Data Protection and the Promotion of Health Research
VALERIE STEEVES

Wait Time Benchmarks, Research Evidence and the Knowledge Translation Process
DIANE E. WATSON, MORRIS L. BARER, HEIDI M. MATKOVICH
AND MICHELLE L. GAGNON

The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada
PAUL GROOTENDORST AND LIVIO DI MATTEO

Governance, Health Policy Implementation and the Added Value of Regionalization
NASSERA TOUATI, DANIÈLE ROBERGE, JEAN-LOUIS DENIS, RAYNALD PINEAULT,
LINDA CAZALE AND DOMINIQUE TREMBLAY

Data Matters • Discussion and Debate
Linkage and Exchange
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From The Editor in Chief

10 Cracks in the Foundation: The Precarious State of Canada’s Primary Care Infrastructure
   Brian Hutchison

The Undisciplined Economist

18 Green Leviathan? Thomas Hobbes, Joel Bakan and Arnold Schwarzenegger
   Robert G. Evans

Discussion and Debate

26 Data Protection and the Promotion of Health Research
   Valerie Steeves
   Rather than harming research by unduly restricting access to personal health information, data protection laws promote public trust in research practices and protect the accuracy of data.

39 Commentary: Data Protection and the Promotion of Health Research: If the Laws Are Not the Problem, Then What Is?
   Donald J. Willison
   Research ethics boards and data custodians need clearer guidance regarding acceptable conditions for releasing data to researchers without consent. Clear rules for data protection will reinforce public trust, which is essential for continued access to personal data for research.

44 Commentary: Data Protection and the Promotion of Health Research
   Cameron A. Mustard
   Empirical research is needed to identify risks to personal privacy and to the production of high-quality research evidence that arise from the inappropriate application of data protection legislation.

Data Matters

47 Connectedness within Social Contexts: The Relation to Adolescent Health
   Melanie Yugo and Mélanie Josée Davidson
   Health survey data are analyzed to assess which developmental assets contribute to positive health outcomes and participation in risky health behaviours in children aged 12 to 15.
**Linkage and Exchange**

56  
Wait Time Benchmarks, Research Evidence and the Knowledge Translation Process  
DIANE E. WATSON, MORRIS L. BARER, HEIDI M. MATKOVICH AND MICHELLE L. GAGNON  
In the space of 10 months, the Canadian Institutes of Health Research commissioned, and research teams produced, a set of evidence-based benchmarks for cataract surgery, joint replacement and cancer services in response to a federal/provincial policy imperative.

**Research Papers**

63  
The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada  
PAUL GROOTENDORST AND LIVIO DI MATTEO  
The authors estimate that the value of increased R&D following the granting of extended pharmaceutical patent protection exceeds the resulting increase in drug expenditures. Our commentators aren't so sure.

85  
Commentary: The Effect of Pharmaceutical Patent Term Length on R&D and Drug Expenditures in Canada  
BOHUMÍR PAZDERKA

90  
Commentary: Do Patent Terms Impact Domestic R&D Spending in the Pharmaceutical Industry?  
HAROLD SCHROEDER

95  
Response to Pazderka and Schroeder  
PAUL GROOTENDORST AND LIVIO DI MATTEO

97  
Governance, Health Policy Implementation and the Added Value of Regionalization  
NASSERA TOUATI, DANIELLE ROBERGE, JEAN-LOUIS DENIS, RAYNALD PINEAULT, LINDA CAZALE AND DOMINIQUE TREMBLAY  
This qualitative longitudinal case study of the implementation of Quebec's Program to Combat Cancer in the Montérégie health and social service region identifies the value of partnership between the regional board and clinical leaders in the governance of change.
Healthcare Use of Families of Injured Workers Before and After a Workplace Injury in British Columbia, Canada

JUDY A. BROWN, HARRY S. SHANNON, PEGGY MCDONOUGH AND CAMERON A. MUSTARD

Differences in the patterns of change in health services utilization among both spouses and children of injured and non-injured workers were small and, for mental health services, not statistically significant.

Determinants of Unacceptable Waiting Times for Specialized Services in Canada

CLAUDIA SANMARTIN, JEAN-MARIE BERTHELOT AND CAMERON N. MCINTOSH

Acceptability of waiting times for specialized healthcare services is determined by the length of waiting time and the effects of waiting on the patient's life, and, to a lesser extent, by age, education and place of residence.

Determinants of Waiting Time for a Routine Family Physician Consultation in Southwestern Ontario

AMARDEEP THIND, CATHY THORPE, ANDREA BURT, MOIRA STEWART, GRAHAM REID, STEWART HARRIS AND JUDITH BELLE BROWN

Longer physician-reported wait times for family physician care were associated with female physician gender, fewer patients seen, physician involvement in teaching and urban or suburban practice location.

Wait Times for Paediatric Rehabilitation

LISA GRILLI, DEBBIE EHRMANN FELDMAN, BONNIE SWAINE, JULIE GOSSELIN, FRANÇOIS CHAMPAIGNÉ AND RAYNALD PINEAULT

Many children with disabilities referred from Montreal tertiary care paediatric hospitals for physio- and occupational therapy experience long waits for service. Average wait times appear to have increased over time.

Peer Reviewed
TABLE DES MATIÈRES

Du rédacteur en chef

10 Des fissures dans les fondations : L’état précaire de l’infrastructure des soins de santé primaires au Canada
BRIAN HUTCHISON

L’économiste indiscipliné

18 Un Léviathan vert? Thomas Hobbes, Joel Bakan et Arnold Schwarzenegger
ROBERT G. EVANS

Discussion et débat

26 Protection des données et promotion de la recherche sur la santé
VALERIE STEEVES
Au lieu d’entraver la recherche en restreignant indûment l’accès aux renseignements personnels sur la santé, les lois sur la protection des données renforcent la confiance du public à l’égard des pratiques de recherche et protègent l’exactitude des données.

39 Commentaire : La protection des données et la promotion de la recherche sur la santé : si les lois ne sont pas le problème, alors quel est-il?
DONALD J. WILLISON
Les comités d’éthique de la recherche et les dépositaires de données ont besoin de lignes directrices plus claires pour déterminer quand il leur est loisible de divulguer des données aux chercheurs sans consentement. Des règles claires en matière de protection des données contribueront à renforcer la confiance du public, un élément essentiel pour assurer un accès continu aux renseignements personnels à des fins de recherche.

44 Commentaire : Protection des données et promotion de la recherche en santé
CAMERON A. MUSTARD
Des travaux de recherche empiriques sont nécessaires pour déceler les risques que pose une mauvaise application des lois sur la protection des données pour le respect de la vie privée et la production de données de recherche de haute qualité.
Le sentiment d’appartenance au sein des contextes sociaux : le lien avec la santé de l’adolescent

MÉLANIE YUGO ET MÉLANIE JOSÉE DAVIDSON

Des données provenant d’une enquête sur la santé sont analysées afin de déterminer lequel parmi cinq atouts développementaux est responsable des résultats positifs en matière de santé et de l’adoption de comportements dangereux pour la santé chez les jeunes de 12 à 15 ans.

Repères pour les temps d’attente, preuves cliniques pour la recherche et processus d’application des connaissances

DIANE E. WATSON, MORRIS L. BARER, HEIDI M. MATKOVICH ET MICHELLE L. GAGNON

En l’espace de dix mois, en réponse à un impératif de politique fédéral/provincial, les Instituts de recherche en santé du Canada ont commandé et les équipes de recherche retenues ont élaboré un ensemble de repères axés sur les preuves pour les chirurgies de la cataracte, le remplacement d’articulations et les traitements contre le cancer.

Leffet de la durée des brevets pharmaceutiques sur les dépenses en R&D et en médicaments au Canada

PAUL GROOTENDORST ET LIVIO DI MATTEO

Les auteurs estiment que la valeur de la R&D accrue découlant de la prolongation de la durée des brevets pharmaceutiques dépasse l’augmentation des dépenses en médicaments qui en résulte. Nos commentateurs n’en sont pas si sûrs.

Commentaire : L’effet de la durée des brevets pharmaceutiques sur les dépenses en R&D et en médicaments au Canada

BOHUMÍR PAZDERKA

Commentaire : Les durées des brevets ont-elles une incidence sur les dépenses nationales en R&D dans l’industrie pharmaceutique?

HAROLD SCROEDER

Réponse à Pazderka et Schroeder

PAUL GROOTENDORST ET LIVIO DI MATTEO
Gouvernance, mise en œuvre des politiques de santé et valeur ajoutée de la régionalisation

NASSER A. TOUATI, DANIÈLE ROBERGE, JEAN-LOUIS DENIS, RAYNALD PINEAULT, LINDA CAZALE ET DOMINIQUE TREMBLAY

Cette étude de cas qualitative et longitudinale de la mise en œuvre régionale du Programme de lutte contre le cancer au Québec, notamment dans le réseau de la santé et des services sociaux de la Montérégie, dévoile la valeur du partenariat entre la région régionale et les cliniciens dans la gouvernance du changement.

En ligne seulement

Le recours aux soins de santé par les familles de travailleurs blessés avant et après un accident du travail en Colombie-Britannique, Canada

JUDY A. BROWN, HARRY S. SHANNON, PEGGY MCDONOUGH ET CAMERON A. MUSTARD

Les différences dans le recours aux services de santé chez les conjoints et les enfants de travailleurs blessés et non blessés étaient faibles et, en ce qui concerne le recours aux services de santé mentale, elles n'étaient pas statistiquement significatives.

Facteurs déterminants des temps d'attente inacceptables pour l'obtention de services spécialisés au Canada

CLAUDIA SANMARTIN, JEAN-MARIE BERTHELOT ET CAMERON N. MCINTOSH

L'acceptabilité des temps d'attente pour l'obtention de services de santé spécialisés est déterminée par la durée de l'attente et les effets de l'attente sur la vie du patient, et, à un degré moindre, par l'âge, le niveau d'instruction et le lieu de résidence.

Facteurs déterminants du temps d'attente pour consulter un médecin de famille dans le sud-ouest de l'Ontario

AMARDEEP THIND, CATHY THORPE, ANDREA BURT, MOIRA STEWART, GRAHAM REID, STEWART HARRIS ET JUDITH BELLE BROWN

Selon ce que rapportent les médecins, des temps d'attente plus longs pour consulter un médecin de famille étaient liés aux facteurs suivants : les médecins de sexe féminin, un nombre plus faible de patients consultés, la participation du médecin à des activités d'enseignement et le lieu de pratique – milieu urbain ou banlieue.

Temps d'attente pour la réadaptation pédiatrique

LISA GRILLI, DEBBIE EHRMANN FELDMAN, BONNIE SWAINE, JULIE GOsselIN, FRANÇOIS CHAMPGNE ET RAYNALD PINEAULT

Beaucoup d’enfants handicapés aiguillés par des hôpitaux de soins pédiatriques tertiaires de Montréal vers des traitements de physiothérapie et d’ergothérapie doivent attendre longtemps avant de recevoir ces services. Les temps d’attente moyens semblent avoir augmenté au fil des ans.

Examen par les pairs
Cracks in the Foundation: The Precarious State of Canada’s Primary Care Infrastructure

Primary care is widely acknowledged by politicians, pundits, policy makers and healthcare providers to be the foundation of Canada’s healthcare system. A recent Commonwealth Fund survey of primary care physicians in seven countries – Australia, Canada, Germany, New Zealand, the Netherlands, the United Kingdom and the United States – has vividly illustrated the sorry state of that foundation’s underpinnings (Shoen et al. 2006). The survey examined information technology, clinical information systems, care coordination, use of teams, participation in quality initiatives and financial incentives.

Canadian primary care physicians’ use of clinical information and office systems to support the provision of high-quality care lags well behind those of other countries. Only 8% of Canadian respondents have systems in place to perform seven or more of the 14 clinical information functions that were assessed – compared to 72–87% of physicians in Australia, New Zealand and the UK. Canadian physicians ranked lowest on 12 of the 14 functions. Only 23% use electronic medical records (vs. 79% or more of primary care physicians in Australia, the Netherlands, New Zealand and the UK). Only 8% provide patients with “easy access” to their medical records; 27% have electronic access to patients’ test results; and 15% have electronic access to patients’ hospital records. Ten per cent or fewer Canadian respondents have computerized systems that generate drug alerts, prompts to provide patients with test results or patient reminder notices for preventive or followup care. Roughly one-half find it very difficult or impossible to produce lists of patients by diagnosis or health risk, lists of patients who are due for tests or preventive care or lists of patients’ current medications. Even among Canadian practices with electronic medical records (EMRs), their clinical information systems have less functionality than those of practices with EMRs in New Zealand, Australia and the UK.

The picture that emerges from the survey is almost equally grim with respect to mechanisms for coordinating care, caring for people with chronic health problems and
delivering team-based care. Canadian primary care physicians were the least likely to routinely provide written instructions to people with chronic diseases about how to manage their care at home (14%), and their practices were the least likely to routinely use non-physician clinicians to help manage patients with chronic diseases (25%) or to provide primary care services to patients (22%).

Compared to physicians in other countries – and to any reasonable performance target – Canadian primary care physicians’ engagement in quality management falls short. In the last two years, fewer Canadian physicians participated in collaborative quality improvement efforts (48%) or training in quality improvement methods (44%) than physicians in the six other countries. They were also least likely to have data available on patients’ clinical outcomes (24%) and patients’ experiences with care (11%). Forty-five per cent of Canadian respondents had conducted a clinical audit of patient care in the past two years – compared to 76%, 82% and 96% of Australian, New Zealand and UK respondents, respectively. Only 27% of Canadian primary care physicians reported that their practice sets specific formal targets for clinical performance.

How did all this come about – or rather not come about? Relative to other countries and to levels that would have been desirable, Canada’s investment in primary care infrastructure, including information management systems, quality management programs and interdisciplinary staffing, has been woefully inadequate. Although none of these supports guarantees the provision of appropriate, high-quality, patient-centred care, they can provide a powerful boost in that direction, especially in the areas of disease and injury prevention, early detection and chronic disease management.

Despite fairly general awareness among policy makers, health system managers and care providers of this reality, why has investment in primary care infrastructure been so paltry? While many other jurisdictions such as Australia, New Zealand, the UK and the Netherlands were making major investments in primary care infrastructure, provincial and territorial governments in Canada have largely left investment in infrastructure to the discretion of primary care physicians. Until recently and with few exceptions, primary care physicians in Canada have received payment for the provision of patient care (usually in the form of fees-for-service) with no funding specifically designated for staffing, clinical information systems or quality improvement activities. As a result, investments in infrastructure represent income forgone from the physician’s perspective. In the absence of competition (most primary care physicians have more than enough work), there is little incentive for physicians to make these investments. Arguably, the provincial/territorial medical associations could have bargained for enhanced funding for primary care infrastructure in their negotiations with provincial and territorial governments. However, this has happened to only a modest extent, perhaps reflecting traditional specialist dominance in Canadian medical associations and primary care physicians’ focus on closing the income gap between themselves and their specialist colleagues.
Not surprisingly, public pressure on government to respond to the infrastructure needs of primary care has been absent. Primitive clinical and quality management systems are hardly the stuff of newspaper and television headlines. When governments are strapped for cash (even if the revenue shortfall is self-inflicted as a result of tax cuts), only the squeakiest of wheels (read hospital and pharmaceuticals sectors) are greased. Governments and regional health authorities are undoubtedly deterred from responding to the need by the sheer magnitude of the investments required, particularly in information technology. However, it should be clear by now that information systems of the required complexity and interconnectivity will not emerge in an environment characterized by a host of IT firms developing systems (albeit often in conformity with provincially-defined minimum standards) tailored to the purchasing decisions of myriad physicians with little to spend, acting individually or in small groups.

Sophisticated information management systems that include decision support and support for patient self-management will not come cheaply. Group Health Cooperative in Seattle, Washington, a user-governed, not-for-profit HMO with over 500,000 members, recently invested US$78 per plan member in the development and implementation of a core clinical information system “to promote patient-centered and planned care for healthier lifestyles, disease prevention, early detection of disease and optimal chronic disease management” (Reid 2006). Not allowing for economies (or diseconomies) of scale, this corresponds to an investment of roughly $1.2 billion Canadian in Ontario or $3 billion for all of Canada.

Perhaps the results of the Commonwealth survey, if they become widely known, will inspire (embarrass?) healthcare funders to address the sad reality that Canada’s primary care sector lacks the basic infrastructure needed to support the provision of appropriate and effective services. Unless they rise to the need, Canadian primary care will fail to achieve its potential for major health gains through improved preventive care and chronic disease management. Encouragingly, many provincial/territorial ministries of health and regional health authorities, animated by funding from the now expired federal Primary Healthcare Transition Fund, have taken some initial steps forward. For example, Ontario has funded and provided developmental assistance to 150 interdisciplinary Family Health Teams and has announced a quality management initiative to support the teams’ health promotion, disease prevention, chronic disease management, team building and quality improvement activities. Such efforts, while praiseworthy, are merely a beginning.

REFERENCES
Des fissures dans les fondations :
L’état précaire de l’infrastructure des soins de santé primaires au Canada

Les politiciens, les grands pontes, les décideurs et les fournisseurs de soins de santé conviendront aisément que les soins de santé primaires constituent le fondement du système de soins de santé canadien. Une récente étude menée par le Fonds du Commonwealth auprès de médecins de premiers recours dans sept pays – l’Australie, le Canada, l’Allemagne, la Nouvelle-Zélande, les Pays-Bas, le Royaume-Uni et les États-Unis – illustre de façon frappante l’état déplorable des piliers de ce fondement (Shoen et al. 2006). L’étude s’est penchée sur la technologie de l’information, les systèmes d’information clinique, la coordination des soins, l’utilisation d’équipes, la participation à des initiatives sur la qualité et des encouragements financiers.

Les médecins canadiens de premier recours tirent de l’arrière par rapport à leurs homologues des autres pays pour ce qui est d’utiliser des renseignements cliniques et des systèmes de bureautique pour appuyer la prestation de soins de haute qualité. Seulement 8 % des répondants canadiens disposent de systèmes pouvant exécuter au moins sept des 14 fonctions reliées aux renseignements cliniques qui ont été évaluées – comparativement à 72 à 87 % des médecins en Australie, en Nouvelle-Zélande et au R.-U. Les médecins canadiens se sont classés au dernier rang pour 12 des 14 fonctions. Seulement 23 % d’entre eux utilisent des dossiers médicaux électroniques (comparativement à 79 % ou plus des médecins de premier recours en Australie, aux Pays-Bas, en Nouvelle-Zélande et au R.-U.). Seulement 8 % donnent aux patients un...
« accès facile » à leurs dossiers médicaux; 27 % ont accès, par voie électronique, aux résultats des examens médicaux des patients et 15 % ont un accès électronique aux dossiers d’hospitalisation des patients. Dix pour cent ou moins des répondants canadiens disposent de systèmes informatisés qui produisent des alertes pharmaceutiques ou qui rappellent de fournir aux patients les résultats d’examens médicaux ou des avis de rappel pour des soins préventifs ou de suivi. Environ la moitié des répondants ont dit avoir trouvé difficile ou impossible de produire des listes de patients par diagnostic ou par risque pour la santé, des listes de patients qui doivent passer des examens médicaux ou recevoir des soins préventifs, ou encore des listes des médicaments que prennent les patients. Même dans les cabinets où on utilise des dossiers médicaux électroniques (DME), les systèmes d’information clinique ont moins de fonctions que ceux des cabinets utilisant des DME en Nouvelle-Zélande, en Australie et au R.-U.

Le tableau qui se dégage de l’étude est presque aussi sombre pour ce qui est des mécanismes permettant de coordonner les soins, de soigner les patients qui ont des problèmes de santé chroniques et de fournir des soins en équipe. Les médecins de premier recours étaient les moins susceptibles de fournir systématiquement aux personnes atteintes de maladies chroniques des instructions écrites sur la façon de gérer leurs soins à domicile (14 %), et leurs cabinets étaient les moins susceptibles d’avoir systématiquement recours à des cliniciens non-médecins pour les aider à gérer les patients souffrant de maladies chroniques (25 %) ou pour fournir des soins primaires aux patients (22 %).

Comparativement aux médecins d’autres pays – et à toute cible de rendement raisonnable – la participation des médecins canadiens de premier recours à la gestion de la qualité laisse à désirer. Au cours des deux dernières années, moins de médecins canadiens ont participé à des efforts de collaboration visant à améliorer la qualité (48 %) ou ont reçu une formation sur les méthodes d’amélioration de la qualité (44 %) comparativement aux médecins des six autres pays. Ils étaient également les moins susceptibles d’avoir des données disponibles sur les résultats cliniques des patients (24 %) et sur les expériences des patients en ce qui a trait aux soins (11 %). Quarante-cinq pour cent des répondants canadiens avaient effectué, au cours des deux dernières années, une vérification clinique des soins fournis aux patients – comparativement à 76 %, 82 % et 96 % des répondants australiens, néo-zélandais et britanniques respectivement. Seuls 27 % des médecins canadiens de premier recours disent que leur cabinet établit des cibles précises et officielles en matière de rendement clinique.

Comment tout cela est-il arrivé – ou plutôt n’est pas arrivé? Comparativement aux autres pays et aux niveaux qui auraient été souhaitables, les investissements dans l’infrastructure des soins primaires au Canada – y compris les systèmes de gestion de l’information, les programmes de gestion de la qualité et la dotation pluridisciplinaire – ont été nettement insuffisants. Bien qu’aucune de ces mesures ne garantisse la prestation de soins adéquats, de haute qualité et axés sur les patients, elles peuvent constituer
un grand pas dans cette direction, surtout dans les domaines de la prévention des maladies et des blessures, du dépistage précoce et de la gestion des maladies chroniques.

Considérant que cette réalité est largement connue des décideurs, des gestionnaires des systèmes de santé et des fournisseurs de soins, pourquoi les investissements dans l’infrastructure des soins primaires ont-ils été si dérisoires? Alors que de nombreux autres pays comme l’Australie, la Nouvelle-Zélande, le R.-U. et les Pays-Bas consentaient des investissements majeurs dans l’infrastructure des soins primaires, les gouvernements provinciaux et territoriaux du Canada ont, pour la plupart, laissé cette tâche à la discrétion des médecins de premier recours. Jusqu’à tout récemment et à peu d’exceptions près, les médecins de premier recours du Canada étaient rémunérés pour les soins qu’ils prodiguaient aux patients (habituellement sous forme de paiements à l’acte), sans avoir de financement spécialement désigné pour la dotation en personnel, la mise en place de systèmes d’information clinique ou des activités d’amélioration de la qualité. Les investissements dans l’infrastructure représentaient donc des revenus perdus pour les médecins. En l’absence de concurrence (la plupart des médecins de premier recours ont plus de travail qu’il n’en faut), les médecins sont peu incités à effectuer ces investissements. On pourrait soutenir que les associations médicales provinciales/territoriales auraient pu, dans le cadre de leurs négociations avec les gouvernements provinciaux et territoriaux, chercher à obtenir un meilleur financement pour l’infrastructure des soins primaires. Mais cela ne s’est produit que dans une très faible mesure – une indication possible de la dominance traditionnelle des spécialistes dans les associations médicales canadiennes et du grand désir des médecins canadiens de premier recours de combler le fossé entre leurs revenus et ceux de leurs collègues spécialistes.

Il n’est pas surprenant que le public n’ait exercé aucune pression en vue d’amener le gouvernement à combler les besoins d’infrastructure des soins de santé primaires. De primitifs systèmes cliniques et de gestion de la qualité ne font pas exactement la manchette dans les journaux et à la télévision. Quand les gouvernements sont à court d’argent (même si ce manque à gagner résulte de baisses d’impôts qu’ils ont eux-mêmes décrétées), ce sont les roues les plus grinçantes (autrement dit, les secteurs hospitalier et pharmaceutique) qui obtiennent la graisse. Sans aucun doute, l’ampleur des investissements requis – surtout en matière de technologie de l’information – suffit, à elle seule, à dissuader les gouvernements et les régies régionales de la santé d’essayer de combler ce besoin. Toutefois, il devrait maintenant être clair que les systèmes d’information ayant le degré de perfectionnement et d’interconnectabilité requis ne verront pas le jour dans un environnement où une foule d’entreprises de TI mettent au point des systèmes (même si ces derniers sont souvent conformes aux normes minimales établies par la province) adaptés aux décisions d’achat d’une multitude de médecins qui ont peu d’argent à dépenser et qui agissent individuellement ou en petits groupes.

Des systèmes de gestion de l’information perfectionnés qui appuient le processus décisionnel et l’autogestion des patients ne sont pas donnés. Le Group Health
Cooperative à Seattle, Washington, une OSSI sans but lucratif, administrée par les utilisateurs et comptant plus de 500 000 membres, a récemment investi 78 $US par participant au régime dans l’élaboration et la mise en place d’un système d’information clinique central visant à « promouvoir des soins planifiés et axés sur les patients, afin de favoriser des habitudes de vie plus saines, la prévention et le dépistage précoce des maladies, ainsi qu’une gestion optimale des maladies chroniques » (Reid 2006). Si l’on ne tient pas compte des économies (ou des déséconomies) d’échelle, cela correspond à un investissement d’environ 1,2 G$ CA en Ontario ou 3 G$ pour tout le Canada.

Peut-être que les résultats de l’enquête du Fonds du Commonwealth, s’ils viennent à être largement diffusés, encourageront (mettront dans l’embarras?) les bailleurs de fonds du domaine des soins de santé à se pencher sur cette triste réalité : le secteur des soins de santé primaires au Canada ne possède pas l’infrastructure de base nécessaire pour appuyer la prestation de services appropriés et efficaces. À moins qu’ils ne comblent ce besoin, le secteur des soins de santé primaires canadien n’atteindra pas son plein potentiel et ne permettra pas de réaliser d’importants progrès en matière de santé grâce à des soins préventifs améliorés et une meilleure gestion des maladies chroniques. Il est encourageant de constater que plusieurs ministères provinciaux/territoriaux de la Santé et des régies régionales de la santé, stimulés par un financement du défunt Fonds fédéral pour l’adaptation des soins de santé primaires, ont déjà pris quelques mesures concrètes en ce sens. L’Ontario, par exemple, a financé et fourni une aide au développement à 150 équipes pluridisciplinaires œuvrant dans le domaine de l’hygiène familiale et a annoncé le lancement d’une initiative de gestion de la qualité visant à appuyer les activités de ces équipes dans les domaines de la promotion de la santé, la prévention des maladies, la gestion des maladies chroniques, la création d’équipes et l’amélioration de la qualité. De tels efforts, bien que louables, ne sont qu’un simple début.

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BRIAN HUTCHISON, MD, MSC, FCFP
Rédacteur en chef
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Abstract

Thomas Hobbes postulates that men are driven by “a perpetual and restless desire of power after power, that ceaseth only in death.” The miserable consequences of this drive for power and the competing “desire of ease and sensual delight” and “fear of death and wounds” lead them to establish and obey. Substituting “profit” for “power” yields a description of the modern corporation, but without the desires or fears of natural persons. Such “unnatural persons” lack the Hobbesian ground of obligation, yet have appropriated the privileges and protections of natural persons. They challenge or undermine the sovereign wherever it limits their profits. Governor Schwarzenegger’s re-election in California, however, on a strong anti-CO$_2$ program, suggests a willingness by threatened natural persons to re-empower Leviathan.
Résumé


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Thomas Hobbes’s famous phrase, “nasty, brutish and short,” was offered as a description not of a marginalized ethnic group but of life in a (purely hypothetical) “state of nature,” where there is no central authority and power:

In such condition, there is no place for industry; because the fruit thereof is uncertain: and consequently no culture of the earth; no navigation, nor use of the commodities that may be imported by sea; no commodious building; no instruments of moving, and removing, such things as require much force; no knowledge of the face of the earth; no account of time; no arts; no letters; no society; and which is worst of all, continual fear, and danger of violent death; and the life of man, solitary, poor, nasty, brutish, and short.

This grim yet rather poetic passage bears a remarkable similarity to Thomas Homer-Dixon’s description of conditions in modern “failed states,” torn by communal violence, in which the scarce supply of human effort and ingenuity is devoted not to bettering the human condition but to plundering one’s neighbours (Homer-Dixon et al. 1993). Hobbes’s description, however, owes nothing to observation; it is a pure thought experiment, derived from a priori assumptions about human nature:

So that in the first place, I put for a general inclination of all mankind, a perpetual and restless desire of power after power, that ceaseth only in death.
This essentially mechanical drive for (individual) power results in a perpetual “war of all against all,” in which all men share an equal vulnerability in the most fundamental sense that the weakest can kill the strongest (you have to sleep sometime) and no man’s person or property is ever secure. But human nature includes other (equally mechanical) drives:

Desire of ease, and sensual delight, disposeth men to obey a common power.
… Fear of death and wounds disposeth to the same.

All men therefore agree, in order to escape the state of nature, to enter into an equally hypothetical “social contract” by which they give up ultimate power and accept the over-arching authority of a sovereign, acting through the State. The sovereign might be a hereditary monarch, but the later Crown-in-Parliament, with an elected parliament, will also serve so long as the sovereign has absolute authority, in any way it chooses, to impose peace on its otherwise warring subjects.

The state of nature is a logical consequence of Hobbes’s assumptions about human nature. He seems to have made no effort — though by the mid-17th century he might have done — actually to collect information on societies at different levels of development. In reality, all societies, human and non-human, have a complex social structure and a web of relationships, of expectations, obligations and unwritten rules.

The greater complexity of human societies may result, at some stage of development, in the establishment and acceptance of a sovereign power, but the relation of authority and obedience between sovereign and subject is only one component of this complex web.

What has disappeared from political thinking is the notion of “bonding”—the horizontal links between citizens. … The family, clan, neighbourhood, religious order, or any traditionally “unwritten laws” determined by custom as the basis for political life are forbidden, unless the sovereign permits them. (Johnston 1999)

Political behaviour is thus emptied of moral content, and men in Hobbes’s world are no longer moral agents. Their individual behaviour arises from a mechanical response.

In reality, all societies, human and non-human, have a complex social structure and a web of relationships, of expectations, obligations and unwritten rules.
to the limitless drive for power, and their collective political behaviour – the social contract – arises from their need to reconcile the consequences of this drive with their desires to increase pleasure and avoid pain.

As a description of human psychology, and of actual behaviour, this is pretty thin stuff. But as economic theory amply demonstrates, a priori reasoning about social behaviour is dangerously attractive. The well-organized mind makes rapid intellectual progress without the tedious process of collecting and sorting out all the baggage of empirical reality, producing coherent, logically consistent, and aesthetically pleasing model worlds that may be rather distant, in critical respects, from our own.

In the centuries since Hobbes, however, an entirely new class of “persons” has emerged, legal rather than natural, that fit his framework rather well. Rephrase his second postulate as “profit” for “power” in the postulate of “a perpetual and restless desire of power after power,” and you have the modern corporation.

The corporation is, of course, ultimately owned by natural persons. But in the modern capital market these owners are numerous, typically dispersed and anonymous, and constantly shifting. Corporations own shares in other corporations, while much of the ultimate human ownership is indirect, through mutual or pension funds. Most of these ultimate “owners” neither know nor care what they own. What they care about is the rate of return. Paraphrasing Vince Lombardi, “Profit is not the most important thing. It’s the only thing.”

Moreover, “the market” demands not merely high profits, but continuously compounded growth, and builds growth expectations into stock prices. A “perpetual and restless desire of profit after profit” is not a psychological postulate but an immediate consequence of the structure of capital markets. If (expected) earnings growth slackens, stock prices fall, and management will probably fall with them.

A person who does not recognize the bonding relationships – the normal horizontal links among natural persons – and who pursues his or her own objectives indifferent to their impact on others is considered to be psychologically disturbed, a “sociopath.” As argued in the documentary film The Corporation, based on Bakan (2004), the modern corporate “person” is thus essentially sociopathic. Its motives and behaviour meet the technical definition of the diagnosis. The corporation is not immoral; it is simply amoral.

Moreover, the corporation is the real Hobbesian thing. His political animals were radically stripped-down versions of human beings (rather like the consumers of economic theory). Then as now, real people were embedded in complex webs of obligations and objectives that shaped their behaviour. The wars of religion, for example, were not simply the aggregate consequence of individual self-aggrandizement. The corporation really is a “person” with a single, unbounded objective. But it differs from Hobbesian individuals in a couple of respects that are, I think, crucial.

First, despite its name, the corporation has no physical body to be threatened
or delighted. Lacking fear of death or wounds, or desire of ease or sensual delight, it has no motivation to respect a social contract. Hobbes’s arguments for accepting the authority of the sovereign and obeying its orders – the “ground of obligation” – do not apply to the new class of corporate persons. Respecting or breaking the law is simply a business decision: which behaviour yields the greater expected profit?

Second, the economically successful corporation commands resources on a scale unimaginable for any individual person, even Bill Gates. All these assets belong, legally, to natural persons who are in principle identifiable. But if the corporation is to fulfill its single mandate of profit maximization, it must have full control over their use. And it does.

The picture that emerges is of a collection of immensely wealthy and powerful sociopathic “pseudo-persons” with Hobbesian drives, but without Hobbesian fears. It is therefore not surprising that, as Bakan documents, the historical evolution of the modern corporation was accompanied by deep suspicion on the part of the natural persons among whom it operated. On the other hand, there is also no denying that the corporation has been an engine of economic growth and prosperity, of technical and institutional innovation, unmatched in human history. It is hard to imagine a modern world without the modern corporation. It works.

But we seem to have lost sight of the fact that this “legal person” is a social construction, owing its existence and powers to specific legal and political decisions. Unlike natural persons, it is not in the Kantian sense an end in itself but rather a means, an institution created by a society of natural persons to serve their ends.

Natural persons have “human rights” simply because they are human. But corporations are not human. Logically, they have no claim to inherent rights. Rather, they should be assigned only those rights that can be shown to further the purposes and promote the well-being of the society of natural persons (not just their owners!) that brings them into being. Yet over the last century, the corporate “person” has succeeded (quite deliberately) in portraying itself as, in effect, a big natural person, entitled to all the same legal and constitutional privileges and protections. Our political and legal representatives have been persuaded to look the other way, while a bamboozled public have not even noticed.

So now, when CanWest Global challenges the Canadian ban on advertising of
prescription drugs, the case is being argued on the basis of a constitutionally protected right to free speech, a right that is inherent, not simply instrumental. (Tobacco companies have previously made the same claim.) Much dust is kicked up about the alleged informational, even educational, role of corporate advertising. One might get the impression that a pharmaceutical firm is “an eleemosynary outfit” (Robertson 1976). But the more fundamental question is, why does a corporation have constitutionally protected rights at all?

Humans have many purposes, and insofar as those purposes are lawful we assign them value, or at least protection. But the corporation’s sole purpose, profit maximization, has no inherent value at all. The assignment of particular rights to such entities can be justified only insofar as it tends to promote the well-being of natural persons. The notion that restricting the right of these immensely powerful sociopaths to make propaganda in pursuit of profit is somehow akin to preventing me from talking to my neighbours, or placing my opinions in the public domain, is bizarre. But it follows from a (carefully nurtured) confusion between legal and natural persons, between means to ends, and ends in themselves.

A similar confusion has arisen, during the last generation, over patents. Throughout their history, patents have been understood as a special privilege, a monopoly granted and enforced by the State to advance a particular public purpose – encouragement of innovation. Lawyers and economists were perfectly clear that patents were not a reward for past behaviour, but an incentive to future behaviour. As an instrument of public purposes, patents could – and should – be modified and adapted as the State saw fit so as to sharpen their efficiency and limit their interference with other public objectives.

The past generation has seen this historical interpretation turned inside out. The new concept of “intellectual property” creates a new form of rights that the State is obliged to respect and protect. Patents are no longer instruments of public policy; they are now private entitlements. For any government to tamper with them is to violate private property rights that are constitutionally protected … in the United States.

In 1969, the Canadian government introduced compulsory licensure for patented drugs. Big Pharma objected strenuously, since the intent and the effect was to create a more competitive market and lower drug prices in Canada. They fought the policy long and hard, and eventually (with the assistance of the United States government) successfully.

No one, however, questioned the authority of the Canadian government to pass such legislation. Today, in the world of NAFTA, TRIPS, and indeed the 1982 Canadian constitution, such a measure is hard to imagine. Patents have been transformed from instruments of social policy to private property rights, primarily through the initiative, and certainly to the benefit, of private corporations.

That the modern corporation may attempt to undermine the authority of the sov-
ereign state wherever that authority impedes the pursuit of profit is not a new insight. But the Hobbesian perspective suggests that the behaviour of the tobacco industry – concealing health data, lying under oath and engaging in deliberate criminal activity to protect its markets – is not aberrant, as anti-smoking activists would have it. Such corporate behaviour is a predictable response to threats to profits. What makes tobacco different is only the particularly noxious nature of its product.

This point is made by Terry Tamminen (2006), who draws an explicit parallel between the tobacco industry and the behaviour of the automobile and oil industries in the United States from the 1920s onward. He describes an actual corporate conspiracy initiated by General Motors, through a corporation called National City Lines, to buy up and shut down urban electric railways in 45 American cities, in order to expand the market both for diesel buses and, more significantly, for the private automobile.

The oil and automobile industries systematically concealed data and lied to regulators about the health effects of automobile emissions – just like the tobacco industry. If American legislators had had a more realistic picture of the environmental effects of the oil economy, would they have launched, in 1956, the gigantic federal subsidy of the Interstate Highway Program?

Tamminen is a lifelong environmental activist, and his claims are neither new nor uncontested. What makes him interesting is that he is also an environmental adviser to Governor Arnold Schwarzenegger of California. Arnie, the derider of “girlie men,” driver of Hummers and, allegedly, political acolyte of Attila the Hun, has just ridden to easy re-election on the back of a really serious and multi-pronged legislative program to reduce greenhouse gas emissions. This is the sort of thing that other state governors might notice, whatever their political stripe, and according to Tamminen, they have (CBC 2006).

The Bush administration still has its collective head firmly buried in the environmental sands, but Tamminen argues that the US government will either wake up over the next couple of years, or simply be pushed aside as the individual states move forward. (In Ottawa, Stephen Harper has woken much more quickly to the political threat, and the embarrassing contrast between California’s legislation and his own, but extracting one’s head from the tar sands may be more difficult.)
And here we come back to Hobbes. Crucial to his analysis was the universally shared vulnerability in the state of nature that could be escaped only by accepting the authority of the sovereign. Governor Schwarzenegger’s success, over the strong resistance of the legal but unnatural persons in his state, can perhaps be interpreted as reflecting a growing sense among natural persons of their shared vulnerability to global warming. That sense of shared vulnerability – to death and wounds, in a general sense – was in this case powerful enough to overcome corporate resistance and re-assert the ultimate authority of the sovereign.

Where will it all end?

ACKNOWLEDGMENTS
I am indebted to Ian Johnston for his two lectures on Hobbes prepared for students in Liberal Studies at Malaspina University-College, Nanaimo, British Columbia. These refreshed my memory of C.B. Macpherson’s lectures at the University of Toronto in the early 1960s (and provided the exact quotes).

REFERENCES
Data Protection and the Promotion of Health Research

Protection des données et promotion de la recherche sur la santé

by VALERIE STEEVES, JD, PHD
Assistant Professor
Department of Criminology
University of Ottawa

Abstract
This paper challenges the argument that data protection legislation may harm research by unduly restricting the flow of personal health information. I unpack the assumption that privacy is an individual right that must give way to research as a social good, and explore how data protection laws facilitate the flow of information for research purposes. I conclude that researchers should embrace data protection laws because they help construct trust in research practices, mitigate the commercial imperatives that flow from the fact that research is a public–private enterprise and protect the accuracy of data. Good research design should recognize that privacy is a social value and an essential element of psychological health and social relationships. And since research databases do not exist in isolation, researchers must respect the fact that the non-consensual flow of information poses risks of harm, including the secondary use of health research databases for social control, that must be managed.
Résumé

Cet article conteste l’argument voulant que les lois sur la protection des données entravent la recherche en restreignant indûment la circulation de renseignements personnels sur la santé. J’examine l’hypothèse selon laquelle la protection de la vie privée est un droit individuel qui doit céder le pas à la recherche en tant que bien social, et j’explore comment les lois sur la protection des données facilitent la circulation d’information à des fins de recherche. Je conclus que les chercheurs devraient adhérer volontiers aux lois sur la protection des données parce qu’elles aident à susciter la confiance à l’égard des pratiques de recherche, réduisent les impératifs commerciaux découlant du fait que la recherche est une entreprise publique-privée et protègent l’exactitude des données. Une bonne conception de recherche devrait reconnaître que le respect de la vie privée est une valeur sociale et un élément essentiel de la santé psychologique et des relations sociales. Et puisque les bases de données de recherche n’existent pas isolément, les chercheurs doivent respecter le fait que la divulgation non consensuelle de renseignements comporte un risque de préjudice – dont l’utilisation secondaire de bases de données de recherche sur la santé pour le contrôle social – qui doit être géré.

IN 2000, THE GOVERNMENT OF CANADA ENACTED THE Personal Information Protection and Electronic Documents Act (PIPEDA) to give individuals control over the collection, use and disclosure of their personal information. Even before PIPEDA became law, the health sector expressed concerns that the data protection principles it contained would unduly restrict the flow of health data to researchers (Korman 1999; Turner 1999; Poston 1999; Sholzberg-Gray 1999; Lingberg 1999; Fineberg 1999). Since the Act was proclaimed in force with respect to health information on January 1, 2002, many researchers have continued to argue that the law hampers their ability to access research data1 (see Tu 2004; Ingelfinger and Drazen 2004; Wysong 2004).

In this paper, I argue that this position is based on six misconceptions about the relationship between privacy, research and the law. I conclude that privacy is an essential element of good research design, and that researchers should embrace data protection principles because they help build the social trust that enables research to flourish.

Misconception No. 1: Data Protection Laws Restrict Research

Data protection laws typically contain seven or eight of the following 10 principles:
1. An organization should be accountable for the personal information it holds.
2. It should identify the purpose for which information will be used.
3. It should collect information only with the data subject’s knowledge and consent,
except under specified circumstances.

4. It should collect only information that is necessary to accomplish the identified purpose.

5. Information should not be used or disclosed for other purposes without consent.

6. Information should be retained only as long as necessary to accomplish the identified purpose.

7. The organization should ensure that information is accurate, complete and up to date.

8. Information should be kept secure.

9. The organization should be open about its policies and practices.

10. Data subjects should have the right to access and correct their information.

The legislative landscape dealing with the protection of personal health information in Canada is a patchwork of federal and provincial laws. PIPEDA applies to personal information (including health information) collected, used or disclosed in the course of commercial activity in both the federal and provincial sectors, unless there is substantially similar legislation in force in a province.

The provinces listed in Table 1 have health-specific data protection in place or private sector laws that have been declared to be substantially similar to PIPEDA. However, there is still the potential for cross-jurisdictional problems; for example, public sector health legislation in Manitoba and Saskatchewan applies to pharmacists, but pharmacists are also subject to PIPEDA when they collect information in the course of commercial activity. In addition, general public sector data protection legislation may apply to hospitals and/or regional health authorities (see, for example, the BC Freedom of Information and Privacy Act, SBC 1996, c. 165). For a more detailed discussion of the jurisdictional difficulties associated with health information legislation, see Keeshan (2004: 1–6).

### TABLE 1. Health information protection legislation in Canada

<table>
<thead>
<tr>
<th>PROVINCE</th>
<th>SUBSTANTIALLY SIMILAR PRIVATE SECTOR LEGISLATION</th>
<th>PUBLIC SECTOR HEALTH LEGISLATION</th>
</tr>
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<tbody>
<tr>
<td>Alberta</td>
<td>Personal Information Protection Act, SA 2003, c. P-6.5</td>
<td>Health Information Act, RSA 2000, c. H-5</td>
</tr>
<tr>
<td>British Columbia</td>
<td>Personal Information Protection Act, SBC 2003, c. 63</td>
<td>Personal Health Information Act, CCSM June 28, 1997, c. P-33.5</td>
</tr>
<tr>
<td>Ontario</td>
<td>Act Respecting the Protection of Personal Information in the Private Sector, RSQ 1993, c. P-39.1</td>
<td>Health Information Protection Act, SS 1999, c. 29</td>
</tr>
<tr>
<td>Quebec</td>
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<td>Saskatchewan</td>
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Some researchers have argued that these principles – especially the requirement to obtain consent – threaten the research enterprise because they make it difficult for researchers to access data that would otherwise be available to them. For example, in an influential article published in the *New England Journal of Medicine*, Jack Tu (2004) and his co-authors conclude that data protection laws are overly strict and may constrain the viability of observational research. In support of this conclusion, they point to examples where registries have been required to obtain patient consent before adding personal health information to the registry database.

This position is problematic, primarily because it “mixes apples with oranges.” Data protection laws, or the apples, are the most common form of privacy regulation. As of 2004, 43 states in Europe, North America, South America, the Middle East and Asia had passed some combination of the 10 data protection principles into law. However, the principle of consent is often not included in these laws or, if included, is subject to broad exceptions. Although PIPEDA requires consent, it applies only to information collected in the course of commercial activity and, like virtually every other data protection law, it expressly provides that researchers do not have to obtain consent or even inform individuals that their information is being collected where the information is used for statistical or scholarly study or research and obtaining consent is impracticable. Similarly, under Ontario’s new *Health Information Protection Act*, health information custodians may disclose personal health information to researchers without consent where the research plan has been approved by a research ethics board. The Act specifically mandates that the ethics board should consider whether or not obtaining consent would be impracticable in the circumstances.

Special rules for research are not a new phenomenon. Since 1974, data protection laws have exempted information used for statistical, scientific or historical purposes from the application of data protection principles (Council of Europe 1974). This is no accident. Data protection laws were not developed to restrict the flow of personal information to bureaucrats, state authorities and researchers but to facilitate it (Rodota 1976; Rule et al. 1980; Simitis 1987; Gandy 1993; Steeves 2002). Data protection is the friend of research because it is designed to ensure that data are accurate and available for research purposes.

When Tu and his colleagues (2004) argue that data protection laws have harmed registries in Germany and the United States, they have jumped out of the apple cart into the oranges. Germany is the only country in the world with a constitutional right to informational self-determination. As a constitutional guarantee, that right trumps data protection laws. The United States is also a special case because it is the only Western country that has not enacted comprehensive data protection laws; it relies instead on piecemeal legislation and litigation. Countries like Canada, on the other hand, that rely on data protection legislation to protect personal information typically do not legally restrict the flow of data to researchers.2
This does not mean that personal health information is not subject to ethical standards. Clearly, ethical questions remain when researchers wish to place patients under surveillance to facilitate the development of generalizable knowledge. However, many, like Tu, argue that individual privacy rights must not be allowed to constrain medical research because research is a social good that competes with, and trumps, the individual interest in privacy. But closer examination demonstrates that research is not an unencumbered public good.

**Misconception No. 2: Health Research Is an Unencumbered Public Good Free of Any Private Interest**

Clearly, we all benefit from advances in medical science. But medical research is not a purely academic exercise. Policy makers increasingly discuss medical research in economic terms (see Leader’s Forum 2004: 6). Researchers are increasingly pressured to match public funding with private dollars and to pursue economically exploitable intellectual property rights. And health information itself is a now valuable commodity in the electronic marketplace (see IMS Health 2004).

This complicates the privacy/research debate because it raises serious questions about research as a public good. Marcia Angell (2004) argues that pharmaceutical research is structured by commercial imperatives that discourage innovation. In 2004, the US House of Representatives held hearings on the pharmaceutical industry because of a growing public outcry over the suppression of medical studies. Across the Atlantic, David Healy testified before a British House of Commons committee that many of the articles published in the British Medical Journal and The Lancet are ghost-written by pharmaceutical companies that then pay respected clinicians to publish the articles under their own names (Kmietowicz 2004).

Commercial imperatives pose serious risks to research, not only because the public is distrustful of these kinds of corporate practices. Once health information is alienated from the individual and reconstituted as property in the corporation’s hands, access to that information will be limited. This is precisely what happened with the Icelandic Health Sector Database. The database was created by statute in 1998 and contains the genealogical history, genetic information and personal health records for every Icelander. Since the population of Iceland is relatively small, homogeneous and isolated, it is an ideal sample for genetic research. The Icelandic government sold the exclusive rights to use the data for research purposes to deCode Genetics, a US biomedical company, which then entered into a licence with the Swiss pharmaceutical company Hoffman-LaRoche to use the database to study 12 specific diseases. That business arrangement has effectively barred any other researcher from using the...
data for research purposes for 12 years, the duration of deCode’s contract with the Icelandic government (Hloden 2000).

Privacy protects research from these kinds of restrictions because it mitigates against commodification. And this reflects the fact that privacy is not only an individual human right; it is a social good in and of itself.

**Misconception No. 3: Privacy Is an Individual Right**

This leads us to the third misconception about privacy and research, that privacy is an individual right and must give way to research as a social good. Some go further and suggest that patients in a publicly funded healthcare system have a social obligation to let researchers use their medical data to improve the system for the benefit of all (Upshur 2001; Al Shahi and Warlow 2000).

Priscilla Regan (1993) argues that pitting the individual’s interest in privacy against the public good to be facilitated by invading that privacy creates a zero-sum game where privacy must be “balanced” against the social interest in efficiency and security. However, as Regan concludes, this dichotomy is a false one:

> Most privacy scholars emphasize that the individual is better off if privacy exists. I am arguing that society is better off when privacy exists. I argue that society is better off because privacy serves common, public and collective purposes. If you could subtract the importance of privacy to one individual in one particular context, privacy would still be important because it serves other important functions beyond those to the particular individual. (Regan 1993: 16)

Indeed, privacy is rich in sociality. Alan Westin’s seminal work on privacy, *Privacy and Freedom*, suggests that privacy is an essential element of intimacy and the ability to enter into “close, relaxed and frank relationships” (Westin 1967: 31). The respect shown by others for anonymity and reserve creates a “psychological barrier against unwanted intrusion” that is dependent upon the interaction between the individual seeking privacy and the others with whom he or she interacts (p. 32), and private communications enable us to enter into relationships of trust (p. 39). Psychologist Irwin Altman (1975) builds on Westin’s insights, and argues that privacy is a boundary control mechanism than divides the self from the non-self. Dissolving the boundary weakens both our sense of self and our ability to enter into relationships with others.

One of the most difficult aspects of the emerging health research infrastructure is that it collapses the boundary between the patient’s primary interest in healthcare and secondary interests such as research. To argue that privacy must give way to these secondary interests misses the fact that healthcare is delivered in the context of social relationships between real social actors. Practices that violate the social experience of
privacy as it is lived in our daily lives will break down the trust that is an essential part of healthcare delivery.

Surveillance, or the systematic monitoring of a person or a group for institutional purposes, is an exercise of social power; that is why people are wary of electronic health records and data matching. That does not mean that all surveillance is necessarily a bad thing. People accept surveillance for all kinds of reasons, but there is always the assumption in the background that the institution will be accountable for its actions within a framework of democratic principles. Researchers who seek to use personal health information for research purposes must be sensitive to that fact, or they will not be viewed by the public as trustworthy.

**Misconception No. 4: Observational Research Data Collected without the Patient’s Knowledge and Consent Will Lead to Unbiased Data**

The fourth misconception is that data collected without the patient’s knowledge and consent will be unbiased. But privacy is more than a social value; it is a social construction. In practical terms, this means that when privacy is not respected, trust will be lost and people will lie, withhold information or forgo services to reconstruct their sense of privacy.

For example, researchers in South Australia found that just under 10% of survey participants felt that doctors would not use their personal health information responsibly, and that for some, this lack of trust was based on the fact that their information had been released without consent (Mulligan 2001). A study in Massachusetts found that over one-quarter of teens would not go to the doctor if they had concerns about confidentiality (Cheng et al. 1993). In California, one in 10 people have changed their behaviour to protect their medical privacy by going to another doctor; paying for services directly; forgoing medical care; providing an inaccurate or incomplete medical history; or asking the practitioner not to write down details of the health problem. And people who know their medical privacy has been breached in the past are four times more likely to participate in these behaviours (California Healthcare Foundation 1999).

As Altman noted (1975: 22) privacy is “an interpersonal event.” This means that failing to respect patient privacy will lead to biased data because patients will change their behaviour to account for the invasion.

**Misconception No. 5: Privacy Is a Roadblock to Better Health**

The fifth misconception is that privacy is a roadblock to better health because it creates an obstacle to medical research. Ingelfinger and Drazen (2004) put it this way:
“Public health is threatened by incomplete data more than individual privacy is threatened by disease registries.” In the logic of the zero-sum game of privacy versus health research, increasing one means decreasing the other.

But social-psychological research indicates that privacy may be a determinant of psychological health in its own right. In his seminal study of mental institutions, Erving Goffman (1966) found that the patient’s lack of privacy meant that the patient was never “off-stage,” never free to drop his or her social mask and relax free of others’ expectations. Patients were also unable to maintain the boundaries between the various social roles they played. Since they were always under observation, they were accountable to the watchers for all facets of their behaviour. Altman’s work on personal space and territorial behaviours led him to conclude that these kinds of privacy violations are “a deterrent to rehabilitation, because they expose the self, eliminate a number of normal self-boundary control processes, and make the person extremely vulnerable to others” (Altman 1975: 40). Leontine Young (1966) argues that “without privacy there is no individuality,” and Westin (1967: 34) links the loss of privacy to emotional breakdown and suicide. Woogara (2001) argues that health professionals’ respect for the patient’s privacy is vital for the patient’s emotional, psychological and physical well-being.

Simple equations that mandate a “minimal loss” of privacy to advance research as a “public good” simply do not fit with the complex social-psychological meaning of privacy as it is experienced by real social actors. Privacy defines the boundary between self and others. It cannot be traded in exchange for some other benefit, such as efficiency or convenience. Carving out an autonomous space for medical research to the detriment of privacy will have social consequences that flow beyond the original goal of facilitating research. And that leads to our final misconception.

Misconception No. 6: De-identified Health Information Does Not Pose a Risk of Harm to the Patient

Researchers are interested in trends and patterns, not what individuals do with their lives. However, the value of electronic databases lies in the fact that files in different databases can be linked by matching personal identifiers. In its Health InfoWay
report, Health Canada (1999) argued that one of the benefits of an electronic health network is that it will enable researchers to explore the non-medical determinants of health and develop “empirically based information” on lifestyle choices, nutritional habits, family support, housing, working conditions and financial status. However, extending research into such a wide range of personal activities connects the health record to non-traditional sources of data, and creating networks of personally identifiable data creates risks to privacy that must be managed.

To argue that researchers are trustworthy and can therefore operate outside of established legal rules regarding the privacy of personal information is to miss the point. Law is not a best-case scenario exercise; legal rules are written to protect us from the consequences of the worst-case scenario. The mere creation of a pool of data poses risks because the powerful are able to use those data for social control. David Flaherty (1989: 84) puts it this way: in a surveillance society, “record linkages are so easy to accomplish that the power holders cannot resist using them to try to solve real and alleged social problems.” Westwood (1999: 231) talks about the “almost biological imperative” of governments and corporations to operate more efficiently in the promotion of collective interests. Westin (1967) concludes:

Although organizations often seek to use surveillance to solve problems of genuine social importance, … if all that has to be done to win legal and social approval for surveillance is to point to a social problem and show that surveillance would help to cope with it, then there is no balancing at all, but only a qualifying procedure for a licence to invade privacy. (Westin 1967: 370)

Once medical databases are created, they become useful to employers, insurers and the state. And the way that researchers access information affects the ability of these others to do so as well. The law is an exercise in line drawing; with respect to privacy, the line of protection is drawn when the individual has a “reasonable expectation” of privacy (Hunter v. Southam). Non-consensual access by others creates a de facto loss of expectation, and this has ramifications for the legal remedies available. For example, the Kyllo case held that police cannot use thermal radiation scanners to “see” into a private dwelling unless the technology is in “common public use.” Accordingly, common use may negate any expectation that activities that occur within four walls are “private.” Similarly, non-consensual access to medical records may negate the patient’s expectation that the information will be kept confidential.

This is precisely the argument that was used by the United States Justice Department when it wanted access to hospital records to identify patients who were given late-term abortions, for the purposes of enforcing the Partial Birth Abortion Act. The Justice Department argued that common access by researchers, insurers and others meant that patients no longer have an expectation of privacy with respect
to their medical records (O’Connor 2004). Although the argument was ultimately unsuccessful, it demonstrates the permeability of “reasonable expectations” in a social environment structured by invasive practices. And the issue is far from over. In 2004, British Columbia struggled with the implications of contracting out its health records management to US companies that are subject to the USA PATRIOT Act. Under s. 215 of the Act, these companies may be ordered to secretly hand over “any tangible thing” to the FBI – including records containing personal health information. Again, the implementation of new technological infrastructures that are exempt from privacy rules facilitates other uses of health records, and researchers must be cognizant of the fact that their access to health data does not occur in isolation of these broader social and legal dynamics.

The non-consensual flow of health data poses significant risks of harm to the patient, because this opens up the data to secondary uses. Caplan and Cosgrove (2004) argue that the mere fact a psychiatric diagnosis is recorded can lead to loss of custody, health insurance, employment and the legal right to make decisions on financial and other matters. This is even more problematic when one factors in research that indicates that the patient’s gender, race, socio-economic status, physical disability, and sexual orientation can bias the diagnosis process.

Privacy is a flashpoint precisely because medical research is both an objective and a subjective exercise. As Andrew Feenberg (1995: 97) wrote, “The body is the site of medical knowledge and action. It enters medicine as both object and subject insofar as it is both the thing on which medical technique operates and the bearer of the person who commands medical services.” The research subject is therefore more than “the bearer of a mechanical body”; he or she is one of the social actors involved in an ongoing relationship that encompasses researcher, patient, physician and scientist. Research infrastructures that fail to take account of the sociality inherent in the relationship between researcher and subject will be resisted.

In conclusion, privacy is not a barrier to research. It is an essential part of the social relationships that facilitate the development of new knowledge. Arguments that privacy must “give way” to research are both counter-productive and overly simplistic. Good policy should be based on realities, not misconceptions. Data protection laws are useful tools for researchers because they help to construct trust in research practic-
es, mitigate the commercial imperatives flowing from the fact that research is a public–private enterprise and protect the accuracy of data. Good research design recognizes that privacy is a social value and an essential element of psychological health and social relationships. And since research databases do not exist in isolation, researchers must respect the fact that the non-consensual flow of information poses risks of harm.

There may be times when individual consent for research uses is indeed impracticable, but the answer does not lie in exempting research from legal and ethical oversight. What is needed is ongoing dialogue that moves us out of the zero-sum game so we can create infrastructures that account for the role that respect for privacy must play in the advancement of knowledge.

Correspondence may be directed to Valerie Steeves, PhD, Department of Criminology, University of Ottawa, 25 University Street, Ottawa, ON K1N 6N5; tel.: 613-562-5800 Ext. 1793; fax: 613-562-5304; e-mail: vsteeves@uottawa.ca.

NOTES
1. Although there is health-specific data protection legislation in place in six provinces (see Table 1), these laws are all modelled on the data protection principles set out in the Organization for Economic Co-operation and Development's Guidelines on the Protection of Personal Privacy and Transborder Flows of Personal Data (1980) and the Canadian Standard Association's Model Code for the Protection of Personal Information (1996). The CSA code was incorporated into law in PIPEDA and, as such, PIPEDA continues to serve as a template for data protection legislation in the health sector, especially given the public–private character of the health industry. Private sector use of health information must comply with PIPEDA unless there is substantially similar legislation in place in the province. Moreover, much of the debate around health information was initiated when PIPEDA was being debated in the Senate prior to its passage into law. Accordingly, PIPEDA remains a key focal point of analysis.

2. More specifically, data protection laws do not unduly restrict the flow of information for research purposes. Protocols are subject to certain requirements, such as the prior approval of a research ethics board.

3. Provincial health sector laws (set out in Table 1) give a significant data protection role to research ethics boards (REBs); however, vague statutory requirements in this regard and the lack of a coherent regulatory regime do raise questions about the ability of many REBs to play this role effectively.

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Data Protection and the Promotion of Health Research: If the Laws Are Not the Problem, Then What Is?

La protection des données et la promotion de la recherche sur la santé : si les lois ne sont pas le problème, alors quel est-il?

by DONALD J. WILLISON, SCD
Centre for Evaluation of Medicines, St. Joseph’s Healthcare
Department of Clinical Epidemiology & Biostatistics,
McMaster University, Hamilton, ON

Abstract
Data protection laws offer such broad exemptions for research that research ethics boards and data custodians lack sufficient guidance as to when it may be acceptable to release data to researchers without consent. The result: idiosyncratic institutional policies that create major challenges for researchers conducting multi-centred studies. The 2005 CIHR Best Practices for Protecting Privacy in Health Research provide an important first step towards greater clarity. However, there is still a need to translate these Best Practices into harmonized policies. This should be seen as an opportunity rather than a threat. Clear rules for data protection will reinforce public trust, which is essential for continued access to personal information for research.

Résumé
Les lois sur la protection des données prévoient des exemptions si vastes pour la recherche que les comités d’éthique de la recherche et les dépositaires de données n’ont pas suffisamment de balises pour déterminer quand il leur est loisible de divulguer des données...

In her paper, Steeves argues that data protection laws are not barriers to research, as some researchers contend. Instead, they govern the rules for information access for a variety of purposes, including research. If this is the case, then why are researchers experiencing increased difficulty with access to information for research? There are several interrelated issues at play here.

The Problem

Lack of clear guidance

In general, data protection laws offer such broad exemptions for research that research ethics boards (REBs) and data holders (e.g., hospitals, provincial Ministries of Health) lack sufficient guidance as to the conditions under which it may be acceptable to release data to researchers without consent. Similarly, the Tri-Council Policy Statement (TCPS) offers little guidance in this area (Canadian Institutes of Health Research et al. 1998). Nor are there consistent messages coming from legal counsel. All this reinforces the anxiety of data holders over releasing the information in their custody. So, idiosyncratic policies have been developed, many of which go beyond the requirements of the law. This creates major challenges for researchers conducting multi-centred studies – both in terms of start-up delays and consistency in protocol across sites. The problem is further compounded when research crosses borders – not because there are major differences in legislation, but because of uncertainty over the equivalency of legislation and concern over loss of control over the data.

New models of research

Our frameworks for governing research – data protection laws, the TCPS, REBs and other institutional structures – are still largely geared towards discrete studies with
tightly defined research goals that can be tied to specific data collections. Increasingly, though, researchers are developing registries and data/biobanks that will serve as research platforms for numerous research studies yet to be conceived. As electronic health records are harnessed for research, the distinction between what is care, what is quality improvement and what is research has blurred, as has the distinction between surveillance for public health purposes versus research. With regard to these databases, several questions arise. For example:

- Are the approval and ongoing oversight of these research platforms the purview of the institutions from which the data were gathered or the research ethics board? If the registries are a compilation of data from several sites, how can one coordinate the review process?
- What are the criteria by which these research platforms will be reviewed – both at the time of their creation and for ongoing monitoring?
- Once the database has been approved, is it necessary for a REB to review each and every project that emanates from such a database? If so, is there a need for full review?
- Is individual consent required for inclusion of individuals’ data in these prospectively developed databases? If so, what constitutes a valid consent if the research questions cannot all be explicitly defined ahead of time?

An Important First Step towards Greater Clarity

The Canadian Institutes of Health Research have taken an important initial step in addressing these problems. After months of development and consultation, in October 2005, the CIHR Best Practices for Protecting Privacy in Health Research were released (CIHR 2005). These guidelines were developed for researchers, REBs and data holders to assist them in how best to apply data protection principles in the design and conduct of research involving humans. They build on the TCPS and the Fair Information Principles that are the foundation of our data protection legislation. The guidelines provide concrete examples, ethical principles and frameworks to assist researchers and REBs, thus preserving the decision latitude for REBs in their deliberations. While not restricted to observational studies, it is in this area that the guidelines offer their greatest potential for assistance.

The guidelines cover use of population records, administrative databases, clinical databases, survey data and linkages of these. They also wade into the murky territory of registries and biobanks for which the future uses of personal information are either unarticulated or only generally described. The document is particularly instructive in the area of determining whether it is impracticable to obtain individual consent for the use of personal data.
Further Steps Needed

Mere promulgation of these guidelines, though, is insufficient. The document itself is lengthy and does not provide “off-the-shelf” answers. There is still a need for readers to take the guidelines and adapt the principles-based approaches to their specific context. The CIHR is working with the National Council on Ethics in Human Research and the Canadian Association of Research Ethics Boards to implement these guidelines into practice. Similar efforts need to be undertaken with health information custodians (e.g., hospitals, provincial Ministries of Health) and with researchers. If the guidelines do become widely adopted by the research community and data holders as their source document in making policies, they could go a long way in providing a harmonized approach to privacy protection across provincial jurisdictions and in guiding any future legislation in this area.

In addition, the appropriate infrastructures are needed to conduct research using health data. While methods currently exist to anonymize data sets while still allowing for linkage of information from different data sources (Statistical Policy Office et al. 1994; Eurostat 1996; Sweeney 1997, 2002), outside of a handful of large research data centres across the country, there is very little expertise in appropriately de-identifying and managing these large data sets to maintain security and confidentiality. Many provinces lack the staff to manage data requests for research purposes or the expertise to de-identify data sufficiently before releasing them.

Finally, the future of health research lies in going beyond linkage and analysis of administrative data sets. Increasingly, research will combine administrative data with clinical records, individual surveys, and genetic information. These latter activities require individual contact, so consent will still be required. To manage this, we need to move from a project-by-project to a broader, more systemic approach to consent for research use of personal information (O’Neil 2001; Willison 2003; Caulfield et al. 2003). Our current structures for doing this just do not fit.

What Can We Expect in the Future?

Data protection laws call for accountability in the use of personal information. Researchers can anticipate closer scrutiny regarding their use of such information. For example, researchers may be asked to justify whether particular data elements such as date of birth are needed and whether the data can be collected in a less identifiable format – e.g., year of birth rather than date of birth. REB approval will probably be required before data collected for one study can be used to answer a new, unrelated research question, or to permit one researcher to share data with another.

Researchers can also expect greater accountability for safeguarding data in their possession, whether through physical means (e.g., locked doors and filing cabinets),
Commentary: If the Laws Are Not the Problem, Then What Is?

technical means (e.g., password protections for computer files) or procedural means (e.g., confidentiality agreements, data sharing agreements). This point raises concerns about the liability of research institutions for the management of data on the part of their faculty. Again, this calls for a systemic response on the part of research institutions and not just individual researchers.

Adapting to the new data protection laws will take time and will require creative solutions on the part of the research community. It will also have real costs. This should be seen as an opportunity rather than a threat. Clear rules for data protection will reinforce public trust, which is essential for continued access to personal information for research.

Correspondence may be directed to Don Willison, Centre for Evaluation of Medicines, St. Joseph’s Healthcare, 105 Main Street East, P1, Hamilton, ON L8N 1G8; tel.: 905-522-1155 Ext. 4911; fax: 905-528-7386; e-mail: willison@mcmaster.ca.

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COMMENTARY

Data Protection and the Promotion of Health Research

Protection des données et promotion de la recherche en santé

by CAMERON A. MUSTARD, SCD
President & Senior Scientist, Institute for Work & Health
Professor, Public Health Sciences, University of Toronto Faculty of Medicine
Toronto, ON

The paper by Valerie Steeves provides a well-presented series of arguments concerning research access to personal health information. Her perspective is clear, and her voice often challenges some of the stereotypic attitudes and values she attributes to the perspective of research interests when confronted with privacy protection policies and practices.

To those of us who encounter the consequences of health information privacy legislation in our scientific work in population health, health services or clinical research, Dr. Steeves’s perspective will seem provocative. Her objective is constructive. It is her view that privacy protection legislation enables research by constructing trust in research practices and contributing to the accuracy of personal health information. She presents and discusses six misconceptions about the relationship between privacy, health research and the law. In her view, the perspective of health researchers concerning privacy protection legislation can be represented in six stereotypic statements:
Misconception 1: Data protection laws restrict research
Misconception 2: Health research is an unencumbered public good, free of any private interests
Misconception 3: Privacy is an individual right and so must give way to research as a social good
Misconception 4: Observational research data collected without the patient’s knowledge and consent will lead to unbiased data
Misconception 5: Privacy is a roadblock to better health
Misconception 6: De-identified health information does not pose a risk of harm to the patient

Dr. Steeves’s paper is primarily informed by the perspective of legal scholarship. The paper is therefore flavoured by some characteristics of this field: (1) strongly voiced perspectives in the tradition of rhetorical argument, (2) the use of cases (single instances) as evidence and (3) a general disregard for the argument that might be offered from the opposite position. In addition, the “opposite position” (the perspective of researchers concerning privacy) is often stereotyped and overdrawn.

The paper presents an original set of perspectives on the social value of privacy. Many of these arguments very nicely extend the rights-based perspective on individual privacy to elaborate on how individual rights to privacy protection have social value. These contributions are a real strength of this paper.

On the other hand, the strongly voiced perspective of the author is not well anchored in evidence concerning the prevalence or frequency of research/privacy conflicts and the consequences of these conflicts to both research and privacy. As noted above, the paper makes selective use of “cases” to build an argument. For example, the study by Tu and colleagues (2004) is important for a host of reasons. One value is that it provides the best documented evidence of the scale of the trade-off in external validity that arises when consent is required. Dr. Steeves glosses over this evidence of the negative consequence of rigidly applying the consent principle to make a (less important) point about premises. In the case of the evidence documented by Dr. Tu, the requirement to obtain informed consent did emphatically result in a biased research sample, with significant limitations on the value of the study sample for deriving inferences. Ironically, the reference to the paper by Tu et al. is an excellent example not of a misconception, but of the real threat to the validity of observational research if consent requirements are rigidly applied.

Over the past decade in Canada, many provinces have established or clarified the legislative basis for the protection of personal health information. The great majority of health researchers would agree with Dr. Steeves that the improved clarity of rights and responsibilities contained in this legislation will strengthen personal privacy rights and will also strengthen appropriate access to health information for research.
purposes. While Dr. Steeves has produced a helpful analysis of some points of tension between the objectives of research and the objectives of privacy protection legislation, what is needed at present are careful empirical studies of the frequency of research/privacy conflicts and their consequences for both research and privacy. What will be helpful in the years ahead is greater clarity in the recognition of potential risks to personal privacy and the potential risks to high-quality evidence arising from health research in the inappropriate application of health information privacy legislation.

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Discussion and Debate
The Discussion and Debate section of Healthcare Policy offers a forum for essays and commentaries that address: (1) important health policy or health system management issues; or (2) critical issues in health services and policy research. Submissions should be a maximum of 2,000 words exclusive of (no more than 20) references. The main points of the paper should be highlighted in an abstract (summary) of 100 words or less.

Appel aux auteurs
Discussion et débat
La section « Discussion et débat » de Politiques de santé offre un forum pour la publication de comptes rendus et de commentaires portant sur les sujets suivants : (1) d’importantes questions liées aux politiques de santé ou à la gestion du système de soins de santé; ou (2) des questions cruciales concernant les services de santé et la recherche sur les politiques. Les articles devraient être d’au plus 2000 mots, sans compter les références (pas plus de 20). Les points saillants de l’article devraient être mis en évidence dans un résumé (sommaire) de 100 mots ou moins.

For more information contact Rebecca Hart, Managing Editor, at rhart@longwoods.com.
Abstract

International studies have shown that the more developmental assets adolescents possess, the greater their likelihood of engaging in health-enhancing practices and the lesser their likelihood of engaging in practices that put health at risk. Logistic regressions were conducted on data from the 2000–2001 National Longitudinal Survey of Children and Youth (NLSCY) for 12- to 15-year-old Canadian youth to examine which of five assets accounts for the most variance in positive health outcomes and participation in risky health behaviours. Connectedness within social contexts, particularly to family and school, was associated with several self-reported positive health
outcomes and behaviours (excellent or very good health, high self-worth, and less alcohol, tobacco and marijuana use). Connectedness among peers was associated with better self-assessed health and higher self-worth but also with more use of alcohol, tobacco and marijuana. A comprehensive approach to healthy youth development that emphasizes and increases positive relationships in these contexts may facilitate the transition of Canadian youth into healthy adulthood.

Résumé
Des études internationales ont montré que plus l’adolescent a de ressources développementales, plus il aura tendance à adopter de saines habitudes de santé et moins il sera enclin à adopter des habitudes qui mettent sa santé en péril. Des régressions logistiques ont été effectuées à partir des données de l’Enquête longitudinale nationale sur les enfants et les jeunes de 2000-2001 chez de jeunes Canadiens âgés de 12 à 15 ans afin de déterminer laquelle de cinq ressources est responsable des plus importants écarts dans les résultats positifs en matière de santé et l’adoption de comportements dangereux pour la santé. Le sentiment d’appartenance au sein des contextes sociaux – en particulier les contextes familial et scolaire – a été associé à plusieurs résultats et comportements positifs autodéclarés en fait de santé (excellente ou très bonne santé, haute estime de soi et consommation réduite d’alcool, de tabac et de marijuana). Le sentiment d’appartenance avec les pairs a été associé à un meilleur état de santé autodéclaré et à une meilleure estime de soi, mais également à une consommation accrue d’alcool, de tabac et de marijuana. Dans ces contextes, une approche globale à l’égard du développement de la santé chez les jeunes, qui met l’accent sur les relations positives et augmente celles-ci, peut aider les jeunes Canadiens à devenir des adultes en santé.

Adolescent health and well-being has been linked to a broad range of health determinants, including characteristics of the social environment (CIHI 2005). Positive relationships, opportunities, competencies, values and self-perceptions, or developmental “assets,” can facilitate a youth’s transition into healthy adulthood (Scales and Leffert 2004). International studies have shown that the more of these assets adolescents possess, the greater their likelihood of engaging in health-enhancing practices and the lesser their likelihood of engaging in health-deteriorating practices (Kirby 2002; Kobus 2003; Murphey et al. 2004; Oman et al. 2004a; Scales et al. 2003; Vesely et al. 2004). Analyses of data from the National Longitudinal Survey of Children and Youth (NLSCY) by the Canadian Institute for Health Information (CIHI) showed that the more assets, or positive ties, that
Canadian youth reported having with their families, schools, peers and communities, the more likely they were to report better health and higher self-worth and the less likely they were to report participating in risky health behaviours such as using alcohol, tobacco and marijuana (CIHI 2005). For example, youth who reported having a combined total of four or five assets were less likely to report using alcohol, tobacco and marijuana than youth with three or fewer assets.

In this study, CIHI conducted additional analyses of 2000–2001 NLSCY data to examine further which of these assets accounts for the most variance in positive health outcomes and participation in risky health behaviours as reported by youth.

Methods

Data source

Statistics Canada’s NLSCY is a longitudinal study that follows a sample of Canadian children from birth to early adulthood. The first cohort of approximately 25,000 Canadian children aged 0 to 11 years was recruited in the fall of 1994 (children and youth living on Indian reserves or Crown lands, in institutions or in the territories were excluded). The cohort has been surveyed every two years since, with information provided by parents, teachers, principals and children above 10 years of age.¹

Population and data analysis

Data for youth aged 12 to 15 years old in 2001 (n=3,725 and representing 1,625,819 youth of the same age in Canada) were examined. All analyses were done through the Statistics Canada Remote Data Access program, using NLSCY Cycle 4 cross-sectional weights. Variables from the NLSCY used to represent the five assets – parental nurturance, parental monitoring, school engagement, peer connectedness and community engagement – were first dichotomized into high and medium to low levels. The odds ratios (with 95% confidence intervals) associated with high levels of each of the assets in relation to five self-reported health outcomes and behaviours (excellent or very good health, high self-worth, alcohol, tobacco and marijuana use) were then calculated using the Bootvar 3.0 program in SAS, logistic regression models and the bootstrap method for variance estimation. The variables, analyses, outcomes and methodology are based upon those developed, used and initially presented in the CIHI report Improving the Health of Young Canadians (CIHI 2005). Some variables in the aforementioned report, however, were not of direct relevance to this study, and consequently they were not included in this study's analyses.
**TABLE 1.** Summary of odds ratios and confidence intervals (CI, 95%) associated with the five assets, by health outcome and behaviour

<table>
<thead>
<tr>
<th>HEALTH OUTCOME OR BEHAVIOUR</th>
<th>DEVELOPMENTAL ASSET (MEDIUM-LOW LEVEL=0; HIGH LEVEL=1)</th>
<th>ODDS RATIO</th>
<th>LOWER CI</th>
<th>UPPER CI</th>
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<tr>
<td>Excellent or Very Good</td>
<td>High Levels of Parental Nurturance</td>
<td>1.87</td>
<td>1.38</td>
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<td>Self-Rated Health (No=0; Yes=1)</td>
<td>High Levels of School Engagement</td>
<td>1.90</td>
<td>1.38</td>
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<td></td>
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<td>High Levels of Community Engagement</td>
<td>0.96</td>
<td>0.70</td>
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<td>High Levels of Parental Monitoring</td>
<td>1.09</td>
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<td></td>
<td>High Levels of Parental Monitoring</td>
<td>0.95</td>
<td>0.69</td>
<td>1.32</td>
</tr>
<tr>
<td>Marijuana Use</td>
<td>High Levels of Parental Nurturance</td>
<td>0.50</td>
<td>0.36</td>
<td>0.69</td>
</tr>
<tr>
<td>(No=0; Yes=1)</td>
<td>High Levels of School Engagement</td>
<td>0.37</td>
<td>0.26</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>High Levels of Peer Connectedness</td>
<td>1.66</td>
<td>1.12</td>
<td>2.46</td>
</tr>
<tr>
<td></td>
<td>High Levels of Community Engagement</td>
<td>0.74</td>
<td>0.54</td>
<td>1.02</td>
</tr>
<tr>
<td></td>
<td>High Levels of Parental Monitoring</td>
<td>0.84</td>
<td>0.61</td>
<td>1.15</td>
</tr>
</tbody>
</table>

Source: CPHI analysis of NLSCY (Cycle 4, 2000-01), Statistics Canada.

* Odds ratio equal to 1.00 due to rounding, p=0.049.

Odds Ratios and associated confidence intervals were calculated using multiple logistic regressions.
Results

Table 1 summarizes the odds ratios and confidence intervals associated with each of the assets in relation to the five health outcomes and behaviours examined.

Parental nurturance and school engagement

Under the deployed bootstrapping methodology, high levels of two of the five assets – parental nurturance and school engagement – were associated with positive health outcomes and less reported participation in risky health behaviours.

- Compared to youth with medium to low levels of these assets, youth with high levels of parental nurturance or school engagement had increased odds of reporting excellent or very good health and high self-worth.
- Youth with high levels of parental nurturance or high levels of school engagement were also less likely than youth with medium to low levels of the asset to report using alcohol, tobacco and marijuana.

Peer connectedness

High levels of peer connectedness were also associated with positive health outcomes (excellent or very good health status and high self-worth). However, youth with high levels of peer connectedness were more likely than youth with medium to low levels to report using alcohol, tobacco and marijuana.

Community engagement and parental monitoring

The community engagement asset did not explain a significant amount of the variance associated with the positive health outcomes or youths’ participation in risky health behaviours. Similar results were found for the parental monitoring asset, with one exception: youth with high levels of parental monitoring were less likely to report high self-worth than youth with medium to low levels of parental monitoring.

Discussion

The associations between parental nurturance, school engagement and the different health measures in this study were consistent with those from the 1994–1995 US National Longitudinal Study of Adolescent Health, in which approximately 12,000 youth in grades 7 through 12 participated (Resnick et al. 1997). In the US study, parent–family connectedness and perceived school connectedness were found to be protective against emotional distress, suicidality, violence and age of sexual initiation, as
well as cigarette, alcohol and marijuana use (Resnick et al. 1997).

Compared to those who reported medium to low levels, youth who reported high levels of parental nurturance were more likely to report high self-worth. Youth who reported high levels of parental monitoring, however, were less likely to report high self-worth. Previous research shows that among high school students, regardless of ethnicity, socio-economic status or family structure, a nurturing parenting style is associated with less psychological distress and higher self-esteem, while an authoritarian parenting style is associated with greater psychological distress and lower self-esteem (Avenevoli et al. 1999).

High levels of peer connectedness were associated with positive health outcomes and higher participation in risky health behaviours as reported by youth. Similarly, data from the Canadian component of an international study of youth health found that youth who reported high levels of social integration felt less depressed and helpless and had high self-esteem (King 1999).

However, of youth in the international study who said most of their friends smoked, took drugs or consumed alcohol in excess, 85%, 88% and 58%, respectively, reported they had engaged in the same behaviour (King 1999). Studies increasingly show that interactions with peers who exhibit positive behaviours are linked to better health outcomes (McLaren 2002). For example, youth with positive peer models are more likely to abstain from using tobacco, drugs or alcohol (Kobus 2003; Oman et al. 2004b).²

Markers of socio-economic status, such as income and education, were not included in these analyses. Analyses of these variables in the CIHI report *Improving the Health of Young Canadians* and the literature in general suggest that the relationship between socio-economic status, assets and health is complex. The CIHI report found that, with the exception of parental nurturance, “the distribution of assets was relatively consistent across the different income and education levels” (CIHI 2005). The proportion of youth who reported high levels of parental nurturance is higher in the highest income level than in any of the other income levels, and is higher in households with college or university graduation compared to households with some college or university. Further analyses showed that “higher or lower levels of household income and education do not appear to be related to increased odds that youth aged 12 to 15 years will report high levels of health status and self-worth” (CIHI 2005).
Similarly, household income and education levels “do not appear to increase the odds that youth will report using tobacco, alcohol or marijuana” (CIHI 2005). These findings, however, are not meant to discount the relationship between income and health; as noted above, income plays a varied yet complex role in determining health behaviours and outcomes. The results of this study show that some assets have more predictive value, statistically, of health measures or behaviours than other assets. Multiple assets interact in multiple environments and are associated with specific health outcomes and behaviours (Scales and Leffert 2004; CIHI 2005). Based on previous research, programs and policies that may be most beneficial to youth health are those that increase the number and quality of positive family, school, peer and community connections. Research shows that characteristics of successful initiatives include approaches that

- are comprehensive and address common factors associated with multiple behaviours;
- support positive youth development rather than focusing on avoidance of risky behaviours;
- engage youth in meaningful activities (CIHI 2005; Centre of Excellence for Youth Engagement 2003; Flay 2002; Public Health Agency of Canada 2004; Catalano et al. 2004; Collaborative Community Health Research Centre 2002; Minnesota Department of Health 2001).

Limitations

As with any cross-sectional study, conclusions cannot be made regarding the cause/effect relationship between positive assets and health outcomes and behaviours. Further, measures used in this survey are self-reported by youth. Socially acceptable answers may have been given in response to some questions.

Conclusion

Connectedness within social contexts, particularly connectedness to family, school and peers, is associated with several health measures among Canadian youth. A comprehensive approach to healthy youth development that emphasizes and increases positive relationships in these contexts may facilitate the transition of Canadian youth into a healthy adulthood. Parents, peers, schools, communities, volunteer organizations, program developers, levels of government and youth themselves all have a role to play in healthy youth development.
Correspondence may be directed to: Melanie Yugo, Canadian Institute for Health Information, 495 Richmond Road, Suite 600, Ottawa, ON K2A 4H6; tel.: 613-241-7860; e-mail: myugo@cihi.ca.

NOTES
2. The peer connectedness variable in our study does not assess whether peers exert a positive or negative influence on the youth respondent.

REFERENCES


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Wait Time Benchmarks, Research Evidence and the Knowledge Translation Process

Repères pour les temps d’attente, preuves cliniques pour la recherche et processus d’application des connaissances

by DIANE E. WATSON, PHD, MBA
Director of Research and Analysis
Health Council of Canada
Vancouver, BC

MORRIS L. BARER, PHD
Former Scientific Director
Institute of Health Services and Policy Research
Canadian Institutes of Health Research
Vancouver, BC

HEIDI M. MATKOVICH
Associate, Communications and Knowledge Translation
Institute of Health Services and Policy Research
Canadian Institutes of Health Research
Vancouver, BC
Abstract

The first set of evidence-based benchmarks for medically acceptable wait times, announced in December 2005, were developed, in part, through a novel partnership between the Provincial and Territorial Ministries of Health, the Canadian Institutes of Health Research (CIHR) and Canada’s health services research community. Responding to a direct request for assistance and demanding timelines from the Provincial and Territorial Ministries of Health, CIHR mounted a rapid-response funding process and supported eight Canadian teams to synthesize evidence to inform the development of the first set of benchmarks. This experience demonstrated that both the research funding process and research syntheses themselves can rapidly inform policy making in even the most heated of environments.

In September 2004, as a key part of the $41 billion, 10-year plan to strengthen healthcare, Canada’s First Ministers agreed to build on past efforts to reduce wait times and improve access to care (Government of Canada 2004). In the following months, especially in the wake of Chaoulli v. Québec, the commitment to...
establish evidence-based benchmarks for medically acceptable wait times in five clinical areas by December 31, 2005, became the highest-profile element of this agreement.

The Ministers of Health announced the first set of these benchmarks on December 12, 2005. These benchmarks were, at least in part, the product of a partnership between the Provincial and Territorial Ministries of Health, the Canadian Institutes of Health Research (CIHR) and Canada’s clinical and health services research community. While research and policy making processes are often distinct and asynchronous, in this case the research community and intermediaries such as CIHR were able to mobilize themselves to seize a window of opportunity to inform public policy. The purpose of this paper is to describe this successful knowledge translation process – the rapid-response commissioning of research teams to systematically identify, select, appraise and synthesize evidence – and to reflect briefly on factors in the policy environment that may have increased the potential for this research to have an influence.

Research Synthesis Can Be Rapid and Responsive

In January 2005, the Provincial and Territorial Deputy Ministers of Health requested assistance from CIHR in assembling research evidence in time to inform the development of wait time benchmarks for a December 2005 deadline. Only once before had CIHR developed a Request for Application (RFA) process – during the SARS crisis – with such unforgiving timelines. But by May 2005, an international review committee, established by CIHR to conduct an arm’s-length assessment of the relevance and scientific merit of the proposals, had adjudicated 17 grant applications and chosen eight Canadian research teams to conduct research syntheses in sight restoration, joint replacement and cancer. Research syntheses in cardiac services and diagnostic imaging were not funded, because proposals were either not received or not ranked highly enough to be fundable.

Funded teams were not asked to recommend specific benchmarks, nor to undertake primary research. Rather, they were to (1) synthesize Canadian and international evidence on the relationships between patient characteristics, health service wait times and mortality, health status or quality of life; (2) summarize wait time benchmarks already in use, nationally or internationally, and the research evidence (if any) used...
to support their selection; and (3) (after the December 2005 deadline facing the Ministers) identify priority areas and questions for future research.

The teams reported on the first two objectives only five months after the start of funding, in October 2005. These reports were submitted directly to the Ministries, and CIHR facilitated opportunities for real-time knowledge translation, bringing the researchers and policy makers together to discuss the findings in more detail. CIHR released plain-language summaries of the main findings and links to the full reports on its website for general access in November. On December 12, 2005, the Ministers of Health announced Canada’s first set of wait time benchmarks, which related closely to benchmarks suggested by the research syntheses.

What Made This Knowledge Translation Process Successful?
The policy making process is not linear or predictable. It always takes place in the context of a complex array of institutional arrangements (e.g., structures, past policies), interests (e.g., among elected officials, civil servants, societal interest groups) and ideas (e.g., research and other forms of evidence), as well as values, which are influenced by individuals and external events (Lavis 2006).

This complexity means that the policy making process often appears to be a “black box,” with little apparent way to determine if, how and to what extent research evidence has been considered in a given decision. The establishment of wait time benchmarks, which took place in a heated political environment, was undoubtedly as subject to the array of institutional arrangements, interests and ideas as any other policy decision. Yet the influence of research evidence in this policy decision was clear, in both the original request to CIHR for assistance and the development of the resulting benchmarks. A number of factors appear to have contributed to the success of this particular knowledge translation process.

Timeliness

The timeliness of research evidence can obviously increase its prospects for research use (Lavis 2006). Researchers who can provide scientific evidence in a timely manner, using methods of communication appropriate to their audiences, are more likely to have their work inform decision-making. In this case, there was an urgent need for a policy decision owing to the prevailing political climate and prior public commitments to establish “evidence-based benchmarks for medically acceptable wait times … by December 31, 2005” (Government of Canada 2004). CIHR and the research community were able to respond to this requirement for high-quality, timely research evidence with sufficient speed to inform the policy decision.
Investment in evidence-informed decision-making

In the last few months of 2005, questions were occasionally raised by the media and others on the value of looking for research evidence to inform the development of benchmarks when other jurisdictions had proceeded without it. Yet from the outset, the Ministers were committed to investing in reviews of scientific evidence and to ensuring that their benchmarks were informed by the best internationally available research evidence. They and CIHR recognized that the research syntheses would be but one source of relevant information. The Ministers and CIHR also knew, going into this process, that there might be clinical areas in which rigorous evidence of the type being sought would be thin. But it is important to know when there is no research evidence, or when current evidence is insufficiently convergent to support an evidence-informed benchmark. This knowledge can assure Canadians that policy decisions do not contradict existing scientific evidence, and it provides the research community and policy makers with a clear picture of where further work is required.

The Ministries partnered with CIHR in funding successful research teams, and were able to interact directly with the researchers to discuss the resulting evidence.

Trusted relationships

It is well known that regular interactions between researchers and policy makers increase the prospects for research use (Lavis 2006). Decision-makers who seek trusted research partners with whom to work, and who engage actively and from the outset in defining their needs for evidence, are more likely to use it when making decisions. In this case, key senior CIHR staff had established relationships with key Provincial and Territorial Ministries of Health. The Ministries partnered with CIHR in funding successful research teams, and were able to interact directly with the researchers to discuss the resulting evidence. Importantly, CIHR was able to act as an “honest broker” in this process, suggesting that credible intermediaries can play an important brokering role to bring policy and research communities together.

Credible, accessible evidence

An important corollary is the credibility of both the message and the messenger, in this case. Systematic reviews based on all extant research are a more reliable source of
research evidence than individual studies, which can be biased or easily contested. The responsible research teams were selected using high-quality peer review processes. The evidence was presented in a format that directly spoke to the Ministers’ needs, and conference calls were conducted between the Ministries and researchers to ensure clarity and completeness in the translation of new knowledge.

This paper is not intended as a comprehensive overview of this particular policy making process. Many external factors (including input from other parties, such as the Federal Adviser on Wait Times), as well as internal factors not known to us, will also have influenced the political decisions. However, this example does offer some insights for researchers and organizations interested in ensuring that their research is taken into account in the complex process of policy formulation.

Looking Ahead

The process of establishing wait time benchmarks allowed healthcare system leaders to forge new types of working relationships with CIHR and broaden existing relationships with researchers. Most encouragingly, the landmark announcement of the first set of national benchmarks in December 2005 was just the beginning of one phase of this partnership. CIHR hosted an invitational workshop in December 2005, as part of the partnered process of mapping a forward research and knowledge translation agenda on improving timely access to high-quality care. Among the themes that emerged from that workshop were the importance of further work focusing on the key determinants of wait times at a local level; the need to ensure that “appropriateness” screens become an integral part of wait time management systems; and the huge potential of applying a “process flow” lens to the re-engineering of access queues across the country. An additional research team was funded in 2006 under a second round of the original competition to conduct a systematic review of wait times for cardiac services and procedures. In June 2006, CIHR, in partnership with the Provincial and Territorial Ministries of Health and Health Canada, launched a second Request for Applications to fund pilot projects and research syntheses in new priority areas, identified in part through gap analyses conducted by the original eight research teams and in part through the invitational workshop.

The establishment in December 2005 of a set of evidence-informed benchmarks would not have been possible without committed policy makers, nimble clinical and health services researchers and a flexible and responsive research funding agency. These and other factors resulted in an environment conducive to research-informed policy. We hope that this experience will be a powerful and positive precedent, leading to strong, productive and enduring partnerships for the benefit of all Canadians.
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The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada

L’effet de la durée des brevets pharmaceutiques sur les dépenses en R&D et en médicaments au Canada

by PAUL GROOTENDORST
Faculty of Pharmacy, University of Toronto
Toronto, ON

LIVIO DI MATTEO
Department of Economics, Lakehead University
Thunder Bay, ON

Abstract
While pharmaceutical patent terms have increased in Canada, increases in patented drug spending have been mitigated by price controls and retrenchment of public prescription drug subsidy programs. We estimate the net effects of these offsetting policies on domestic pharmaceutical R&D expenditures and also provide an upper-bound estimate on the effects of these policies on Canadian pharmaceutical spending over the period 1988–2002. We estimate that R&D spending increased by $4.4 billion (1997
dollars). Drug spending increased by $3.9 billion at most and, quite likely, by much less. Cutbacks to public drug subsidies and the introduction of price controls likely mitigated drug spending growth. In cost–benefit terms, we suspect that the patent extension policies have been beneficial to Canada.

Résumé

The last two decades have seen several countries extend drug patent terms – the period of market exclusivity afforded to new pharmaceutical drugs – so as to conform to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and other international trade agreements. Indeed, Canada extended drug patent terms in 1987 (as part of the US–Canada Free Trade Agreement), in 1993 (as part of the North American Free Trade Agreement) and again in 2001 (as part of TRIPS). Was this a good policy for Canada? The answer depends on the value to Canada of these trade agreements, an issue discussed by Britton (1998), Mehanna and Shamsub (2002) and Singh (2002). The answer also depends on the value of longer patent terms per se. The standard rationale for lengthened patent terms is to postpone competition from “generic” firms, thereby allowing incumbent firms to charge higher prices for a longer period of time and collect additional profits with which to recoup the costs of research and development (R&D). Longer patent terms should therefore be judged on the value of the innovation generated by the attendant increase in R&D.

The value of longer drug patent terms is the value of the increase in the length and health-related quality of life due to new drugs that would have been delayed, or
not introduced at all, had patent terms not been extended. Offsetting this benefit is the cost of higher drug prices. From an economic perspective, the additional drug expenditures due to longer patent terms is not a cost — it is merely a transfer from drug payers to drug patent holders to support R&D. The primary economic cost of higher drug prices is the value of health not realized due to the reduced consumption of drugs attributable to higher drug prices. The patents policy is economically desirable if the benefits exceed the costs.

In this paper, we investigate aspects of the benefits and costs of longer drug patent terms in Canada. We do so by estimating the effects of the patent policy changes on drug spending, drug prices and drug R&D in Canada. We also investigate how expenditure control policies introduced by the federal government (in the form of direct drug price controls) and provincial government drug plans (in the form of subsidy cutbacks) after 1987 may have mitigated the effects of higher drug prices.

We were unable to conduct a comprehensive assessment of the value of the patents policies. Such an assessment would require the valuation of the drugs that have been developed on account of these policies. This would be difficult to do for several reasons. First, drug development is a lengthy process, and the health impacts of the new drugs developed owing to the patent term extensions are likely only now being realized. Second, most patent-holding drug firms operating in Canada are multinationals who have discretion over the location of R&D. One would therefore need to assess the impact on global R&D and drug innovation of the domestic patent act extension. Third, one would need to assess the health impact of these new drugs, which is no trivial undertaking.

Instead of assessing the health “output” of pharmaceutical R&D, we focus on the “inputs” in the drug development process — Canadian pharmaceutical R&D expenditures. We assess the change in such expenditure before and after the introduction of the 1987 patent term extension. The corresponding change in motor vehicle sector R&D expenditure is used to control for growing domestic R&D tax credits and other factors that could have independently increased R&D. We verify these estimates using an independent source of data on domestic pharmaceutical R&D. We also speculate on the economic value of this increase in R&D expenditure.

Further, we estimate the amount of money transferred from drug payers to drug firms on account of the patent term extension. We do so by examining rates of growth in adjusted per capita prescription drug costs over time. We use regression methods to adjust per capita drug spending for demographic composition, income, provincial drug plan cost controls and other factors that may have changed over our sample period, 1976–2002. We then examine the adjusted per capita drug cost series for any pronounced increases after patent terms were extended. This method is admittedly imprecise because we cannot control for the single largest determinant of recent drug cost growth: the substitution of relatively costly new drugs for older drugs (Morgan
Any observed increases in adjusted drug costs therefore could be due to both “patent extension” – higher drug prices of existing patented drugs – and replacement of older drugs by newer drugs (some of which may have been introduced on account of the patent extension). Faced with this identification problem, the best we can do is to estimate an upper bound on the effect of patent extension on drug costs – the effect that would exist if there were no drug substitution-induced increases in drug costs.

The regression models estimated to adjust drug spending, described above, provide estimates of the impact of provincial government drug cost controls on total drug spending. To gain insight into the effect of federal drug price regulation on drug expenditure, as distinct from the changes in drug plan subsidies and patent term extension, we also analyze time trends in drug price indices and per capita drug expenditures in Canada and the United States, which has not experienced federal price regulation nor recently lengthened patent terms.

Briefly, we find strong evidence that domestic pharmaceutical R&D increased after 1987. We estimate the increase at about Cdn$4.4 billion (1997 dollars). We find little evidence of increased drug expenditures immediately after drug patent terms were extended in 1987; this finding is likely due to the retrenchment of public sector drug insurance plans and the introduction of price regulation of patented drugs. We do find a marked increase in drug expenditures after 1996, which we estimate at Cdn$3.9 billion (1997 dollars). While this increase is consistent with a delayed response to the patent term extension, similar increases were also observed in the United States, suggesting that other factors, such as the introduction of new drugs, may have been primarily responsible.

A Brief History of Canadian Drug Patent Policy

Concerns over high drug prices and low levels of R&D by patent-holding multinational pharmaceutical drug manufacturers led the Canadian federal government in 1969 to modify the “compulsory licensing” provisions of the Patent Act. Generic drug firms were permitted to import and sell patented drugs in exchange for payment of 4% of sales to the patent holder. The 29 patented drugs marketed during the period 1969–1984 that faced generic competition received an average of 7.6 years of market exclusivity (Canada 1985). However, during the last three years of the compulsory licensing regime (1985 to November 1987), periods of market exclusivity for some popular drugs, such as the ulcer drug cimetidine, were as low as four years. Pressure applied during trade negotiations and promises by patent-holding firms to increase domestic R&D led to the weakening in December 1987 and elimination in March 1993 of compulsory licensing, under the auspices of bills C-22 and C-91, respectively. Bill C-22 guaranteed patentee firms seven years of market exclusivity (10 years if generic firms imported active ingredients) after receiving federal approval, known as
“Notice of Compliance” (NOC), to market the drug. Bill C-91 eliminated compulsory licensing and provided 20-year patent terms from the date of patent filing. According to industry sources, it takes about 10 years for a drug to receive a patent, and then undergo testing and receive an NOC, so effective patent terms are about 10 years. Bill C-91 also provided patentee firms the right to delay the market introduction of generic drugs by up to 24 months by claiming patent infringement. Furthermore, the onset of Bill S-17 in July 2001 extended patent protection to 20 years from the date of patent filing for non-expired drug patents issued before 1989, when they lasted only 17 years from time of patent grant. These legislative changes have brought Canadian patent policy into conformity with the TRIPS agreement.

Several government policies initiated in the late 1980s may have mitigated the profits flowing to patentees (Vandergrift and Kanavos 1997; Anis 2000). First, as part of Bill C-22, in 1988 the federal government created the Patented Medicine Prices Review Board (PMPRB), a quasi-judicial agency charged with regulating the introductory prices and increases of drugs. Bill C-91 strengthened the enforcement powers of the PMPRB by enabling it to fine and order price rollbacks on non-compliant firms. Second, the provincial government prescription drug subsidy programs began to reduce subsidy levels via beneficiary co-payments, prescribing restrictions and other cost control measures (Grootendorst 2002). If the drug use of public drug plan beneficiaries is not price sensitive, public drug expenditures were simply shifted to the private sector in the form of higher direct patient expenditure and expenditures on private drug insurance plans, leaving patentee profits largely unaffected. Conversely, if drug use is price sensitive, the retrenchment of provincial drug subsidies has likely reduced industry profits.

Empirical Methodology

Pharmaceutical drug R&D

We estimated the effect of patent protection on pharmaceutical R&D, as measured by the level of expenditure on Canadian pharmaceutical R&D. These include outlays on basic research (identifying new therapies), applied research (establishing that such therapies are safe and efficacious, according to standards of evidence set by federal regulators, as well as research into manufacturing processes) and “other qualifying” research (drug regulation submissions, bioavailability studies and post-marketing drug safety/effectiveness studies). Data assembled by the PMPRB indicate that over the period 1988–2002, about 20% of total pharmaceutical R&D expenditures conducted by firms selling patented drugs were allocated to basic research, and 60% to applied research (PMPRB 2004).
There is anecdotal evidence that some of the post–1987 R&D expenditure increase in Canada is due to the negotiations that resulted in the extension of patent terms. With the passage of Bill C-22, the domestic patent-holding pharmaceutical industry association promised to increase its annual R&D expenditure as a percentage of sales from under 6% in 1987 to 10% by 1996. With the elimination of compulsory licensing in 1993, the association affirmed this commitment into future years and promised both an additional $200 million in support for biomedical research and training in academic institutions across Canada over five years (1993–1998) as well as an additional $400 million in unspecified new investments by the end of 1996 (Industry Canada 1997). While some of the R&D increase is undoubtedly due to changes to the Patent Act, these may not be the sole contributing factor. In particular, the growth in federal and provincial tax credits for domestic R&D might have independently increased pharmaceutical R&D expenditure (Iqbal 1995; Pazderka 1999; Dahlby 2005; MacKenzie 2005).

We had access to data on annual domestic pharmaceutical R&D expenditures from both the PMPRB and Statistics Canada. Under the terms of Bill C-22, firms selling patented drugs in Canada must report on their R&D activity to the PMPRB. Research and development activity is defined as those expenditures eligible for an Investment Tax Credit for scientific research and experimental development under the provisions of the Income Tax Act in effect on December 1, 1987. These data are limited in that the R&D activity for those firms that developed but did not sell drugs in Canada is excluded; moreover, these data cover just the post-policy period, 1988–2002. The Statistics Canada data are available for a longer period of time (1972–2002) and include R&D activities of all firms, irrespective of their patent-holding status, in the “pharmaceutical and medicine” and other industrial subsectors. These data include all R&D expenditure (such as capital purchases including land, buildings and equipment), exclude expenditures related to drug marketing and promotion, and are defined according to the tax legislation in effect in the reporting year. Data are collected from a combination of direct surveys and administrative data required of firms claiming R&D tax credits.

The impact of patent term extension policies on pharmaceutical R&D is defined as the difference between what R&D would have been had patent terms not been extended and actual R&D expenditures (with patent terms extended). To estimate the former, in the first instance we extrapolated trends in pharmaceutical R&D expenditures (using the Statistics Canada data) from before the introduction of Bill C-22 in 1987 to the period when the policy was in place (after 1987). The slope and position of the baseline trends were estimated by linear regression. This approach assumes that all post-1987 R&D growth above the pre-1987 trend line is due to the patent policies. Next, we relaxed this assumption. We subtracted from the pre–post 1987 change in pharmaceutical R&D estimated above the component that would have occurred even
without the patent changes. This latter component was proxied by the pre–post 1987 change in motor vehicle sector R&D. Like the pharmaceutical sector, the motor vehicle sector is capital- and research-intensive; has long product development cycles; is characterized by a high degree of foreign ownership; and could have responded to increasingly lucrative federal R&D tax subsidies by shifting the location of their R&D to Canada.

Finally, we estimated the patent-induced increase in pharmaceutical R&D using the PMPRB data to ensure that the estimates from the Statistics Canada data were reasonably robust to the definition of R&D-eligible expenditures and the set of pharmaceutical firms sampled. Using the PMPRB data, we estimated the effect of post–Bill C-22 patent extension as any growth of the pharmaceutical R&D expenditures-to-sales ratio in excess of 6%, the ratio that prevailed in 1987. From the Statistics Canada data, it appears that this ratio was relatively stable prior to 1987, making this a sensible identification strategy.

Prescription drug spending

To estimate the effects of both the Patent Act amendments and the countervailing reductions in public drug subsidies on pharmaceutical sector revenues, we constructed regression models of provincial total retail prescription drug expenditures as a function of year and region dummies and lagged public drug expenditures, while controlling for other variables that could affect drug spending. The coefficients on the year dummies allow us to assess whether there was a marked increase in drug spending after the introduction of the Patent Act changes. We recognize that our estimate might be confounded by other factors that might increase drug costs over time, in particular, the introduction of new drugs (Morgan 2001). The year effects therefore likely identify the maximum possible impact of patent extension on drug expenditures and allow us to make an upper-bound estimate. Region dummies were included in the model to capture time-invariant regional differences in provincial drug plan generosity. Lagged real public drug expenditure was included to control for changes in provincial drug plan generosity. The idea here is that if public drug plan beneficiaries are price sensitive, then reductions in public drug expenditure should be only partially offset by increased private (out-of-pocket) spending, thereby reducing total drug expenditures.

We also controlled for real per capita GDP, its square and the proportion of the population in various age groups (18–44, 45–64, 65–74, 75 years and older), as well as the squares of these variables, since the medical need for drugs varies systematically through the life cycle. The per capita number of physicians, both primary care and specialists, who likely prescribe to outpatients, as well as the square of this variable, were included to control for changes in prescriber availability. In addition, the de-institutionalization of hospital patients in Canada during the 1990s shifted the location of drug use from inpatient to outpatient settings (Tully and Saint-Pierre 1997). A
hospital share of total healthcare expenditures variable and its square were included to control for the attendant impact on outpatient drug expenditures.

Retail drug expenditures information is produced by IMS Health Canada. These data are dollar-value estimates (excluding dispensing fees but including wholesale markups) and unit volumes of pharmaceutical products purchased by Canadian retail pharmacies. Data from purchase invoices are collected monthly from a representative sample of 210 retail pharmacies, stratified by region, store size (large or small) and type (independent vs. chain). The sample data are then projected to the universe of Canadian drugstores. Data were provided annually over the period 1976–2002 for the provinces of British Columbia, Alberta, Ontario, Quebec, the Prairie region (comprising the provinces of Saskatchewan and Manitoba) and the Atlantic region (New Brunswick, Nova Scotia, Prince Edward Island and Newfoundland and Labrador).

As our focus is on pharmaceutical manufacturers’ revenues, we subtracted expenditures on drug distribution. Data compiled by industry sources suggest that wholesale markups are roughly 5% of factory gate drug expenditures, and therefore, these drug expenditures were divided by 1.05.

Data on provincial government drug plan and other public drug expenditures aggregated by province and year over the period 1975–2002 were obtained from public accounts records and assembled by the Canadian Institute for Health Information (CIHI). Like the IMS data, the CIHI public drug expenditures data exclude hospital use, but include dispensing fees and wholesale markups. Based on statistics from the Ontario government drug subsidy program, retail and wholesale markups account for about 18% of program expenditures, so public drug expenditures were then divided by 1.18 to reflect payments made to drug manufacturers. The data used to construct other variables came from a variety of sources. Data on population counts (by age and sex, GDP and expenditure deflators) were obtained from Statistics Canada CANSIM II. Data on physician counts and total healthcare spending by expenditure category were obtained from CIHI. Further details on these and other data are available in the Appendix (http://www.longwoods.com/product.php?productid=18677).

Source of drug spending growth

Because the Patent Act amendments resulted in both longer periods of market exclusivity for patented drugs and the introduction of patented drug price regulation, we were unable to identify their separate effects on domestic drug expenditures. To shed light on the sources of drug expenditure growth, we analyzed growth in various drug price indices before and after the onset of the patent changes in 1987. Changes in a drug price index will reflect the effects of federal regulation of rates of price inflation of existing patented drugs, but will not reflect the effect of price regulation on introductory prices of new drugs; they also are unlikely to capture the effect of delayed
generic competition on drug prices. The reason is that all new drugs, irrespective of their therapeutic substitutability for existing drugs, count as distinct products in the index. The index will therefore not register the price drop when generics are substituted for brand-name drugs, nor will it register the price increase when new patented drugs are substituted for older drugs (Griliches and Cockburn 1995).

We had access to the patented medicines price index (PMPI), a measure of the ex-factory prices of patented drug products sold in Canada constructed by the PMPRB, but these data are available for the post–Bill C-22 period only (1988–2002). We instead focused on growth in the ex-factory prices of all drugs sold in Canada (irrespective of patent status) using the pharmaceuticals component of the Statistics Canada Industrial Product Price Index (IPPI) over the period 1981–2002. As patented medicines account for over two-thirds of total prescription drug expenditures (PMPRB 2004), this index should capture variation in patented drug prices. Moreover, there is evidence that some manufacturers raised off-patent brand drug prices in order to mitigate the effects of patented drug price regulation (Anis and Wen 1998), so an index that captures price change in both patented and non-patented drugs is preferable. Growth in the price indices was expressed in real terms by subtracting growth in the national all-item CPI.

We also compared Canadian drug price inflation and per capita drug expenditure growth to inflation and expenditure growth observed in the United States in order to control for factors that could have independently affected North American trends in drug spending. Given that the United States, like Canada, has a mixed public–private system of drug finance, but has not introduced drug price regulation or recently lengthened patent terms, the comparison serves as a useful benchmark for evaluating Canadian policy changes.

The parameters of all regression models were estimated using ordinary least squares (OLS). The presence of non-spherical disturbances, however, renders the OLS estimates of the standard errors inconsistent. We therefore used the Newey–West heteroscedasticity and autocorrelation consistent covariance matrix estimator (Newey and West 1987) to ensure that hypothesis testing was valid in the presence of up to two-year autocorrelation. The regression equations and specifications used are described briefly in Appendix II (http://www.longwoods.com/product.php?productid=18677).

Results

Pharmaceutical drug R&D
We first describe time trends in pharmaceutical R&D activity, expressed as a share of total industrial R&D (Figure 1), and in relation to total sales revenue (Figure 2) along with comparative data from the total industrial, total manufacturing, and motor vehicle
FIGURE 1. Pharmaceutical and medicine sector share of total industrial R&D expenditures, Canada, 1972–2002

![Graph showing the share of R&D expenditures in the pharmaceutical and medicine sector from 1972 to 2002.](image)

Source: Statistics Canada.

FIGURE 2. Ratio of R&D expenditures to sales revenue by sector, Canada, 1975–2001

![Graph showing the ratio of R&D expenditures to sales revenue by sector from 1975 to 2001.](image)

Note: The two outlier observations on pharmaceutical R&D to sales, in 1976 and 1978, arise owing to particularly low sales revenue estimates for those years.

Source: Statistics Canada.
and parts sectors. Pharmaceutical R&D expenditures increased substantially after 1987, both in relation to R&D conducted in other industrial sectors and also relative to pharmaceutical sales. In order to estimate the magnitude of the R&D expenditure increase, we initially assumed that all post-1987 R&D growth was due to patent term extension and that the pre–Bill C-22 linear trend in R&D spending would have continued into the future, had the patents policy not been modified. We estimate that the changes to the Patent Act increased real pharmaceutical R&D spending by $4.6 billion over the 15-year period 1988–2002 (with a 95% confidence interval of $4.1–$5.1 billion).

We next re-estimated the increase in pharmaceutical R&D expenditures, this time relaxing the assumption that all post-1987 R&D growth was due to patent term extension. Our identifying assumption is that R&D expenditure growth in the motor vehicle and parts sector mimics what pharmaceutical R&D would have been had patent terms not been modified. As Figure 3 indicates, prior to the introduction of Bill C-22, this comparator had R&D expenditure levels that were very similar to those in the pharmaceutical sector. We estimate that patent term extension increased real pharmaceutical R&D spending by $4.4 billion over the 15 year period 1988–2002 (with a 95% confidence interval of $3.8–$5.0 billion). This estimate is $200 million lower than the previous estimate, implying that pharmaceutical sector R&D has increased.

**FIGURE 3.** Nominal R&D expenditure in pharmaceutical and medicine vs. motor vehicle and parts sectors, Canada, 1972–2002

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Source: Statistics Canada.
by $200 million over and above its pre–Bill C-22 trend during 1988–2002 for reasons other than patent term extension.

Finally, to ensure that our results were robust to the choice of R&D data used, we re-estimated the patent-induced increase in pharmaceutical R&D using the PMPRB data, albeit with the identifying assumption that the ratio of R&D to sales observed in the year before the introduction of Bill C-22 (6%) would have remained fixed into the future. We estimate that the patent extensions increased real pharmaceutical R&D spending by about $4 billion over the period 1988–2002. This estimate is in line with the estimates produced using the Statistics Canada data.

Prescription drug spending

We inspected trends in annual growth of real per capita retail prescription drug expenditures since 1976. The total expenditures growth data (“total” in Figure 4) suggest that while real outpatient drug expenditures increased by over $250 per person during the period 1976–2002, there does not appear to have been a particularly rapid increase in drug expenditures after the extension of patent terms in 1987. Indeed, after 1988 expenditures grew less rapidly and stabilized after the introduction of Bill C-91 in 1993. After 1996, however, total expenditures increased sharply. Based on this unconditional analysis, the combination of patent term extension and direct price regulation introduced in 1987 has at most resulted in a delayed increase in drug costs. Figure 4 also displays growth in public sector drug expenditures. The distance between the total and public curves, representing private drug expenditure growth, is negligible until the mid-1980s. Thereafter, during the era of retrenchment of the public sector drug plans, private expenditure costs increased substantially; by 2002, cumulative private cost growth had almost caught up to the cumulative growth in public costs.

We next estimated regression models in order to assess whether the pattern of total drug expenditure growth observed in the unconditional analyses remained after conditioning on lagged public prescription drug spending and other covariates. The estimates indicate substantial regional variation in real per capita retail drug expenditure, with spending highest in the province of Quebec and lowest in the Prairie region. Drug expenditures increase with the fraction of the population in older age groups, peaking with age 75+, but the relationship is not monotonic: the estimates suggest dips in per capita expenditure at 18–44 years and 65–74 years. The relationship between the density of prescribing physicians and real per capita drug expenditure follows an inverted U-shape pattern, with a maximum at 1.4 physicians per 1,000 population. This relationship is consistent with the hypothesis that at low levels of physician density, increases in density facilitate patient access to prescribers, thereby increasing medication use. Continued increases in density free physicians’ available time per patient to the point where physician time replaces medication prescribing.
Real per capita GDP and the hospital share of total healthcare spending also follow an inverted U-shape relationship with per capita drug expenditure, with maxima at $31,600 and 0.40, respectively. The coefficient on lagged real per capita public drug expenditures is 0.54. Converting this figure into an elasticity, and evaluating it at the sample means, suggests that a 1% decrease in public drug expenditures will reduce total drug expenditures in the next period by 0.27% (95% confidence interval: 0.20%–0.35%). The retrenchment in public sector drug subsidies has therefore modestly reduced drug expenditures.

Turning next to the year-effects estimates, the sharp increase in drug expenditures after 1996 observed earlier is still apparent in the conditional analyses (Figure 5), suggesting that this increase is not entirely a result of changes in real per capita GDP or other time-varying covariates. Proceeding on the assumption that the increase represents a delayed response to the lengthened patent terms, we estimated the incremental per capita drug costs as the difference in the growth in drug costs between 1996 and
2002 less the growth in drug costs during the equal-length period immediately prior to the introduction of Bill C-22, 1981–1987. Incremental per capita drug costs were converted into national figures by multiplying by the average provincial population of Canada over the period 1996–2002. This calculation yielded an estimate of $3.92 billion, with a 95% confidence interval range of $2.97–$4.87 billion.

Source of drug spending growth

We next turned to comparative US data on both drug price inflation and nominal per capita drug expenditures to better inform the determinants of observed drug expenditure growth. Several observations emerge from inspection of rates of inflation of real drug prices in Canada and the United States (Figure 6). Viewing the top panel of Figure 6, which plots growth in real drug prices in Canada (all drugs, and patented drugs only), indicates no evidence of sustained drug price inflation after the extension of patent terms in 1987. As noted earlier, the price indices presented here are not sensitive to delays in generic drug market entry, so this finding is perhaps not surprising. The indices are sensitive, however, to the regulation of rates of growth of prices of exist-
ing patented drugs by the PMPRB. The PMPRB mandates that patented drug price growth not exceed the three-year cumulative change in the CPI. Although this criterion has been satisfied, it is unclear whether PMPRB regulations are binding, as there is some evidence of a downward trend in all drug prices in Canada even before 1988.

The bottom panel of Figure 6 compares Canadian all-drugs real price inflation with that in the United States (where there is no federal price regulation). US drug price inflation has generally declined since 1986, suggesting that Canadian price declines are in part due to a North American-wide phenomenon, such as increasingly restrictive reimbursement policies instituted by drug insurers. On the other hand, the rates of drug price inflation have been consistently lower in Canada since 1987, suggesting that the PMPRB could have had some influence. Regardless of the reason, the lower rates of drug price inflation are consistent with the slowdown in the growth in real per capita prescription drug expenditures observed in the late 1980s.5

While the sharp increase in per capita drug costs observed after 1996 could have been due to delayed generic drug competition brought about by the extension of pat-

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**FIGURE 6.** Year-over-year growth rates in real drug price indices 1982–2002, Canadian patented drugs, all Canadian drugs and all US drugs

Note: All series measured as drug price inflation less inflation in the CPI. Beginning in 1999, the Canadian patented medicines price index (PMPI) reflects changes in the prices of patented drugs for human use only.
ent terms, patent extension is perhaps not the sole reason. Inspection of Organisation for Economic Co-operation and Development (OECD) data on per capita nominal drug expenditures in Figure 7 indicates that the post-1996 expenditure growth has been even more pronounced in the United States than in Canada. This finding points to exogenous factors, such as the introduction of new drugs, as possible reasons. While it is possible that the patent changes were responsible for the entire increase in additional drug costs, it is highly unlikely; therefore, our estimate represents an upper-bound estimate of the impact of patent extension on drug costs.

**FIGURE 7.** Nominal per capita prescription drug expenditures in the United States and Canada, 1975–2002

![Graph showing nominal per capita prescription drug expenditures in the United States and Canada, 1975–2002.](image-url)


**Discussion and Policy Implications**

During the period 1969–1987, pharmaceutical drugs were not given patent protection, and Canada in effect gained a “free ride” on pharmaceutical innovation. In response to pressure applied by trading partners, and promises by patent-holding pharmaceutical firms to increase R&D spending, over the period 1987–2001 Canada increased pharmaceutical patent term lengths to meet international standards. These increases in patent terms have been mitigated by federal drug price controls and
increasingly restrictive reimbursement of pharmaceuticals by public prescription drug programs. Have these policy changes been good for Canada? This is a difficult question to answer fully. We provide some partial evidence on the benefits and costs of the policy changes in this study.

To assess benefits, we need to value the gains in health associated with the use of new drugs that were introduced, both domestically and abroad, because of these policy changes. It is difficult to quantify precisely the domestic value of the R&D increase, but we attempt at least to estimate its order of magnitude (below).

This study provides strong evidence that the policy changes were associated with increased domestic R&D spending in the order of $4 billion (1997 dollars). While we find that domestic R&D has increased since 1987, it is unclear how much of the additional R&D expenditure represents an increase in global R&D, as opposed to R&D that multinational firms shifted to Canada from elsewhere and would have occurred anyway. OECD data do suggest, however, that the worldwide rate of pharmaceutical R&D grew at an increasing rate after 1987 (OECD 2002). This finding is consistent with the notion that the domestic policy changes increased global R&D.

One way to gauge indirectly the health impact of the patent term extension is to assess the number of innovative drugs – commonly referred to as “new molecular entities” or NMEs – that can be purchased for $4 billion. Di Masi et al. (2003) estimate the average cost of bringing an NME to market to be US$403 million in 2000 dollars; adding the forgone interest on funds tied up between the time of R&D investment and marketing raises the cost to US$802 million. According to these estimates, the additional R&D spending in Canada could have supported the development of four to six NMEs.

Lichtenberg (2004) offers a way of quantifying the value of these additional NMEs. He provides a formula that converts NMEs into health outcomes, measured using life expectancy (LE) at birth. Using annual US time-series data on LE, health expenditure and NMEs introduced over the period 1960–2001, he estimates that every percentage increase in NMEs increases LE by 0.039%. Evaluating this proportional response at his sample mean values of LE (73.1) and NME (21.1) implies that every NME increases LE by 0.135 years (1.62 months). Taking Lichtenberg’s estimate at face value, and assuming that the four to six NMEs developed domestically are as productive, on average, as the NMEs in his data, we estimated that the $4 billion domestic pharmaceutical R&D increase has increased Canadians’ LE by between 0.54 and 0.81 years. Topel and Murphy (2003) estimate that the average value of a life-year is approximately US$150,000. Ignoring US–Canada exchange rates, the Topel and Murphy value of life-year estimates implies that the domestic pharmaceutical R&D increase is worth between $81,000 and $121,500 per Canadian.

Some argue that pharmaceutical R&D is valuable for its impact on economic development: pharmaceutical jobs are “good jobs.” We note that most pharmaceutical
R&D takes the form of pre-marketing testing. Indeed, Canada has historically not been a centre for drug discovery; only three of the 1,061 NMEs introduced globally during the period 1975–1994 were discovered in Canada (PMPRB 1997). While such pharmaceutical sector jobs are indeed well paid, assessment of the economic development impact of pharmaceutical R&D involves comparison of the value of the productivity of personnel in the pharmaceutical sector compared to what the value of their productivity would have been had they been instead deployed in some other sector. We are agnostic on this issue.

How much has been transferred to drug firms because of the policy? After controlling for real per capita GDP, prescriber density and other time-varying covariates, we find no marked increases in drug expenditure immediately after patent terms were extended in 1987. Indeed, per capita drug expenditures growth slowed in the early 1990s. Our results differ from those reported by Jones et al. (2001), who analyze prices paid for 82 different drugs by the British Columbia Pharmacare program over the period 1981–1994 and conclude that prices increased substantially in the post-patent period 1988–1994.

We do detect a sharp increase in drug expenditures after 1996. Assuming that this increase represents the effects of delayed competition from generic drugs, we estimate a profit increase over the period 1996–2002 of about $4 billion (1997 dollars). This works out to $667 million per year, or under 4% of the $18 billion spent on prescription drugs annually (CIHI 2005a). This estimate represents an upper bound of the patent-induced drug cost increase, as costs likely have increased for other reasons. First, in an analysis of the sources of oral solid drug expenditure growth since 1998, Morgan (2004) finds no evidence of price inflation. Increases in drug use and substitution of new drugs for old drugs, on the other hand, were major drivers of drug costs. Second, since 1996, per capita drug expenditure has increased faster in the United States, where patent terms have not been extended, suggesting that other factors may indeed be at work. Third, we estimate that the elasticity of total retail prescription drug expenditure with respect to lagged public drug expenditure is 0.27. This estimate implies that the retrenchment of public sector drug plans following the economic slowdown of the early 1990s has likely depressed pharmaceutical expenditure growth. Assessment of the role of price regulation by the PMPRB in constraining drug spending is less clear, given that real drug price inflation has been slowing in both Canada and the United States, even before the introduction of the PMPRB in 1988. On the other hand, rates of real drug price inflation have been consistently lower in Canada after 1988, suggesting that the PMPRB may have had some role. Taken together, these factors suggest that the combination of the federal patent term extension, coupled with federal price regulation and provincial drug plan cutbacks, has boosted the value of pharmaceutical R&D by an amount greater than the amount transferred to patent holders.

What have been the economic costs of the policy? These take three forms: (1) the
health gains not realized because of the reduction in drug consumption due to higher drug prices, discussed earlier; (2) the value of the reduction in consumption and work effort (i.e., the disincentive effects) associated with the additional taxation of consumption and labour levied in order to raise the public sector funds needed to cover additional drug spending; and (3) the cost of “rent seeking” activities – the value of societal resources used for the purpose of securing and maintaining lengthened patent terms (this would include the costs of litigation surrounding the so-called NOC link regulations that were introduced as part of Bill C-91). On the first and second points, the drug use for the majority of the population appears to be relatively price insensitive, and post-patent drug price growth in Canada has been muted, suggesting that welfare losses may be modest. The magnitude of the third cost component remains an open question. We suspect, however, that it is much less than the value of the increase in R&D, suggesting that the policy changes have been beneficial for Canada.

Correspondence may be directed to: Paul Grootendorst, Faculty of Pharmacy, University of Toronto, 144 College Street, Room 601, Toronto, ON M5S 3M2. Tel: 416-946-3994. E-mail: paul.grootendorst@utoronto.ca.

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NOTES

1. A referee notes that the pressure to increase domestic drug patent terms was exerted out of concern that Canada’s use of compulsory licensing would be emulated by large developing countries such as Brazil, China and India. Doern and Sharaput (2000) provide further insights into the political economy of intellectual property protection in Canada.
2. After a generic drug firm has satisfied the conditions required to receive an NOC, under the terms of Bill C-91 it is required to serve a “Notice of Allegation” on the incumbent that the new product will not infringe any active patents. The incumbent then has 45 days to apply to the courts for an order prohibiting the issuance of an NOC. If such an application is filed, the regulator is automatically precluded from issuing an NOC until 24 months have elapsed, the court hearing, or until patent expiry, whichever occurs first (Hore 2000). According to the generic drug industry, this “NOC-linkage” legislation, combined with the industry practice of “evergreening” – listing additional patents on the colour, clinical indications or other features of the medication throughout the life of the initial patent (Anderson 1997) – has further extended effective patent terms and has led to a sharp increase in patent-related litigation. For perspectives by the associations of brand and generic drug firms, see, respectively, http://www.canadapharma.org/Industry_Publications/Information_Guide/section2_e.html and http://www.cdma-acfpp.org/en/news/dec_06_04.shtml. (Retrieved December 25, 2006.)

3. These programs apply to seniors, the indigent and other beneficiary groups, and collectively account for about 40% of total national retail prescription drug spending (CIHIa).

4. The square of GDP, per capita physicians, the hospital share of total health expenditures and age variables were included in the model to account for potential non-linearities between the covariates and drug costs. See Di Matteo (2003) for a discussion.

5. It should also be noted that the use of drug price indexes as a means of separating market exclusivity from drug price regulation may be problematic, given that the index does not capture the effect of price regulation on new drugs and the introduction of new drugs seems to be a significant factor after 1996.

6. This finding could also reflect the increase in foreign pharmaceutical R&D due to the domestic policy changes. Alternatively, a referee notes that the global increase in pharmaceutical R&D observed after 1987 could imply that domestic pharmaceutical R&D would have increased even without the patent extension. While we cannot discount this possibility, we note that Pazderka (1999) finds the impact of the global R&D expansion on domestic R&D to be modest at best.

7. Dahlby (1994) has estimated that the welfare cost associated with the use of provincial income taxes to raise an additional dollar of public funds is about $0.66. This means that the welfare gain from $1 of public sector outlays needs to be $1.66 just to be welfare-neutral.

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The Effect of Pharmaceutical Patent Term Length on Research and Development and Drug Expenditures in Canada

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The Effect of Pharmaceutical Patent Term Length on R&D and Drug Expenditures in Canada

L’effet de la durée des brevets pharmaceutiques sur les dépenses en R&D et en médicaments au Canada

by BOHUMÍR PAZDERKA, PHD
School of Business, Queen’s University
Kingston, ON

Abstract
The authors make a useful and original contribution to evaluating the impact of strengthened patent protection of pharmaceuticals on Canadian healthcare expenditures. This commentary argues that their second task – measuring the impact of strengthened patent protection on R&D spending in Canada – faces an insurmountable conceptual problem: Corporate decisions on the location of R&D activities bear no theoretical relationship to the location of sources of R&D funding and are guided by other factors, including political considerations.

Résumé
Les auteurs font une contribution utile et originale à l’évaluation de l’incidence d’une protection accrue des brevets pharmaceutiques sur les dépenses en soins de santé.
au Canada. Ce commentaire soutient que leur seconde tâche – mesurer l’incidence d’une protection accrue des brevets sur les dépenses en R&D au Canada – se heurte à un obstacle conceptuel insurmontable, à savoir, les décisions des grandes entreprises quant à l’endroit où se déroulent les activités de R&D n’ont aucune relation théorique à l’emplacement des sources de financement pour la R&D et sont guidées par d’autres facteurs, dont des considérations d’ordre politique.

The objective of Grootendorst and Di Matteo’s study is two-fold: first, to evaluate the contribution of the strengthened Canadian patent protection of pharmaceutical innovation to R&D spending in Canada, and second, to determine its impact on drug prices and thus on healthcare spending. This commentary argues that while the latter is a useful and worthwhile exercise, the former is an impossible task.

The tenuous link between domestic patent protection and domestic R&D spending

Stronger patent protection increases the profits available to the innovator for increased R&D spending anywhere in the world. The total contribution to global R&D effort made in the form of increased profits (patent rents) collected from Canadian users of prescription drugs can, in principle, be greater or smaller than the extra R&D spending in Canada. The authors explicitly recognize that the multinationals have “discretion over the location of R&D” and that, therefore, the relevant objective would be to assess the impact on global R&D. Yet they assert that they “estimated the effect … on … expenditure on Canadian pharmaceutical R&D.”

Global pharmaceutical innovation is financed primarily from the extra profits (rents) generated by patent holders, and to a lesser extent by public funds. The contribution each country makes to the financing of global innovation is therefore largely a function of the strength of its patent system. Until the TRIPS agreement came into force (on January 1, 1995), the strength of patent protection was determined by national authorities and varied across countries. The TRIPS agreement made a minimum standard of contribution mandatory; those countries that previously contributed less joined TRIPS because it was a condition of membership in the World Trade Organization.

The location of R&D activity (or R&D spending), as distinct from the location of the sources of financing, is a function of private decision-making by the management of the (multinational) drug companies. For example, a typical Swiss drug corporation
locates much of its R&D activity in the home country, but collects well over half of its rents in the US market, while most of the rest comes from countries other than Switzerland.\(^3\) Indeed, the Swiss patent legislation was historically relatively weak; for example, until 1978 only pharmaceutical process, but not product, could be patented (Schiff 1971; Zutshi 1998: 41). The determinants of location of pharmaceutical R&D activity listed in the literature typically include historical factors, availability and cost of skilled personnel, proximity to centres of academic research and to clinical testing facilities, and government incentives, such as the tax treatment of R&D expenditures.

Controls on prescription drug spending

With patent protection more or less uniform in the post-TRIPS world,\(^4\) attention has focused on policies and practices seeking to control prices or influence the selection of prescribed drugs and thus reduce the burden of prescription drug spending. Specifics include encouragement of generic prescribing; promulgation of formularies that restrict reimbursement for certain (high-priced) drugs, making the percentage of a drug’s reimbursement conditional on independent evaluation of its therapeutic efficiency; and influencing physician prescribing behaviour (Grootendorst and Di Matteo briefly list the Canadian programs in their paper; those of other countries are reviewed in Jacobzone 2000).

The authors controlled for the impact of these policies by reference to drug price inflation and per capita drug expenditure in the United States, on the grounds that the United States “has not introduced drug price regulation.” It should be noted, however, that a similar role is performed by private sector players, such as the health insurance industry or pharmaceutical benefits management companies. US drug prices and per capita drug expenditures have therefore not increased as much as would be the case with “unrestricted” patent protection.

R&D spending trends

The R&D-to-sales ratio in the Canadian pharmaceutical industry, both during the latter part of the period covered by the study and during the post-study period, has been declining, although the stronger patent protection remains in place. It reached its peak...
of 11.7% in 1995 and declined to a low of 8.3% in 2004 before rising (marginally) to 8.7% in 2005. The absolute value of R&D expenditures (in current dollars) increased in all years during the period since 1988, except for 2003 and 2004, when it dropped by 0.4% and 2%, respectively (PMPRB 2006: 39).

In contrast, the R&D-to-sales ratios of the US-based companies, members of the Pharmaceutical Research and Manufacturers of America (PhRMA), have been much more stable: the ratio of domestic (US) R&D to global sales was 13.1% in 1995, rose to 14.0% in 1997 and dropped to a minimum of 12.2% in 2004 before rising to an estimated 12.6% in 2005. The ratio of R&D spending abroad to global sales over the same period fluctuated within the range of 2.8% to 3.6%, with no apparent trend (calculated from data in PhRMA 2006: 52, 57).

Conclusion

The authors have made a sophisticated attempt at evaluating the extra contribution Canadian consumers are making to global pharmaceutical innovation as a result of the 1987 and 2003 modifications of the Patent Act. Given the data problems, their results have to be qualified; however, theirs is an imaginative and useful effort. On the other hand, while the strength of a national patent system determines the contribution of a country’s consumers to global innovation, it has no necessary relationship to the size of the R&D activity on its territory. The “bulge” in the pharmaceutical R&D-to-sales ratio in Canada, which occurred after 1987 and peaked in 1995, has to be explained by other factors. The allusion the authors make to the “discretion” the multinationals have, to the “negotiations that resulted in patent terms being extended” and to the political commitment made by the Pharmaceutical Manufacturers Association of Canada should have been given more prominence than they received in the paper. (Incidentally, the PMAC commitment to a 10% R&D-to-sales ratio has not been kept since 2001.)

Correspondence may be directed to: Bohumír Pazderka, School of Business, Queen’s University, Kingston, ON. E-mail: BPazderka@business.queensu.ca.

NOTES

1. International comparison of the strength of patent protection (in general, not just in pharmaceuticals) gives considerable support to the “exploitation hypothesis” from the theory of alliances: when the size of the contribution is determined by national governments, smaller (or poorer) countries exploit the larger (or richer) ones, in the sense that the larger (richer) countries provide disproportionately larger contributions to the financing of innovation (Ginarte and Park 1997: 285, 291; Park 2001: 110–11).
Commentary: The Effect of Pharmaceutical Patent Term Length on R&D and Drug Expenditures in Canada

2. This link is explored in detail in Pazderka and Stegemann (2005).


4. Inter-country differences remain with respect to such matters as protection of data originating from clinical trials, “evergreening” of patents, and flexibility in parallel imports and compulsory licensing (especially in developing countries). The speed of introduction of generic drugs is affected by legislative provisions permitting the use of patented product for testing purposes to produce and stockpile generic drugs before patent expiry. Some of these provisions have been dealt with by the WTO (Howse 2000).

REFERENCES


Abstract

Grootendorst and Di Matteo’s study showed that extended patent terms in Canada significantly increased domestic R&D spending in the pharmaceutical industry. However, some of the authors’ assumptions and methods, including the choice of control variables, the technique used in calculating policy impacts over time and the failure to incorporate the influence of global factors, are problematic. The overall impression is that the study highlights a correlation between extended patent terms and increased R&D expenditure in Canada but does not provide firm evidence of a causal link.
Résumé

L'étude de Grootendorst et de Di Matteo a révélé que la prolongation des brevets au Canada a fait augmenter de manière significative les dépenses nationales en R&D dans l'industrie pharmaceutique. Des observateurs ont remis en cause certaines des hypothèses et des méthodes utilisées par les auteurs, y compris le choix des variables de contrôle, la méthode employée pour calculer l'incidence des politiques avec le temps et la non-considération de l'influence des facteurs mondiaux. L'impression générale est que l'étude met en évidence une corrélation entre la prolongation des durées des brevets et une augmentation des dépenses en R&D au Canada, mais ne fournit pas de preuves solides quant à l'existence d'un lien causal.

Grootendorst and Di Matteo analyze the net effects of extended pharmaceutical patent terms on domestic pharmaceutical R&D expenditures and pharmaceutical spending between 1988 and 2002, taking into account the mitigating effects of price controls and the retrenchment of public prescription drug subsidy programs. They find that the policy changes were indeed associated with substantially increased domestic R&D spending in the pharmaceutical sector of around $4 billion. The authors also calculate the resulting per capita increased life expectancy value of this additional expenditure.

This is a complex area to research because of the difficulties of adequately isolating the impact of legislation as distinct from other external influences on R&D expenditure, and the problem of how to place economic value on the individual and social benefits of pharmaceutical R&D. The authors acknowledge that their analysis is not a fully comprehensive one, and clearly set out the limitations of the study, which on the whole is well argued. However, some of their assumptions are rather simplistic, particularly when extrapolating R&D expenditure to an assessment of overall value for Canada. Moreover, the methodology used to calculate expenditure appears questionable in several areas, and there are a few inaccuracies that may have affected the analysis and its outcomes. There are also some definitional inconsistencies that may have a bearing on the efficacy of the analyses. For example, R&D is defined differently between Statistics Canada and the Patented Medicine Prices Review Board, while data from the Canadian Institute of Health Information (CIHI) include some non-drug costs.

These points are important, because reliability of the results hinges on the assumptions made and the indicators chosen for use in measuring costs and benefits. The overall impression is that the study highlights a correlation between extended patent terms and increased R&D expenditure in Canada, but it does not provide real evidence of a causal link.
Problematic assumptions also relate to the choice of control variables. First, the use of the United States as a comparison country with only recently lengthened patent terms seems misguided. There are also major differences between Canada and the United States in terms of the time it takes to approve patents; these differences complicate the comparative analysis of impacts over time. Second, in assessing what would have happened to R&D in the absence of patent restoration, the validity of using the motor vehicle industry as a control is highly questionable. The motor vehicle industry is much less dependent on patent protection than the pharmaceutical industry, and investment in R&D in the Canadian motor vehicle industry has been artificially inflated by the Auto Pact agreement with the United States. It is somewhat puzzling that the authors did not select an industry subject to similar patent regulations as the pharmaceuticals industry, such as the software industry.

There are also potential weaknesses in the analysis regarding the way that impacts over time are calculated. In general, there is a significant time lag between R&D investment and the realization of quantifiable benefits, a disparity that suggests the 14-year time frame for this study may be inadequate. It can take up to 20 years from the initial development of the research infrastructure to the realization of commercial benefits of new drugs. Even if the research capacity already exists, it generally takes at least 10 years for a new product to reach the market, so realistically the benefits from new molecular entities (NMEs) produced from 1988 onwards would not be realized until at least the late 1990s.

Moreover, as Joel Lexchin of the Faculty of Health at York University has pointed out (J. Lexchin, personal communication, September 2006), overall sales of many drugs are generally lower at 10–12 years into their life cycle, when generics are now introduced, compared with five to seven years into their life cycle, when generics were introduced prior to 1987. As a result, the potential savings are lower. As Grootendorst and Di Matteo note in their paper, one of the main reasons for the increase in drug expenditures in Canada is the substitution of newer, more expensive drugs for older ones. If compulsory licensing were still in existence, there would be generic competition for these more expensive drugs about four to six years earlier than is now the case.

Lexchin also argues that the monopoly sales period would be more accurately calculated as 11 years rather than the 10 years used by the authors in their calculations, owing to a decrease over time in patent approval times. Others, on the other hand, have suggested that a slowdown in provincial reimbursement of innovative medicines has added more than a year to listing times.

Furthermore, with its focus on domestic drug spending and R&D expenditure, this study seems to underestimate the extent to which the Canadian pharmaceuticals industry is affected by international influences. The global nature of the pharmaceuticals industry makes it very difficult to establish a relationship between domestic
Commentary: Do Patent Terms Impact Domestic R&D Spending in the Pharmaceutical Industry?

policies and R&D expenditure, since decisions regarding R&D activity are often taken at a global headquarters level and are influenced by many factors other than patent terms. So, for example, some have suggested that the availability of research expertise in countries such as India is a key variable contributing to an increase in generic R&D. Additionally, the authors’ assumption that R&D spending would have remained at 6% in the absence of extended patents and increased drug costs does not take account of the possible impact of external factors, such as the increasingly competitive nature of global pharmaceutical R&D.

Moreover, it is extremely unlikely that the domestic R&D environment would be capable of producing four to six NMEs independently, that an additional $4–6 billion invested in R&D would result in drugs launched solely out of Canada, or that they would be developed exclusively for the small Canadian market. It is much more likely that the drugs would be developed with global collaboration and for a world market, with the overall costs and benefits to Canada being much more difficult to estimate.

There is also a need to consider the specific relationship between R&D input and level of benefits, as it can by no means be assumed that a certain level of investment can be equated to particular levels of output. The type of R&D being carried out should also be taken into account when measuring outputs and benefits. Federal and provincial governments intentionally invest in “basic research,” which often has no immediate practical application, yet important new discoveries are often made in this field of research. Some have also questioned the value of R&D that is focused only on copying molecules and doing bioequivalency studies compared to, for example, conducting clinical trials – an area of difference in the R&D focus of generic versus brand-name companies, with the latter concentrating more on clinical trials in Canada.

Perhaps one of the major problems is that the pharmaceutical industry does not lend itself easily to macro-analysis, as there are big differences between different types of drugs and their relative values that considerably complicate the relationship between R&D inputs and outcomes. Not only are there different pricing structures and usage patterns for prescription medicines, over-the-counter drugs, and generic and brand drugs, for example, but there are changes over time in the uses of different drugs, increases in the efficacy of some drugs and differences in side effects, all of which need to be quantified. It might also be argued that the increasing efficacy of drugs may have a ripple effect in the sense that it keeps people alive longer and therefore drives up drug costs, or alternatively that increasing drug use may be damaging to health. Moreover, it can’t necessarily be assumed that all NMEs represent significantly increased value in terms of therapeutic advance, since this varies among drugs and over time. Neither should it be assumed, as Grant Perry, Director, Federal Affairs and Reimbursement at GlaxoSmithKline has noted (G. Perry, personal communication, November 2006), that later entrants into a therapeutic class are necessarily of lower value. In any case, there is likely to be considerable spin-off value from R&D invest-
ment, in terms of research capacity, knowledge generation and more, whether or not NMEs are actually produced. It would be helpful to see a measure of spin-off value included in the analysis.

Although the authors do attempt to control for demographic factors, the results might be more accurate if they also incorporated the effects of population change over time, since this is likely to have a major impact on drug use and expenditure. Provincial-level analyses would also likely produce more meaningful results, as there will be considerable variations in the costs and benefits of R&D spending among different provinces, particularly given provincial controls on drug costs.

According to Lexchin, the proportion of total sales devoted to R&D in Canada has declined significantly since 2002 and now stands at 8.8%, while total prescription drug spending has continued to increase. Perry, on the other hand, notes that R&D investment has continued to rise in dollar terms, but that Canada’s position in global R&D markets has declined due to increasing competition. Clearly, there are a range of factors involved, and the results of this analysis cannot therefore be assumed to apply to the current situation regarding pharmaceutical R&D and its value to Canada.

Correspondence may be directed to: Harold Schroeder, President & CEO, Schroeder & Schroeder Inc., Toronto, ON. E-mail: harold@schroeder-inc.com.

NOTES
1. Back in 1993, Canada’s Research-Based Pharmaceutical Companies (Rx&D) was claiming that there was 10 years of effective patent protection (J. Lexchin, personal communication, September 2006). In 1993, drug approval times were 1,044 days compared to 717 days in 2001, or almost a year longer. Somehow, the decrease of a year did not get reflected in the patent life that Rx&D presented. It might be postulated that the one-year gain in approval time was taken up by longer clinical testing times, but that does not seem to be the case. At most, times from the start of clinical testing to the filing of a submission for approval have increased by 3.5 months during the 1990s. In the United States, effective patent life for selected drugs is between 13.9–15.4 years. Some of that time is accounted for by provisions not available in Canada (patent term restoration = 2.3 years, paediatric exclusivity = 0.5 years), and approval times are about 0.8 years faster in the United States. Using these figures, Canadian effective patent times should be 10.3–11.8 years, a number roughly consistent with the calculation based on shorter approval times.
Response to Pazderka and Schroeder

Réponse à Pazderka et Schroeder

by PAUL GROOTENDORST
Faculty of Pharmacy, University of Toronto
Toronto, ON

LIVIO DI MATTEO
Department of Economics, Lakehead University
Thunder Bay, ON

Pazderka and Schroeder comment on the marked increase in domestic pharma R&D spending that occurred immediately after the federal government lengthened the period of market exclusivity afforded to patented drugs. They suggest that this increase has to be explained by factors other than the policy change. We disagree – we are not aware of any other factors that could explain as effectively the dramatic increase in R&D. That is why we believe that, had the Patent Act revisions not been made, domestic pharma R&D would have been much lower. We recognize that some of the additional domestic pharma R&D spending might have been shifted from other jurisdictions (so that global R&D increased by less than domestic R&D). OECD data, however, suggest that international pharma R&D increased markedly after 1987, and the Patent Act changes may have played a role.
Schroeder expresses concerns about our “simplistic” assumptions, “questionable” calculation of expenditures and “inconsistencies” in our definition of R&D expenditures, but does not identify specific issues. It is therefore difficult to respond to his concerns. For instance, we assessed the effect of the Patent Act changes on two different measures of pharma R&D to ensure that our results were reasonably robust. (They were.) His criticism of our use of the motor vehicle industry R&D as a comparator to pharma R&D is clearer. He argues that the “motor vehicle industry is much less dependent on patent protection than the pharmaceutical industry, and investment in R&D in the Canadian motor vehicle industry has been artificially inflated by the Auto Pact agreement with the United States.” These statements may be true, but it does not follow that the change in motor vehicle sector R&D cannot reflect the effects of factors like changes in federal and provincial R&D tax credits on pharma R&D. Both are capital intensive industries composed of large multinational corporations who exercise discretion over the location of their R&D – it is unclear why inter-industry differences in the degree of reliance on intellectual property protection would matter.

Schroeder further characterizes our comparison of drug cost growth in Canada to that in the US as “misguided.” We agree that patent approval times are shorter in the US, but while differences like these might affect the level of drug costs in the two countries, they do not invalidate a comparison of pre–post 1987 changes in drug costs in the two countries. We agree with Schroeder that the Patent Act changes likely have delayed generic competition until after sales of the brand drug have peaked – this is undoubtedly one of the sources of the increase in drug costs we observed after 1996.

Schroeder points to several difficulties in valuing the health gains from the increase in pharma R&D. Our calculations are based on averages reported in the literature – the mean cost of developing NMEs, the mean health gain from NMEs and mean willingness to pay for health gains. We certainly agree that the value of the drugs actually developed on account of the Patent Act changes could be higher or lower – our intent was to determine the order of magnitude of the estimated value of the policy. That being said, we disagree with the criticism that “… it is extremely unlikely that the domestic R&D environment would be capable of producing four to six NMEs independently, that an additional $4–6 billion invested in R&D would result in drugs launched solely out of Canada, or that they would be developed exclusively for the small Canadian market.” We did not state that the additional NMEs that could be supported with the additional outlays on pharma R&D would necessarily be developed entirely in Canada; indeed, we stated that most domestic R&D involves safety and efficacy testing of drugs developed elsewhere. Nevertheless, such testing is a necessary part of the R&D that might not have occurred without the policy change, and the drugs that were developed on account of this R&D were likely of value to Canadians (and others as well).
Governance, Health Policy Implementation and the Added Value of Regionalization

Gouvernance, mise en œuvre des politiques de santé et valeur ajoutée de la régionalisation

by NASSERA TOUATI, PHD
Assistant Professor, École Nationale d’Administration Publique
Montreal, QC

DANIELLE ROBERGE, PHD
Researcher, Centre de recherche Hôpital Charles Lemoyne
Greenfield Park, QC

JEAN-LOUIS DENIS, PHD
Professor, Université de Montréal
Montreal, QC

RAYNALD PINEAULT, PHD
Researcher, Direction de santé Publique de Montréal
Montreal, QC

LINDA CAZALE, PHD
Fellow Student, Centre de recherche Hôpital Charles Lemoyne
Greenfield Park, QC
Abstract

Objectives: In this paper we focus on governance and the added value of regionalization in the context of health policy implementation.

• What are regional boards’ patterns of action in the governance process?
• How do these patterns favour policy implementation?

Analytical framework: To enhance our understanding of the role of regional boards in governance processes, we relied on four conceptual constructs that corresponded to models of collective action: political, technocratic, democratic and cognitive.

Alongside the four models, we analyzed the impact of governance on health policy implementation using Mazmanian and Sabatier’s general analytical framework, which identifies three types of variables that affect public policy implementation: (1) variables related to the complexity of the problem, (2) statutory variables that structure the implementation of the policy and (3) non-statutory variables related to the context.

Methods: We conducted a qualitative, longitudinal case study of the regional implementation of the Program to Combat Cancer in Quebec.

Findings: This research stresses the added value of a clinico-administrative governance of change, whereby regional boards, in synergy with clinical leaders, participate in the orientation of collective action. Analysis of the regional board’s patterns of action reveals the utility of combined technocratic, democratic, political and cognitive actions.

Résumé

Objectifs : Le présent article porte sur la gouvernance et la valeur ajoutée de la régionalisation dans le contexte de l’application des politiques de santé.

• Quelle est la façon d’agir des régies régionales dans le processus de gouvernance?
• Comment cette façon d’agir favorise-t-elle l’application des politiques?

Cadre analytique : Afin de mieux comprendre le rôle des régies régionales dans les processus de gouvernance, nous nous sommes appuyé sur quatre construits conceptuels correspondant aux modèles d’action collective : politique, technocratique, démocratique et cognitif.

En plus des quatre modèles, nous avons analysé l’incidence de la gouvernance sur
Governance, Health Policy Implementation and the Added Value of Regionalization

la mise en œuvre des politiques de santé en utilisant le cadre analytique général de Mazmanian et Sabatier, qui cerne trois types de variables influençant l’application des politiques publiques : (1) les variables reliées à la complexité du problème, (2) les variables d’origine législative qui structurent la mise en œuvre des politiques et (3) les variables d’origine non législative reliées au contexte.

Méthodes : Nous avons effectué une étude de cas qualitative et longitudinale de la mise en œuvre régionale du Programme de lutte contre le cancer au Québec.


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MANY DEVELOPED NATIONS, THE LEGITIMACY OF THE STATE’S ROLE IN public policy implementation is increasingly being questioned. That a recent issue of Public Administration was devoted to the topic illustrates the scope and relevance of these concerns (see Barrett 2004; Exworthy and Powell 2004; O’Toole 2004; Schofield 2004). Explanations of the problems afflicting policy implementation have long focused on the approach adopted – i.e., top-down (Sarbaugh-Thompson and Zald 1979) or bottom-up (Berman 1978; Hjern et al. 1978). Proponents of the top-down approach address control and communication among hierarchical levels. Supporters of the bottom-up approach, however, consider the political micro-processes at play among stakeholders that have different interests and, often, irreconcilable values. In their view, the implementation of public policy results from negotiation (Strauss 1978) that depends on the structure of the network of stakeholders, their interaction and the distribution of power among them.

Most recent research (e.g., O’Toole 2000; Meier et al. 2004) devoted to public policy analysis places greater emphasis on the question of governance, understood in the broadest sense as the organization of collective action (Prakash and Hart 1999). Governance is concerned more with strategic issues than with management. It centres on a continuous process of interaction and negotiation among stakeholders at multiple levels. To govern is to adopt common representations, structures, rules and performance indicators with a view to coordinating stakeholders so that power can be exercised in a pluralistic manner. Taking a governance perspective makes it possible to go beyond the top-down versus bottom-up debate because it accounts for both process and the distributed nature of collective action. Because governance emphasizes that a number of stakeholders who do not necessarily share the same interests can – and often do – participate in managing public affairs, the concept makes it possible to link...
various levels of analysis concerning the role of the community, civil society, private enterprise, local and regional government and the state (Daly 2003).

In this paper, we focus on governance and the added value of regionalization in the context of health policy implementation. In most Canadian provinces, regionalization – the establishment of an intermediate governing structure at the regional level that assumes functions previously fulfilled by a central or local government (Lewis and Kouri 2004) – has been aimed at reinforcing governance capacity. Ambitions have been high: redefining accountability rules, democratizing decision-making, enhancing responsiveness to public needs, increasing the fairness of resource distribution among regions, developing a more comprehensive approach to health problems, using resources more efficiently and improving continuity of care. Opinions on the effectiveness of regionalization are, however, divided (Church and Barker 1998; Davis 2004; Levine 2004; Sullivan et al. 2004). Even if some progress has been made (Gosselin 1984; Lewis and Kouri 2004; Denis et al. 2004), regionalization's full potential has not been realized (Church and Barker 1998; Lamarche 1996; Lewis 1997; Hurley 2004; Lewis and Kouri 2004).

Our objective here is not to offer an opinion on the potential of regionalization but to generate a more thorough understanding of the role regionalization plays in health policy implementation. We carry this out by exploring two main questions:

- What are regional boards' patterns of action in the governance process?
- How do these patterns favour policy implementation?

In order to answer these questions, we take the Programme de lutte contre le cancer (PLC) (Program to Combat Cancer) adopted by Quebec’s Ministry of Health and Social Services in 1998 (Ministère de la santé et services sociaux 1997) as a good illustration of regionalization’s potential to be an effective governance tool.

We begin our discussion by clarifying the form regionalization has taken in Quebec and the objectives and means PLC adopted. Next, we describe our analytical framework and methodology. We then present and analyze our findings based on an evaluation of PLC’s implementation in the Montérégie region (Roberge et al. 2004). Our paper ends with a general consideration of regionalization and the threats it faces.

Overview

Regionalization in Quebec

Beginning in the 1970s and extending through the end of the 1990s, Quebec was the first Canadian province to gradually regionalize its healthcare system (Turgeon et al. 2003). The province’s regional boards have three main responsibilities:
Governance, Health Policy Implementation and the Added Value of Regionalization

- planning health services
- organizing health services
- allocating resources among healthcare institutions

On the last point, it should be noted that Quebec’s regional regulatory bodies do not control payments to physicians.

Quebec’s Program to Combat Cancer

Quebec’s Ministry of Health and Social Services adopted PLC in response to the province’s high rate of cancer and to address gaps in the organization of services affecting responsiveness to the needs of cancer patients and their families as well as the quality and efficiency of care. To enhance accessibility, continuity and service quality, a provincial task force developed a program that included reorganizing services and establishing integrated regional oncology networks. The reorganization comprised

- creation of regional centres of excellence, whose role was to offer, in conjunction with other local institutions, specialized and ultra-specialized oncological services;
- introduction of procedural and organizational measures to foster healthcare coordination, including the creation of multidisciplinary local, regional and supra-regional teams in oncology; the introduction to each team of a nurse case manager in oncology who would assess clients’ overall needs and coordinate services; the harmonization of professional practices; and the formalization of links between institutions.

Implementing these networks implied strengthening collaboration among professionals as well as various organizations such as hospitals, private medical clinics, community organizations and local community health centres (Centres locaux de service communautaires [CLSCs]), which are primary care facilities offering medical and psychosocial services.

The context in Montérégie

In 1999, the Montérégie health and social service region undertook this process change. Located south of Montreal, Montérégie is the second most populated region in Quebec. Its residents are highly mobile and use health services in neighbouring cities. At the time, oncological services in the region were provided by eight local hospitals, a regional university hospital that in the mid-1990s became a centre of excellence in oncology, 19 CLSCs and several private medical clinics.

In its 1999–2002 strategic plan, Montérégie’s regional board gave high priority to
the fight against cancer. The regional hospital’s recruitment in 1999 of a leading oncologist (one of PLC’s designers and promoters) played a key role in this decision.

Analytical Framework and Methodology

Analytical framework

In order to answer our research questions, we needed first to clarify our understanding of governance and the role of regional boards in governance processes and the determinants of policy implementation success.

GOVERNANCE MODELS

For the purposes of our study, we understood governance to be based on an interactive, multi-centric view of collective action. This means, in particular, that our analysis of governance focused on the roles various stakeholders played in steering change. For instance, regional boards in Canada are often expected to influence physicians – particularly powerful members of the healthcare community – through levers such as resource allocation. Regionalization is also expected to redistribute power among health institutions by strengthening the role of community organizations, which have, historically, been less powerful than hospitals.

To enhance our understanding of the role of regional boards in governance processes, we relied on conceptual constructs that corresponded to models of collective action. These models constitute ideal types as defined by Weber (1992, cited in Encyclopedia Britannica 2006): a “common mental construct in the social sciences derived from observable reality although not conforming to it in detail because of deliberate simplification and exaggeration.” As a conceptual tool, an ideal type is useful for comprehending the reality of a given situation, relationship or organization.

Denis et al. (1998) and Contandriopoulos et al. (2004) identify three models of collective action. The technocratic model involves obedience to a central government, which sets policies, delegates and controls. Under this model, the legitimacy of Quebec’s regional boards derives from the Ministry of Health and Social Services. The political model corresponds to a political perspective on change. Accordingly, a regional board’s “legitimacy” derives from “the fact that significant actors and organizations perceive themselves as being part of the decision process” (Contandriopoulos et al. 2004: 632). Regional boards thus enjoy broad autonomy and adopt tactics, set agendas, define rules of negotiation to influence the redistribution of power and foster negotiation among stakeholders. Under the democratic model, which corresponds to an institu-
tional perspective, a regional board’s legitimacy “comes from making plausible the claim that deliberative processes are not biased and that the governing body can implement policies according to the collective will” (Contandriopoulos et al. 2004: 633). The role of regional boards is therefore to contribute to the democratization of society by fostering public participation and limiting the risk of domination by influential interest groups. As Contandriopoulos (2004) has shown, public participation is a complex political phenomenon. Yet this should in no way be interpreted as a fatalistic statement implying that we should not care about institutional arrangements. Consequently, in this paper we maintain the democratic model as a separate analytical model.

While useful, these three models do not reveal the cognitive nature of the processes by which public policy is implemented. Increasingly, research in this area (Aggeri 1999; Hall 1993; Sabatier and Jenkins-Smith 1993; Schofield 2004) supports placing greater emphasis on the role that knowledge plays in change processes (Touati et al. 2004, 2005). This emphasis gives rise to the cognitive model, which describes the role regional boards play in promoting learning. While the cognitive model is closely linked to the political model, by fostering exploratory learning regional boards are not necessarily aware of the strategic interests for which they are working. Even if knowledge production can be used to change the rules of the game and the distribution of power, comprehending this variable needs to take into account its relative freedom as a distinct phenomenon.

In the final analysis, we have adopted all four possible models of action in order to comprehend fully the role of regional boards in governance processes. As we noted earlier, these models are ideal types, which means that reality often corresponds to a complex combination of the four.

POLICY IMPLEMENTATION AND ITS DETERMINANTS

Alongside the four models, we analyzed the impact of governance on health policy implementation using Mazmanian and Sabatier’s (1983) general analytical framework, which identifies three types of variables that affect public policy implementation. The advantage of this framework is that it allows us to understand, without imposing a restrictive assumption, the variables activated by the regional authority to favour policy implementation. These variables are

- those related to a problem’s complexity (e.g., technical difficulties, behavioural diversity, scope of change);
- “statutory” variables that structure policy implementation (e.g., clarity and coherence of objectives, clarity of a theory of causality, allocation of initial resources, coordination among institutions, possibility of intervention by outsiders, decision-making rules available to stakeholders); and

HEALTHCARE POLICY Vol.2 No.3, 2007 [103]
• “non-statutory” variables related to implementation context (e.g., socio-economic conditions, support from interest groups and stakeholders, stakeholders’ leadership).

Figure 1 illustrates our analytical framework. It reveals that the specific form of governance and its impact on health policy implementation are influenced by a particular context at two levels: the provincial (e.g., the organizing principles of the healthcare system) and the regional (e.g., availability of human and physical resources, nature of pre-existing relationships among stakeholders).

FIGURE 1. Analytical framework: Relations between governance and health policy implementation

Methodology

RESEARCH STRATEGY

In keeping with our analytical framework, our research strategy involved a qualitative, longitudinal case study (Patton 1990; Yin 1994) of PLC’s implementation at the regional level from the project’s inception in 1999 to fall 2003. This approach made it possible to examine the governance process from a dynamic, contextual viewpoint.

DATA SOURCES

Our analysis drew primarily on qualitative data derived from the following sources:
• non-participant observation (beginning October 2001) at most administrative
meetings (N=50) involving regional governance of change;
• semi-structured interviews (N=65) with network promoters (e.g., clinicians and representatives from the regional board), professionals from multidisciplinary teams and hospital managers (e.g., nurse managers, heads of oncology outpatient clinics). We transcribed all interviews and coded them using Nudist 6.0 software;
• documentary analysis, including all inter-organization agreements, task force reports and the steering committee’s financial reports.

We also cross-tabulated the various data sources to strengthen the study’s internal validity.

DATA ANALYSIS

Our data analysis focused primarily on two strategies: a narrative strategy that highlighted the context in which PLC was implemented and a chronological breakdown strategy (Langley 1999) that enabled us to examine how previous actions affected the context in which subsequent actions took place. During the course of our study, we used intermediate written reports and oral presentations to create interactions between our research team and the local stakeholders involved in the policy implementation. This validation process revealed a convergence between our theory of action and stakeholders’ perceptions.

Findings

Descriptive

WAS THE POLICY IMPLEMENTATION SUCCESSFUL?

Considerable progress was made in implementing PLC during the period covered by our study (Roberge et al. 2004). Most of the respondents shared the philosophy and vision the program promoted. We also found that inter-professional trust and respect had developed within local teams in all the hospitals. Similarly, inter-organizational trust appeared to be strong.

From a clinical standpoint, multidisciplinary teams were implemented and met regularly in all the region’s hospitals, and the position of nurse case manager in oncology was created. Numerous measures to coordinate team members were introduced (e.g., patient profiles). Tools to aid clinical intervention, however, were adopted at a slower pace (e.g., quality standards and clinical protocols). In almost all instances, organizational efforts were made to enhance the management of oncological emergencies.

From an administrative standpoint, every hospital made an effort to enhance
the stability of its oncology teams (e.g., by reducing staff rotations). In all instances, respondents said they had benefited from management’s administrative support to create clinical teams. The nature and intensity of such support varied, however, among the hospitals. Those differences appeared, in particular, in professionals’ participation rates in training and the presence or absence of coordinators (e.g., the replacement of nurse case managers during vacation periods).

WHAT DID THE REGIONAL BOARD DO TO SUPPORT POLICY IMPLEMENTATION?

By and large, progress resulted from effective governance. Initially, the regional board decided in early 1999 to mandate the main regional hospital to implement the integrated oncological service network in order to take advantage of its key oncologist’s expertise. In light of resistance from the other hospitals in the region, whose directors and physicians feared the loss of their clientele and their professional autonomy, the regional board decided to involve itself more extensively in the governance of change. The director of the regional board’s medical affairs department approached hospital medical directors with whom he had good relations in order to create a temporary committee responsible for PLC’s implementation. To encourage the hospitals to take part in the change process, this committee divided funding among the various organizations, based on a study of their needs, to cover pharmaceutical services. It also invited the haemato-oncologists to a meeting of the regional medical directors’ advisory board to explain the reorganization objectives. Although the status quo was maintained, it was decided to move ahead with the project.

To this end, a steering committee was created comprising representatives of the regional board and the region’s health organizations. During the period of our study, the steering committee played a decision-making role with regard to developing strategy related to the integrated oncological services network. It also managed the budget granted by the regional board to implement the program. At the same time, the regional board attempted to broaden participation in governance by adding an advisory committee to the steering committee. This advisory committee comprised representatives of healthcare organizations, various types of healthcare professionals, community organizations and users.

Because of physician resistance, the steering committee adopted an incremental, small-step approach to change (Touati et al. 2006). In phase 1, it sought to overcome stakeholder resistance. This endeavour led to a search for regional allies and a revision of the governance structure. During phase 2, the committee introduced case manager nurses, hoping these agents of change would gradually alter teams’ practices. Considerable effort was invested in training these nurses, who received extensive supervision from a regional expert. In phase 3, the committee consolidated change by gradually training the other members of the hospital teams and partner organizations.
Psychosocial professionals were also added to the outpatient clinic teams. Finally, in phase 4 the committee sought to involve the physicians more extensively by establishing a regional haematology-oncologists’ committee, which was responsible for harmonizing and enhancing medical practices using evidence-based information. The steering committee also endeavoured to broaden the role of primary care physicians in managing cancer patients by promoting the idea that they could devote part of their practices to the treatment of acute-stage cancer patients. However, the regional board department responsible for organizing general medical services has, to date, not accepted this approach, arguing that it could hamper primary care.

During all four phases, the clinical leaders played a predominant role insofar as they often initiated the measures adopted and worked hard to ensure the measures’ success. By relying on their expertise and several tactics to exercise influence, they succeeded in altering practices (Touati et al. 2006). This experience highlights the importance of the clinical governance of change, and the role played by the regional board has been essential in several respects. As one clinical leader told us:

> Working with the regional authority is innovative. We assume that regional boards and hospitals talk to each other. But, it is not the real life. We have proven that, in Montérégie, we are able to work together. The regional authority has been very helpful; probably without this partnership with the regional authority, things would have been different. We have seen what a regional authority can do for the network. Yes, I think that is innovative.

The regional board’s essential role in implementing PLC and steering change was illustrated in several ways and on numerous occasions:

- The board’s initial intervention (i.e., revision of governance structures and recruitment of new stakeholders) was key to defusing the implementation crisis and overcoming resistance.
- The board provided funding to implement PLC.
- The board planned the care continuum by assessing the needs of Montérégie’s population with respect to services and organization.
- Sustained participation by board representatives in various governance committees and working groups fostered discussions and helped to coordinate initiatives.
- The board’s practical support (e.g., organizing committee teleconferencing) enabled necessary discussions.
- Evaluations undertaken by the board, especially on the role of psychosocial professionals, encouraged stakeholders to question the relevance of certain choices pertaining to service organization.
- The board guaranteed coherence of the overall organization of services (e.g., involvement of general practitioners in treating cancer patients).
Analytic

HOW CAN WE UNDERSTAND THE REGIONAL BOARD’S MODELS OF ACTION?

Our retrospective analysis of the regional board’s initiatives revealed the combined mobilization of the four models discussed earlier. Following a technocratic model, at the outset the regional board adopted measures designed to defuse the crisis by reviewing governance structures and emphasizing its ministry-mandated responsibilities. The democratic model surfaced during the implementation crisis. At that time, there was an attempt to include stakeholders who traditionally have wielded less power (e.g., community organizations and users) in the advisory committee. To date, this model of action has had relatively little impact, most likely because the crisis was resolved.

Use of the political model was, however, essential to PLC’s implementation. Evidence of this model arose in the deployment of the regional board’s economic power (i.e., funds drawn from its own budget) to influence negotiations among stakeholders. The political model was also manifested through the board’s contacts with allies in the region, alliances with clinical leaders, orientation of the decision-making agenda through governance structures and authority over service organization.

The regional board also adopted several measures that conform to the cognitive model. In order to encourage a collective learning process, it facilitated exchanges among stakeholders, implemented information systems (e.g., tumour registry), planned service organization using evidence-based information, assessed the new role of psychosocial professionals and involved an evaluation team.

HOW HAS GOVERNANCE SUPPORTED POLICY IMPLEMENTATION?

In order to deal with suboptimal conditions, the regional board gradually tackled the variables that affected policy implementation, whether associated with context, formal structuring or problem complexity. It is clear that an effort was initially made to intervene to influence context-related variables. For example, an attempt was made to gain the support of certain stakeholders, such as nurses. Nurses were allies of change in light of their increased prestige as case managers. Some hospital medical directors also rallied to the program. In fact, they trusted the regional board and were also more
Governance, Health Policy Implementation and the Added Value of Regionalization

aware of PLC’s potential because of the precariousness of their institutions in terms of medical staff availability.

In light of such support, governance focused on structuring implementation. Change was initiated through the allocation of resources, PLC’s objectives were specified and clarified (e.g., the regional action plan and its dissemination, measures adopted to assess the effects of change) and efforts were made to promote stakeholder coordination at the regional and provincial levels. The participation of regional stakeholders in the deliberations of the provincial committee also ensured feedback on the provincial implementation strategy.

Reducing the scope of change also helped by limiting the complexity of implementation. For example, it was decided to avoid broaching at the outset the question of modifying service corridors. Indeed, stakeholders counted more on possible gains in the comprehensiveness and continuity (especially among team members) of care.

Success resulted from establishing synergy between clinical and administrative leadership. Stakeholder support, for instance, was made possible by the efforts of the regional board, which rallied to champion certain hospital medical directors and clinical leaders, who in turn banked on the nurse case managers. Similarly, stakeholder coordination was carried out by relying on administrative and clinical leaders.

Table 1 summarizes the phases involved in PLC’s implementation. For each phase, we have highlighted the governance process, emphasizing the regional board’s patterns of action (Denis et al. 1998) and the roles of other stakeholders. The final column explains, following Sabatier and Mazmanian (1983), how the governance process supported policy implementation.

Discussion and Conclusion

Our research underscores the added value of a clinico-administrative governance of change, whereby regional boards, in co-operation with clinical leaders, orient and direct collective action. Such a governance strategy can help to ensure the implementation of health policies and, as we have shown, can influence the determinants of policy implementation: complexity, implementation structure and context.

As the PLC case revealed, the specific form of governance and its impact on health policy implementation depend on pre-existing context (e.g., the availability of financial resources, relationships among stakeholders, the presence of leaders). More precisely, our analysis of the regional board’s actions reveals the utility of a combined adoption of technocratic, democratic, political and cognitive models.

A question that naturally arises is, however, whether another stakeholder could have assumed the role played by Montérégie’s regional board. Our study strongly suggests that fulfillment of this role required a sufficient knowledge of local context, which was particularly useful during negotiations. We believe that a provincial body
<table>
<thead>
<tr>
<th>PHASE</th>
<th>GOVERNANCE</th>
<th>VARIABLES MOBILIZED TO FOSTER PLC’S IMPLEMENTATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 1: Overcame stakeholders’ resistance</td>
<td>Political model: Mobilized stakeholders with whom trusting relationships existed; influenced the decision-making agenda by participating in governance. Technocratic model: Relied on the regional board’s political legitimacy to broaden stakeholders’ participation. Democratic model: Involved stakeholders that traditionally exercised little power in governance. Clinical leaders: Forged alliances with nurses.</td>
<td>Context: Sought allies. Implementation: Reviewed governance structures.</td>
</tr>
<tr>
<td>Phase 2: Introduced agents for change</td>
<td>Political model: Used financial resources to fund the role of case manager nurses and to orient the decision-making agenda. Clinical leaders: Trained and supported nurses in fulfilling their role.</td>
<td>Complexity: Simplified change by initially confining the initiative to the introduction of the nurse case manager role. Implementation: Provided resources for change.</td>
</tr>
<tr>
<td>Phase 3: Consolidated change</td>
<td>Political model: Used financial resources to fund the expansion of clinical teams and to orient the decision-making agenda. Cognitive model: Targeted priorities in light of the assessed needs and validated them by means of evaluation projects related to the choices adopted. Clinical leaders: Trained and supported the entire team.</td>
<td>Implementation: Clarified the pattern of action by designing and disseminating a regional action plan; validated the theory of action by evaluating the service organization model and the change process; coordinated stakeholders.</td>
</tr>
<tr>
<td>Phase 4: Involved physicians more extensively</td>
<td>Cognitive model: Supported exchanges among professionals and promoted the process using evidence-based information. Political model: Relied on the regional board’s authority to ensure the program’s implementation did not harm primary care services. Clinical leaders: Led the regional medical committee.</td>
<td>Implementation: Clarified the pattern of action by fostering the emergence of consensus concerning medical practices; endeavoured to involve primary care physicians more extensively.</td>
</tr>
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would have had more difficulty gathering this information and that a local stakeholder in possession of levers similar to those described above (e.g., financial incentives, alliances) was best positioned to carry out such a role.

Analyzing the role of regional boards illuminates the ways in which governance structures can support complex changes. That said, we believe that if what is at stake is no longer to implement a health policy but to coordinate such policies to produce optimal efficiency, population-based regional governance is probably more effective than other models (e.g., governance centred on the organization of services by diseases). Regionalization’s added value resides precisely in the coordination of disease-based networks with primary care services. Such coordination is essential to the continuity and comprehensiveness of care.

The Montérégie experience indeed shows that making a regional board responsible for ensuring the integration of services by disease does not lead to the disintegration of primary care (Leutz 1999). As some experts have noted (Lenay et al. 2002), industrialized jurisdictions are witnessing a major change in the purpose of governance, which henceforth will focus on the care of people suffering from multiple diseases. To this end, the role played by stakeholders (e.g., regional boards) that have a systemic perspective and are accountable for the health of entire populations is all the more relevant.

Beyond the lessons to be drawn from implementing PLC in Montérégie, insights concerning regional boards’ models of action can be gained. First, it is important to emphasize the value of the cognitive model. Indeed, this model could provide a counterbalance to the political model, which is often associated with regionalism (a tendency by regional boards to demand resources for their regions while claiming that doing so enhances access to healthcare). It seems not unreasonable to believe that the cognitive model could limit the perverse effects of a model of action that induces strategic actors to attempt to bolster their power by, for example, monopolizing resources. Deployment of the cognitive model would make it possible to validate choices with respect to service organization (e.g., by referring to their effect on healthcare accessibility).

Unlike certain analysts (e.g., Church and Barker 1998), we do not believe that regionalization must go hand in hand with the containment of service utilization to avoid transaction costs stemming from inter-regional transfers. ...
possible to serve the population of one region by means of another region’s resources if such a transfer allowed for gains in the overall efficiency of care, notwithstanding transaction costs. Such a scenario would be especially possible in regions surrounding large cities, where there are fewer problems in access to care.

It is important at this point, however, to insert a note of caution. While the utility of the cognitive model is obvious, its implementation is nonetheless far from straightforward. Evaluating service organization is complex (Pineault et al. 1993), and regional boards do not necessarily have the staff necessary to oversee the process. This dilemma certainly warrants consideration in terms of central authorities’ responsibility to provide adequate support for regions. No doubt, the expertise of public health departments would prove highly useful in this learning process.

Correspondence may be addressed to: Nassera Touati, PhD, École nationale d’administration publique, 4750 avenue Henri-Julien, 5th floor, Montreal, QC H2T 3E5; tel.: 514-849-3989, Xrt. 3986; fax: 514-849-3369.

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Governance, Health Policy Implementation and the Added Value of Regionalization


Healthcare Use of Families of Injured Workers Before and After a Workplace Injury in British Columbia, Canada

Le recours aux soins de santé par les familles de travailleurs blessés avant et après un accident de travail, en Colombie-Britannique, Canada

JUDY A. BROWN, HARRY S. SHANNON, PEGGY MCDONOUGH AND CAMERON A. MUSTARD

Abstract

Objectives: To examine the overall healthcare and mental healthcare services use of families of injured workers before and after a workplace injury.

Methods: We use an administrative database that links individual publicly funded healthcare data and Workers’ Compensation Board (WCB) data for the entire population of British Columbia (BC), Canada. The spouses and children of all injured workers who filed a WCB claim in 1994 and missed one or more days of work due to the injury (lost time) were included. We compare their change in use of healthcare services relative to a year before the injury to families of workers who did not require time off for their injuries (no lost time) and families of individuals who were not injured (non-injured comparisons).

Results: Differences in healthcare services use among the three groups of spouses were marginal, and differences for increases in mental healthcare services use were non-significant. As well, all three groups of children decreased their use of physician and hospital services and increased their use of mental healthcare services, with very little difference among groups.

Conclusion: This was a descriptive study looking at a broad group of injured workers and their families. Even modest increases in healthcare use following a workplace injury have some basis for further study.

Résumé

Objectifs : Examiner le recours général aux soins de santé et de santé mentale par les familles de travailleurs blessés, avant et après un accident de travail.

Méthodes : Nous utilisons une base de données administrative reliant des données individuelles sur les soins de santé publics et celles du Workers’ Compensation Board (WCB) pour toute la population de la Colombie-Britannique, Canada. Les conjoints et enfants de tous les travailleurs blessés qui ont présenté une demande d’indemnisation en 1994 et qui ont manqué une journée de travail ou plus (temps perdu) à cause de l’accident de travail ont été inclus. Nous avons comparé leur recours aux soins de santé à celui qu’il était un an avant l’accident de travail, à celui des familles...
de travailleurs qui n’ont manqué aucune journée de travail (aucun temps perdu) à la suite de l’accident, ainsi qu’à celui des familles de travailleurs qui n’avaient subi aucun accident de travail (comparaisons avec des non blessés).

**Résultats :** Les différences entre les groupes de conjoints étaient minimes et les différences dans les augmentations du recours aux soins de santé mentale n’étaient pas significatives. On a observé également, chez les trois groupes d’enfants, une diminution du recours à des services médicaux et hospitaliers et une augmentation du recours à des services de santé mentale; il y avait très peu de différence entre les groupes.

**Conclusion :** Il s’agissait d’une étude descriptive qui visait à examiner un vaste groupe de travailleurs blessés et leurs familles. Même de faibles augmentations du recours aux soins de santé après un accident de travail justifient une étude plus poussée.

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**FULL TEXT ONLINE**

**Determinants of Unacceptable Waiting Times for Specialized Services in Canada**

**Facteurs déterminants des temps d’attente inacceptables pour l’obtention de services spécialisés au Canada**

**CLAUDIA SANMARTIN, JEAN-MARIE BERTHELOT AND CAMERON N. MCINTOSH**

**Abstract**

**Background:** Much of the current evidence regarding timely access to healthcare services focuses on the duration of the waiting time as the principal determinant of wait time acceptability. We conducted the first national-level analysis of wait time acceptability in Canada to identify the determinants of unacceptable waits for specialized healthcare services, including selected demographic and socio-economic variables.

**Methods:** We analyzed data reported by respondents to a national survey on access to healthcare services who accessed specialized services (i.e., specialist visits, non-emergency surgery and selected diagnostic tests) during a 12-month period. We used univariate analyses and weighted logistic regression to examine the relation between wait time acceptability and selected demographic, socio-economic and health status factors for each specialized service.

**Results:** Between 17% and 29% of patients who waited for a specialized service declared that their waiting time was unacceptable. Most individuals reported waiting less than 3 months for their services. Between 10% and 19% of those who waited indi-
cated that waiting for care affected their lives. Results of the logistic regression analyses showed that longer waits and adverse experiences during the waiting period were significantly associated with higher odds of reporting an unacceptable waiting time for all three types of specialized services. The role of socio-economic and demographic factors on wait time acceptability was limited. Individuals with lower education were consistently less likely to consider their waiting times unacceptable. Patients less than 65 years of age were more likely to consider their waiting times unacceptable for specialist visits and diagnostic tests.

Interpretation: Our study shows that the primary determinants of waiting time acceptability are the length of the waiting time and the effects of waiting on the patient’s life. In addition, some patient characteristics, such as age and education, may play a role, pointing to the potential role of patient expectations in determining the acceptability of waits for specialized services.

Résumé


Méthodes : Nous avons analysé des données recueillies dans le cadre d’un sondage national sur l’accès aux services de santé auprès de répondants qui ont cherché à obtenir des services spécialisés (c.-à-d. consultation de spécialistes, chirurgies non urgentes et tests diagnostiques sélectionnés) sur une période de 12 mois. Nous avons utilisé des analyses univariées et une régression logique pondérée pour examiner la relation entre l’acceptabilité du temps d’attente et des facteurs démographiques, socio-économiques et de santé sélectionnés pour chaque service spécialisé.

Résultats : Entre 17 % et 29 % des patients qui ont dû attendre pour recevoir un service spécialisé ont déclaré que le temps d’attente était inacceptable. La plupart des répondants ont dit avoir attendu moins de trois mois pour obtenir les services. Entre 10 % et 19 % de ceux qui ont attendu ont indiqué que l’attente a eu une incidence sur leur vie. Les résultats des analyses de régression logistique ont révélé que des temps d’attente plus longs et des expériences négatives pendant l’attente étaient associés de manière significative à une probabilité accrue de déclarer un temps d’attente inacceptable pour les trois types de services spécialisés. Les facteurs socio-économiques et démographiques n’ont joué qu’un rôle limité dans l’acceptabilité des temps d’attente. Les personnes ayant un niveau d’instruction moins élevé étaient constamment moins susceptibles de considérer leurs temps d’attente comme étant inacceptables. Les patients âgés
de moins de 65 ans étaient plus susceptibles de considérer leurs temps d’attente pour cons- 
ulter des spécialistes et obtenir des tests diagnostiques comme étant inacceptables.
Interprétation : Notre étude montre que les principaux facteurs déterminants de l’acceptabilité des temps d’attente sont la durée de l’attente et les effets de cette dernière sur la vie du patient. Certaines caractéristiques des patients, telles que l’âge et le niveau d’instruction, peuvent également influer sur l’acceptabilité, ce qui laisse soupçonner que les attentes des patients jouent peut-être un rôle dans la détermination de l’acceptabilité des temps d’attente pour l’obtention de services spécialisés.

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Determinants of Waiting Time for a Routine Family Physician Consultation in Southwestern Ontario
Facteurs déterminants du temps d’attente pour consulter un médecin de famille dans le sud-ouest de l’Ontario

AMARDEEP THIND, CATHY THORPE, ANDREA BURT, MOIRA STEWART, GRAHAM REID, STEWART HARRIS AND JUDITH BELLE BROWN

Abstract

Waiting times are a reality in Canada’s publicly financed single-payer healthcare system. While there are ample data about waiting times for specialized investigations and procedures, few data exist about waiting times to see family physicians, and determinants of this wait. We analyzed data from a survey of 731 family physicians in southwestern Ontario to understand physician- and practice-level determinants of waiting time. Physician gender, usual number of patients seen per week, involvement in teaching and population served were the key determinants of physician-reported waiting time.

Résumé

Les temps d’attente sont une réalité du système de soins de santé canadien – un système à payeur unique financé par l’État. Bien qu’il existe amplement de données sur les temps d’attente pour les enquêtes et procédures spécialisées, il en existe peu sur les temps d’attente pour consulter les médecins de famille et sur les facteurs déterminants de ces temps d’attente. Nous avons analysé des données provenant d’une enquête menée auprès de 731 médecins de famille dans le sud-ouest de l’Ontario afin de comprendre les facteurs déterminants liés aux médecins et à leur pratique et qui influent
Wait Times for Paediatric Rehabilitation
Temps d’attente pour la réadaptation pédiatrique

LISA GRILLI, DEBBIE EHRMANN FELDMAN, BONNIE SWAIN, JULIE GOSSLIN, FRANÇOIS CHAMPAGNE AND RAYNALD PINEAULT

Abstract

Background: Early therapy intervention for children with disabilities may improve functional outcomes. Access to paediatric rehabilitation services can sometimes be difficult. Objectives: To describe waiting time to receive physical therapy (PT) and occupational therapy (OT) services at rehabilitation centres for young children with physical disabilities; to examine factors associated with these waiting times. Design: Prospective cohort. Subjects: Two hundred and six children with physical disabilities, aged 6 to 72 months, referred in 2002–2004 from the Montreal Children’s Hospital and Sainte-Justine Hospital to paediatric rehabilitation centres. Measures: Data on date of referral, age, gender and diagnosis were obtained from the hospital databases. Data on date of first PT or OT appointments at the rehabilitation centre, family socio-demographics and disability severity (WeeFIM) were obtained during parental interviews. Results: Half of the sample waited more than 7 and 11 months for PT and OT services, respectively. Shorter waiting time was significantly associated with younger child’s age and referral to one particular rehabilitation centre. Conclusion: Children with physical disabilities experience long waiting times for PT and OT rehabilitation services. Strategies to improve timely service delivery are needed.

Résumé

Contexte : Une intervention thérapeutique précoce chez les enfants atteints de handicaps pourrait améliorer les résultats fonctionnels. L’accès à des services de réadaptation pédiatrique peut parfois s’avérer difficile.
Objectifs : Décrire les temps d’attente pour recevoir des traitements de physiothérapie et d’ergothérapie dans des centres de réadaptation pour les jeunes enfants handicapés; examiner les facteurs associés à ces temps d’attente.
Conception : Cohorte prospective.
Mesures : Les données sur la date de la recommandation, l’âge, le sexe et le diagnostic ont été obtenues à partir des bases de données des hôpitaux. Les données sur la date du premier traitement de physiothérapie ou d’ergothérapie au centre de réadaptation, la composition sociodémographique de la famille et la gravité du handicap (WeeFIM) ont été obtenues dans le cadre d’entrevues avec les parents.
Résultats : La moitié de la cohorte a attendu plus de sept et onze mois pour obtenir des traitements de physiothérapie et d’ergothérapie respectivement. Les temps d’attente moins longs étaient associés de manière significative à des enfants plus jeunes et à un aiguillage vers un centre de réadaptation particulier.
Conclusion : Les enfants atteints de handicaps physiques doivent attendre plus longtemps pour obtenir des services de physiothérapie et d’ergothérapie. Des stratégies visant à améliorer la prestation des services en temps opportun doivent être élaborées.

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