Understanding the Impact of Intergovernmental Relations on Public Health: Lessons from Reform Initiatives in the Blood System and Health Surveillance

KUMANAN WILSON
Department of Medicine, University of Toronto, Toronto, Ontario
Institute of Intergovernmental Relations, School of Policy Studies, Queen's University, Kingston, Ontario
Toronto General Research Institute, Toronto, Ontario

JENNIFER MCCREA-LOGIE
Toronto General Research Institute

HARVEY LAZAR
Institute of Intergovernmental Relations

Établir des relations intergouvernementales efficaces constitue un défi majeur pour le développement d'une politique de santé publique qui donne des résultats satisfaisants. Pour constituer une documentation sur le sujet, il faut commencer par créer une structure de base afin de caractériser les différentes formes de relations intergouvernementales qui existent en matière de santé publique. Notre article fournit une structure qui permet de faire la synthèse de la documentation pertinente existant actuellement, d'identifier les lacunes dans le domaine de la connaissance et, en fin de compte, de développer des politiques nationales plus favorables à la santé publique. Nous appliquons ce modèle au cas de la sécurité concernant le sang, nous faisons des comparaisons avec la surveillance dans le domaine de la santé et nous en tirons une série de propositions dans le dessein d'optimiser l'impact qu'ont les relations intergouvernementales sur la santé publique.

Establishing effective intergovernmental relations is a key challenge to the development of successful public health policy. The first step in establishing a literature on this subject is to create a framework for characterizing the different forms of intergovernmental relations that exist in public health. This article provides a framework for synthesizing existing relevant literature, identifying gaps in knowledge, and ultimately developing national 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.

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 decisionmakers has now turned to the mechanisms 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 multi-governmental response to the SARS outbreak, in particular, has accelerated discussions on the need for either major legislative or structural reform of the public health system (Health Canada 2003; Wharry 2003). Recently, the National Advisory Committee on SARS provided several recommendations on public health reform, including the development of a Canadian agency for public health (Health Canada. National Advisory Committee on SARS 2003). This report focused attention on the dysfunctional nature of intergovernmental relations in public health and the serious negative consequences to which these relationships could lead. However, in considering the various alternatives to addressing this situation, the committee and policymakers in general 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 that deals with medical and hospital insurance (Romanow 2002). The absence of research on federalism in public health is somewhat surprising given that the nature of many public health activities has a substantial intergovernmental component.

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 Inquiry (Krever 1997*a*). 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 policymakers on the benefits of different governance structures for public health reform. Furthermore, based on our analysis we also examine the potential impact of the governance recommendations put forth by the National Advisory Committee on SARS.

A Framework for Describing Intergovernmental Relations in Public Health

In the past decade public health decision-making 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 health (Braen 2002; Jackman 1996). The allocation of these responsibilities across orders of government have, consequently, 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/regional, provincial/territorial, and national borders. Decisions made by one government, therefore, have a direct impact upon the public health activities of adjacent governments. Therefore, 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" (Alphonso and York 2003). 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, decisionmakers will be able to construct more effective approaches to managing 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 care (Lazar and McIntosh 1998, 4). 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 to ensure that policy is successfully developed and implemented. If interdependence is present, its nature is then 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 effectively coerce another into taking a specific policy action. Hierarchy can result from legislative authority or financial mechanisms.[1] For example, in blood safety, the federal government can enforce safety standards through legislation (*Food and Drugs Act*, R.S., c. F-27, s.1.). In health care, the federal government uses its spending power to enforce the standards of the *Canada Health Act* (Canada 1984).

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: 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 independently of each other. The key point here is that the governments involved act largely independently of each other.[2] If interdependence exists and 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. Intergovernmental agreements can serve as the policy instrument that establishes collaborative, non-hierarchical relationships between orders of government.

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 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.

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 (Sgro 2002). 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 relationships between members within an order of government may also exist. A confederal relationship between provinces, referred to as *interprovincial 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 areas (Courchene 1997). Similarly, a *confederal* relationship may exist between local governments that could cross provincial/territorial borders. In this form of relationship, local governments work together to establish policy, sometimes under the guidance of a national organization. Table 1 summarizes the various types of intergovernmental relations that may occur in public health.

Limitations of the Framework

The understanding of any complex system has to begin with a basic breakdown of its properties, which this framework provides. By doing so it allows for an evaluation of the different sets of intergovernmental arrangements to determine where trade-offs in policy outcomes are occurring. There are, however, limitations to forcing complex policy-making systems into a specific model. In particular it should be recognized that within a specific policy area the nature of the intergovernmental relationships could be variable at a given point in time or across time. For example, at a given point in time, the relationship of the federal government with some provinces may be viewed as hierarchical, if the provinces need to be coerced into following federal policy, while the relationship with other provinces may be viewed as collaborative, if they are in agreement with the federal policy direction. Similarly, the form of federalism could change as the policy process evolves. A collaborative approach may be employed at the early stages to establish widespread agreement while the actual implementation may utilize a hierarchical approach. It is also important to draw a distinction between theoretical intergovernmental

TABLE 1
Descriptive Analysis Framework: Characterization of Intergovernmental Relationships

	Federal-Provincial/Territorial Relationships		
	Interdependence	**Hierarchical**	**Form of Relationship**
Federal-provincial	Yes	Yes	Federal-provincial unilateral
Federal-provincial	Yes	No	Federal-provincial collaborative
Federal-provincial	No	No	Federal-provincial disentangled
	Federal-Local Relationships		
	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	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

Note: This table 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.

arrangements and the practicalities of the implementation of these arrangements. As an example, potential hierarchical arrangements may exist in which the federal government has the ability to coerce provincial cooperation. However, the reality of the policy environment would be such that actual utilization of such powers could be so damaging to other policy initiatives that they would never be employed.

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 transfusions. 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 C (Krever 1997*b*). The blood system was heavily criticized for the decision-making process that led to the transfusion transmission of infections. The criticisms 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 actors (Krever 1997*a*; Picard 2002). 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 by 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 (Krever 1997*c*, 1023).

This observation highlighted the interrelated nature between public health governance and the effectiveness of public health policies.

Six 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 policymakers who are considering major public health reform in Canada that would alter the intergovernmental nature of public health policy-making. Previously conducted studies provided insights into decision-making in the blood system in the pre- and post-Krever era with respect to management of infectious risks as well as the impact of changing financial structure on delivery of blood services (Wilson *et al*. 2001; Wilson *et al*. 2003). These analyses involved over 70 taped-transcribed interviews with key stakeholders in the blood system as well as a full review of key related documents. Both of these studies have provided important insights into the relevance of intergovernmental relations in public health and an opportunity to provide lessons for public health policymakers considering public health reform. Based on the information obtained from these studies we are able to characterize the sets of intergovernmental relationships that exist 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 system.[3] The federal government is responsible for regulating the safety of the blood supply and the provincial/territorial governments for funding and ensuring the effective delivery of blood services. While the existence, roles, and responsibilities of these two 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 linked in a cross-provincial collaborative manner under the governance of a national not-for-profit organization, the Canadian Blood Services. Canadian Blood Services is the national operator of the blood system and was created through a memorandum of understanding between the federal/provincial/territorial governments. The agency is responsible for collecting, testing, manufacturing, distributing, purchasing, and supplying blood products to all provinces except Quebec. Héma-Québec is the operator of the blood system in Quebec and performs much of the same functions

as the Canadian Blood Services, but solely for that province. It is at the regional 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-Québec are bound by federal regulations. The federal government derives formal legislative authority over the area of blood safety through the *Food and Drugs Act*. 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 the act a drug is considered to be "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 the act, blood and blood derivatives are specifically identified as being drugs. The federal government has obtained the authority to pass this legislation from section 91(27) of the *Constitution Act* which provides the government with power over criminal law. This allows Parliament to pass legislation to prevent the transmission of a "public evil" which is a danger to public health.

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 of charge from the operators. Funding is divided among the 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. (Wilson *et al*. 2003). The ministers of health of the provinces/territories are the members of Canadian Blood Services. They are responsible for supervising the overall expenditure of public funds by Canadian Blood Services in delivering the blood program, ensuring the effectiveness of the blood supply system and making recommendations to the federal minister of health regarding any proposed changes to Canadian Blood Services legislation. The provincial/territorial ministers of health are also responsible for appointing the board of directors which consists of four regional representatives as well as representatives of groups with various interests and content expertise. The ministers of health specifically do not have the power to direct operational decisions of the board of directors or Canadian Blood Services staff (Canadian Blood Services Web site). However, on at least an annual basis Canadian Blood Services approaches the provinces/territories directly to seek approval for new funding. Importantly, Canadian Blood Services has the authority to introduce safety measures without approval of the provinces for this necessary funding. It can do so by drawing on a contingency fund. However, the organization often approaches the ministers of health to obtain support prior to introducing a new program, recognizing the importance of working collaboratively with the provinces/territories.

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 United States, in particular, are influential given that Canada imports a 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

donations.[4] Other nations' blood safety practices also indirectly influence Canadian blood policy by setting international standards that Canada may be expected to meet.[5]

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, 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 federal-unilateral. 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.

However, there are many nuances to the system of intergovernmental relations that need to be recognized. Fundamentally the question arises as to what is the functional, as opposed to theoretical relationship, between the provinces and the operator. Although envisioned as an arm's length relationship the provinces ultimately have the potential to impact the operators' activity through their control of funding. In addition, while we have categorized the relationship between the federal government and the provinces/territories as hierarchical, some uncertainty also exists about the exact extent of the federal government's ability to enforce its legislative mandates. In theory, if provinces/territories are not in agreement with new federal safety regulations they have the option to refrain from approving a budget from Canadian Blood Services that would include costs associated with these new safety measures. This would then require the federal government to enforce their legislative mandate by penalizing those in violation of these mandates, in this case the provinces and the

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

operator. If the federal government fails to enforce these regulations concerned individuals could bring an action to attempt to force the federal government to carry out its mandates and enforce the regulations. The provinces might also be held liable for knowingly violating federal safety standards, if such actions are viewed as negligent and result in harm to individuals. It would be more challenging for the operator to be able to insist provinces/territories pay the cost of non-federally mandated safety measures. However, the moral and political pressure on the provinces/territories to fund these measures would be substantial in a high profile area such as blood safety, which has previously suffered through a public health tragedy. Ultimately, responsibility would lie with the board of directors to draw public attention to the failure of the provinces/territories to fund a safety measure that they believe would be necessary.

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 McIntosh (1998, 4). 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 has produced a blood system that has improved the protection of the health of Canadians by enhancing the safety of the blood supply, which 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-ineffective (van Hulst *et al.* 2002).[6] There is 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 so (Weinberg *et* al. 2002). Another consequence of such an incentive structure is the potential for money to be diverted to protect the blood supply from infectious risks from other initiatives to improve safety; for example, reducing transfusion reactions, which do not have as high a public profile.

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 decision-making 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. Hence, resources may

be diverted from other policy sectors in order to maintain the blood system. As a consequence, the blood system would be viewed as being more favourable 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. However, the primary limitation to the current accountability structure is that the federal government does not have to pay the costs of the regulations it introduces. Improved accountability and well-defined roles and responsibilities have also contributed to an improvement in the transparency of the decision-making process. Nevertheless, transparency 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-management assessments which can be difficult for the general public to understand. As a consequence, 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 process (IBM 2002).

Respect for Principles of Federalism. While the current set of intergovernmental arrangements 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 percent increase in blood system costs since the creation of the new blood system (Wilson and Hébert 2003).[7] Again, as per design, there are few opportunities for the provinces/territories to 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. As well, there is 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 policies (IBM 2002).

Summary

To summarize, the Canadian blood system introduced substantial organizational reform in an attempt to improve its safety. 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 cost-effectiveness 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 allocation of roles and responsibilities across orders of government in the Canadian blood system and the effectiveness of the set of intergovernmental arrangements.

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

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 • 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

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 initiatives (Wilson 2001). 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. All orders of government recognized the dangers of a fragmented approach to health surveillance and the need to rectify this problem. The NHSI was intended to be an Internet-based network/infrastructure designed to build capacity to help coordinate health surveillance activities across the country. In developing the NHSI, governments moved from a previous disentangled approach toward health surveillance toward a more collaborative approach. The collaborative approach to surveillance reform was initially successful and, in a comparatively brief period of time, Ottawa and the provinces were able to work together to develop a design and proceed with implementation of pilots. While the NHSI was federally conceived, Ottawa's choice of embarking upon a collaborative approach to the negotiations was instrumental in ensuring provincial cooperation, particularly at a time when there was intergovernmental acrimony surrounding the interpretation of the *Canada Health Act* and the reductions in health-care funding associated with the Canadian Health and Social Transfer. The initial success of the collaborative approach was attributed to the relatively low-profile nature of health surveillance, which was at the time one of the least contentious federal/provincial areas.

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. In particular, for a coordinated surveillance system to succeed local public health agencies must collect similar surveillance data of a standard quality to allow for the sharing of this data. This would produce substantial costs at the local level. Difficulties in agreeing on how these costs would be distributed across orders of government were viewed as an important obstacle in the establishment of a successful surveillance system. 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 as 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 place (Office of the Auditor General of Canada 1999). In 2002, the auditor general's report indicated 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 activities (Office of the Auditor General of Canada 2002). Ongoing problems in health surveillance governance have also been highlighted by the response to the SARS outbreak. During the outbreak there was concern about the inability of different organizations to share information due to inconsistencies in the standards for data-collection (Abraham and Priest 2003).

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 more effectively 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 program 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, as 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 programs or legislation. Provinces/territories may not welcome conditional funding programs because of past experiences with such programs 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 United States since the 1960s, 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 billion (Conlan, Riggle and Schwartz 1995). The impact of these additional costs precipitated a movement to 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 programs, 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 burden (ibid.; Kelly 2003).

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 programs. 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 program rather than waiting until after the need for them arises.

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 tend to create the perception amongst the public that important decisions concerning the public health of Canadians are occurring behind closed doors. While this concern may not exist at the time decision-making is taking place, it could arise if problems emerge in the system, as was the case with 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 to reduce scenarios in which one order of government blames the other for perceived failures in the policy-making process. Table 5 summarizes suggestions for public health governance reform that emerge out of a comparison of blood system reform to health surveillance reform.

In preparing its report on public health reform in the wake of the SARS outbreak the National Advisory Committee on SARS addressed the challenges of establishing effective intergovernmental relationships. The committee recommended a collaborative approach to developing a Canadian Agency for Public Health based on the recognition of the mutual interdependence of the different orders of government when it comes to developing and implementing public health policies. The proposed agency is to be at arm's length from government, although it would be federally financed and the Chief Public Health Office would report to the federal minister of health. The agency would provide funding on a project-by-

TABLE 5
Suggestions for Public Health Governance Reform

1. Initially utilize a collaborative multigovernmental approach to establish a plan for reform.
2. Establish federal-hierarchical approach to policy implementation either legislatively or through conditional-funding programs.
3. If a legislative approach is taken, ensure that a mechanism is introduced to protect against unfunded mandates.
4. Introduce an 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.

project basis through local and provincial/territorial partnerships and would work with provincial/territorial orders of government in a collaborative manner. However, the agency would have several options to coerce cooperation if collaboration fails. These include the ability to attach standards to the programs that it has co-funded, and the threat of withdrawing funding if these standards are not met. Furthermore, the committee also recommended that the federal government implement back-up health protection legislation if negotiations with the provinces/territories to develop this legislation on a collaborative basis fail. Such legislation could provide the federal government with additional power to ensure cooperation from provincial/territorial governments. This, of course, could lead to the problem of unfunded mandates and further intergovernmental acrimony (Wilson 2004).

Further Questions for Public Health Governance

While examination of the blood system and health surveillance reform initiatives generates some suggestions for different governance approaches to public health reform, it also raises 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 law provisions of the *Constitution Act, 1982* permits 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 the maintenance of 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 both within and outside a 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 provinces (Jackman 1996). Arguably, in light of recent developments, proposed public health-related legislation governing issues such as data transfer could be seen as meeting all three criteria. However, in the past, the courts have been hesitant to approve legislation based on these residual powers (Choudhry 2002). Additionally, the use of these powers would certainly create substantial intergovernmental acrimony, which could threaten future collaborations when federal unilateral approaches are not an option.

Another question that arises for public health governance is the role of public health agencies which 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 in this position. 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 when 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 several regional organizations with collaboration occurring across these regional bodies. Such an 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 Quebec'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 who believe that this results in a fragmentation of the 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 into 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 which may arise, due to its smaller size (Wilson *et al*. 2001). 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 borders (Kickbusch 2000). 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 not participating 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 a supranational government fits into the public health intergovernmental spectrum.

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 toward this goal, a framework for describing intergovernmental relationships in public health. We used 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 (Naus and Scheifele 2003; Health Canada 2002). 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.

Notes

Blood safety case study research was conducted in conjunction with the University of Ottawa Centre for Transfusion Research and was funded by grants from the Canadian Institutes of Health Research.

Dr. Wilson is supported as a New Investigator by the Canadian Institutes of Health Research.

[1]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 programs. 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.

[2]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 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.

[3]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.

[4]In developing donor deferral criteria for individuals who had travelled to the United Kingdom to protect the blood supply from variant Creutzfeldt-Jakob disease, Canadian and American blood officials made efforts to coordinate their policies. Both blood systems chose to defer individuals who had spent six months in the United Kingdom between 1980 and 1996. However, Canadian and American officials subsequently developed separate policies for deferring individuals who had travelled to France.

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

[6]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.

[7]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.

References

Abraham, C. and L. Priest. 2003. "Cutbacks Fed SARS Calamity, Critics Say," *Globe and Mail* (National Edition), 3 May, pp. A1, A6.

Alphonso, C. and G. York. 2003. "Canadian Health Officials Rapped by WHO," *Globe and Mail* (National Edition), 13 June, pp. A1, A6.

Braen, A. 2002. *Health and the Distribution of Powers in Canada*. Discussion Paper No 2. Commission on the Future of Health Care in Canada. Ottawa: National Library of Canada.

Canada. Supreme Court. 1984. *Canada Health Act*, S.C. 1984, c. 6.

Choudhry, S. 2002. "Recasting Social Canada: A Reconsideration of Federal Jurisdiction Over Social Policy," *University of Toronto Law Journal* 52(3):163-252.

Conlan, T.J., J.D. Riggle and D.E. Schwartz. 1995. "Deregulating Federalism? The Politics of Mandate Reform in the 104th Congress," *Publius* 25(3):23-40.

Courchene, T.J. 1997. "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, 31 October 1996. Kingston: Institute of Intergovernmental Relations, Queen's University.

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

_____ 2003. Health Protection Legislative Renewal. At renewal.hc-sc.gc.ca.

Health Canada. The National Advisory Committee on SARS and Public Health. 2003. *Learning from SARS: Renewal of Public Health in Canada*. Ottawa: Health Canada.

IBM. 2002. *Performance Review of Canadian Blood Services*. Final Report. 15 October.

Jackman, M. 1996. "The Constitutional Basis for Federal Regulation of Health," *Health Law Review* 5(2):3-10.

Kelly, J.M. 2003. "The Unfunded Mandate Reform Act: Working Well For No Good Reason," *Government Finance Review* 19(1):28-31.

Kickbusch, I. 2000. "The Development of International Health Policies – Accountability Intact?" *Social Science & Medicine* 51(6):979-89.

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

_____ 1997*b*. "The Consequences of Contamination of the Blood Supply," in *Commission of Inquiry on the Blood System in Canada. Final Report*. Ottawa: Canadian Government Publishing, pp. 708-18.

_____ 1997*c*. "The Initiatives of the Federal, Provincial and Territorial Governments to Reform the Blood System," in *Commission of Inquiry on the Blood System in Canada. Final Report*. Ottawa: Canadian Government Publishing, p. 1023.

Lazar, H. and T. McIntosh. 1998. *Federalism, Democracy and Social Policy: Towards a Sectoral Approach to the Social Union*. Kingston: Institute of Intergovernmental Relations, Queen's University.

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," *Canadian Medical Association Journal* 168(5):567-68.

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

Office of the Auditor General of Canada and the Commissioner of the Environment and Sustainable Development. 1999. *Report of the Auditor General of Canada*. Chapter 14: "National Health Surveillance: Diseases and Injuries." Ottawa: Canadian Government Publishing.

Picard, A. 2002. "RCMP Lay 32 Charges in Tainted-Blood Case," *Globe and Mail* (National Edition), 21 November, p. A4.

Romanow, R.J. 2002. *Building on Values. The Future of Health Care in Canada. Final Report*. Commission on the Future of Health Care in Canada. Ottawa: National Library of Canada.

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

van Hulst, M., J.T. de Wolf, U. Staginnus, E.J. Ruitenberg and M.J. Postma. 2002. "Pharmaco-economics of Blood Transfusion Safety: A Review of the Available Evidence," *Vox Sanguinis* 83(2):146-55.

Weinberg, P.D., J. Hounshell, L.A. Sherman, J. Godwin, S. Ali, C. Tomori and C.L. Bennett. 2002. "Legal, Financial, and Public Health Consequences of HIV Contamination of Blood and Blood Products in the 1980s and 1990s," *Annals of Internal Medicine* 136(4):312-19.

Wharry, S. 2003. "Will SARS Crisis Give Canada Its Own CDC?" (News). *Canadian Medical Association Journal* 168(11):1381.

Wilson, K. 2001. "The Role of Federalism in Health Surveillance: A Case Study of the National Health Surveillance 'Infostructure,'" in *Federalism, Democracy, and Health Policy in Canada*, ed. D. Adams. Montreal and Kingston: McGill-Queen's University Press and School of Policy Studies, Queen's University, pp. 207-37

_____ 2004. "The Canadian Agency of Public Health: Could it work?" *Canadian Medical Association Journal* 170(2):222-23.

Wilson, K. and P. Hébert. 2003. "The Challenge of an Increasingly Expensive Blood System," (Commentary) *Canadian Medical Association Journal* 168(9):1149-50.

Wilson, K., P. Hébert, A. Laupacis, C. Dornan, M. Ricketts, N. Ahmad and I. Graham. 2001. "A Policy Analysis of Major Decisions Relating to Creutzfeldt-Jakob Disease and the Blood Supply," *Canadian Medical Association Journal* 165(1):59-65.

Wilson, K., L. MacDougall, B. Pinard, M.A. Amin, D. Fergusson, I. Graham, M. Blajchman, J. Freedman, D. Angus and P. Hébert. 2003. "How Should Canada Fund the Blood System? An Evaluation of the Chargeback Proposal," *Hospital Quarterly* 6(3):47-54.