

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

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

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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

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

Table 1: Federal Roles and Activities in Immunization Governance

(last column optional)

Ministry	Activities & Legislation (where the federal government has regulatory powers)
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Minister and Receiver
 General of Canada
 Department of Public
 Works

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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

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

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

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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

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

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	2,118,39		3,822,8	3,063,5	30,688,6	50,463,2	4,765,32
	3	564,354	03	44	50	83	4
2005-06	2,180,72		3,942,3	3,156,5	31,773,8	52,588,8	4,933,93
	8	583,863	37	70	58	58	5
2006-07	2,161,71		3,914,9	3,131,9	31,678,4	52,773,3	4,919,22
	7	581,664	65	09	84	01	5
2007-08*	1,500,00		2,800,0	2,300,0	23,400,0	39,000,0	3,600,00
	0	400,000	00	00	00	00	0
2008-09*	1,500,00		2,800,0	2,300,0	23,400,0	39,000,0	3,600,00
	0	400,000	00	00	00	00	0
2009-10*	1,500,00		2,800,0	2,300,0	23,400,0	39,000,0	3,600,00
	0	400,000	00	00	00	00	0
Beneficiary 's							
Total Allocation	10,960,8 38	2,929,881	20,080, 106	16,252, 023	164,340, 992	272,825, 442	25,418,4 83
Proportion ate 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	4,052,72		17,024,				130,000,
	1	13,011,125	921	122,522	172,643	129,717	000
2005-06	4,167,37		17,659,				135,000,
	9	13,566,793	304	129,188	179,931	137,255	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.

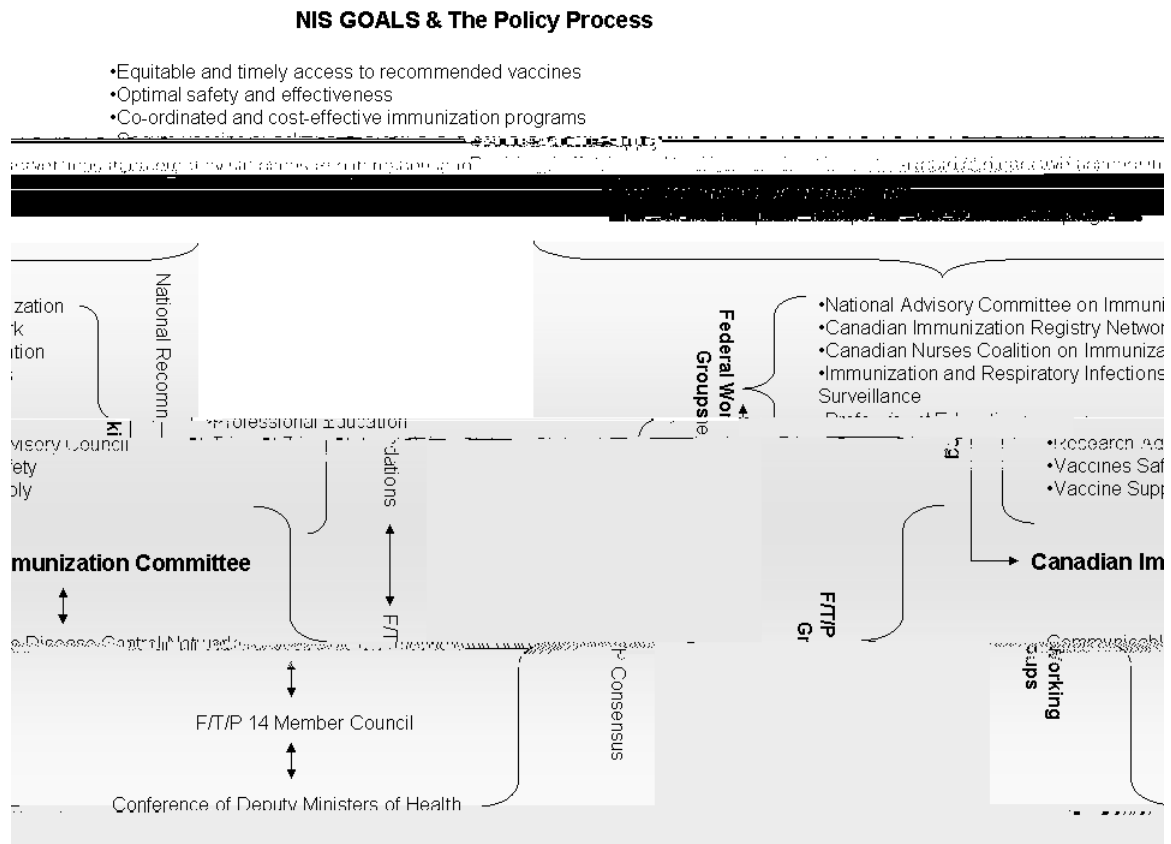
Vaccine	First Licensed	immunization routine recommends	Advisory Committee on Immunization	provincial/territorial uptake Pre-National Immunization Strategy; c. 2003	2007 Post National Immunization Strategy	provincial/territorial uptake Post National Immunization Strategy
Varicella	1998	1999		5	13	
Pneumococcal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

human

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)

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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.

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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

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	<i>Public Health Act, regional health authorities Act</i>	<i>Health Protection and Promotion Act, Immunization of School Pupils, Day Nurseries Act</i>
Activities		
Vaccine Purchasing	Alberta Health and Wellness	Ontario Ministry of Health and Long-term Care
Setting Goals and Planning Immunization Programmes	<p>Vaccination voluntary</p> <p>Provinces set vaccine schedules but regions are largely autonomous</p> <p>Provinces transfers block payments to the regions to be used for all program planning including immunization; regions have latitude to set their own priorities</p> <p>Program costs covered by block transfers</p>	<p>Set of immunizations are required for School Entrance</p> <p>Provinces set vaccine schedules but Boards are largely autonomous in determining programming</p> <p>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</p>
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
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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 in

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	<i>Form of Relationship</i>

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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

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While policy research suggests that collaborative rather than coercive inter-governmental relationships produce the most

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

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

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

	<i>Summary</i>
Policy Effectiveness	
Health	<p>Co-sharing of costs through the Immunization Trust allowed for a rapid resolution of inequities in access to new vaccines across Canada</p> <p>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</p> <p>Continued problems with coordinating the introduction and evaluation of new vaccines (e.g., human papillomavirus vaccine)</p>
Economic	

Federalism	<p>The National Immunization Strategy in principle respects the jurisdictional sovereignty of the provinces and territories</p> <p>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</p> <p>The implications of the combined National Immunization Strategy and the Trust are distinctly different for have-not provinces</p> <p>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</p>
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