ABSTRACT

Establishing effective intergovernmental relations is a key challenge to the development of successful health policy. While a growing amount of literature has appeared on the subject of federalism and health care, very little has been written on federalism and public health, which is oriented toward the entire population rather than individual patients. The first step in establishing such a literature is to develop a framework for characterizing the different forms of intergovernmental relations that exist in public health. This Working Paper attempts to provide such a conceptual framework with the intention that it will serve as a basis for synthesizing existing relevant literature, identifying gaps in knowledge, and ultimately developing national and international policies more favourable to public health. We apply this model to the case of blood safety, draw comparisons with health surveillance and derive a set of proposals to optimize the impact of intergovernmental relations on public health.

I. INTRODUCTION

After years of examining the structure and nature of intergovernmental relations in a variety of social policy sectors, the attention of the Canadian public and decision-makers has now turned to the mechanism by which governments interact to develop *public health* policy. This focus on governance in public health has largely been precipitated by the emergence of several new infectious threats including West Nile virus, Bovine Spongiform Encephalopathy (BSE) and Severe Acute Respiratory Syndrome (SARS). The nature and effectiveness of the multigovernmental response to the SARS outbreak, in particular, has accelerated discussions on the need for either major legislative or structural reform of the public health system¹ ². In considering such reform, policy makers have little literature to draw upon as the majority of governance research in health has focused on our health care system, specifically that part of the system which deals with medical and hospital insurance³. The absence of research on federalism in public health is somewhat surprising given that the nature of many public health activities is fundamentally intergovernmental.

In this article we hope to partially remedy the lack of literature on this important emerging area of study. We begin by proposing a framework for understanding the various combinations of intergovernmental relations that could exist in public health. We then apply this framework to describe intergovernmental relations in the blood system after it underwent reform in response to

the Krever Inquiry⁴. We next compare the effectiveness of the new set of relationships in the blood system to the set of governmental relationships in the field of health surveillance. With this information we provide recommendations for policy makers on the benefits of different governance structures for public health reform.

II. A FRAMEWORK FOR DESCRIBING INTERGOVERNMENTAL RELATIONS IN PUBLIC HEALTH

In the past decade public health decisionmaking has come under increased scrutiny as a consequence of the Krever Inquiry, the Walkerton Inquiry and most recently the examination of the public health response to the SARS outbreak. While each of these represent serious problems in and of themselves, they are also symptoms of a larger problem, that of public health governance. The origins of this problem can be traced to the Canadian Constitution, specifically its lack of clear allocation of roles and responsibilities for public health⁵ ⁶. This has created a situation in which the allocation of these responsibilities across orders of government has been pieced together in a post hoc manner producing a variety of systems of intergovernmental relationships. Confusion, however, remains in many public health sectors as to which order of government is ultimately responsible for doing what, producing a situation in which coordination of activities is challenging and gaps and overlaps in activities can arise. The consequences of these problems are magnified in public health because of the ability of public health threats to cross local, provincial/territorial

¹ Health protection legislative renewal. Health Canada (http://renewal.hc-sc.gc.ca).

² Wharry S. Will SARS crisis give Canada its own CDC? (news). CMAJ 2003;68:1381.

³ Romanow RJ. Building on values. The future of health care in Canada. Final Report. Commission on the future of health care in Canada. November 2002. National Library of Canada.

⁴ Krever H. Commission of Inquiry on the Blood System in Canada. Final Report. Canadian Government Publishing. Ottawa, Canada. 1997.

⁵ Braen A. Health and the distribution of powers in Canada. Discussion paper No 2. Commission on the future of health care in Canada. July 2002. National Library of Canada.

⁶ Jackman M. The constitutional basis for federal regulation of health. *Health Law Review* 1996;5(2):3-10.

and national borders. Decisions made by one government have a direct impact upon the public health activities of adjacent governments. This creates a situation in which federal, provincial, regional/local and at times supranational governments must coordinate their approaches to public health challenges to ensure they are effectively managed.

The importance of intergovernmental relations in public health clearly emerged during the international response to the SARS outbreak. In commenting on this response Dr. David Heymann, the World Health Organization's chief infectious disease expert, stated; "SARS has shown us that relationships between federal, or central, and provincial or state governments are very important in public health, and very difficult to establish". He added: "We understand that this has been a problem in China. It certainly has been a problem in Canada, where there have been difficulties between Health Canada and the provincial government". By gaining a better understanding of the various combinations of intergovernmental relations that can exist in public health and their potential impact on the development of policy, decision-makers will be able to construct more effective approaches to manage threats, such as SARS, in the future.

The Descriptive Framework

The first step to understanding the impact of intergovernmental relations on public health is to describe the set of intergovernmental relations that exists in specific public health sectors. To do so we adapt a descriptive model developed by Harvey Lazar and Tom McIntosh, which has been used in a series of analyses of public sector policy areas including health care⁸. The original model focuses on the relationship between the

federal government and the provinces/territories. This methodology first determines the level of interdependence that exists between the two orders of government. Interdependence refers to the requirement of one order of government for actions by another order of governments to ensure that policy is successfully developed and implemented. If interdependence is present, the nature of the interdependence then is characterized based on whether the relationship between the two orders of government is hierarchical. Hierarchy refers to the ability of one order of government to coerce another into taking a specific policy action. Hierarchy can result from legislative authority or financial mechanisms⁹. For example, in health care, the federal government uses its spending power to enforce the standards of the $Canada\ Health\ Act^{10}$. In blood safety, the federal government can enforce safety standards through legislation¹¹.

Based on the existence and the nature of the interdependence, three forms of intergovernmental relationships can be described. If no interdependence exists, the relationship is described as *disentangled* (*classical*). In this form of federalism, one of two conditions prevails. Either one order of government is active in the field while the other is inactive. Alternatively, both orders of government carry out functions in the same policy area independent of each other. The key point here is that the government(s) involved act largely independently of any other government¹². If interdependence exists and the

⁷ Alphonso C and York G. Canadian health officials rapped by WHO. *Globe and Mail (national edition)*. June 13, 2003. Pps A1, A6.

⁸ Lazar, H and T McIntosh. *Federalism, Democracy and Social Policy: Towards a Sectoral Approach to the Social Union*, Kingston: Institute of Intergovernmental Relations, 1998, p.4.

⁹ In the original methodology hierarchy referred to the ability of the federal government to exercise its influence in an area of exclusive provincial legislative jurisdiction through conditional funding programmes. In the methodology we present here we restate hierarchy to refer to the ability of one order of government to coerce another order of government into actions either through legislation or attaching conditions to financial transfers.

¹⁰ Canada Health Act, S.C. 1984, c. 6.

¹¹ Food and Drugs Act. R.S., c. F-27, s. 1.

¹² While not originally described, in a later analysis based on the original methodology, Lazar identified the possibility of *independence* and *hierarchy* existing in the case of health care cost-containment. The

relationship is hierarchical, the form of federalism is referred to as federal-unilateralism. The federal-provincial relationship in health care could largely be characterized as unilateral. By attaching conditions (i.e. the Canada Health Act) to its funding of hospital and medical insurance, the federal government is able to coerce provinces into delivering a specific type of service. If interdependence exists and there is no hierarchy, the relationship is described as collaborative. Collaborative relationships involve constant interactions between orders of government as they attempt to develop consensus on the policy that needs to be developed. They do not necessarily imply harmonious relationships.

To accurately characterize the nature of federalism in public health, the importance of a third order of government, local governments, and the various kinds of bodies that operate under it must be included in the model. While public health policy development mainly occurs at federal and provincial/territorial levels, actual policy implementation is largely a local responsibility. The inclusion of a third order of government in the federalism model increases the number of potential intergovernmental combinations threefold. While the previously described federal-provincial/territorial relationships may exist, there may also be similar forms of relationships between provincial/territorial and local governments. For example, a disentangled provincial-local relationship describes a situation where provincial and local governments act largely independently of one another. A provincial-local hierarchical relationship describes a situation where a province coerces the local governments into acting in a specific manner. This is likely to be the most common form of relationship that exists between provincial and local jurisdictions

federal government and provincial government independently went about introducing measures to control rising health care costs. The federal government's measures, specifically the reduction in funding associated with the Canadian Health and Social Transfer, directly impacted upon provincial policy making. It may be important to consider this form of federalism in analysis of public health policy.

since the provinces have complete legislative control over them. A provincial-local collaborative relationship may also exist where the province works in a non-coercive manner with the local governments to develop or to implement policy. The nature of provincial-local relationships has come under increased scrutiny largely as a consequence of the provinces downloading responsibilities to the local level and reducing funding as the federal and provincial governments seek to address their deficit and debt concerns. Provinces have experimented with a variety of forms of relationships with the local governments in an attempt to achieve the most effective working relationship. These relationships have given varying degrees of responsibility, funding and revenue raising power to the local governments and have involved different levels of amalgamation of activities. Theories on local government have been developed to help describe these changes¹³.

A variety of federal-local relationships may also exist in public health. The relationships can again be *disentangled*, *federal-local unilateral* or *collaborative*. Interest in federal-local relationships is increasing as the local governments begin looking to the federal government for revenue to compensate for their own limited revenue generating power and recent reductions in provincial funding ¹⁴. However, these relationships have to be carefully designed so as not to violate provincial jurisdiction. They are most likely to develop on a collaborative or contract basis in which all orders of government see the need for direct federal involvement at a local level.

In addition, to the vertical intergovernmental relationships we have described, horizontal

¹³ Tindal, CR and SN Tindal. *Local Government in Canada*, 5th ed. Scarborough: Nelson. 2000, 207-52.

¹⁴ Towards a Canadian Urban Strategy. Framework for Government of Canada Involvement in Urban Affairs. Prime Minister's Caucus Task Force on Urban Issues. March 11, 2002. (http://www.cip-icu.ca/English/institute/utf_subm.pdf)

relationships between members within an order of government may also exist. A confederal relationship between provinces, referred to as inter-provincial collaboration, has been proposed as an alternative to federal involvement in provincial public policy arenas. In this form of relationship provinces and/or territories would work together, either in regions or nationally, to establish agreements to govern the management of policy areas¹⁵. Similarly, the possibility exists of a *confederal* relationship existing between local governments that could cross provincial/territorial borders. In this form of relationship local governments work together to establish policy, possibly under the guidance of a national organization. Table 1 summarizes the various types of intergovernmental relations that may occur in public health.

III. APPLICATION OF THE FRAMEWORK TO THE CANADIAN BLOOD SYSTEM

Public health policy making previously leaped into the national spotlight when the health system discovered that both HIV and hepatitis C had been transmitted to patients through blood transfusion. The "tainted blood tragedy", as it came to be called, was the largest public health crisis this country had faced. Thousands of individuals became infected with HIV and tens of thousands were infected with hepatitis C¹⁶. The blood system was heavily criticized for the decision-making process that led to the transfusion transmission of infections. The criticism led to a large-scale inquiry into the blood system led by Justice Horace Krever as well as criminal charges against some of the

blood system actors⁴ ¹⁷. The Krever Inquiry provided several recommendations on how a new blood system should function to protect against such a tragedy happening again. In response to the interim report of the Krever Inquiry, federal-provincial-territorial ministers met to design a new blood system based on the report's recommendations.

The Krever Inquiry had repercussions not only in the blood system but also throughout all of public health. Justice Krever clearly illustrated the problems of unclear roles and responsibilities in public health stating:

"responsibility for the blood system is fragmented... the various functions integral to the supply of blood, such as regulation, funding and planning, are undertaken by different stakeholders. The respective functions, authority and accountability of each party are not well defined ... This lack of definition may affect accountability within the system, and ultimately its safety" 18.

This observation highlighted the inter-related nature between public health governance and the effectiveness of public health policies.

Five years have now passed since blood system reform measures were implemented and many important observations can be made about the success of these initiatives. These observations present an excellent learning opportunity for policy makers who are considering major public health reform in Canada that would alter the intergovernmental nature of public health policy making. We have previously conducted studies of decision-making in the blood system in the pre and post Krever era with

¹⁵ Courchene TJ. ACCESS: A Convention on the Canadian Economic and Social Systems. In *Assessing ACCESS*. Towards a new social union. Proceedings of the symposium on the Courchene proposal. Institute of Intergovernmental Relations (Oct 31-Nov 1, 1996). Queen's University, 1997.

¹⁶ Krever H. The consequences of contamination of the blood supply. Chapter 26 in: Commission of Inquiry on the Blood System in Canada. Final Report. Canadian Government Publishing. Ottawa, Canada. 1997. Pps 708-718.

¹⁷ Picard A. RCMP lay 32 charges in tainted-blood case. *Globe and Mail (national edition)*. Nov 21, 2002. Pp A4.

¹⁸ Krever H. The initiatives of the federal, provincial and territorial governments to reform the blood system. Chapter 38 in: Commission of Inquiry on the Blood System in Canada. Final Report. Canadian Government Publishing. Ottawa, Canada. 1997.p. 1023.

respect to management of infectious risks as well as the impact of changing financial structure on delivery of blood services¹⁹ ²⁰. These analyses involved over 70 taped-transcribed interviews with key stakeholders in the blood system and a full review of key related documents. Both of these analyses have provided important insights into the relevance of intergovernmental relations in public health and an opportunity to provide lessons for public health policy makers considering public health reform. Based on the information obtained from these analyses we are able to characterize the set of intergovernmental relationships that exists in the Canadian blood system and determine their effectiveness.

Structure and Allocation of Responsibilities in the Blood System

The federal, provincial/territorial and local orders of government have distinct but interrelated roles in the current blood system²¹. While the existence, roles and responsibilities of the federal and provincial/territorial orders of government are fairly clear, it is more difficult to identify whether local government exists in the blood system and, if so, what form it takes. Ostensibly, the local governments are the regional blood operators. These however, are

¹⁹ Wilson K, Hébert P, Laupacis A, Dornan C, Ricketts M, Ahmad N, Graham I. A policy analysis of major decisions related to Creutzfeldt-Jakob disease and the blood supply. *CMAJ* 2001:165:59-65.

linked in a cross-provincial collaborative manner under the governance of a national organization, the Canadian Blood Services. Canadian Blood Services is the national operator of the blood system. It is responsible for collecting, testing, manufacturing, distributing, purchasing and supplying blood products to all provinces except for Quebec. Héma-Québec is the operator of the blood system in Quebec and performs much of the same functions as Canadian Blood Services, but solely for the province of Quebec. It is at the regional operator level that much of the operational function of the blood system occurs including the delivery of blood products to hospitals. The regional blood agencies, however, have limited decision-making power in the area of blood safety. For the purposes of this analysis we will refer to the operators as representatives of local governance in the blood system.

The federal government's primary responsibility in the blood system is to protect the safety of the blood supply. The responsibility for regulating the blood system occurs at Health Canada in the Biologics and Genetics Directorate. Both Canadian Blood Services and Héma-Ouébec are bound by federal regulations. The federal government derives formal legislative authority over the area of blood safety through the Food and Drugs Act¹¹. The Act gives the federal government legislative authority over a wide range of areas concerning drugs, primarily concerned with protection of individuals from harm. Under this Act a drug is considered "any substance or mixture of substances manufactured, sold or represented for use in the diagnosis, treatment, mitigation or prevention of a disease. disorder or abnormal physical state, or its symptoms, in human beings or animals ...". Under Schedule D of this Act blood and blood derivatives are specifically identified as being drugs.

The funding of the blood system is a purely provincial/territorial responsibility. Provinces/territories provide block funds directly to the operators (Quebec to Héma-Québec, the rest of the provinces/territories to Canadian Blood Services). In exchange, provinces/territories receive blood products free

²⁰ Wilson K, MacDougall L, Pinard B, Amin MA, Fergusson D. Graham I. Blaichman M. Freedman J. Angus D, Hébert P. How Should Canada Fund the Blood System? An Evaluation of the Chargeback Proposal. Hospital Quarterly 2003; Spring: 47-54. ²¹ For this analysis we are considering blood safety in the regulatory sense. This involves the introduction of safety measures at a national level to protect the blood supply from primarily infectious threats. Important components of blood safety occur at the hospital level, including ensuring appropriateness of transfusion and preventing and managing transfusion reactions. This component of blood safety is primarily the responsibility of hospitals with some involvement of provincial governments. However, we are not considering this component of blood safety in this analysis.

of charge from the operators. Funding is divided among provinces/territories depending on the share of blood products they have been using. Both Héma-Québec and Canadian Blood Services use the funds provided by the provinces/territories to carry out all of their services. This includes the purchase of fractionated products from the country's primary manufacturer of fractionated blood products, Bayer Inc. The provinces/territories primary representation at Canadian Blood Services is through regional representatives on the board of directors. Their responsibility is much the same as shareholders.²⁰

While there are no supranational bodies that have a direct impact upon blood policy in Canada, blood officials are influenced by decisions made by other countries. Decisions in the US, in particular, are highly influential given that Canada imports a substantial portion of its fractionated products from that country. For this reason, it is important, although not essential, that the Canadian and US blood systems' have consistent policies for accepting and screening donations²². Other nations' blood safety practices also indirectly influence Canadian blood policy by setting international standards that Canada may be expected to meet²³.

The Form of Federalism in the Blood System

The federal, provincial/territorial governments and operators must work together to provide a coordinated, comprehensive approach to blood safety. The relationship between the three orders of government is, as a consequence,

²² In developing donor deferral criteria for individuals who had traveled to the United Kingdom to protect the

blood supply from variant Creutzfeldt-Jakob disease, Canadian and US blood officials made efforts to coordinate their policies. Both blood systems chose to defer individuals who had spent 6 months in the UK between 1980 and 1996. However, Canadian and US officials subsequently developed separate policies for deferring individuals who had traveled to France.

²³ In responding to a performance review conducted by IBM consulting services which recommended a reevaluation of NAT testing for hepatitis C, Canadian Blood Services stated that this would not be consistent with international trends.

interdependent. Agenda setting in the area of blood safety occurs at both the level of the federal government and the operators. While the federal government is primarily responsible for introducing legislation to protect the blood supply, the operators may exceed these safety standards or introduce safety measures that have not been mandated by legislation. The provinces/territories, per design, are largely removed from the agenda setting process.

Based on the framework we have described, both the relationship between the federal government and the provinces/territories and the federal government and the operators are highly hierarchical and best described as federalunilateral. The operators must implement safety measures legislated by the federal government and the provinces/territories must pay the cost of these safety measures. The relationship between the provinces/territories and the operators is generally non-hierarchical and best described as collaborative. However, at times, either the provinces/territories or the operator can indirectly impose some level of hierarchy on the other. Canadian Blood Services can dictate provincial/territorial expenditures through the introduction of safety measures. Provinces/territories, through their regulation of hospital transfusion practices, can influence the amount of blood that needs to be collected and provided by the operators. Table 2 summarizes the forms of federalism that exist in the blood system, specifically with respect to ensuring blood safety.

Impact of Form of Federalism on Development of Blood Policy

To determine the impact of the form of federalism on development of blood safety policy we again modify evaluation criteria previously developed by Lazar and McIntosh⁸. These criteria examine the impact of a form of intergovernmental relationship on the domains of policy effectiveness (health outcomes and efficiency), democracy and federalism.

Policy Effectiveness

The current governance regime in the blood system has produced a system that has improved the protection of the health of Canadians by enhancing the safety of the blood supply. This was the primary objective of structural reform. The coordination of activities of regional blood systems by a central operator and the clear allocation of regulatory authority to the federal government has reduced the likelihood of gaps occurring in the execution of blood safety activities. The blood system is also able to respond rapidly to new infectious challenges because the operators are empowered to introduce safety measures without the approval of the provinces/territories or the federal government. However, perhaps the most important quality of governance in the current blood system that improves safety is the separation of funding responsibilities from decisions to improve the safety of the blood supply. This system has allowed Canada to introduce safety measures, such as universal leukoreduction of the blood supply and nucleic acid amplification testing for hepatitis C, in advance of other nations.

While the current organizational structure protects the safety of the blood supply it does so partially at the expense of efficiency, defined as the amount of outcome produced for a given input of resources. The current system does have some economies of scale advantages with activity centralized in two operators. However, this benefit is offset by the negative impact on efficiency of separation of funding responsibility from the authority to introduce safety regulations. This separation of functions has led to the introduction of safety measures that have been considered highly cost-ineffective²⁴ ²⁵. There is

Respect for Principles of Democracy

The current organization of the blood system has had a positive impact upon principles of democracy although challenges still exist in this area. While the technical nature of many blood safety initiatives makes them somewhat inaccessible to the general public, high volume blood users actively participate in decisionmaking due to their vested interest in the safety of the blood supply. The participation of these groups, and the absence of the general public in decision-making, creates pressure for the blood system to introduce measures that protect the blood supply and its safety regardless of cost. This produces a situation in which resources are potentially diverted from other policy sectors in order to maintain the blood system. As a consequence, the blood system would be viewed as being more favorable to the rights of minorities rather than the rights of majorities.

Lines of accountability are clear in the current organization of the blood system, particularly when compared to the previous system. The provinces/territories, federal government and the operators have well-defined roles and responsibilities. Improved accountability and well-defined roles and responsibilities have also produced an improvement in the transparency of the decision-making process. Transparency, however, still remains a problem, a consequence of both the nature of the issues being discussed and the impact of organizational factors. Many blood safety decisions involve complex risk-

no financial disincentive for the federal government to introduce safety measures with comparatively poor cost-effectiveness ratios. However, there are substantial political and legal disincentives for not doing so²⁶.

²⁴ van Hulst M, de Wolf JT, Staginnus U, Ruitenberg EJ, Postma MJ. Pharmaco-economics of blood transfusion safety: a review of the available evidence. *Vox Sanguinis* 2002;83:146-155.

²⁵ As evidence, several recently introduced blood safety measures have cost-effectiveness ratios in the millions of dollars per quality adjusted life year (QALY) saved. For example, the estimated cost-

effectiveness ratios for NAT testing for hepatitis C virus and p24 antigen testing for HIV are \$2 000 000/QALY.

²⁶ Weinberg PD, Hounshell J, Sherman LA, Godwin J, Ali S, Tomori C, Bennett CL. Legal, financial, and public health consequences of HIV contamination of blood and blood products in the 1980s and 1990s. Ann Intern Med 2002;136:312-9.

management assessments that can be difficult for the general public to understand. This produces a situation in which blood system decision-making is susceptible to developing into discussions between experts and policy officials that exclude the public. However, both the operators and the regulators have made substantial efforts to protect against this by involving stakeholders throughout the decision-making process²⁷.

Respect for Principles of Federalism

While the current set of intergovernmental arrangement has improved policy effectiveness and respect for democratic principles, it has had a negative impact upon principles of federalism. This is again due to the purposeful separation of funding and regulatory responsibility. This set of arrangements has allowed for the emergence of unfunded mandates, the ability of one order of government to pass legislation that will incur costs for a second order of government and not provide supportive funding. Specifically, the federal government has introduced a series of directives to protect the blood supply and has not contributed to the potential costs of the initiatives, which have been borne by the provinces/territories. In addition, Canadian Blood Services has also independently introduced safety measures to increase the safety of the blood supply, which also produces costs for the provinces/territories. These safety measures have been partly responsible for the 50% increase in blood system costs since the creation of the new blood system²⁸ ²⁹. Again, as per design, there are few opportunities for the provinces/territories to

²⁷ Performance review of Canadian Blood Services. Final Report. IBM. October 15, 2002.

provide input on the necessity and the appropriateness of the cost-benefit profile of these safety interventions. There are also few dispute resolution mechanisms available to the provinces/territories to address their concerns over the appropriateness of the introduction of certain blood safety measures. There is also limited direct communication between the provinces/territories and Canadian Blood Services. This has led to an environment in which the provinces/territories believe they are not provided with adequate information to make budget decisions and Canadian Blood Services, at times, perceives it is not provided with guidance on the development of policies²⁷.

Summary

To summarize, the Canadian blood system introduced substantial organizational reform in an attempt to improve the safety of the blood system. In the current blood system there is interdependence between all orders of government. Hierarchy exists between the federal government and the provinces/territories and regions. The regions, represented by the operators, and the provinces/territories work together collaboratively to achieve policy goals. This system of governance promotes the safety of the blood supply. It removes cost and political considerations from influencing blood policy. However, it encourages the implementation of safety measures with comparatively poor costeffectiveness ratios. The current system of governance has improved accountability, although it is susceptible to problems with transparency. It also creates the potential for long-term conflict to exist between the provinces/territories and the federal government due to the fact that the provinces/territories have to pay the increasing costs of transfusion services that result from federal regulations. Tables 3 and 4 summarize the allocations of roles and responsibilities across orders of government in the Canadian blood system and the effectiveness of the set of intergovernmental arrangements.

²⁸ Wilson K, Hébert P. The Challenge of an increasingly expensive blood system. (Commentary) *Canadian Medical Association Journal* 2003:168:1149-1150.

²⁹ Between 1988/99 and 2001/02 blood system costs have increased from an annualized total of \$422 to \$638.8 million. These increases are due to both the cost of safety measures and the increased use of blood products such as intravenous immunoglobulin. Further increases in costs are expected due to the introduction of additional safety measures such as NAT testing for West Nile virus.

IV. FEDERALISM IN HEALTH SURVEILLANCE REFORM

The analysis of governance in the blood system demonstrates some of the advantages and disadvantages of a hierarchical approach to federalism. Alternative forms of intergovernmental relationships have been tried in other public health sectors, and each bring with them different sets of advantages and disadvantages. Health surveillance has been undergoing reform in an attempt to address a series of concerns, including unclear roles and responsibilities, the presence of important gaps in health surveillance and the lack of a coordinated national approach to health surveillance. We have previously described the nature and impact of federalism on these reform initiatives³⁰. This analysis specifically focused on the relationship between the federal and provincial governments in their efforts to develop the National Health Surveillance Infostructure (NHSI), a component of the Network for Health Surveillance in Canada. The NHSI is an Internet-based network/infrastructure designed to build capacity to help coordinate health surveillance activities across the country.

Our analysis observed that health surveillance reform was triggered by a combination of events including recognition by all orders of government about the dangers of a fragmented approach to health surveillance that produced important gaps in surveillance activities as well as the emergence of information technology that provided an opportunity to address this situation. As a consequence, a multigovernmental initiative was started to develop a national approach to health surveillance. This initiative represented a shift from a disentangled approach to health surveillance, in which governments largely acted independently of each other, to a collaborative approach. The approach

was successful in developing widespread agreement amongst the orders of government about the design of the National Health Surveillance Infostructure. At the conclusion of our study we identified potential obstacles to the eventual full implementation of the health surveillance system. These included developing agreements on data sharing, standardization of data and distribution of funding responsibilities.

Since the completion of our analysis, full implementation of the plan for health surveillance reform has not occurred. The lack of a national approach to health surveillance was identified on two separate occasions by the Auditor General to be a point of serious concern. In 1999, the Auditor General stated that federal, provincial/territorial and local governments needed to establish partnerships, develop agreements on data sharing and clearly outline roles and responsibilities for governing health surveillance activities. The report identified serious gaps in health surveillance and stated that the federal government needed to take a leadership role in ensuring that health surveillance reform takes place³¹. In 2002, the Auditor General's report identified that only limited progress had been made on addressing many of these concerns. It specifically stated that few data sharing agreements existed between governments and there were no agreements to ensure common standards on data collection activities³². Ongoing problems in health surveillance governance have also been highlighted by the response to the SARS outbreak. During the outbreak there has been concern about the inability of different organizations to share information due to

³⁰ Wilson K. The role of federalism in health surveillance. A case study of the National Health Surveillance "Infostructure". Chapter 7 in *Federalism*, *Democracy, and Health Policy in Canada* (ed. D. Adams). Pps 207-237. Kingston: McGill-Queen's University Press. 2001.

³¹ 1999 Report of the Auditor General of Canada. Chapter 14 National Health Surveillance: Diseases and Injuries. Office of the Auditor General of Canada and the Commissioner of the Environment and Sustainable Development. September, 1999.

³² 2002 Report of the Auditor General of Canada. Status Report, National Health Surveillance. Office of the Auditor General of Canada. 2002. http://www.oag-bvg.ca/domino/reports.nsf/html/20020902ce.html

inconsistencies in the standards for data collection³³.

V. LESSONS FOR PUBLIC HEALTH GOVERNANCE REFORM DERIVED FROM THE EXPERIENCES OF THE BLOOD SYSTEM AND HEALTH SURVEILLANCE

Health surveillance and blood safety share many features in common. Both domains are highly technical and of little public interest until the emergence of a problem in the system. The emergence of problems in either field has the potential to have a large-scale adverse impact on the health of the population. Because of these similarities, the two public health areas lend themselves well to comparison. Based on such a comparison, the following preliminary observations can be made regarding the effectiveness of different intergovernmental regimes in public health. Collaborative approaches appear to be successful in designing and rapidly developing widespread consensus on reform. The plan for a reorganization of the Canadian blood system largely occurred collaboratively and the collaborative approach to health surveillance resulted in the design of a comprehensive approach to national health surveillance. However, once collaboration produces a plan for reform, hierarchical approaches, in which the federal government takes the lead, may be more effective than collaborative approaches to ensure timely implementation of the system. This is primarily a result of the susceptibility of collaborative approaches to providing slow, incremental change due to the necessity of achieving consensus across all orders of government. The resultant delay in implementation of a new programme could have serious consequences in public health areas in which rapid reform is needed to deal with existing and emerging challenges. In contrast, a hierarchical approach has the advantage of clearly allocating roles and responsibilities across orders of government, producing better defined accountability and

allowing for the introduction of reform in a faster manner. A primary concern with this approach is that provinces/territories may view the use of hierarchy as a violation of their jurisdictional sovereignty. However, in many instances the provinces/territories may actually desire stronger federal leadership, which has been the case in health surveillance reform.

The federal government has two options available if it chooses to pursue a hierarchical approach in public health sectors: introduction of conditional funding programmes or legislation. Provinces/territories may not welcome conditional funding programmes because of past experiences with such programmes in hospital and medical insurance. Their specific concerns would be that the federal government might initially agree to a generous cost-sharing agreement (e.g. 50:50 cost sharing) and then slowly reduce funding while insisting that provinces/territories maintain certain standards. However, while the provinces/territories may be reluctant to agree to such a funding system, they likely will find it difficult to refuse federal dollars. If conditional funding agreements cannot be reached the federal government may be forced to rely upon legislation to achieve hierarchy. If the federal government does introduce legislation, efforts must be taken to protect against some of the adverse effects of this approach. Again, learning from the blood system's experience with reform, measures specifically need to be taken to protect the provinces/territories from the financial consequences resulting from unfunded mandates. In this area lessons could be derived from the US experience. Regulatory federalism has become prominent in the US since the 1960's, with the federal government introducing a number of regulatory relationships with state and local governments. One analysis stated that between 1983 and 1992 federal mandates produced costs amongst state and local governments of an estimated \$10.85 billion³⁴. The impact of these additional costs precipitated a movement to

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³³ Abraham C and Priest L. Cutbacks fed SARS calamity, critics say. *Globe and Mail (national edition)*. May 3, 2003. Pps A1, A6.

³⁴ Conlan TJ, Riggle JD, Schwartz DE. Deregulating federalism? The politics of mandate reform in the 104th Congress. *Publius* 2003;25:23-40.

restrict further federal legislation that would produce additional financial burdens for states and local government, eventually resulting in the Unfunded Mandates Reform Act of 1995. While the Act permits conditional funding programmes, it forces cost-benefit analysis of regulations and explanations of intergovernmental mandates that would exceed \$50 million. Amongst other components of the Act is a stipulation that federal agencies must consult with state and local governments and make efforts to introduce rules and regulations that impose the least amount of burden³⁴ 35. The Canadian federal government, if it chooses to pursue a legislative approach to reform, should consider the introduction of similar measures to protect against unfunded mandates in the Canadian context. While in the short term such measures may be perceived as impeding reform, in the long term they may protect against intergovernmental conflict thus allowing for the long-term viability of the public health programmes. In addition to such measures, other structural changes may need to be introduced to address intergovernmental conflict in a timely manner. These include the creation of independent dispute resolution mechanisms as well as the development of interfaces that allow for effective communication between the different orders of government. These bodies are best established prior to the introduction of a public health programme, as opposed to after the fact.

Governments must also take measures to improve transparency in the public health policy making process. The content of public health issues and the nature of intergovernmental decision-making are both susceptible to creating the perception amongst the public that important decisions concerning the public health of Canadians are occurring behind closed doors. This concern may not exist at the time decision-making is taking place but could arise if problems emerge in the system, a situation which arose in the Canadian blood system. Some steps governments could take to improve transparency

include publishing the transcripts of intergovernmental discussions on the Internet or allowing discussions to be open to the public. In addition to improving transparency, these steps may also facilitate decision-making by creating clearer accountability for decisions. This would allow the public to retrospectively identify why a decision was or was not made, who was primarily responsible, and reduce scenarios in which one order of government blames the other order of government for perceived failures in the policymaking process. Table 5 summarizes suggestions for public health governance reform that emerge out of a comparison of blood system reform to health surveillance reform.

VI. FURTHER QUESTIONS FOR PUBLIC HEALTH GOVERNANCE

While examination of the blood system and health surveillance reform initiatives generate some suggestions for different governance approaches to public health reform, they also generate several questions. For example, if the federal government adopts a legislative approach to achieve hierarchy, the question arises as to whether the provinces/territories could successfully challenge this approach as being unconstitutional. While the Criminal Code provision of the Constitution Act has permitted federal regulations for the purposes of health protection, the question remains as to whether this provision would permit legislation that mandates such activities as data transfer and maintaining common data standards. The residual powers given to the federal government under the peace, order, and good government clause may also provide the federal government with authority in this area. These powers can potentially be applied to areas in which the impact of policy within a province and outside of the province are linked, provinces cannot effectively regulate a policy area on their own and the failure of one province to regulate would affect the health of residents of other provinces⁶. Arguably, in light of recent developments, proposed public health related legislation that governs issues such as data transfer could be seen as meeting all three criteria. However, in the past,

³⁵ Kelly JM. The unfunded mandate reform act: Working well for no good reason. *Government Finance Review* 2003;February:28-31.

the courts have been hesitant to approve legislation based on these residual powers³⁶.

Another question that arises for public health governance is the role of governing public health agencies that are at arm's length from federal and provincial/territorial governments. The blood system has demonstrated some of the advantages of implementing a national coordinating body, Canadian Blood Services, which is at arm's length from government. The utilization of a similar approach in other public health sectors, for example health surveillance, would involve the creation of an agency that coordinates the activities of local public health agencies. This agency would have to follow federal regulations but would also have the ability to exceed these regulations if it believed that was necessary. The primary advantage of such a system is that the political considerations of federal and provincial/territorial governments would play a lesser role in the execution of public health services. It would create an environment in which decision-making is more likely to be driven by the need to address public health concerns. While one coordinating body may be an initial goal, it is possible that some provinces/territories may opt out of this arrangement. This may result in regional organizations with collaboration occurring across these regional bodies. This approach may allow for more targeted, region specific approaches to public health but would lose the advantage of economies of scale and national standards. This scenario has also partially occurred in the blood system with the presence of a second operator, as a consequence of Ouebec's choice to exclude itself from the federal/provincial/territorial discussions to develop a national blood service. The presence of a second operator has caused concern amongst some individuals in the blood system that believe that this results in a fragmentation of transfusion service and the potential for two different standards of transfusion care to exist in Canada. Others argue that the presence of a second

operator introduces checks and balances in the system and introduces a level of healthy competition. The smaller operator, Héma-Québec has also been viewed as having the ability to respond more quickly to transfusion related emergencies that may arise, due to its smaller size¹⁹. However, the presence of more than one coordinating agency potentially results in a loss of economies of scale advantages. It also reintroduces the problem of developing agreements across agencies for coordination of activities, a necessity for many public health activities.

While it did not directly arise in our examinations of the blood system and health surveillance, another question that public health officials will have to address is how to develop agreements to govern interactions with supranational governments. Supranational governments will play an increasingly important role in public health due to the challenges created by public health threats crossing national borders³⁷. These governments have the potential to influence the development of policy at the national level. The federal government's decision to enter into international agreements could also have a direct impact upon the provinces/territories that may not have participated in the discussions surrounding the agreement. In general, rules need to be established to govern the role of supranational governments in public health policy. Future applications of the model we have described need to identify how supranational government fit into the public health intergovernmental spectrum.

VII. CONCLUSION

Given the central importance of coordination in public health, the rapid development of public health technologies and the continued emergence of public health threats a more thorough understanding of the impact of intergovernmental relationships on public health is essential. In this article we have provided an initial step towards

³⁶ Choudhry S. Recasting Social Canada: A Reconsideration of Federal Jurisdiction over Social Policy. *University of Toronto Law Journal* 2002;52:163-252.

³⁷ Kickbusch I. The development of international health policies – accountability intact? *Social Science & Medicine*, 2000;51:979-989.

this goal, a framework for describing intergovernmental relationships in public health. We demonstrated the application of this framework to describe governance in the blood system and evaluated the impact of the set of intergovernmental relationships on the domains of policy effectiveness, democracy and federalism. We also demonstrated the value of drawing comparisons with other public health sectors, in this instance, health surveillance. The material presented here, however, is only a first step. More work needs to be done refining these analytic techniques and additional study of governance regimes in other public health sectors also needs to be conducted. There are many opportunities for such analyses as several national initiatives have been proposed or are in the process of development, including the National Immunization Strategy and the Centre for Emergency Preparedness and Response^{38 39}. By comprehensively and systematically examining the governance challenges of the past and the present, public health officials should be better prepared to address public health governance challenges in the future.

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³⁸ Naus M, Scheifele DW. Canada needs a national immunization program: an open letter to the Honourable Anne McLellan, federal minister of health. *CMAJ* 2003;168:567-568.

³⁹ Health Canada. *Centre for Emergency Preparedness and Response*. 2002. http://www.hc-sc.gc.ca/pphb-dgspsp/cepr-cmiu/cepr.html

TABLE 1
Descriptive Analysis Framework: Characterization of Intergovernmental Relationship

Form of Relationship

Interdependence Hierarchical

Federal-Provincial/territorial Relationships

	inter dependence	Therar chicar	1 of in of Actationship
Federal-Provincial	Yes	Yes	Federal-Provincial Unilateral
Federal-Provincial	Yes	No	Federal-Provincial Collaborative
Federal-Provincial	No	No	Federal-Provincial Disentangled
	Federal-Local		
	Relationships	TT' 1' 1	E CDIA I
	Interdependence	Hierarchical	Form of Relationship
Federal-Local	Yes	Yes	Federal-Local Unilateral
Federal-Local	Yes	No	Federal-Local Collaborative
Federal-Local	No	No	Federal-Local Disentangled
	Provincial-Local		
	Relationships		
	Interdependence	Hierarchical	Form of Relationship
Provincial-Local	Yes	Yes	Provincial-Local Unilateral
Provincial-Local	Yes	No	Provincial-Local Collaborative
Provincial-Local	No	No	Provincial-Local Disentangled
	Confederal		
	Relationships		
	Interdependence	Hierarchical	Form of Relationship
Provincial-Provincial	No	No	Interprovincial Collaborative
Local-Local	No	No	Interregional Collaborative
Local-Local	110	110	inciregional Conabolative

This chart shows that the relationship between the two orders of government could be characterized as collaborative if it is interdependent and non-hierarchical. It would be considered unilateral if the relationship were interdependent and hierarchical. It would be considered an independent, non-hierarchical relationship (i.e. disentangled) if each government acted solely in its own jurisdiction.

TABLE 2 Allocation of Roles and Responsibilities in Blood Safety

	Federal	Provincial/ territorial	Operator
Agenda setting	X		X
Legislative authorities	X		
Funding responsibilities		X	
Delivery of Service			X

TABLE 3

Nature of the Intergovernmental Relationship in the Blood System

	Interdependent	Hierarchical	Form of Relationship
Federal-provincial	Yes	Yes	Federal-unilateral
Provincial-operator	Yes	No	Collaborative
Federal-operator	Yes	Yes	Federal-unilateral

TABLE 4

Effectiveness of Intergovernmental Arrangements in Blood Safety

Policy Effectiveness		
Health	Improved coordination of activities Channels and manageribilities.	
	Clear roles and responsibilities	
	 Cost considerations have limited impact upon introduction of safety measures 	
Economic	Economies of scale advantages	
	 Separation of funding and regulatory functions increase the likelihood of introducing cost-ineffective safety measures 	
Democracy	Improved accountability	
	Minorities better represented than majorities	
	Improved but not optimal transparency	
Federalism	Potential for conflict due to unfunded mandates	
	Lack of intergovernmental interfaces	
	No clear dispute resolution mechanism	

TABLE 5

Suggestions for Public Health Governance Reform

- 1. Initially utilize a collaborative multi-governmental approach to establish plan for reform
- 2. Establish federal-hierarchical approach to policy implementation either legislatively or through conditional-funding programmes
- 3. If legislative approach taken ensure mechanism introduced to protect against unfunded mandates
- 4. Introduce independent dispute resolution mechanism and effective intergovernmental interfaces. Ensure such systems are transparent.
- 5. Consider establishing a national body, or several regional bodies, at arm's length from government. This body would coordinate local public health activities and would be independent from federal/provincial/territorial governments, except for having to meet regulatory requirements.
- 6. Develop rules by which interactions will occur with supranational bodies.