to determine critical public health policies, such as disease surveillance, program planning, and evaluation. This fragmented approach often creates incommensurable policies, overlaps in program development and evaluation,

[1] National Advisory Committee on Immunization was first formed in 1964 by the Dominion Council of Health to review new immunizing products and to make national recommendations. Between 1975 to 2000, the Committee reported to the Assistant Deputy Minister, Health Protection Branch. In June 1978, the committee was formally named the National Advisory Committee on Immunization and from 2000-2004 National Advisory Committee on Immunization reported to the Assistant Deputy Minister, Population and Public Health Branch (PPHB). Since October 2004 National Advisory Committee on Immunization reports to the Chief Public Health Officer, Public Health Agency of Canada (PHAC). See National Advisory Committee on Immunization terms of reference: http://www.phac-aspc.gc.ca/naci-ccni/tor_e.html. Accessed 1 February, 2005.

nation-wide inefficiencies and a patchwork of programs that are ill suited to face emerging disease threats and the rapid evolution of relevant medical science and technologies (Murray 2002, 19) , "… Canada is not well prepared to face new and emerging problems due to globalization and the evolution of infectious diseases" (Romanow 2002, 134). Immunization was identified as a key policy area targeted for renewed federal leadership to actively harmonize the provincial and territorial programs, and rationalize, from a national perspective, all aspects of immunization policy making from vaccine development to program delivery and evaluation.

Across the country, what vaccines are covered by public health insurances, the number of doses administered, and what age they are given at have often diverged from National Advisory Committee on Immunization (federal) recommendations. At the national level, this plurality of practices poses a series of structural challenges. First and foremost, it means that some vaccines are available in some parts of the country and not in others. The lack of a national tracking system, or a vaccine registry and national standards for data collection and transferring protocols, also complicates federal agencies' ability to monitor the safety of new vaccines and to evaluate the effectiveness of immunizations recommended by their own advisory body. At the provincial and territorial level, few health ministries have developed a vaccine research and evaluation capacity comparable to the federal government. This constrains their ability to respond to the ever-expanding set of national recommendations for program planning in their jurisdictions. For example, of the ten billion dollars spent on Health Care in Alberta (2004-5), 98 million were spent on Health Protection, Promotion and Prevention (0.9%). Resources to evaluate new vaccines were limited and research projects evaluating the cost-effectiveness of new vaccines were ad-hoc (Jin et al. 2003). There is also varying capacity for each province and territory to deliver an ever-expanding immunization program, to perform their own surveillance for safety, and ultimately to evaluate the impact that newly implemented vaccines have on target diseases in their own jurisdiction.

Regional disparities in immunization programs increased between 1999 and 2003 when four new vaccines were added to the *Canadian Immunization Guide*. By 2003 only Alberta and Nunavut publicly funded at least three of the new vaccines for routine use (Sibbald 2003). In provinces and territories where the vaccines were not covered by

government insurance programs, clinicians were reportedly reluctant to inform their patients of new Canadian guidelines when the purchase costs for a full complement of the new vaccines exceeded $800 per child, a prohibitive expense for many families (Paterson et al. 2004). However, a position paper from the Canadian Medical Protective Association (2002) suggested that even in provinces and territories where vaccines were uninsured, once the federal advisory committee on vaccination (National Advisory Committee on Immunization) had approved the new vaccines, physicians had an obligation to recommend them to their patients: "It seems likely that a court would hold that recommending pneumococcal, meningococcal and varicella vaccines has become part of the standard of care for physicians"(Sirnick and Ross 2002). Thus, similar to the findings of the Ontario auditor general, the medico-legal opinion implied that National Advisory Committee on Immunization recommendations were effectively national standards that provinces and territories would have to find the means to comply with, i.e., an unfunded mandate.

The lack of a process to align progressive federal guidelines with provincial and territorial priorities for insured health services was exacerbated by years of federal claw-backs to health transfer payments. Cash-strapped provinces and territories were left with essentially an unfunded and ever-expanding federal mandate to expand immunization programs, increasing the odds that all three levels of government involved (federal, provincial and territorial and municipal/regional) would be out of sync with respect to their immunization recommendations. In the late 1990s, predictions that the coming decades would see an influx of relatively expensive new vaccines brought these governance issues to the forefront of the provincial and territorial agenda.

The formulation of the National Immunization Strategy

By 1999, growing concerns about the scope of variability in immunization programs across the country, prompted the Federal/Provincial/Territorial Deputy Ministers of Health to endorse developing a national immunization strategy to remedy the "patchwork" of provincial/territorial immunization policies across Canada (Naus and Scheifele 2003). Shortly thereafter, an editorial in the Canadian Medical Association's journal reported the death of a young girl in Ottawa from bacterial meningitis noting that

if the child lived across the river, in Quebec, the C-meningococcal vaccine would have been covered under Quebec's provincial health insurance. She might not have died had she received the new vaccine, or in this case, had she lived a few kilometres across the river in the province of Quebec (Editorial 2003). This story was picked up in newspapers across the country and uneven access to new vaccines became emblematic of the gaps created by the lack of a coherent national immunization program. Monika Naus, then the associate director of epidemiology services at the British Columbia Centre for Disease Control, and Dr. David Scheifele, the director of the vaccine evaluation centre at the British Columbia's Children's Hospital, wrote an open letter to the federal Minister of Health requesting that the federal government itself implement a national strategy for immunization, "We must end the current provincial vaccination hodgepodge that results in treating some children (and adolescents and adults) as more precious than others"(Naus and Scheifele 2003, 568). National goals and objectives such as the Canadian Coalition for Immunization Awareness & Promotion the Canadian Paediatric Society, the Canadian Public Health Association, the Canadian Coalition for Public Health and other local, national and international agencies pressured the federal government for a coherent national immunization strategy (Canadian Paediatric Society 2003). The full scope of the problems confronting immunization policy-makers is captured in the quote below:

> ... until December 1998, when varicella vaccine was licensed for use in Canada, the provinces and territories were doing a good job of introducing newly licensed vaccines to prevent childhood morbidity and mortality, and of making sure their populations were immunized. Federal support has been limited to regulating vaccine licensure and lot-by-lot release, supporting the National Advisory Committee on Immunization and maintaining a small staff and budget to assist provinces and territories in coordinating limited activities. But, during the 1990s — a time of cutbacks in health care budgets and a gradual weakening of public health in Canada— provinces and territories began to delay adopting new programs such as vaccination against *Haemophilus influenzae* type b disease

> and hepatitis B, which eventually were implemented in all provinces and territories. But provincial and territorial disparities have grown since the licensure of vaccines to prevent varicella, meningococcal group C infection, pneumococcal disease, and pertussis in adolescents: in most provinces and territories, none or few of these vaccines are publicly funded. These disparities are likely to widen as even more new vaccines reach the Canadian market…. We need a national strategy, national leadership and national funding (Naus and Scheifele 2003).

The federal government had in fact made several attempts to coordinate provincial and territorial immunization policies and to set agreed-upon national goals before the implementation of the National Immunization Strategy. Examples of this type of activity were a series of topical conferences spearheaded by the federal government. These conferences ultimately led to the establishment of the biennial Canadian Immunization Conferences (1994-). Public health officers and vaccine experts interviewed for this project universally agreed that these conferences served to establish important research and policy networks across the country (interview with King 2005). These conferences successfully brought together governmental and non-governmental vaccine advocates and immunization scientists under one roof for an intensive exchange and consolidation and articulation of national interests. However, while four *preliminary* consensus conferences were sponsored by the federal government between 1992 and 1994, and successfully established national goals for immunization and targets to eliminate vaccine-preventable diseases, real Federal/Provincial/Territorial agreements failed to materialize and the fragmented immunization schedules, program evaluation and surveillance capacity remained problematic. Federal public health officials also superintended an agreement to eliminate measles by the year 2005, as recommended by National Advisory Committee on Immunization and signed by the Deputy Ministers of Health. The goal however did not translate into a national re-vaccination or catch-up program for measles immunization as recommended by the Pan-American Health Organization. A similar process was repeated in the yet unsuccessful attempts to create a

comprehensive Canadian Immunization Registry Network (Public Health Agency of Canada 2005).

A National Immunization Strategy was first drafted in 1999 by a federal committee called the Federal/Provincial/Territorial Population Health and Health Security Advisory Committee (Advisory Committee on Population Health and Health Security). It was presented to, and endorsed by, the Deputy Ministers of Health in June 1999, and in 2001 they agreed to further develop the Strategy. Adopted in 2003, the National Immunization Strategy was implemented to create common criteria to assess and implement new vaccines across the country and to make these vaccines more financially feasible by increasing central purchasing opportunities. The National Immunization Strategy also outlined guidelines for information and communication systems for the monitoring and assessing of vaccines' safety, and finally it sought to establish a more comprehensive Immunization registry network that each province and territory could access and send information to in a consistent manner.

The five key components of the National Immunization Strategy were defined as:

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

Federal interest in the National Immunization Strategy and its willingness to fund such an initiative was sharpened in 2002 in the aftermath of a series of highly publicized public health crises such as the contamination of the blood supply with Hepatitis C, food supply with Bovine Spongiform Encephalitis, the water supply with E. Coli (in Walkerton, Ontario), and the outbreak of Severe Acute Respiratory Syndrome. In the wake of these public health disasters, there was renewed interest in the role the federal government played in the governance of public health and impact of disentangled policymaking (Health Canada 2003; Kirby 2003; Naylor 2003; Warry 2003; Wilson 2004b).

Funding for the National Immunization Strategy was announced in February of 2003 as part of 1.6 billion dollar federal investment in targeted health care initiatives outlined in the First Minister's Accord on Health Care Renewal. In the 2004 federal budget, a per capita allocation of $400 million dollars was made available to provinces and territories in the form of an ad hoc third party trust, the "Public Health and Immunization Trust" (Table 2). $300 million of this was earmarked for the implementation of four newly recommended vaccines. Within three years (by 2007) all thirteen jurisdictions had added four new vaccines to their routine schedule, ending a period of significant inequity (Table 3) (Butler-Jones 2006). The federal government also committed ten million dollars per year of infrastructure funding to PHAC to develop the inter-governmental processes inscribed in the National Immunization Strategy.

Table 2: Public Health and Immunization Trust Provincial/Territorial Allocations. Shares of this $400 million expenditure were provided to provinces/territories on May 18, 2004 by way of trust funds following passage of Bill C-30. In 2006, the federal government put an additional 300 million into the trust for 2007-10. This money was explicitly earmarked for the human papillomavirus vaccination and the trust was renamed accordingly, The human papillomavirus vaccine trust. Table compiled by Author May 2007. Sources: personal correspondence with Ministry of Finance, May 2006; 2007 Federal Budget 2007 http://www.budget.gc.ca/2007/bp/bpc3e.html#cancer [Accessed February 5 2008].

Fiscal Year	N.L.	P.E.I.	N.S.	N.B.	Que.	Ont.	Man.
2004-05	2,118,393	564,354	3,822,803	3,063,544	30,688,650	50,463,283	4,765,324
2005-06	2,180,728	583,863	3,942,337	3,156,570	31,773,858	52,588,858	4,933,935
2006-07	2,161,717	581,664	3,914,965	3,131,909	31,678,484	52,773,301	4,919,225
2007-08*	1,500,000	400,000	2,800,000	2,300,000	23,400,000	39,000,000	3,600,000
2008-09*	1,500,000	400,000	2,800,000	2,300,000	23,400,000	39,000,000	3,600,000
2009-10*	1,500,000	400,000	2,800,000	2,300,000	23,400,000	39,000,000	3,600,000
Beneficiary's							
Total Allocation	**10,960,838**	**2,929,881**	**20,080,106**	**16,252,023**	**164,340,992**	**272,825,442**	**25,418,483**
Proportionate Share	1.5%	0.4%	2.8%	2.2%	22.5%	37.4%	3.5%

Fiscal Year	Sask.	Alta.	B.C.	Nvt.	N.W.T.	Y.T.	Total
2004-05	4,052,721	13,011,125	17,024,921	122,522	172,643	129,717	130,000,000
2005-06	4,167,379	13,566,793	17,659,304	129,188	179,931	137,255	135,000,000

2006-07	4,126,497	13,622,031	17,638,609	131,170	180,578	139,851	135,000,000
2007-08	3,000,000	20,400,000	13,200,000	100,000	100,000	100,000	109,900,000
2008-09	3,000,000	20,400,000	13,200,000	100,000	100,000	100,000	109,900,000
2009-10	3,000,000	20,400,000	13,200,000	100,000	100,000	100,000	109,900,000
Total Allocation	**21,346,597**	**101,399,949**	**91,922,834**	**682,880**	**833,152**	**706,823**	**729,700,000**
Proportionate Share	2.9%	13.9%	12.6%	0.1%	0.1%	0.1%	100.0%

Table 3 Vaccine coverage before and after the implementation of the National Immunization Strategy.

Vaccine	First Licensed	Advisory Committee on Immunization recommends routine immunization	provincial/territorial uptake Pre-National Immunization Strategy; c. 2003	provincial/territorial uptake Post National Immunization Strategy 2007
Varicella	1998	1999	5	13
Pneumococcal	2001	2002	3	13
Meningococcal-C conjugate	2001	2001	3	13
Acellular Pertussis (14-16 yo)	1997	2003	7	13
human papillomavirus (12-24 yo)	2006	2007	--	4

Provincial and Territorial Health Insurance Coverage for Four new Vaccines recommended by National Advisory Committee on Immunization between 1999 and 2006 (Health Canada January 2003) and Post implementation of the National Immunization Strategy (April 2005) (PHAC 2005). Nunavit added Meningococcal in December 2006. For 2008 human papillomavirus vaccine information see (Public Health Agency of Canada 2008). Data Compiled by author, Feb 2008.

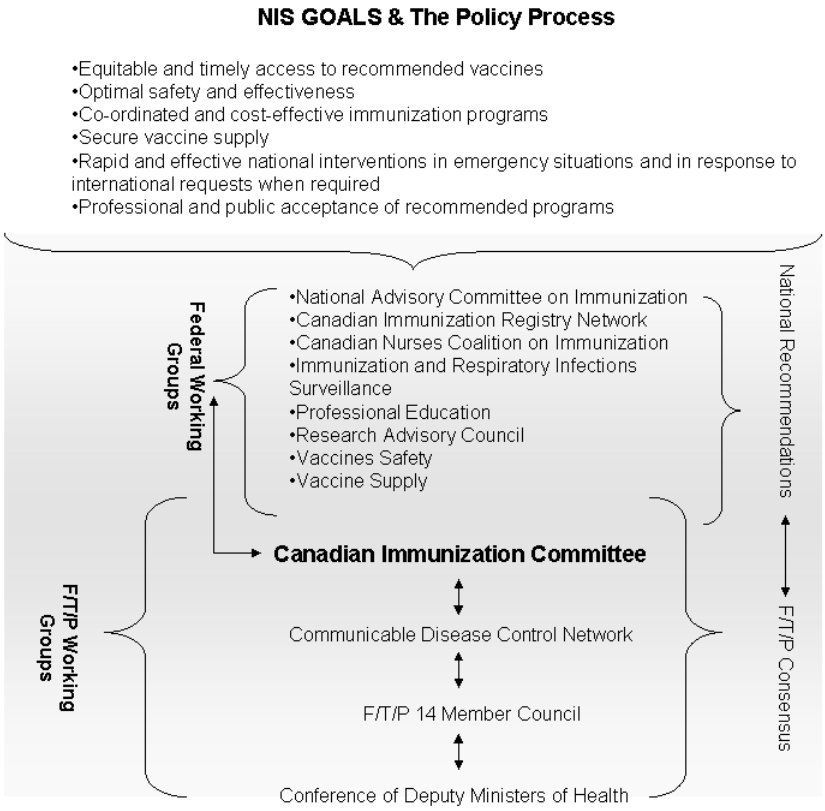
In 2006, the federal government renewed the immunization trust and National Immunization Strategy infrastructure funding by adding $300 million for 2007-10 and continuing the $10 million dollar support to the Public Health Agency of Canada (PHAC) for the National Immunization Strategy bureaucracy. The Immunization Trust was renamed in 2006 to explicitly earmark funds to roll out a Human Papillomavirus (human papillomavirus) Vaccine program and in doing so, the federal government clearly signalled that the Trust was intended to assist provinces and territories with the start up costs of introducing a new vaccine but would not provide long-term funding to sustain these programs. This appears to have reconciled the federal Conservative government's professed desire to restrain federal activity in areas of exclusive provincial/territorial jurisdiction whilst responding to political pressure to maintain federal funding for immunization for what was clearly a successful and popular public initiative. The human papillomavirus vaccine was recommended for routine use by National Advisory Committee on Immunization soon after the Trust announcement, in early 2007, however, under the terms of the Trust, provinces/territories are not restricted from using funds to support other immunization priorities. One year later, as of February 2008, only four jurisdictions (ON, NS, PEI, NFLD) have added human papillomavirus to their insured schedules. However, the delay for implementation of this new vaccine is as much due to lingering scepticism about its utility and a lack of regional capacity to rapidly assess the need for the vaccine as the long-term cost commitments required to implement the program in each jurisdiction (Comeau 2007).

These federal funding initiatives represent a significant federal investment in immunization policy. For example, in Ontario, before the institution of the Trust, the overall spending on immunization was reported to be 65 million dollars and this did not include any of the new vaccines (Ontario Provincial Auditor Report 2003, 235). The transfer payments from the Immunization Trust (2004-06) nearly doubled the annual immunization budget and enabled the Ontario government to cover the purchasing costs of four new vaccines. Having National Advisory Committee on Immunization recommendations and flexible federal funding via a trust has, to date, been effective in equalizing provincial/territorial policies with limited intergovernmental discord. Yet it is unclear whether or not the Trust funds will continue to entice jurisdictions to meet federal

guidelines, especially when provinces and territories are expected to take over the new program costs in a relatively short fiscal cycle (approximately three years). While this bridge funding may buy provinces and territories time to implement programs until competing vaccine manufacturer's products are brought to market, bringing purchasing costs down significantly, any future savings will not likely nullify the added costs of maintaining new programs.

In 2004, the Canadian Immunization Committee (Canadian Immunization Committee) was established to implement the National Immunization Strategy (Public Health Agency of Canada 2006a). The 19 member Canadian Immunization Committee, unlike the federal advisory committee National Advisory Committee on Immunization, includes decision-makers from each province and territory and its recommendations represent a consensus achieved through a joint-decision making process involving all jurisdictions (including federal). This encourages harmonization of Federal/Provincial/Territorial policies from the first (the decision-making process is complex as seen in the table below). The Canadian Immunization Committee is advised by other PHAC sub-issue groups such as National Advisory Committee on Immunization, and groups overseeing vaccine safety, professional and public education, and infection control (Interview with A. King 2005; (King 2005)) and would themselves come to a consensus about National Advisory Committee on Immunization recommendations. They would then present their recommendations to the Communicable Disease Control Network who reports to a 14 member Federal/Provincial/Territorial infectious disease "Council" which in turn reports to the Conference of Deputy Ministers of Health. This multi-stage process encourages consensus among jurisdictions and further brings these recommendations to high level decision makers from each jurisdiction (see Figure 1).

Figure 1: **Advisory relationships Federal Federal/Provincial/Territorial expert groups and the Federal/Provincial/Territorial Conference of Deputy Ministers. Modified from (King 2005, 21). – reprinted with permission from Keelan J, Lazar H, Wilson K. The National Immunization Strategy: a model for resolving jurisdictional disputes in public health. Canadian Journal of Public Health 2008;99:376-379.**



The Canadian Immunization Committee was intended to provide a routine forum to bridge the yawning gap between medical recommendations made by (National Advisory Committee on Immunization) and provincial and territorial immunization policies providing the missing pieces of programming that are increasingly critical for the federal government to fulfill its own responsibilities with respect to public health emergencies, national security and inter-provincial and territorial infectious disease control. Through the Canadian Immunization Committee, the federal government has greatly expanded its traditional role from approving and purchasing vaccines to partnering with provinces and territories to set national goals, promote approved immunizations, and engage in program planning, implementation, and evaluation.

However, it is difficult to see how the federal government would enforce Canadian Immunization Committee agreements without some form of regulatory authority to set national goals and standards for routine immunization.

Provincial and Local Immunization Programmes: Case studies of Alberta and Ontario

Models of Delivery: Private v. Public Settings

To assess the impact of the National Immunization Strategy and the use of a Trust to fund its objectives two provincial case studies were selected for review. Alberta and Ontario were chosen because they have distinctly different public health policies and regulations, and different fiscal profiles at the time of the Strategy's implementation. Given the different fiscal situation in Alberta and Ontario, it was presumed that the financial incentives of the Trust might operate differentially in regional priority setting and program planning. Alberta's system of immunization delivery conformed to best practices according to a leading immunization expert (Interview with N. MacDonald 2005) and recent literature (Guttmann et al. 2006). In Alberta, more than 98% of immunizations (and 70% of adult immunizations) are performed in regional public health clinics run by the nine regional health authorities (Interview with E. Sartison 2005). The regional health authoritiess are staffed by trained public health professionals responsible for monitoring the immunization of both infants and school aged children. Immunizations are largely administered by the public health nurses, free of charge, in community health care centres, or in district schools. Public health nurses are highly integrated in community life providing information and programs for pregnant women, infants and children, and counselling for child care, nutrition, dental health, injury prevention, prevention of communicable diseases, family planning and birth control (Interview with E. Sartison 2005).

Provincial legislation permits each regional health authorities to collect patient-linked data in their region and all regions have the capacity to closely monitor vaccination levels and compliance to provincial schedules. Alberta's system has led to relatively high levels of compliance, and has sufficient data to characterise gaps in vaccine coverage and to initiate programs to target resistance to immunization. While

Alberta's government has not restricted private practitioners from vaccinating, they have removed vaccination as a billable service from the provincial insurance program (Interview with S. Virani 2005). This provides a strong disincentive for private physicians to vaccinate at the same time reducing the overlap in the administration and delivery of publicly funded services and making data collection and transferring protocols more consistent.

By contrast, in Ontario, only 10% of immunizations are provided by trained public health professionals and 90% by private health practitioners (Health Canada 1996). Infant vaccines are generally administered by paediatricians or general practitioners and school-aged children receive their routine immunizations through their family physician, health clinics and school immunization programs (Ontario Provincial Auditor Report 2003). The Ontario government purchases all required vaccines and distributes them through the Ontario Government Pharmaceutical and Medical Supply Service to private physicians and local boards of health. Public Health in Ontario is organised around local, largely municipal Boards of Health whose budgets are supported by a mixture of provincial and local property taxes. Thus the capacity and range of services offered varies considerably depending on the size and tax base of the municipality or region serviced. Though there has been some amalgamation of regional public health board to assist smaller communities, some communities still do not have functioning Boards of Health, in contravention to provincial law.

Table 5: Allocations of Roles and Responsibilities in Alberta and Ontario

	Alberta	Ontario
Organization		
Provincial Public Health Organisation	Alberta Health and Wellness	Ontario Ministry of Health and Long Term Care
Regional Organization	9 regional health authorities	37 Municipal and Regional Public Health Units, governed by separate Boards of Health
Principle Legislation	*Public Health Act, regional health authorities Act*	*Health Protection and Promotion Act, Immunization of School Pupils, Day Nurseries Act*
Activities		
Vaccine Purchasing	Alberta Health and Wellness	Ontario Ministry of Health and Long-term Care
Setting Goals and Planning Immunization Programmes	• Vaccination voluntary • Provinces set vaccine schedules but regions are largely autonomous • Provinces transfers block payments to the regions to be used for all program planning including immunization; regions have latitude to set their own priorities • Program costs covered by block transfers	• Set of immunizations are required for School Entrance • Provinces set vaccine schedules but Boards are largely autonomous in determining programming • Province purchases all vaccines, reimburses physicians for delivery through OHIP, and provides cost-sharing via block transfers (75:25% provincial to municipal) to local Public Health Unites for program planning, evaluation and delivery
Vaccine Delivery	• regional health authorities primarily vaccinate in provincial clinics	• Private Practitioners (primarily) and Public Health clinics vaccinate (generally specific school programs, catch-up

	• public health nurses perform most vaccinations and collect and maintain immunization records	programs) • vaccination is primarily performed in physicians offices • schools collect information based on their own data systems/requirements and transfer the information to local Boards of Health

Setting Goals for Immunization and Programme Planning

In Alberta, it is ultimately the Ministry of Health and Wellness who determines which vaccines will be covered by Alberta Health Insurance. An advisory committee, the Alberta Advisory Committee on Communicable Disease Control is appointed by the Minister and, working with Provincial Health Officers, defines the policies for immunization programs including provincial goals and strategies. These guidelines are summarised in the *Alberta Immunization Manual* and are the standards used by public health nurses (Interview with S. Virani 2005). In response to the Severe Acute Respiratory Syndrome outbreak, Ontario created the Provincial Infectious Disease Advisory Committee which acts as the chief advisory body to the Chief Medical Officer of Health. The Sub-committee on Immunization, among other things, establishes provincial goals for immunization coverage, performs infectious disease surveillance, oversees immunization registries and monitors vaccine safety (Interview with Finkelstein 2006).

In Ontario, the immunization of school-aged children is governed by the *Immunization of School Pupils Act*, which legislate mandatory immunizations. Provincial insurance covers all vaccines listed under the Act, and all recommended immunizations are scheduled under the Ontario Health Insurance Program. Alberta Health and Wellness sets guidelines that regional health authorities are expected but not legally required to follow. In both cases the resulting inter-governmental relationship between the provinces and localities is broadly hierarchal. The provinces determine the immunization schedule, set the listed/insured vaccines, pay for the vaccines and allocate funds for delivery and are responsible for disease surveillance and program evaluation. Surveillance of vaccine-

safety however is shared between local providers, provincial health authorities and the federal government's active surveillance system IMPACT. This is the clearest instance of collaborative federalism between all levels of government.

However, critical gaps exist in the area of data sharing between all levels of government. In Ontario, the data collected by public health departments is supplied by district school boards, but the provincial legislation is not specific as to what information must be transferred or how local school board will verify or secure accurate data from parents. While school boards must collect basic information such as the name, age and address of each child, they have latitude to interpret the act such that they are not required to collect Ontario Health Insurance Plan numbers. This introduces the possibility of ambiguous records being transferred (i.e., two children of the same name or a child moving addresses and submitting two sets of records) and other reporting inaccuracies (Ontario Provincial Auditor Report 2003).

In Alberta, regional health authorities have access to complete patient-linked immunization data, but two of the largest regional health authorities (Capital Health and Calgary Health Region) will not routinely transfer this data to the province, instead they transfer aggregate data (S. Verani 2005). Neither province has implemented legislation that would enable routine transfer of complete immunization records to Alberta Health and Wellness or the Ontario Ministry of Health and Long Term Care. This limits the provinces ability to perform vaccine safety surveillance and to also share data with other levels of government. The implementation of the National Immunization Strategy has highlighted some of the issues surrounding vaccine informatics and disease surveillance and the federal government is actively engaged in creating a national immunization registry using standard data collection protocols.

As the federal government increases its capacity to collect data and perform surveillance, there is some anxiety that regional health authoritiess might begin directly reporting data to the federal government. Experts from Alberta Health and Wellness emphasized their concern that the federal government may initiate collaborate policies to interact directly with regional health authoritiess, completely disentangled from the provincial government. However, the trend in provincial/territorial-local relationships

both in Alberta and Ontario is increasingly hierarchal, where provinces impose mandatory standards on all aspects of infectious disease control and immunization policy despite the devolution of the management of the delivery of these services to regional authorities.

Table 6: General Summary of the Allocation of Roles and Responsibilities (excluding special populations)

Activities	Federal	Provincial/ Territorial	Local	Supranational
Agenda/standard setting	X	X	Potential	X
Legislative authority to determine programming		X		
Safety assessment	X	X		
Funding responsibilities	Ad-hoc	X	X	
Drug Approval and Licensing	X			
Promotion and related funding	X	X	X	
Information provision	X	X	X	
Programme Delivery			X	

Table 7: Nature of the Inter-governmental Relationships in three key areas of the National Immunization Strategy: Setting Unified National Goals, Programme Planning, and Evaluation

	Hierarchical	Interdependent	*Form of Relationship*
Federal-provincial	Ambiguous	Yes	*Pseudo-collaborative
Federal-local	No	No	Disentangled
Provincial-local	Yes	Yes	Hierarchal

Federalism in Immunization Policy-Making

Overview

The National Immunizations Strategy was a Federal/Provincial/Territorial initiative whose objectives were ultimately supported by federal infrastructure funding and a dedicated trust. Hence, what could not be achieved through direct federal regulation and central planning could be pursued using multi-lateral agreements and an explicitly collaborative inter-governmental process. The combination of setting national recommendations for immunization and funding these recommendations with a flexible federal funding via a trust has, to date, been effective in minimizing differences in provincial and territorial immunization programs.

After the implementation of the National Immunization Strategy, there was a marked reduction in the inequities in access to federally-recommended vaccines across provincial/territorial jurisdictions and this has been achieved with limited intergovernmental discord (Table 4). The long-term success of the initiative and its full implementation however, will largely depend on a complex of factors: ongoing federal financial support, the continued alignment of provincial/territorial and federal interests in contributing to a nation-wide immunization strategy or the perceived utility of national standards, and provincial and territorial relationships with federal agencies involved in national standard-setting. While the inter-governmental relations inscribed in the National Immunization Strategy are avowedly collaborative, the use of a federal Trust to fund the objectives of the National Immunization Strategy raises the spectre of the federal government coercing jurisdictions to comply with national immunization standards by using its spending powers as an inducement to participate—creating a hierarchal relationship and a type of federal unilateralism. However, unlike the federal government's use of its ability to fine provinces and territories for violations of the Canada Health Act, the Trust represents an ad-hoc spending "bonus" rather than an entitlement, and is used to entice compliance rather than penalize lack of adherence to national goals and recommendations. In the former case, compliance is maintained through punitive measures and in the latter, by at least some degree of voluntary agreement. The perceived degree of freedom to set policy in areas under their own

jurisdiction is a critical factor that can strengthen or sour inter-governmental relationships between provinces/territories and the federal government.

When provinces and territories are coerced to comply with federal regulations in areas under their own jurisdiction, and hence areas of policy that they are ultimately held accountable for by their publics, they have historically responded with great resistance. No government wishes to be bound to another's regulations but simultaneously required to pay for them and accountable for the outcomes. A consensus-driven, collaborative approach to national policy-making that involves the federal government financing policies of national significance whilst taking a lead in setting national guidelines may well provide the solution to the intractable problems facing those attempting to create national public health policy in a federalist system.

Form of federalism

The implementation of the National Immunization Strategy has transformed the arena of immunization policymaking by solidifying the trends toward collaborative governance of public health. Both the federal government and all provinces and territories have committed to the Federal/Provincial/Territorial processes inscribed in the National Immunization Strategy and hence what was once a firmly disentangled relationship is now overtly collaborative in this policy arena. Provinces and territories have always co-determined immunization policy however there is a residual degree of disentangled policymaking in areas now critical to setting rational immunization policy especially in the area of vaccine informatics, i.e., data collection standards and the need for a comprehensive vaccine registry. There also remains some diversity in the resulting relationships between provincial/territorial and localities that is contingent on the regulatory climate and degree of devolution of powers from the provincial and territorial ministries of health and those delivering immunization at the local level. In this sense the relationship between provinces/territories and local authorities mirrors those between the federal government and provinces and territories. Compliance to provincial and territorial recommendations is often in principle voluntary. However, in all cases, provinces and territories maintain jurisdiction over immunization policy and have powers to effectively set provincial and territorial standards. In practice, provincial/territorial – local

relationships can thus be broadly described as provincial/territorial-hierarchal even if the situation in principle is more complex.

While the form of federalism embodied in the National Immunization Strategy is collaborative, the continued existence of unilaterally determined federal guidelines, and the use of a federal Trust to fund these guidelines, modifies the ability of all parties to equally co-determine immunization policy, especially with respect to the introduction of new vaccines into the routine schedule. This creates an asymmetry in power between the federal government and the provinces and territories and introduces an element of coercion to comply with national standards, resulting in a fiscal federalism that falls somewhere between the stark unilateralist approach used to enforce the Canada Health Act and a pure form of collaborative federalism. Neither hierarchal nor collaborative descriptions of the inter-governmental relationships, nor unilateral versus collaborative federalism, suffices to describe the form of federalism employed to execute the National Immunization Strategy.

Describing the resulting relationships as federal-hierarchal implies that the federal government is unilaterally imposing its will on its constituents and yet this case study suggests that, at least in the first three years of the Trust's existence, provinces and territories were complicit in this process. The Deputy Ministers of Health were the prime movers of the policy seizing on immunization, a discrete and saleable health issue, to extract more federal funding for their social programs. In this finely-balanced chess game of fiscal politics, it is unclear whether the federal government has permanently locked itself into funding immunization programs or if the provinces have gambled their control over priority setting in future budgets for a short-term gain in federal health care spending. Despite the fact that provinces and territories were partners in this process, and may equally be described as having used advocacy for a National Immunization Strategy to secure more money from the federal government, the jurisdictional responsibility for continuing these programs remains heavily skewed toward the provinces and territories. Hence the resulting form of federalism is a contingent rather than static feature of the National Immunization Strategy and depends greatly on whether the implementation of National Advisory Committee on Immunization recommendations is perceived to be inevitable. In other words, the stability of the relationships embodied in the National

Immunization Strategy depends on the perceived utility of national standards, the relationship between different orders of government and continued federal funding of these national standards. The resulting Federal/Provincial/Territorial relationship is moderately federal-hierarchal, and could be newly classified as pseudo-federal hierarchal, but the form of federalism is, by strict definition, collaborative.

Policy Effectiveness

In terms of effectiveness, the implementation of the National Immunization Strategy and the Trust rapidly resolved glaring inequities in access to new vaccines and its continuance has provided provinces and territories with the funds to cover the initial implementation costs. The creation of a Federal/Provincial/Territorial committee (the Canadian Immunization Committee) to coordinate and solicit consensus on a broad range of issues institutionalizes a rational process for creating a national approach to immunization policy. The National Immunization Strategy has however been criticized for failing to execute many of its goals especially in the areas of coordinating research, improving research capacity and in failing to produce a centralized immunization registry (Kondro 2007). However, presentations at the Canadian Immunization Conference in Winnipeg (December 2006) indicated that several new programs would be shortly implemented to address some of the issues surrounding vaccine safety and informatics, including a new vaccine bar-code information system and a decentralized but standardized vaccine registry system (Public Health Agency of Canada 2006b).

The federal government's attempts to secure vaccine supplies and provide cost savings through central purchasing have also not yet been taken up by most provinces who continue to tender contracts for vaccines, with the exception of influenza vaccine procurement which has been centralized largely due to pandemic influenza planning. Other cost-savings that might occur because of increased coordination of immunization programming are more difficult to quantify but likely include a reduction in duplication of services (e.g., unnecessary immunizations) and through resource sharing, one would expect that costs for planning and designing the evaluation of new vaccine implementation would be reduced at all levels of government.

While policy research suggests that collaborative rather than coercive inter-governmental relationships produce the most effective policy outcomes (May and Burby 1996), others argue that a regulatory federalism framework is ultimately more efficient and effective executing national public health programs (Wilson 2004a). In writing about water-quality policy, Hill (2002) argues that the federal government can act more quickly and with impunity to implement policies that serve the needs of the population as a whole because they are distanced from the regional, political and economic consequences of regulation and can create the governing structures to hold regions accountable. If Hill's model of 'governing governments' holds true for vaccination, countries with highly centralized immunization program planning but devolved delivery should lead in the adoption of new vaccination technologies as soon as adequate evidence is available to warrant it (Hill 2004).

However this only holds true if federal governments can sustain their regulatory role without becoming responsible for actually funding or delivering these programs. In medical innovation studies of the UK, where this is not the case, researchers such as Roger Hollingsworth demonstrated the opposite effect. He argued that even in cases of clear technological benefit, adoption of new vaccines was driven by the structure, and degree of the integration of national health care systems, and that countries with large centralized health bureaucracies were slower to adopt a particular technology, but once it was adopted, they had the infrastructure for rapid and even diffusion (Hage and Hollingsworth 2000). This research suggests that a different scenario will occur even after the full implementation of the National Immunization Strategy. Federal/Provincial/Territorial Canadian Immunization Committee consensus will lag both National Advisory Committee on Immunization recommendations for new vaccines and provincial/territorial implementations leading to perennial inequities in access to insured vaccines. However, the existence of a dedicated Trust to fund National Advisory Committee on Immunization recommendations will likely enable provinces and territories to close these gaps more quickly. Without the Canadian Immunization Committee acting near-simultaneously with National Advisory Committee on Immunization to coordinate the implementation of a new program, it is likely that

significant differences will still arise in provincial/territorial programs leading to a sub-optimal environment for federal oversight.

A salient example of this is the recent Trust allocation that is tied to the introduction of routine human papillomavirus immunization. In this first test of the National Immunization Strategy, the federal government announced funding for the new vaccine by way of the trust the summer of 2006, before either National Advisory Committee on Immunization or Canadian Immunization Committee had an opportunity to make recommendations based on either scientific considerations (National Advisory Committee on Immunization) or based on a Canadian Immunization Committee consensus that would have reflected the needs and concerns of all jurisdictions regarding the need for and ideal implementation of this new vaccine. National Advisory Committee on Immunization released its recommendations in February of 2007 while the Canadian Immunization Committee's recommendations were not expected until December 2007. This unilateral approach by the federal government mitigated the usefulness and effectiveness of the Canadian Immunization Committee and to a lesser degree its own scientific advisory committee. As of February 2008, four jurisdictions had introduced human papillomavirus to their insured schedule with other provinces and territories continue to assess the situation. One proxy measure for the National Immunization Strategy's success would be the rapid resolution of gaps in access to human papillomavirus across jurisdictions, or the listing of human papillomavirus vaccine in all provincial/territorial insurance schedules by the end of 2008.

It is precisely because the Canadian Immunization Committee seeks to create Federal/Provincial/Territorial consensus (ultimately a political rather than scientific process) it will always be less nimble than National Advisory Committee on Immunization's unilateral approach. Also, by unifying immunization policy and creating consensus, the Canadian Immunization Committee will likely make provincial and territorial decision making less responsive to regional economic changes and provide less flexibility in this area of policy making. In seeking uniformity in immunization programming, the Canadian Immunization Committee might also provide unintended advantages for pharmaceutical companies, lobbyists and other interested parties who will be able to centralize their efforts to have their products approved nation-wide. On the

other hand, the full implementation of the Canadian Immunization Committee may ultimately undermine the rapid uptake of National Advisory Committee on Immunization recommendations by giving provinces and territories justification to delay the implementation of any new program until a consensus is reached at the Canadian Immunization Committee regarding the scheduling, implementation and evaluation of the new vaccine.

Respect for Principles of Democracy

There are several salient criticisms of the federal government's role in national standard setting, via its advisory committee, National Advisory Committee on Immunization. First, the federal government is not legally or politically accountable for its own advisory committee recommendations. Second, while the National Immunization Strategy should provide a bureaucratic process to resolve program disparities across the country, the federal government has continued to act unilaterally in setting a national agenda for the implementation of new vaccine technologies, as described above for the human papillomavirus vaccine. Canadian Immunization Committee deliberations are however confidential (Kondro 2007), and unlike National Advisory Committee on Immunization, who disseminate detailed reports and post membership and meeting details on their website, there is no mechanism to describe or review decision-making processes and recommendations made by the Canadian Immunization Committee. This severely curtails the transparency and ultimately the accountability of both the Canadian Immunization Committee and National Immunization Strategy processes.

The National Immunization Strategy's Federal/Provincial/Territorial collaborative approach to producing immunization policy is largely enabling for both the majority of Canadians and minorities who might otherwise have been marginalized by provincial and territorial priority setting. The Canadian Immunization Committee also provides a national forum to allow interest groups and NGOs (representing minorities) to make a national case for policy change. It also balances federal leadership and provincial accountability in immunization policymaking.

Impact on Canadian Federalism

The collaborative framework of the National Immunization Strategy, in principle, respects the jurisdictional sovereignty of provinces and territories over delivery of public health services. The federal infrastructure funding for the National Immunization Strategy provides the base budget to staff a Federal/Provincial/Territorial bureaucracy that will be increasingly critical for the coordination of programming, vaccine preventable disease surveillance, and the assessment of vaccine safety in order to maintain public confidence in immunization. The Trust funding is a critical component of the National Immunization Strategy as it signals the federal government's willingness to provide ongoing financial support to meet the objectives of the National Immunization Strategy. This cost-sharing reduces the burden on provinces and territories who might otherwise struggle to meet national standards.

Each province's fiscal situation, coupled with public health infrastructure, were the chief factors in determining how federal leadership in immunization policy was construed before and after the implementation of the National Immunization Strategy. In 2003 when the National Immunization Strategy was formally announced, Alberta had already invested in three of the new vaccine programs recommended by National Advisory Committee on Immunization while Ontario had to implement all four. The relative costs to implement new vaccines also differed as Alberta's system of public clinics and delivery using salaried nurses represented a different cost calculation than Ontario's implementation of four new vaccines with the associated physician billing fees. In addition, Ontario, unlike Alberta, was struggling under perennial provincial budget deficits. Ontario became particularly reliant on the National Immunization Trust to fund these programs. If subsequent federal governments do not sustain this funding, Ontario will be left with the burden of maintaining programs it could not have introduced without the federal government bearing close to 100% of the cost of implementation.

Alberta on the other hand, having already implemented three out of four new vaccines before the National Immunization Strategy was created had already prioritized health care spending to support these programs before the influx of federal funding. Experts interviewed in Alberta Health and Wellness saw the National Immunization Strategy as an opportunity for the federal government to provide research capacity and specialized and expert assessments of new vaccine technologies in development in

addition to providing a mechanism to coordinate programming and evaluation across the country. While Ontario was struggling to catch up to national standards, Alberta public health officers and public health nurses were keenly interested in developing a proactive plan to work with the federal government to anticipate vaccine program expansion for the next ten to fifteen years (Virani, Sartison and Rozanne Hamm 2005).

Conclusions

The federal government actions, albeit with broad support from the Deputy Ministers of Health in 2002, and the 2003 First Ministers' Accord on Health Care Renewal (2003) have redefined the landscape for provincial and territorial priority setting. While the federal government can discontinue the Trust funding, poorer provinces and territories have made program changes that would be hard to reverse or to reintegrate later into their own overall social spending priorities. Once a universal vaccine program is introduced into a population delisting the vaccination for financial reasons would pose insurmountable legal and ethical issues. The choice of a 'carrot'-style federal funding option has also made immunization *exceptional* in terms of other medical interventions; creating a dedicated fund permanently displaces immunization policy from the broader public health planning and general health care expenditures. It also means that the character and nuances of the inter-governmental relations inscribed in the National Immunization Strategy will vary depending on the relative fiscal power of each province or territory.

Despite not having met all of its objectives, the National Immunization Strategy has to be viewed at this point as a successful federally-funded initiative. It rapidly resolved the issue of equitable access to new vaccines with minimal intergovernmental discord. The strategy of combining national guidelines with flexible start-up funding could be a model for intergovernmental cooperation in other public health areas and it could be used to address areas of the National Immunization Strategy currently stalemated by a lack of coordination and engagement, such as the perennial failure to create a working national immunization registry and routine data sharing protocols for all levels of government. While the federal government has invested a significant amount of capital in developing a platform for electronic health records, a dedicated trust for the

nation-wide implementation of compatible information systems might provide the momentum required. The trust fund mechanism is particularly effective in areas in which the start-up costs of developing a program are a major obstacle, for example health surveillance.

Table 8: Effectiveness of Intergovernmental Arrangements in Immunization Policy Making

	Summary
Policy Effectiveness	
Health	• Co-sharing of costs through the Immunization Trust allowed for a rapid resolution of inequities in access to new vaccines across Canada • Failure as of 2007 to meet many of the objectives of the National Immunization Strategy including the coordination of many aspects of immunization policy, e.g., the lack of a national vaccine registry • Continued problems with coordinating the introduction and evaluation of new vaccines (e.g., human papillomavirus vaccine) • The Federal government's use of a Trust to fund national recommendations has the potential to distort provincial/territorial and local priority setting and may divert spending from other health care programs.
Economic	• Advantages of cost-sharing arrangements through the bulk purchasing program, exemplified by Influenza purchasing, but not widely utilized for other routine immunizations
Democracy	• Federal government is not legally accountable for its own advisory committee's recommendations • Federal government continues to act unilaterally in this policy area despite the creation of the Canadian Immunization Committee (i.e., creation of a human papillomavirus vaccine specific Trust before Canadian Immunization Committee recommendations were made) • Canadian Immunization Committee has not implemented adequate reporting measures and the process of making Canadian Immunization Committee recommendations lacks transparency (e.g., membership, reports and recommendations are not public unlike National Advisory Committee on Immunization) • Minorities and Special Interest Groups (e.g., vulnerable populations, vaccine manufacturers) can more efficiently lobby the Canadian Immunization Committee versus 13 jurisdictions for policy change • Majority rights (e.g., typical citizen and health consumer) are better served now that there is a bureaucratic process to discuss regional inequities

Federalism	• The National Immunization Strategy in principle respects the jurisdictional sovereignty of the provinces and territories • The long term success of this strategy will depend on several factors the perceived utility of national standards, the federal government's willingness to fund new vaccines and the long-term ability of provinces and territories to maintain the costs of new programs • The implications of the combined National Immunization Strategy and the Trust are distinctly different for have-not provinces • There is no clear dispute-resolution mechanism between Federal/Provincial/Territorial governments in the event of i) differing recommendations (National Advisory Committee on Immunization versus Canadian Immunization Committee) ; ii) continued idiosyncrasy in the uptake of new vaccines despite Canadian Immunization Committee consensus

References Cited

Butler-Jones, David. 2006. "Opening Session of the 7th Canadian Immunization Conference." In *Seventh Canadian Immunization Conference*. Winnipeg: Public Agency of Canada.

Canadian Paediatric Society. 2003. "Canadian Paediatric Society Calls for Greater Commitment to Children and Youth: Update of Presentation to the House of Commons Standing Committee on Finance."

Canadian Institute of Health Research Institute of Infection and Immunity III. 2003."Toward a national immunization strategy for Canada." *Canadian Institutes for Health Research*

Comeau, Pauline. 2007. "Debate begins over public funding for human papillomavirus vaccine."

CMAJ 176(7):913-914. Editorial. 2003. "A patchwork policy: vaccination in Canada."

CMAJ 168:567-568. Federal/Provincial/Territorial Advisory Committee on Population Health and Health Security

(Advisory Committee on Population Health and Health Security). 2003. "The National Immunization Strategy, Final Report 2003." Ottawa.

Fine, P. 1993. "Herd immunity: history, theory, practice." *Epidemiological Review* 15(2):265-302.

Guttmann, A., D. Manuel, P. T. Dick, T. To, K. Lam and T. A. Stukel. 2006. "Volume matters: physician practice characteristics and immunization coverage among young children insured through a universal health plan." *Pediatrics* 117(3):595-602.

Health Canada. 2003. "Health Protection Legislative Renewal."

Health Canada. 2005. "Regulatory Preparedness for Pandemic Influenza Vaccines: The Regulation of Influenza Vaccines in Canada." Ottawa: Government of Canada.

Hill, Carey. . 2004. "Regulatory Federalism: A Comparative Study of Safe Drinking Water Policy Implementation in British Columbia, Canada, and Washington, USA." In *The Midwest Political Science Association. Palmer House Hilton*, Chicago, Illinois.

Jin, Y, K C Carriere, G. Predy, D Johnson and T J Marrie. 2003. "Summary of Immunization Rates and Hospitalization for Community-Acquired Pneumonia in Alberta." Alberta Centre for Health Services Utilization Research.

King, A. 2005. "Managing Vaccine Supply-The Canadian Perspective." In *2nd NVAC Workshop on Strengthening the Supply of Vaccines in the United States*. Washington, DC, USA.

Kirby, David. 2003. "Reforming Health Protection and Promotion in Canada: Time to Act." *In Standing Senate Committee on Social Affairs, Science and Te*chnology. Ottawa: Government of Canada.

Kondro, Wayne. 2007. "Progress report on the National Immunization Strategy." *CMAJ* 176(13):1811-1813.

Murray, Terry. 2002. "Immunization message is in the cards." *Medical Post* 38(45):1.

National Advisory Committee on Immunization (National Advisory Committee on Immunization). 2005. "Terms of Reference."

Naus, M. and D. W. Scheifele. 2003. "Canada needs a national immunization program: an open letter to the Honourable Anne McLellan, federal minister of health." *CMAJ* 168(5):567-568.

Naylor, David. 2003. "Learning from Severe Acute Respiratory Syndrome: Renewal of Public Health in Canada." Ottawa: Health Canada.

Ontario Provincial Auditor Report. 2003. "Ministry of Health and Long Term Care: 3.09 *Public Health Activity*." Toronto.

Paterson, Michael, Ieva M Neimanis, Cindy R Goebel and D Kraftcheck. 2004. "Informed consent for uninsured services: a primary care perspective on the new childhood vaccines." *CMAJ* 171(8):877.

Peppin, Patricia. 2005. "Vaccines and Emerging Challenges for Public Health Law." *In Public Health Law and Policy in Canada*, eds. Tracey M.Bailey, Timothy Caulfield and Nola M.Ries. Queen's: McGill Queens.

Public Health Agency of Canada. 2005. "National Standards for Immunization Coverage Assessment: Recommendations from the Canadian Immunization Registry Network." CCDR 31(9).

Public Health Agency of Canada. 2006a. "Canadian National Report on Immunization." *CCDR* 3253(Supplement).

Public Health Agency of Canada. 2006b. "Proceedings of the Seventh Canadian Immunization Conference." In *Seventh Canadian Immunization Conference*. Winnipeg: Public Agency of Canada.

Public Health Agency of Canada. 2008. "Publicly Funded Immunization Programs in Canada-Routine Schedule for Infants and Children (including special programs and catch-up Programs."

Romanow, Roy. 2002. "Building on Values: The Final Report of the Royal Commission on the Future of Health Care in Canada." Ottawa: Government of Canada.

Sibbald, Barbara. 2003. "One country, 13 immunization programs." *CMAJ* 168(5):598.

Sirnick, Angela and Margaret Ross. 2002. "New childhood vaccines." *Canadian Medical Protective Association*.

Warry, S. 2003. "Will Severe Acute Respiratory Syndrome Crisis Give Canada Its Own CDC?" *CMAJ* 168(11):1381.

Wilson, K, J McCrea-Logie and H Lazar. 2004. "Understanding the Impact Intergovernmental Relations on Public Health: Lessons from Reform Initiatives in the Blood System and Health Surveillance." *Canadian Public Policy* 30(2):177-194.

Wilson, K. 2004a. "The complexities of multi-level governance in public health." *Can J Public Health* 95(6):409-412.

Wilson, Kumanan. 2004b. "A Canadian Agency for Public Health: Could it work?" *CMAJ* 170(2):222-223.

