Reforming Canadian Primary Care – Don’t Stop Half-Way
BRIAN HUTCHISON

Alternative Level of Care: Canada’s Hospital Beds, the Evidence and Options
JASON M. SUTHERLAND AND R. TRAFFORD CRUMP

Cost-Control Mechanisms in Canadian Private Drug Plans
JILLIAN KRATZER ET AL.

Adverse Events Associated with Hospitalization or Detected through the RAI-HC Assessment among Canadian Home Care Clients
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Data Matters  •  Discussion and Debate  •  Research Papers
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MÉLANIE BOURASSA FORCIER AND FRANÇOIS NOËL

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Adverse Events Associated with Hospitalization or Detected through the RAI-HC Assessment among Canadian Home Care Clients

DIANE DORAN, JOHN P. HIRDES, RÉGIS BLAIS, G. ROSS BAKER, JEFF W. POSS, XIAOQIANG LI, DONNA DILL, ANDREA GRUNEIR, GEORGE HECKMAN, HÉLÈNE LACROIX, Lori MITCHELL, MAEVE O’BEIRNE, ANDREA FOEBEL, NANCY WHITE, GAN QIAN, SANG-MYONG NAHM, ODILIA YIM, LISA DROPPO AND CORRINE MCISAAC

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Relation entre l’adoption des technologies de l’information sur la santé et les schémas de pratique des médecins de famille au Canada : données provenant des sondages nationaux des médecins de 2007 et de 2010
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Path Dependence and Health Policy: Intersections between the Past and the Future

On Walmgate Street in York, England, you can order kebabs or burgers from a restaurant with a storefront that is exactly one perch long, a property boundary and unit of measurement that survives from Viking times. Its persistence hundreds of years and many generations later in the modern streetscape is a classic example of path dependence.

While path dependence is perhaps most obvious in the case of physical structures, they are by no means the only context in which current decisions or situations are shaped by past circumstances. Examples in economic, cultural and other contexts abound.

Indeed, one could argue that embedding effective practice and healthy behaviours – or uprooting well-established practices that no longer serve us well – is one of the key challenges of health management and policy. At the core is the fundamental question: how can we make the right thing to do the easy thing to do? This applies to thousands of micro-level decisions made every day, such as how best to organize a surgical cart, and to broad challenges in health promotion, such as which features of urban design are most likely to encourage physical activity at the population level.

This issue of Healthcare Policy / Politiques de Santé features a number of papers that address aspects of this challenge, from documenting gaps and their causes to exploring policy options to address them. Brian Hutchison focuses on primary healthcare reform. This is an area of enduring policy focus around the world, reflecting its complexity and importance to health and healthcare systems. Hutchison’s paper takes a fresh look at what has changed, what has not and why. In contrast, Sisira Sarma and his colleagues examine a very specific aspect of family practice: whether use of health information technology in primary care is associated with patient visit numbers and visit length.

Pharmaceutical policy is another highly complex area where history and context affect decisions and outcomes today. This issue of the journal explores a number of facets of this domain, from cost-control mechanisms in private or public drug plans (Jillian Kratzer et al.) to potential conflict of interest in reimbursement decisions (David Hughes and Bryn Williams-Jones). The policy choices that we make in these and other areas are likely to influence costs and outcomes for years to come.

Likewise, Jason Sutherland and Trafford Crump address the mismatch between patient needs and resources used represented by alternative level of care in hospitals. Future decisions about the policy alternatives that they discuss may well be informed by the analysis of Saad...
Rais and colleagues on high-cost users of healthcare services. Many of the home care clients studied by Diane Doran and her co-authors from across the country would fall into this category. Their research provides important insight into the frequency and types of adverse events experienced for those receiving home care.

Whichever areas of health policy are your current focus, I hope that you will find new insights and food for thought in the journal’s pages. After all, to twist George Santayana’s famous quotation somewhat, those who are unaware of how the past influences the present are condemned to repeat it – and to reinforce gaps in quality, access and health that exist today or, alternatively, risk inadvertently disrupting those paths that help us to achieve better health, better care and better value.

JENNIFER ZELMER, BSC, MA, PHD
Editor-in-chief

NOTE
Dépendance au sentier et politiques de santé : entrecroisements entre passé et avenir

Sur la rue Walmgate à York, en Angleterre, on peut commander un kébab ou un hamburger à un commerce dont la largeur mesure exactement une perche¹, une unité de mesure foncière qui persiste depuis l’époque des Vikings. Des centaines d’années plus tard et après plusieurs générations, la présence de cette unité de mesure dans un décor urbain moderne est un exemple classique de la dépendance au sentier.

Bien que la dépendance au sentier soit un concept qui s’observe plus facilement dans les structures physiques, ce n’est pas uniquement là que les décisions ou situations actuelles sont dictées par des circonstances du passé. Il en existe une multitude d’exemples en économie, dans la culture et dans bien d’autres contextes.

En effet, on peut avancer que l’inclusion de pratiques efficaces ou de comportements sains – ou encore, l’élimination de pratiques bien établies qui ne sont plus vraiment utiles – et un des principaux défis auxquels se confrontent la gestion et les politiques en santé. La question fondamentale est de savoir quelles sont les bonnes actions pour rendre les choses plus faciles. Cela s’applique aussi bien aux milliers de petites décisions quotidiennes, telles que la meilleure façon d’organiser un chariot de chirurgie, qu’aux grands défis liés à la promotion de la santé, tels que les caractéristiques d’urbanisme qui favorisent davantage l’activité physique dans la population.

Ce numéro de Politiques de Santé / Healthcare Policy présente des articles qui abordent ces défis, allant des causes derrière les lacunes en matière de documentation jusqu’à l’étude des choix politiques pour les traiter. Brian Hutchison se penche sur la réforme des soins de santé primaires. Partout au monde, ce secteur fait l’objet d’une grande attention en raison de sa complexité et de son importance pour la santé et pour les systèmes de services de santé. L’article de Hutchison s’interroge sur ce qui a changé, ce qui n’a pas changé et pourquoi. Pour sa part, Sisira Sarma et ses collègues examinent un aspect précis de la pratique familiale : à savoir s’il y a un lien entre l’utilisation des technologies d’information sur la santé et le nombre ou la durée des consultations auprès du médecin.

Les politiques sur les produits pharmaceutiques constituent un autre secteur très complexe où l’histoire et le contexte affectent les décisions et les résultats actuels. Le présent numéro de la revue en explore certaines facettes, que ce soient les mécanismes de contrôle des coûts dans les régimes d’assurance médicaments privés et publics (Jillian Kratzer et al.) ou encore les possibles conflits d’intérêts dans les décisions touchant le remboursement (David
Hughes et Bryn Williams-Jones). Les choix de politiques que nous faisons dans ces secteurs, comme dans d’autres, auront certainement des répercussions sur les coûts et les résultats pour les années à venir.

Dans le même ordre d’idées, Jason Sutherland et Trafford Crump s’intéressent au décalage entre les besoins des patients et les ressources employées, tel que représenté par la question des autres niveaux de soins dans les hôpitaux. D’éventuelles décisions quant aux choix de politiques qu’ils abordent pourraient être éclairées par l’analyse de Saad Rais et collaborateurs au sujet des usagers qui coûtent cher aux services de santé. Plusieurs des clients qui reçoivent des soins à domicile au Canada, étudiés par Diane Doran et ses coauteurs, pourraient faire partie de cette catégorie. Leur recherche donne d’importantes pistes sur la fréquence et le type d’événements indésirables vécus par ceux qui reçoivent des soins à domicile.

Quel que soit le secteur des politiques de santé qui vous intéresse, j’espère que vous trouverez matière à réflexion dans ces pages. Après tout, on peut reformuler la célèbre citation de George Santayana en disant que ceux qui ne savent pas à quel point le passé influence le présent sont condamnés à le répéter, et à accentuer les écarts de qualité, d’accès et de santé qui existent de nos jours, ou encore, à rompre par mégarde des sentiers qui pourraient nous aider à atteindre une meilleure santé, de meilleurs soins et une plus grande efficacité.

Jennifer Zelmer, BSc, MA, PhD
Rédactrice en chef

NOTE
Reforming Canadian Primary Care – Don’t Stop Half-Way

Réforme des soins de santé primaires au Canada – n’arrêtons pas en plein milieu

BRIAN HUTCHISON

Abstract
Strong primary care is a fundamental underpinning of high-performing health systems. Sadly, primary care infrastructure and performance in Canada lag behind many of our international peers. Although substantial reforms have been implemented over the past decade, progress has been uneven, and no province has all the essential system elements in place. Continued investment is both needed and affordable. However, whether those investments – and others necessary to strengthen medicare – are made will be determined largely by the ongoing clash between communitarian and libertarian values.

Résumé
La force des soins de santé primaires constitue un pilier fondamental pour le rendement optimal des systèmes de santé. Malheureusement, l’infrastructure et le rendement des soins primaires au Canada accusent un retard par rapport à plusieurs de nos pairs internationaux. Bien que d’importantes réformes aient été mises en œuvre au cours des derniers dix ans, la progression reste inégale et aucune province n’a encore en place tous les éléments essentiels du système. Il est nécessaire de poursuivre les investissements, et nous avons les moyens de le faire. Cependant, la réalisation de ces investissements – ainsi que celle des investissements nécessaires pour renforcer l’assurance santé – dépendra grandement du conflit constant entre les valeurs communautariennes et les valeurs libertariennes.
Unfinished Business
The medicare we have today is not the entire program envisioned by Tommy Douglas and Emmett Hall. In 1961, Douglas said: “This [the proposed Saskatchewan Medical Care Insurance plan] ... will prove to be the forerunner of a national medical care insurance plan. It will become the nucleus around which Canada will ultimately build a comprehensive health insurance program which will cover all health services – not just hospitalization and medical care – but eventually ... all other services which people receive.” Featured prominently in the Hall Commission Report (Royal Commission 1964) was a “Health Charter for Canadians” calling for a comprehensive, universal health service program “includ[ing] all health services, preventive, diagnostic, curative and rehabilitative, that modern medical and other sciences can provide.” The Commission made specific recommendations for coverage of vision care, dental care and pharmaceuticals. This vision has yet to be realized.

Nevertheless, Professor Ted Marmor at Yale University has referred to Canadian medicare as a public policy miracle. Perhaps what is truly miraculous is that in an inherently unequal capitalist society, where access to almost all other goods and services depends on ability to pay, the majority of Canadians supported, and continue to support, a program that rests on the fundamental principle that access to care should be determined solely by medical need. Many of us take pride and delight in this anomaly, while brushing aside unsettling questions about the limits of medicare. But if the principle of care based on need deserves our support in relation to hospital and physicians’ services, why should it stop there? What about other beneficial health services such as pharmaceuticals, vision care, dental care, home care, chiropractic services and rehabilitation therapies? We have few principled answers.

Primary Considerations: A Roadmap
Here, however, I narrow the focus to primary care. I hope to make the following points:

• A strong primary care sector is vital to health system performance and outcomes.
• Canada’s primary care performance lags behind that of many of our peer countries.
• Governments at the federal and provincial/territorial levels in Canada have made substantial investments in strengthening primary care since 2000.
• Progress has been uneven across the country, and no province has all the essential elements in place.
• Nevertheless, the reforms are starting to bear fruit.
• Because the process of primary care renewal is incomplete, substantial further investments are required.
• Government spending on primary care remains modest.
• Increased government or total spending on healthcare is unlikely to threaten economic performance and need not crowd out public spending on other social priorities, such as education.
• And finally, although facts and evidence can inform policy discussions, a clash between libertarian and communitarian values underlies ongoing conflict about the future of medicare.
A Consensus of Evidence
There is now a compelling body of evidence, much of it produced or summarized by Barbara Starfield, demonstrating the association between strong primary care systems and superior and more equitable health outcomes (although not necessarily lower costs) (Kringos et al. 2013; Macinko et al. 2003; Starfield 2012; Starfield and Shi 2002).

Canadian policy makers and commentators are increasingly recognizing the fundamental importance of primary care. Fred Horne, Alberta’s Minister of Health and Wellness, has referred to putting “primary health care where it rightfully belongs, at the centre of the health system” (Horne 2012). The Drummond Commission on the Reform of Ontario’s Public Services recommended that the government “[m]ake primary care a focal point of a new integrated health model” (Commission 2012). The federal Minister of Health, Leona Aglukkaq, recently stated that “Community-based primary health care is at the heart of our health care system” (CIHR 2013).

Not Even the Bronze for Canada
But Canada has far to go. Figure 1 summarizes the Commonwealth Fund’s 2010 assessment of the comparative performance of the healthcare systems of seven high-income countries (Davis et al. 2010). The performance rankings were based on Organisation for Economic Co-operation and Development (OECD) health data and international surveys of patients and primary care physicians conducted by the Fund. Underlying this picture are some potential policy lessons about primary care.

**FIGURE 1.** Health system rankings, Commonwealth Fund 2010

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Source: Commonwealth Fund
Two countries stand out in overall performance: the Netherlands and the United Kingdom. Although they differ substantially regarding healthcare financing and the role of private insurance, their primary care policy and system characteristics have much in common. Both have invested heavily over the last two decades in strengthening primary care. Both primary care systems feature mandatory patient registration with a provider, no user charges, local governance, gate-keeping, capitation-based blended payment for physicians, interdisciplinary teams, and major investments in quality improvement initiatives and electronic medical records (EMRs). The relationship between overall health system performance and investment in primary care, and the commonalities between the primary care systems of the highest-performing countries, is unlikely to be pure coincidence. Their policies and system features deserve serious consideration in Canada.

Legacy of a Lost Decade
Many high-income countries focused on primary care during the 1990s. Canada barely managed to tread water. We have yet to catch up; our performance continues to lag, particularly in timely access to care and in primary care infrastructure. The Commonwealth Fund surveys highlight opportunities for improvement in Canadian performance in primary care.

Whether from the perspective of the general population, of people with chronic or recent serious health problems, or of primary care physicians, measures of access to primary care lag well behind our peers. For example, Canada tied for last among 11 countries in the percentage of adults who report having an appointment with a doctor or nurse the same or next day when last sick (Commonwealth Fund 2010). Canada ranked last in the proportion of sicker adults who found it easy or very easy to get medical care outside regular practice hours without going to the emergency room, and second last in primary care physicians who reported having an arrangement for patients to be seen by a doctor or nurse when the practice is closed (Commonwealth Fund 2011a, 2012; Schoen et al. 2012).

Canada’s performance on measures of patient-centredness and engagement is relatively good as seen by patients (Commonwealth Fund 2010, 2011a), but Canada ranks last in the percentage of primary care physicians who report using patient-friendly technologies for requesting appointments or referrals online or e-mailing about medical concerns (Commonwealth Fund 2012).

Canada is among the best performers on most measures of quality of care (though coming in seventh of 11 in the proportion of diabetic patients whose feet were examined in the past year) (Commonwealth Fund 2010, 2011a). However, primary care practices in all countries perform poorly on helping coordinate or arrange care for patients with serious or chronic illnesses.

Canada is solidly back in the bottom half of surveyed countries, however, with respect to human resources and infrastructure such as including at least one FTE non-physician provider in the practice or the use of EMRs (Commonwealth Fund 2012). Infrastructure for
performance measurement, feedback and quality improvement is grossly underdeveloped relative to most comparator countries (Commonwealth Fund 2012).

Responses to these patient surveys are stratified by income, providing an opportunity to examine differences in responses from sicker patients in above- and below-average income groups (Commonwealth Fund 2011b). In some cases – availability of a regular source of care, for example, or help with arranging or coordinating care – differences were minimal or non-existent. But other measures, such as the accessibility of same- or next-day appointments, and help with treatment planning, were associated with higher income.

A New Century: Reforms, But Diverse and Uneven

After two decades of stagnation, many provinces began in the early 2000s to invest in strengthening primary care. An improved fiscal climate and growing public and professional dissatisfaction underpinned the Romanow and Kirby reports, both of which highlighted the centrality of primary care for health system performance (Commission 2002; Standing Senate Committee 2002). Importantly, the federal Primary Health Care Transition Fund in 2000 and the Health Reform Fund in 2003 channelled new money into primary care reform.

Several provincial initiatives have been implemented to improve primary care. They include practice networks, interprofessional teams, patient enrolment with a provider, blended physician payment schemes and targeted financial incentives, local or regional governance, expansion of the pool of providers (both physicians and other health professionals), implementation of EMRs and quality improvement training and support.

The content and pace of reform have been highly variable among the provinces, as illustrated in Figure 2 (Aggarwal and Hutchison 2012). The figure lists features of primary care systems that enable high levels of performance. Cells containing a double check mark indicate (as of a year ago) widespread or system-level implementation of these features; cells with a single check mark indicate limited implementation and empty cells indicate no implementation.

Most of these features have been implemented widely in one or more provinces. As William Gibson (1999) has famously said: “The future is already out there, it’s just very unevenly distributed.” There are, however, three exceptions – features not broadly implemented anywhere in Canada. These are (a) patient engagement as partners both in their own care and in the design of primary care services; (b) systematic, ongoing measurement of primary care performance; and (c) appropriate investment in primary care research, research training and research application.
Are We There Yet? Still Lagging, But Signs of Progress
How these reforms have affected healthcare processes and outcomes has become a burning question for many policy makers, especially in provinces that have invested most heavily in reform. Although understandable, the question is in some respects problematic. First, it ignores the inevitability of time lag. How soon can the impacts of structural reforms be expected to manifest? Delayed effects must be expected for most reforms introduced over the last decade, especially for complex interventions such as interprofessional teams, which require a realignment of primary care culture. Second, impacts need to be measured to be observed – and no province has a performance measurement system in place that tracks change over time across an appropriate set of measures.

Canadians’ confidence in the health system has increased steadily during the 2000s. In 2010, 40% believed it was working well, and only 10% thought it needed a complete overhaul. These numbers compare well with 20% and 25% in 1998, but they still fall far short of 55% and 5% in 1988. The collapse in confidence associated with funding constraints during the 1990s has yet to be fully rebuilt. Canadians’ rating of their regular source of care has risen sharply, and access to care has become more timely, even though the proportion reporting a regular source of care has fallen somewhat and emergency room use is up. Use of EMRs is increasing, but still comparatively very low.

The last decade has seen profound changes in the funding and organization of primary care in most provinces. As Figure 2 shows, however, progress has been uneven and no province has all the system elements in place to match the best-performing systems internationally. These features need to be spread widely.

The biggest improvements in performance will, I believe, come from the following: creation and support of inclusive primary care governance at the local and regional levels; interprofessional teams; patient enrolment with a provider; comprehensive performance measurement systems that can support decision-making, quality improvement and accountability at every administrative level; quality improvement training and support; and expanded use and functionality of EMRs.

Stay the Course: Primary Care Is Not Breaking the Budget
Primary care reform is unfinished business in every province – and barely begun in some. Substantial additional investments are required – and there’s the rub. In Ontario, for example, many policy makers feel that “we’ve done primary care; we’ve spent a lot and have little to show for it, so let’s move on to something else.” In his 2011 report, the Auditor General of Ontario drew attention to the 32% increase in provincial expenditures on primary care between 2006/7 and 2009/10 (Office of the Auditor General of Ontario 2011: 150). He did not, however, note that overall government healthcare expenditures rose by 23%. The primary care share thus rose only from 7.5% to 8.1% – hardly a massive impact on the overall budget. In 2009/10, provincial government primary care expenditures were barely equal to the combined budgets of the nine largest Toronto hospitals.

“We Can’t Afford” Medicare – New Singers, Same Old Song
The plea for continuing investment in primary care – or, indeed, any other health sector – is frequently countered by concerns about the rising share of health spending in provincial government budgets, and more generally about rising total public and private health expenditures as a proportion of gross domestic product (GDP). Often the two are lumped together as a concern about medicare’s alleged “unsustainability,” though the linkage is faulty and confused (or deliberately deceptive). Those who allege unsustainability are in fact arguing for an expanded role for private financing, user payment with or without private insurance.

These issues feature prominently in Jeffrey Simpson’s book, Chronic Condition: Why
Canada’s Health Care System Needs to be Dragged into the 21st Century (Simpson 2012). Simpson worries, understandably, about healthcare “crowding out” other provincial spending such as education. His metaphors, however – healthcare “devouring budgets” and “money … shoveled into health care” – are calculated to conjure up images of massive profligacy and waste – mindless spending, even gluttony. Not only is medicare economically unsustainable, it does not deserve our support. The “glutton” imagery may be hard for patients and providers to recognize, but the core of the “unsustainability” claim lies elsewhere. The central assumption is that taxes cannot or will not – or, clearly visible between the lines, should not – rise to support increased government spending on health. If more money is needed, make the patients pay.

The Low-Tax Agenda: Social Costs, No Economic Benefit

Although not widely advertised as such, Canada is in fact a low-tax country. In 2010, total tax revenue amounted to 31% of GDP, below the 34% average of the 34 OECD countries and lower than 22 of them. Eight countries had tax revenues above 42% of GDP (OECD 2012).

Proclamations about the necessity of maintaining low taxes as a stimulus to economic growth routinely issue from editorials, op-eds, business leaders and politicians. Yet, there is no basis for these claims. In April, the Conference Board of Canada issued a report ranking the performance of 17 high-income countries in seven categories, including economic performance and social quality of life (Conference Board of Canada 2013b). Figure 3 shows the (lack of) correlation between the Conference Board rankings of economic performance and the OECD ranking of tax revenues. Could it be that low taxes are not essential to economic success after all?

FIGURE 3. Economic performance ranking vs. tax revenue in 16 wealthy OECD countries

Sources: OECD 2012; Conference Board of Canada 2013b
Figure 4 shows the relationship between tax revenues and rankings of social quality of life based on 16 measures. The correlation between the two, 0.642, is highly significant \( (p=0.005) \). It appears that low taxes may incur a large social cost without an economic benefit – the worst of both worlds. But they do benefit the already well-off.

**FIGURE 4.** Quality-of-life ranking vs. tax revenue in 17 wealthy OECD countries

Health Spending: Economic Drag or Economic Engine?
Simpson views healthcare as a drag on the economy, observing with alarm its increasing share of national income. “[T]oday it eats up 11.7% of GDP” – again, the glutton metaphor – up from 7% when medicare began. But why is that necessarily a bad thing? Medicine has changed dramatically in scale and scope over the past half century, as every patient and practitioner knows. Would Simpson have us believe that there are no commensurate benefits?

Another recent report from the Conference Board of Canada (2013a) turns the “economic drag” claim on its head, describing the health sector as “an important driver of economic growth”: “Health care spending in Canada contributed (my emphasis) 10.1 per cent of the national GDP in 2011 and supported 2.1 million jobs.”

Ironically, the main “solutions” proposed by Simpson and his ilk to the alleged unsustainability of medicare – a parallel private system of delivery and finance – would actually raise healthcare costs. Those with private insurance or deep pockets would obtain faster or better service outside the public system, while providers who served them would obtain higher fees and other payments. Private health insurance magnifies the cost inflation. The OECD, typically “private sector friendly,” reports: “Whatever [its] role …, private health insurance has added to total health expenditures …” (OECD 2004).

The OECD (2004) also points out that in some countries “private health insurance has
enhanced access to care. But such access is often inequitable, largely because private health insurance is typically purchased by high-income groups … [who obtain] shorter wait times for elective surgery. But there is no clear evidence that waiting times are also reduced in the public sector … .”

Expanding private payment would have the additional perverse effect of exacerbating income inequality, the most potent social determinant of health. The Canadian Institute for Health Information (CIHI 2013) concludes, consistent with earlier Canadian and international research, that publicly financed healthcare redistributes income from richer to poorer Canadians.

To sum up, continued investments are needed to strengthen primary care as the foundation of a high-performing healthcare system. Moreover, there is room, if need be, to increase taxes to make those investments. But facts and evidence are not the main determinants of public policy. When all is said and done, the struggles over medicare are about conflicting interests and values.

Forget the Evidence! Where You Stand Depends on Where You Sit

Simpson, and presumably those he represents, calls for replacing “ideologies, inspired by vacuous slogans” with “a more functional framework of what works best at lower cost for Canadians.” Few would disagree.

But proposals to introduce a parallel system of private delivery and payment would drag Canadian healthcare not into the 21st century, but back towards the early 20th. The notion that the system would be “fixed” by measures that would increase costs, improve access only for those able to pay and shift cost burdens from taxpayers (generally wealthier) to patients (generally less so) is more than a little bizarre. That would certainly benefit some Canadians – the same narrowly based but strategically placed interest groups that opposed medicare in the first place and still do. Simpson speaks for them. But behind the obvious economic interests of the privatizers, there is also a real clash of values. When Simpson contrasts the “ideology” of medicare’s supporters with the supposed pragmatism of its attackers – people like himself – he just has it wrong. The clash is between competing sets of values: libertarian on the one side and communitarian on the other. The libertarian perspective in its most extreme form is captured in Margaret Thatcher’s famous statement, “There is no such thing as society. There are individual men and women, and there are families.” Or, as Lily Tomlin has said with tongue in cheek: “Remember, we’re all in this alone.”

Libertarian values include personal responsibility, unfettered autonomy and choice, small government, low taxes, personal as opposed to public spending and unconstrained opportunities for increasing individual income and wealth.

Communitarian values include shared responsibility, equality, fairness, collective rather than individual solutions to social problems, redistribution of wealth and income, and a sense of community.

But values and beliefs are not randomly distributed in the population. As shown in Figures 5 and 6, which summarize data from a 2012 EKOS poll (Conference Board of
Canada 2012), they vary systematically with income. Figure 5 shows the percentage of high- and low-income Canadians who see lifestyle, the physical environment, publicly funded healthcare and income level as “extremely important” determinants of Canadians’ health. Ironically, the Canadians who benefit the most from income as a determinant of health are the least likely to recognize its importance. As seen in Figure 6, they are also most likely to support private delivery of health services and least likely to see parallel private healthcare as a threat to the public system.

**FIGURE 5.** Determinants of Canadians’ health (% rating as “extremely important”)

![Figure 5. Determinants of Canadians’ health](source)

**FIGURE 6.** Private healthcare delivery

![Figure 6. Private healthcare delivery](source)
The relationship between values and income means that the struggle to maintain, improve and expand medicare as a program that embodies the core value articulated by Douglas and Hall – healthcare access and quality based solely on need – will continue to face opposition from individuals and organizations whose economic and political influence is disproportionate to their numbers. However, the line-up today is essentially the same as it was when medicare was being debated in the 1960s. We won then, and we can win again.

NOTES
1. This column is based on the 2013 Emmett Hall Memorial Lecture delivered on May 29, 2013 at the Annual Conference of the Canadian Association for Health Services and Policy Research. The lecture is available at http://www.hallfoundation.ca/?page_id=599 and http://www.youtube.com/CAHSPR.
2. Read “province[s]” to include territories.
3. The last year for which international comparative data are available.
4. Correlation is not causality, but lack of correlation isn’t either.
5. These include income inequality; poverty among children, working age adults and the elderly; unemployment; the gender income gap; social supports; life satisfaction; and suicides, homicides and burglaries.

References


Reforming Canadian Primary Care – Don't Stop Half-Way


Abstract
Patients designated as alternative level of care (ALC) are an ongoing concern for healthcare policy makers across Canada. These patients occupy valuable hospital beds and limit access to acute care services. The objective of this paper is to present policy alternatives to address underlying factors associated with ALC bed use. Three alternatives, and their respective limitations and structural challenges, are discussed. Potential solutions may require a mix of policy options proposed here.

Inadequate policy jeopardizes new acute care activity-based funding schemes in British Columbia and Ontario. Failure to address this issue could exacerbate pressures on the existing bottlenecks in the community care system in these and other provinces.

Résumé
Les patients qui attendent un autre niveau de soins (ANS) constituent une préoccupation constante pour les responsables des politiques de santé partout au Canada. Ces patients occupent de précieux lits d’hôpital et limitent l’accès aux soins de courte durée. L’objectif de
Some vulnerable Canadians are experiencing difficulty in accessing acute care on a timely basis. Lengthy wait times for hospital admission from the emergency department are widely reported across the country (CBC News 2011; CTV News 2011), while surgical wait times outside those procedures prioritized by federal incentive programs have generally increased (CIHI 2012).

These long delays for accessing hospital beds are occurring in spite of significant increases in hospital spending. The five-year average rate of hospital expenditure growth has increased by 5.9% (CIHI 2010a). Meanwhile, the number of same-day surgical procedures increased 30%, from 1.3 million to 1.8 million, from 1995/96 to 2005/06 (CIHI 2007). Based on these trends, one would expect reduced pressures on hospital beds; but instead, planners are left questioning why some Canadians have significant problems accessing hospital-based services.

Hospital beds are the “choke points” in the system; with a fixed number of beds, they limit the number of admissions and regulate access to hospital-based services. According to the Canadian Institute for Health Information, there are approximately 57,000 hospital beds in Canada (excluding Quebec) (CIHI 2011a). Within Quebec, another 15,999 beds are designated as “physical health and geriatric” (an approximation for acute care beds) (Quebec Databank of Official Statistics 2011). Digging deeper, current estimates report that 13% of Canadian beds are occupied by patients who no longer require the intensity of care provided by acute care hospitals and are awaiting formal discharge (CIHI 2010b). That is, approximately 7,500 hospital beds, every day, are occupied by patients who could be safely discharged elsewhere.

Unfortunately, having patients waiting for discharge from hospital is so common in Canada that there is a term for it – “alternative level of care,” or ALC. Though these patients have been approved for discharge by their physician, they cannot access the appropriate post-acute care for their condition (CIHI 2009). ALC represents an inefficient use of hospital resources – these patients are occupying beds, staff time and equipment that could otherwise be used by patients waiting in the emergency department or those who have had their surgeries postponed. Yet, hospitals cannot be held solely responsible for this inefficient use of resources and funding; lack of capacity and flexibility in post-acute care is directly related to
the gridlock in hospitals. Thus, a quick resolution to accessing hospital beds lies beyond our grasp if there is nowhere for patients “stuck” in hospitals to safely go.

The high prevalence of ALC bed use puts recent healthcare reforms at risk. British Columbia and Ontario have recently made changes to the way they fund hospital-based care, moving away from global budgets towards partially funding hospitals for their patients (i.e., activity-based funding). These policies, as the evidence shows, have the potential to shorten lengths of stay and increase hospital activity (O’Reilly et al. 2012). Yet, without complementary policies for post-acute care, the intended effect of increased activity in hospitals may not occur. The purpose of this paper is to describe some of the key structural challenges to reducing the impact of ALC patients on Canadian hospitals and to propose policy alternatives that could free hospital beds.

Hospital Bed Use: The Case of Alternative Level of Care
What do we know about ALC patients? The data tell us that over 50% of ALC patients are eventually discharged to facility-based post-acute care (CIHI 2010b). The remainder of patients are discharged to assisted living or to their homes (with or without support). Over 35% of ALC patients are 85 years or older, and nearly a quarter of ALC patients have been diagnosed with dementia (CIHI 2011b).

In terms of resources, ALC patients consumed the equivalent of 2.4 million hospital days over the course of fiscal year 2008/09; the equivalent of approximately 7,500 beds are occupied by a patient designated as ALC on any given day (CIHI 2010b). On average, one ALC patient occupying a bed in the emergency department denies access to four patients per hour to that emergency department (Canadian Association of Emergency Physicians 2005).

We also know that waiting in hospital for post-acute care prolongs patients’ exposure to an environment that experiences thousands of avoidable adverse events each year (Baker et al. 2004). Moreover, delays in discharges, particularly for frail geriatric patients, can lead to rapid deterioration in health, eventually requiring additional acute care or necessitating premature admission to long-term care (Canadian Healthcare Association 2009).

The Build More Option
An obvious solution to improving access to hospital beds is to expand acute care capacity. The additional beds would allow a greater number of admissions from the emergency department or for surgery. Optimistically, increasing capacity would improve access to acute care and shorten elective surgery wait times.

The reality is that a “build more” approach is a temporary, and costly, fix. Without addressing the underlying problem of safely transitioning patients to post-acute care in a timely manner, this approach could lead to more beds being occupied by ALC patients, exacerbating the current problem.
Can the build more option be redefined?
Expanding post-acute care capacity is another “build more” solution. Under this option, provincial governments would further increase healthcare spending by expanding post-acute care capacity (in its current form, with a mix of public and private providers). The obvious benefit of this policy option is that current ALC patients could be discharged to post-acute care, vacating hospital beds and facilitating more hospital admissions.

Like building more hospital beds, this option also faces considerable challenges. First, to expand post-acute care capacity effectively, policy makers would be required simultaneously to identify the post-acute care type currently in the most need (i.e., the care needs of current ALC patients) without over- or under-investing for the needs of future ALC patients.

Further challenges to this option include the lack of strong clinical evidence supporting the appropriateness of post-acute care. Recent research in the United States demonstrates how funding policies, not necessarily the care needs of patients, alter the type of post-acute care a patient receives, and clear clinical guidelines for post-acute care settings are often lacking (Buntin et al. 2009).

The reality is that healthcare budgets are under considerable strain, and “build more” options would be less unpalatable if capital funds were easily available. However, in this environment of restraint, expanding acute or post-acute capacity is an expensive experiment with no guarantee of success.

The Integrated Care Option
The prevalence of ALC patients is another indicator of the need for more integrated care, as closer relationships between acute and post-acute care providers have been posited as a way to improve the efficiency and effectiveness of healthcare resource use (Ham et al. 2011; Vedel et al. 2011) and reduce failures of transitional care between settings. Integrated healthcare delivery may produce pressures to minimize the number of ALC patients, because integrated models can have either the administrative authority or the financial incentives (or both) to ensure that patients are treated at the lowest-cost provider appropriate for their condition (Robertson et al. 2004).

Integrating care across provider types was one of the motivations behind the regionalization of many provincial healthcare systems (Hurley 2004). To date, however, regionalization has fallen well short of this goal. Regional authorities have failed to promote clinical guidelines to coordinate care across settings, invest in integrated information technology systems, address unwarranted variations in the utilization of healthcare services, leverage non-physician healthcare professionals, or disseminate efficient and efficacious technologies, all of which are factors that impair the integration of healthcare providers (Leatt et al. 2000). Or, the regional authorities have been unable to resolve policy conflicts among providers beyond their control, such as physicians (Simpson 2011).
Barriers to the integrated care option
Cited examples of effective integrated care models are largely based in the United States, such as the Kaiser Permanente and Geisinger Health systems. These systems are privately operated, often with salaried physicians, and have tightly networked their funding and delivery arms. The results from these systems are likely not generalizable to the Canadian setting, where physicians are remunerated by a third party (i.e., the province), are rewarded for how much they do, and whose costs are externalized from the effects of inefficient hospital care. In addition, many post-acute care providers are privately owned and do not share hospitals’ community-based mission. As well, the penetration of cross-continuum electronic medical records remains poor (McGrail et al. 2010).

One model from the United States that may be worth closer examination is the Program of All-inclusive Care for the Elderly (PACE). Under this program, organizations develop an integrated program of care for those 55 and older who have complex needs and where care is provided in the community, rather than in a nursing home. PACE providers receive a capitated monthly payment for each patient they care for; thus, they have a financial incentive to keep patients out of hospital. Evaluations of the PACE model have reported significant reductions in hospital utilization and improved quality of care (Beauchamp et al. 2008; Meret-Hanke 2011).

A project similar to PACE was piloted in Quebec, raising the prospect of integrated models of care in Canada (Béland et al. 2006). The SIPA (Services intégrés pour les personnes âgées en perte d’autonomie) project used a randomized control trial to evaluate the performance of community-based multidisciplinary teams integrated across health and social services compared to usual care. Costs of community-based services were higher for the integrated care group compared to the usual care group, but facility-based costs were lower, and the integrated care group experienced a 50% reduction in ALC occupancy.

While the PACE and SIPA programs offer a potential model for integrated care, there are several limitations to their broader implementation. First, the scope of these programs extends beyond healthcare into social services, assisting patients in finding work and affordable housing, and in navigating government programs. Second, both the PACE and SIPA programs have policies in place to align incentives of providers with integrated models of care. They both offer their participating providers a capitated payment on a per-patient basis, intended to cover the extra cost associated with integrated care models (e.g., developing care plans, communicating with other providers on patient care, following up with referrals).

The Financial Incentives Option
Creating financial incentives for improving the quantity, quality or effectiveness of healthcare is not the norm in Canadian provinces, as it is frequently associated with private, for-profit care. However, there is an abundance of evidence from other countries – including ones with strong, publicly funded healthcare systems, such as Australia, the United Kingdom, and many European countries – that healthcare institutions respond to financial incentives (Street and Maynard 2007).
Hospitals across Canada have historically been funded by way of a global budget (Sutherland 2011). A global budget is a single payment intended to fund all care over a given period, irrespective of the volume or type of care provided. Similarly, post-acute care tends to be funded through a global budget (though recent changes in Alberta and Ontario’s long-term care sector are the exception), independent of hospital expenditures. Global budgets create incentives for cost controls, and the policy leaves the hospital or post-acute care providers at risk for changes in volume or complexity of patients.

Recently introduced activity-based funding initiatives targeting hospitals in British Columbia and Ontario are creating incentives for hospitals to “push” patients from acute care (because new admissions generate additional revenue). These incentives are expected to put increased pressure on limited post-acute care capacities as a result of hospitals’ (presumed) increase in activity.

Similar financial incentives could be developed for post-acute care providers to admit waiting hospitalized patients and give these providers the ability to create capacity for ALC patients.

**Barriers to the financial incentives option**
Creating financial incentives for post-acute care may be a viable strategy that complements policies encouraging hospitals to increase the volume of care, and this approach targets the post-acute care needs of patients. British Columbia is already experimenting with financial incentives for community-based programs (BC Health Services Purchasing Organization 2011). But these policies necessitate careful surveillance of timely and reliable data on quality to ensure that patients are not discharged from hospitals too early or being cared for in an inappropriate setting. Such surveillance would require linking clinical practice guidelines to current patterns of care – something that is sorely lacking in post-acute care across the country (Buntin et al. 2009).

Introducing new funding policies for post-acute care would also have to include mechanisms to ensure that post-acute care providers were not “cream skimming,” that is, admitting only those patients who are less costly (than the payment amount) to care for, or refusing admission to complex and costly patients. These problems can be avoided by risk-adjusting payments based on the clinical complexity or care needs of the patient.

**Discussion**
High ALC use is a significant barrier to effective use of costly hospital care – a problem that hospitals have largely failed to address over the past decade. The most cost-effective approaches to improving access to hospital beds involve using the bed capacity we have now in a more efficient manner. However, reducing ALC will increase the number of hospitalizations for the same number of beds, challenging fiscal constraints by freeing new bed capacity.

Reducing ALC will cost the healthcare system real money, whether it is done by building more capacity, integrating providers or developing financial incentives. System-level savings
will be realized only by re-tasking hospital beds as long-term care beds or closing a share of hospital beds and reallocating the funds to other sectors.

Yet, the risk of doing nothing is also expensive. Current activity-based funding policies’ singular focus on hospitals, without commensurate changes in post-acute care, jeopardizes the viability of these policies by exacerbating pressures on bottlenecks in the system. We have discussed three policy options – building more, integrated care and financial incentives – that offer potential solutions. These are not intended to be presented as either/or options; given the complexity of the problem, a solution may well involve a combination of all three.

These three options address how policy makers might alleviate current ALC. However, this paper does not address the complementary issue of reducing “future” ALC (such as by expanding primary care, improving the continuity of care and reducing avoidable hospital admissions), a topic that requires further linkages between community and secondary care providers.

Improving access to hospital care and reducing wait times are important goals for many Canadians, yet our current methods for funding care may be inhibiting our ability to realize those goals. Hospitals and post-acute care providers are known to respond to financial incentives. Let’s use this knowledge to explore whether financial incentives could improve access to hospital-based care and expand post-acute care in a way that responds to patients’ medical and social needs.

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Abstract
Approximately 68% of Canadians receive prescription drug coverage through an employer-sponsored private plan. However, we have very limited data on the structure of these plans. This study aims to identify and describe the use of cost-control mechanisms in private drug plans in Canada and describe what private coverage looks like for the average Canadian.

Using 2010 data from over 113,000 different private drug plans, provided by Applied Management Consultants, we determined the overall use of key cost-control measures, and
the cost-control tools that appear to be gaining currency compared to a report on benefits coverage in 1998. We found that the use of common cost-control measures is relatively low among Canadian private benefits programs. Co-insurance is much more common in private coverage plans than co-payments. Deductibles are uncommon in Canada and, when in place, are very small. The use of annual and lifetime maximums is increasing. Canadian private benefits programs use few cost-control measures to respond to increasing costs, particularly in comparison to their public counterparts. These results suggest there are ample opportunities for greater efficiency in private sector drug coverage plans.

Résumé
Environ 68 % des Canadiens bénéficient d’une couverture pour les médicaments sur ordonnance grâce à un régime d’assurance privé offert par l’employeur. Cependant, il y a très peu de données quant à la structure de ces régimes. Cette étude vise à décrire l’utilisation des mécanismes de contrôle des coûts dans les régimes privés d’assurance médicaments au Canada et à dresser le portrait des couvertures privées pour la moyenne des Canadiens.

À l’aide de données de 2010 au sujet de plus de 113 000 régimes privés d’assurance médicaments, fournies par Applied Management Consultants, nous avons déterminé l’utilisation globale de mesures clés de contrôle des coûts ainsi que les outils de contrôle des coûts qui semblaient gagner en popularité, à la lumière d’un rapport de 1998 sur la couverture par les régimes. Nous observons que l’utilisation des mesures courantes de contrôle des coûts est relativement peu fréquente dans les programmes de prestations privés au Canada. Dans les couvertures privées, la coassurance est beaucoup plus répandue que la participation aux coûts. Les franchises sont peu communes au Canada et, là où elles existent, elles sont très petites. L’utilisation de maximums annuels ou de maximums à vie est en augmentation. Au Canada, on utilise peu de mesures de contrôle des coûts pour aborder la question des coûts croissants dans les programmes privés d’assurance, particulièrement comparé à leurs équivalents du système public. Ces résultats laissent voir qu’il y a beaucoup de place pour une meilleure efficience des régimes d’assurance médicaments du secteur privé.

Prescription drugs provided outside of hospital are not universally covered in Canada. Instead, these costs are paid by a blend of various public drug programs, private drug plans and out-of-pocket payments. An estimated 38% of drug expenditures in 2011 were financed through private drug plans, which are most commonly offered as part of employer-sponsored supplemental health benefits packages provided to employees and their dependents (CIHI 2012). In 2010, 23 insurance companies offered private benefits plans that provided health coverage to 68% of Canadians (Canadian Life and Health Insurance Association 2012).

As a result of a confluence of events – rising drug costs, a weak economy and reductions
in the scope of public coverage (Morgan and Yan 2006; Rovere and Bacchus 2012) – the private drug insurance market is currently facing significant pressures. For example, since 1998, drug expenditure by private insurers has tripled from $3.2 billion in 1998 to $9.6 billion in 2010 (CIHI 2012). It is unclear whether the structures of private benefits plans have changed in the face of these external cost pressures (CIHI 2012). The nature of the cost-control mechanisms used by private drug plans is important not only for expenditures, but also because it affects patient access to medicines.

There are a number of mechanisms that drug plans might use to control costs. These can be characterized broadly as either formulary management, controlling the drugs that are available, and cost-shifting, controlling the plan’s liabilities without necessarily modifying which drugs are dispensed. The best evidence on the overall use of cost-control measures in private drug plans is very dated. A Health Canada–funded analysis based on data from 1998 provides the most recent comprehensive overview on the design of private drug plans (Applied Management 2000). The analysis, which examined the benefits and structures of more than 41,000 employer plans, found only limited use of most cost-control strategies. For example, there was no use of generic substitutions or multi-tiered plans – plans that require different levels of co-payments depending on the drug (Applied Management 2000). Furthermore, only 12% of employees were required to make a fixed amount co-payment, and 58% paid co-insurance (Applied Management 2000).

Given the dearth of recent data and the important role of private benefits plans for Canadians, we felt it time to investigate the use of cost-control mechanisms in private drug plans using the most comprehensive data set available.

Methods

Data set
We analyzed 2010 data from employer-sponsored private benefits plans collected by Applied Management Consultants (AMC). These data came from two sources. First, AMC obtained plan design data from third-party claims administrators who act on behalf of several major insurance companies. Second, AMC conducted a purposive survey of large employers who self-administer their drug benefits. This data set included information on 113,121 drug plans, which covered 4,138,297 employees. These plans were sponsored by 72,688 different companies – many companies offered different plans to different employee groups.

This database has two key advantages for investigating the coverage of private drug plans in Canada. First of all, it is the most expansive and comprehensive private benefits data currently available. Secondly, it is from the same company that provided that database used to produce the last comprehensive evaluation of this topic in 1998 (Applied Management 2000).

Analysis
We classified the common cost-control mechanisms into two major approaches: those based
on (a) formulary management, and (b) shifting costs to patients. Our analysis was descriptive in nature, and focused on the number and proportion of plans using different types of common cost-control mechanisms. Further, where comparable data were available from the report based on 1998 data, we compared our results to investigate changes over time.

Formulary management mechanisms control costs by guiding formulary decisions, without necessarily shifting costs to the patient or to the public plan. The two formulary management mechanisms detailed in our data were as follows:

1. Mandatory generic substitution refers to a plan feature that limits reimbursement to the cost of the equivalent generic version, if available. Beneficiaries who choose to fill a brand name version instead are responsible for paying the difference.
2. Multi-tier drug plans use formularies with coverage that differs based on the drug in question. Multi-tier plans create an incentive for patients to use specific drugs by allocating drugs into different tiers – typically two to three tiers, but sometimes as many as five – based on the availability of therapeutically equivalent alternatives. Each plan determines its own formulary structure and allocates drugs into tiers. The first tier requires the lowest co-payment, and will typically include most generic drugs. The second tier requires a greater co-payment by the plan beneficiary, and often includes brand-name drugs.

Second, cost-shifting mechanisms reduce expenditures to plan sponsors by shifting costs to other payers, including out-of-pocket payments by enrollees. Our data included information on a number of cost-shifting mechanisms, including the following:

1. Deductibles are a cost-sharing measure that requires plan beneficiaries to pay a yearly fixed amount before coverage begins.
2. Co-payments and co-insurance are a form of cost-sharing that require the plan beneficiary to pay a portion of each prescription. They come in two forms, either a percentage amount (co-insurance) or fixed-dollar amount (co-payment). In some cases, employees must pay both: a fixed amount per prescription, and then co-insurance on the remainder.
3. Dispensing fee policies require plan enrollees to pay all or a portion of the dispensing fee charged by the pharmacy on each claimed prescription. In Canada, these fees typically range from $4 to $12 (Telus Health 2011).
4. Annual and lifetime maximums refer to a maximum benefit the insurer will provide in any given year (annual) or over the entire enrolment of an individual in the plan (lifetime).

Results
Overall, we found low levels of usage of cost-control mechanisms among private plans (Table 1). Further, while there were some changes, in half of the cost-shifting mechanisms measured the use of cost-control mechanisms was substantively similar to the previously reported rates from 1998.
Cost-Control Mechanisms in Canadian Private Drug Plans

**TABLE 1. Use of cost-control mechanisms by private benefits plans in Canada**

<table>
<thead>
<tr>
<th>% of Employees</th>
<th>1998</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formulary Management Mechanisms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic substitutions mandatory</td>
<td>N/A</td>
<td>67%</td>
</tr>
<tr>
<td>Multi-tiered</td>
<td>N/A</td>
<td>19%</td>
</tr>
<tr>
<td><strong>Cost-Shifting Mechanisms</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient maximum (Annual and/or Lifetime)</td>
<td>N/A(^1)</td>
<td>16%</td>
</tr>
<tr>
<td>Annual maximum</td>
<td>3%</td>
<td>12%</td>
</tr>
<tr>
<td>Lifetime maximum</td>
<td>&lt;3%</td>
<td>6%</td>
</tr>
<tr>
<td>Deductible</td>
<td>48%</td>
<td>12%</td>
</tr>
<tr>
<td>Co-payment (Fixed and/or Percentage)</td>
<td>71%</td>
<td>79%</td>
</tr>
<tr>
<td>Fixed amount</td>
<td>12%</td>
<td>13%</td>
</tr>
<tr>
<td>Percentage amount</td>
<td>58%</td>
<td>61%</td>
</tr>
<tr>
<td>Combination (fixed and percentage)</td>
<td>2%</td>
<td>4%</td>
</tr>
<tr>
<td>Dispensing fee</td>
<td>3%</td>
<td>27%</td>
</tr>
</tbody>
</table>

\(^1\) Numbers have been rounded.

\(^2\) Patient maximums (annual and/or lifetime) were not discussed in the report on 1998 data; however, looking at the use of annual and lifetime maximums separately, we are confident that less than 16% of employees had some sort of limit on their plan.

Sources: Applied Management Consultants in association with Fraser Group and Tristat Resources 2000, and the authors’ calculations using data provided by Applied Management, from their private plan data set, 2010.

**Formulary management mechanisms**

In 2010, 67% of employees in the data belonged to plans that required generic substitution. Multi-tiered plans were introduced to Canada in recent years, and 19% of employees in our data set belonged to such plans (see Table 1). In contrast, the majority of plans are single-tiered, meaning they use the same co-payment for all the drugs they cover. There is no mention of either of these formulary management mechanisms in the data from 1998, and we contend that these mechanisms were seldom used, if at all, in Canada at that time. Furthermore, 85% of plans provided coverage for all prescriptions, while a small proportion adopted formularies from a provincial government formulary (2%) or an insurer-designed list (6%), with the remainder being unknown.

**Cost-shifting mechanisms**

In 2010, 16% of employees had an annual maximum benefit, a lifetime maximum or both. Compared to 1998, the use of lifetime maximums has doubled: less than 3% of enrollees had this type of limit in 1998 (Applied Management 2000), compared to 6% of enrollees in 2010. Annual maximums increased more dramatically, more than doubling from 3% (Applied Management 2000) of employees in 1998 to 12% in 2010.
We found a decrease in the percentage of employees required to pay a deductible, from 48% in 1998 (Applied Management 2000) to just 12% in 2010 (Table 1). Of the employees who paid a deductible in 2010, 65% paid $25 or less and 91% paid $50 or less. This finding was juxtaposed with the increase in the percentage of employees who were required to pay the dispensing fee, from 3% in 1998 to 27% in 2010. The overall usage of co-payments also grew, from 71% of employees in 1998 (Applied Management 2000) required to make a co-payment to 79% in 2010 (Table 1). Specifically analyzing fixed-amount co-payments, we found that only 12% of employees in 1998 paid a fixed-amount co-payment (Applied Management 2000); this figure increased to only 13% in 2010 (Table 1). The remainder of plans using cost-sharing mechanisms used co-insurance. The 1998 data show that 58% of employees were required to pay co-insurance (Applied Management 2000), a figure similar to that in 2010, at 61% of employees. A small number of employees were enrolled in plans that required both types of payments (4% in 2010).

Discussion
Despite a threefold increase in expenditures and an economic downturn, we found that private benefits plans in Canada continue to employ many cost-control measures at fairly low rates. Where cost-control measures are being used, they tend to be more passive forms of managing costs. Active measures that steer patients to more cost-effective medicines for the same condition are relatively underused when compared to their role in public plans (Pomey et al. 2010). Decisions about the use of particular cost-control measures may have direct impacts on access to medicines for the enrollees in these plans.

Formulary management mechanisms aim to lower costs while retaining the same levels of drug coverage. Mandatory generic substitution significantly reduces the cost of prescription drugs while retaining the same level of coverage of different, therapeutically equal, drugs. Notably, after the data for this paper were collected, Sun Life and Great West Life – two of the largest private health insurers in Canada – initiated a mandatory generic substitution policy for all claimants, unless companies explicitly opt out (Blackwell 2012). Whether this approach will lead to wider use of generic substitution remains to be seen.

Managed formularies are another mechanism that can lower expenditures through encouraging the use of less expensive therapeutic alternatives. Multi-tiered plans are the standard in the United States (Goldman 2006), with 89% of covered workers in 2010 belonging to a plan with a tiered cost-sharing formula for prescription drugs (Kaiser Family Foundation 2012). In contrast, only 19% of Canadian employees with drug benefit plans appear to have managed formularies, suggesting this might be a major opportunity for reducing private sector drug costs, again without limiting patients’ access to medicines.

Cost-shifting mechanisms, including deductibles, co-payments and fixed dispensing fees, are more widely used, and their use has increased over time, with one major exception. One important consideration with these measures is that they can form barriers to access, because not everyone is able to afford their prescribed drug regimen. There is strong international...
evidence that cost influences adherence (Goldman et al. 2007). A wealth of literature demonstrates the adverse effects of prescription drug non-adherence, such as increased emergency room visits, morbidities and mortalities (Blackburn et al. 2005; Heisler et al. 2010; Mojtabai and Olfson 2003; Tamblyn et al. 2001). The heavy reliance of Canada’s universal health insurance coverage system on private prescription drug plans also means that significant use of cost-shifting mechanisms may have important equity implications.

While annual and lifetime maximums are still used by only a small number of plans, their rapid growth might present issues for both patients and public drug plans. Specialty drugs are becoming increasingly popular, including some that can cost hundreds of thousands of dollars every year (Goldman 2006; Kim et al. 2011). If this trend continues, it is likely that many Canadians, including those with chronic conditions, will hit these benefits limits. This may result in large out-of-pocket expenditures, or patients’ drug cost becoming the responsibility of the catastrophic public drug plans found in nearly every province (Daw and Morgan 2012).

There are three major possible explanations for the limited use of cost-control measures seen in most private drug plans. First, there are few to no incentives facing Canadian insurers to control costs. Insurance companies typically earn income based on administration charges that are levied as a percentage of total plan expenditures (Silversides 2009). On average, estimates suggest that Canadian private insurance plans charged 13.2% for administration (Woolhandler et al. 2003). This reduces the incentive for insurers to actively promote cost-saving measures to clients, because any resulting reduction in drug expenditures would proportionately decrease the administrative charges the plan would earn. Second, because private drug benefits plans are a mechanism used by employers to attract and retain employees, employers might be reticent to reduce their generosity in a competitive labour market. Further, as the average cost of insuring any particular employee is comparatively low when considered in terms of overall compensation, many employers may be reluctant to initiate changes in plan design, an approach that might lead to conflict with employees and unions. Third, part of the lack of more sophisticated private benefits plans in Canada can be attributed to plans competing with administrative charges and not with design features (Gagnon 2010).

The two mechanisms that saw a great deal of change from 1998 to 2010 were deductibles and dispensing fees. It is unclear why these changes have taken place. One explanation could be that the decrease in the use of deductibles – a relatively low, one-off cost – may have been offset by the increased percentage of employees required to pay the dispensing fee. However, these changes might also be the result of negotiations with benefits providers to avoid discord with beneficiaries.

Limitations
While the AMC data set is the most comprehensive plan design data available in Canada, there are some limitations worth noting. While our data were assembled by the same company that collected the data from 1998, collection was not longitudinal; therefore, we could not compare the same companies over time. Further, as some of the variables were different, we
could not compare all the indicators provided from the earlier report. Finally, while we have no reason to believe the AMC data differ from those of other private plans in Canada, it is possible that our data may not be completely representative.

Another limitation of the data set was that it did not provide any data on premiums, and thus premium sharing as a cost-shifting mechanism. In addition, the data set did not identify the geographic origin of plans, only the province where the company's head office is located. Thus, the data are not necessarily representative of the site of the plans' administration and were left out of our analysis.

Conclusion
As drug costs continue to rise, increasing pressure will continue to push employers to consider the design of their drug benefits programs. These pressures will likely be particularly acute in the face of specialty drugs that are very expensive. Our data indicate that the changes over the past few years have involved both measures that will not unduly influence access to medicines (formularies, generic substitution), but also those that limit plan liability and might lead to an increasing burden on individuals' out-of-pocket payments (in particular, annual and lifetime maximums). There appear to be significant opportunities for the use of effective cost-control measures in Canadian private drug plans. Continued research to investigate private plan design and coverage in Canada is needed, and should identify the types of plans that are most cost-efficient, while still providing comprehensive coverage to beneficiaries.

At some point, escalating prescription drug costs will demand private plans to respond. If plans fail to react, many employers will cease to be able to afford the same level of coverage for their employees, restricting more Canadians from access to their needed prescription medicines. Both employers and employees must ensure that their response maintains access to necessary medicines for plan beneficiaries.

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REFERENCES
Cost-Control Mechanisms in Canadian Private Drug Plans


High-Cost Users of Ontario’s Healthcare Services

Usagers qui coûtent cher aux services de santé en Ontario

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Abstract
Approximately 1.5% of Ontario’s population, represented by the top 5% highest cost-incurring users of Ontario’s hospital and home care services, account for 61% of hospital and home care costs. Similar studies from other jurisdictions also show that a relatively small number of people use a high proportion of health system resources. Understanding these high-cost users (HCUs) can inform local healthcare planners in their efforts to improve the quality of care and reduce burden on patients and the healthcare system. To facilitate this understanding, we created a profile of HCUs using demographic and clinical characteristics. The profile provides detailed information on HCUs by care type, geography, age, sex and top clinical conditions.

Résumé
Environ 1,5 % de la population ontarienne, qui correspondent à 5 % des usagers qui génèrent le plus de coûts pour les services hospitaliers et les soins à domicile en Ontario, comptent pour 61 % des frais hospitaliers et de frais pour les soins à domicile. Des études semblables menées ailleurs montrent également qu’un nombre relativement petit de personnes utilisent une grande partie des ressources du système de santé. Une meilleure compréhension des usagers qui coûtent cher peut aider les planificateurs à améliorer la qualité des services et à réduire le fardeau sur les patients et sur le système de santé. Afin de faciliter cette compréhension, nous avons brossé un profil des usagers qui coûtent cher à l’aide de caractéristiques cliniques et démographiques. Ce profil donne des renseignements détaillés sur ces patients, en fonction du type de soins, de la géographie, de l’âge, du sexe et des principaux états cliniques.

Studies have shown that high-cost users (HCUs) of healthcare, i.e., patients who incur the highest healthcare costs, represent only a small proportion of the population but consume a large proportion of healthcare funding. In British Columbia, for example, 5% of users spent 30% of the provincial physician service funding (Reid et al. 2003). A study in Manitoba also showed that 5% of prescription drug users accounted for 41% of prescription expenditures (Kozyrskyj et al. 2005). In Manitoba, the highest 1% population accounted for 54% of hospital expenditures (Deber and Lam 2009). In the United States, 5% of the population accounted for 49% of total healthcare spending (Center for Healthcare Research and Transformation 2010). The resulting spotlight on HCUs prompted economists and policy makers to acknowledge the influence of HCUs on quality of care and cost-effectiveness of the healthcare system. Gawande’s 2011 article in The New Yorker (“The Hot Spotters”), for example, garnered considerable attention from policy makers, arguing that a focus on a few areas or individuals will have significant impact on patient outcomes and system costs. A 2012 report by The Commonwealth Fund also emphasized the need to address HCUs as the first step to achieving “rapid improvements in the value of services provided.”
Recognizing the importance of HCUs, the Ontario Ministry of Health and Long-Term Care used clinical and demographic patient information to profile HCUs of Ontario’s hospital and home care healthcare services. This profile, as presented below, should inform the management of healthcare funding, support the development of policies and programs that provide better access, quality and value to Ontario patients, and motivate further research on HCUs.

**Methodology**

HCUs were defined as the top 5% cost-consuming users of hospital and home care services at the provincial level during the fiscal year 2009/10. Primary care and long-term care use were excluded. The patient count, total cost and cost per patient were measured for selected demographics, care types and clinical conditions, both for HCUs and for all users. Cost was calculated using the Ontario Cost Distribution Methodology as the product of the unit cost (of a care type within a specific hospital) and the case weight (of a case-mix group) (Ministry of Health and Long-Term Care 2011).

The demographic characteristics examined were geography (by Local Health Integration Network [LHIN] of service), age group (<1, 1–17, 18–45, 45–64, 65–79, 80+) and sex. The care types included Acute In-Patient Care, Acute Day Surgery, Emergency, In-Patient Mental Health, Rehabilitation, Complex Continuing Care and Home Care. The clinical care types studied were limited to In-Patient (by major clinical category), Day Surgery (by major ambulatory cluster) and Emergency (by major ambulatory cluster).

Data used for the analysis were extracted from ministry-accessible administrative databases specific to each care type: In-Patient from the Discharge Abstract Database, Day Surgery and Emergency from the National Ambulatory Care Reporting System, Mental Health from the Ontario Mental Health Reporting System, Chronic from the Continuing Care Reporting System, Rehabilitation from the National Rehabilitation Reporting System and Home Care from the Home Care Database. Records were screened out if they represented services not covered by the Ontario Health Insurance Plan (OHIP), hospital services not funded through Ontario’s case-mix funding model, or services with zero resource intensity measures. Each patient’s age, sex and LHIN of service was based on his/her most recent record.

Formal ethics review was not required because de-identified ministry administrative data were used.

**Results**

Tables 1 through 3 summarize the results of the analysis. Each table presents the patient count, total cost and average cost per patient both for HCUs and for all users (including HCUs) across specified characteristics. Table 1 also includes the standard deviations (SD) of average cost per patient. The tables enable comparison of measures between categories and between HCUs and all users.

Note that the patient count and cost per patient may not be consistent across tables because patients may have contributed to multiple categories for a given characteristic. Ninety-
one per cent of HCUs received care in multiple care types, and within In-Patient, Day Surgery and Emergency, 83% of HCUs received care for multiple clinical conditions.

### Table 1. Distribution of patients and costs across demographic characteristics, 2009/10

<table>
<thead>
<tr>
<th>Demographic</th>
<th># of Patients</th>
<th>Total Cost ($M)</th>
<th>Average Cost per Patient ($K) (SD)</th>
<th># of Patients</th>
<th>Total Cost ($M)</th>
<th>Average Cost per Patient ($K) (SD)</th>
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<tr>
<td>LHIN</td>
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<tr>
<td>ESC</td>
<td>8,758</td>
<td>342</td>
<td>39.07 (37.76)</td>
<td>203,149</td>
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<td>3.12 (11.20)</td>
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<tr>
<td>SW</td>
<td>18,822</td>
<td>820</td>
<td>43.56 (48.01)</td>
<td>371,313</td>
<td>1,318</td>
<td>3.55 (14.43)</td>
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<tr>
<td>WW</td>
<td>7,604</td>
<td>292</td>
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<td>191,818</td>
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<td>6,723</td>
<td>365</td>
<td>54.30 (76.95)</td>
<td>707,323</td>
<td>857</td>
<td>1.21 (9.24)</td>
</tr>
<tr>
<td>18–44</td>
<td>19,976</td>
<td>987</td>
<td>49.39 (65.52)</td>
<td>1,240,331</td>
<td>2,491</td>
<td>2.01 (10.47)</td>
</tr>
<tr>
<td>45–64</td>
<td>47,021</td>
<td>2,100</td>
<td>44.65 (53.11)</td>
<td>983,463</td>
<td>3,543</td>
<td>3.60 (15.03)</td>
</tr>
<tr>
<td>65–79</td>
<td>59,896</td>
<td>2,562</td>
<td>42.78 (47.01)</td>
<td>526,686</td>
<td>3,687</td>
<td>7.00 (20.63)</td>
</tr>
<tr>
<td>80+</td>
<td>56,264</td>
<td>2,316</td>
<td>41.17 (39.92)</td>
<td>282,216</td>
<td>3,096</td>
<td>10.97 (23.60)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>98,259</td>
<td>4,189</td>
<td>42.63 (47.56)</td>
<td>2,088,726</td>
<td>7,390</td>
<td>3.54 (13.71)</td>
</tr>
<tr>
<td>Male</td>
<td>96,822</td>
<td>4,452</td>
<td>45.98 (54.92)</td>
<td>1,812,895</td>
<td>6,824</td>
<td>3.76 (16.35)</td>
</tr>
<tr>
<td>Provincial</td>
<td>195,081</td>
<td>8,641</td>
<td>44.29 (51.37)</td>
<td>3,901,621</td>
<td>14,214</td>
<td>3.64 (14.99)</td>
</tr>
</tbody>
</table>

ESC=Erie St. Clair; SW=South West; WW=Waterloo Wellington; HNHB=Hamilton Niagara Haldimand Brant; CW=Central West; MH=Mississauga Halton; TC=Toronto Central; C=Central; CE=Central East; SE=South East; CH=Champlain; NSM=North Simcoe Muskoka; NE=North East; NW=North West
Table 1 presents analyses by demographic characteristics and at the provincial level. Provincially, HCU s accounted for 61% of all costs and had an average cost per patient that was 12 times that of all users. Within each LHIN, the percentage of all users that were HCUs ranged from 3.7% in Central (C) to 9.5% in Toronto Central (TC), and the percentage of total costs attributed to HCUs ranged from 51.0% in C to 71.8% in TC. TC also incurred the highest total cost and average cost per patient, among both HCUs and all users.

The 65+ age group accounted for the largest proportion (60%) of HCUs and 56% of HCU costs. Furthermore, the percentage of total costs attributed to HCUs was disproportionately higher in the 65+ age group (72%). Among HCUs, while the number of patients and total cost increased with increasing age, the average cost per patient decreased with increasing age. Thus, the age group with the highest average cost per HCU was the <1 group ($59,795), but not for all users, for whom the cost per patient increased with age (after the <1 age group). The cost per patient was slightly – but with statistical significance – higher among males versus females. The percentage of total costs attributed to HCUs was also higher among males (65% versus 57%).

TABLE 2. Distribution of patients and costs across care types, 2009/10

<table>
<thead>
<tr>
<th>Care Type</th>
<th># of Patients</th>
<th>Total Cost ($M)</th>
<th>Average Cost per Patient ($K)</th>
<th># of Patients</th>
<th>Total Cost ($M)</th>
<th>Average Cost per Patient ($K)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IP</td>
<td>170,035</td>
<td>5,365</td>
<td>31.55</td>
<td>819,971</td>
<td>8,096</td>
<td>9.87</td>
</tr>
<tr>
<td>DS</td>
<td>54,775</td>
<td>129</td>
<td>2.35</td>
<td>968,344</td>
<td>1,158</td>
<td>1.20</td>
</tr>
<tr>
<td>ER</td>
<td>158,667</td>
<td>233</td>
<td>1.47</td>
<td>2,926,568</td>
<td>1,319</td>
<td>0.45</td>
</tr>
<tr>
<td>MH</td>
<td>14,868</td>
<td>805</td>
<td>54.14</td>
<td>35,517</td>
<td>904</td>
<td>25.45</td>
</tr>
<tr>
<td>Rehab</td>
<td>23,239</td>
<td>465</td>
<td>20.01</td>
<td>25,536</td>
<td>477</td>
<td>18.68</td>
</tr>
<tr>
<td>CCC</td>
<td>16,852</td>
<td>824</td>
<td>48.92</td>
<td>18,265</td>
<td>833</td>
<td>45.61</td>
</tr>
<tr>
<td>HC</td>
<td>114,270</td>
<td>819</td>
<td>7.17</td>
<td>430,465</td>
<td>1,427</td>
<td>3.32</td>
</tr>
</tbody>
</table>

Table 2 presents results by care type. In-Patient, the most costly one, represented 62% of HCU costs and 57% of all costs. Mental Health was the care type with the highest cost per HCU ($54,140). Most of Mental Health, Rehabilitation and Chronic costs – 89%, 98% and 99%, respectively – were attributed to HCUs. By contrast, only 15% of Emergency and Day Surgery costs combined were attributed to HCUs, as the cost per patient for these care types was relatively small.
Table 3 presents the top five cost-incurring clinical conditions among HCU for In-Patient, Day Surgery and Emergency. In total, there are 21 conditions in In-Patient, 19 in Day Surgery and 19 in Emergency. The top five conditions accounted for 59% of all HCU costs in In-Patient, 81% in Day Surgery and 63% in Emergency.
The table shows that all but one of the top five clinical conditions in In-Patient and Emergency were identical, though ranked differently. Furthermore, in all three care types, circulatory system conditions incurred the highest total HCU costs. Within Day Surgery, circulatory system conditions had a notably higher average cost per patient than any other condition, whether for HCUs or for all users.

Discussion
This HCU profile highlights the preponderant characteristics among HCUs. HCUs are most costly and prevalent in the TC LHIN, possibly because TC is host to hospitals that provide more specialized, costly acute services. Males are more costly than females, but neither age distribution nor frequency of care types was found to explain this observation. Seniors predictably accounted for the majority of HCU patients and costs, but the average cost per patient decreased with age; with age, the increase in patient count was greater than the increase in total costs, suggesting a higher frequency of less costly visits at older ages.

Of the different clinical conditions, circulatory system conditions incurred the most costs in In-Patient, Day Surgery and Emergency. In In-Patient and Emergency, the high cost for circulatory system conditions was due to volume of patients, not due to the cost per patient. In Day Surgery, however, both cost per patient and volume of patients contributed to the high costs, illustrating that the cost and cost drivers associated with a condition vary by care type. In In-Patient, 92% of circulatory system condition costs were from patients aged 45+, 58% of these costs were from males, and 23% were from patients in TC, reconfirming the role of demographics in driving prevalence of conditions. Further investigations concerning the types of treatments used in each demographic may give added insights into the differences observed between demographic categories.

The profile of high-cost users in Ontario presented in this paper is an original contribution to the wide body of published literature on HCUs in other jurisdictions. It confirms previously published findings that a relatively small proportion of patients consume the majority of healthcare resources, but also looks at characteristics that are specific to Ontario.

Moving forward, this profile should guide the development of policies and programs supporting Ontario’s Action Plan for Health Care (Government of Ontario 2012). Furthermore, efforts to manage HCUs should address their complex profile through integrated, multidisciplinary healthcare delivery. The focus of the delivery, moreover, should be on appropriate care as opposed to simply more frequent or more costly care, as Stukel and colleagues (2012) and The Commonwealth Fund (2012) have emphasized. This profile should also help in providing coordinated healthcare services to HCUs by all related care providers in each LHIN. Further research should build upon the profile presented, investigating, for example, how HCUs transition through the system and how different interventions contribute to high costs. Currently, we are looking at the histories of HCUs and the progression of chronic conditions to identify precursors and interventions that may help identify patients at risk of becoming HCUs. Proper interventions and proactive care for such high-risk patients may improve health outcomes and ease fiscal pressures on the healthcare system.
REFERENCES


Coalition Priorité Cancer and the Pharmaceutical Industry in Quebec: Conflicts of Interest in the Reimbursement of Expensive Cancer Drugs?

Coalition Priorité Cancer et industrie pharmaceutique au Québec : conflits d’intérêts dans le remboursement des médicaments anticancéreux coûteux?

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Abstract
In the context of scarce public resources, patient interest groups have increasingly turned to private organizations for financing, including the pharmaceutical industry. This practice puts advocacy groups in a situation of potential conflicts between the interests of patients and those of the drug companies. The interests of patients and industry can converge on issues related to the approval and reimbursement of medications. But even on this issue, interests do not always align perfectly.

Using the Quebec example of Coalition Priorité Cancer (CPC) as a case study, we examine the ethical issues raised by such financial relationships in the context of drug reimbursement decision-making. We collected, compiled and analyzed publicly available infor-
Coalition Priorité Cancer and the Pharmaceutical Industry in Quebec: Conflicts of Interest in the Reimbursement of Expensive Cancer Drugs?

Information on the CPC’s organization and activities; this approach allowed us to raise and discuss important questions regarding the possible influence exerted on patient groups by donors. We conclude with some recommendations.

Résumé
Dans le contexte où les ressources publiques sont limitées, les groupes de défense des intérêts des patients se tournent de plus en plus vers les organismes privés, dont l’industrie pharmaceutique, pour obtenir du financement. Cette pratique met ces groupes dans une situation potentielle de conflit entre les intérêts des patients et ceux des sociétés pharmaceutiques. Les intérêts des patients et ceux de l’industrie peuvent converger sur les enjeux liés à l’approbation et aux remboursements des médicaments. Mais même dans ce cas, les intérêts respectifs ne s’harmonisent pas toujours parfaitement.

Avec l’exemple québécois de la Coalition Priorité Cancer (CPC) comme étude de cas, nous examinons les enjeux éthiques soulevés par une telle relation de financement dans le contexte des décisions touchant au remboursement des médicaments. Nous avons recueilli et analysé des renseignements accessibles au public sur l’organisation et les activités de la CPC; cette démarche nous a permis de soulever et de discuter d’importantes questions au sujet d’une possible influence exercée par les donateurs sur les groupes de patients. En guise de conclusion, nous formulons quelques recommandations.

In October 2011, the national institute for excellence in health and social Services of Quebec (INESSSS) announced that for cost-effectiveness reasons, it could not recommend to the Ministry of Health the reimbursement of four cancer drugs that were under evaluation: Iressa, Tarceva and Alimta for lung cancer, and Afinitor for kidney cancer. This decision was immediately denounced by Coalition Priorité Cancer (CPC) – a Quebec-based patient advocacy group (Lacoursière 2011a). The CPC critique was taken up in the Quebec National Assembly by the then official opposition, the Parti Québécois, further increasing pressure on the Liberal Minister of Health at the time, Dr. Yves Bolduc. The Minister intervened with INESSSS and, in November 2011, announced the reimbursement of three of the four drugs that had initially been rejected (Iressa, Tarceva and Alimta) (Krol 2011). Following this shift, an article published in the French-language newspaper, Le Devoir, raised questions about the possible influence that the pharmaceutical industry had on the CPC (Daoust-Boisvert 2011) and, by extension, on government decision-making. Specifically, the article pointed out that the manufacturers of the drugs in question – AstraZeneca, Eli Lilly, Hoffman-LaRoche and Novartis – had each provided significant financial support to the CPC, bringing into question the interest group’s independence and the potential for indirect influence of the pharmaceutical industry on government decisions. This story was then picked up by various media, to which the CPC responded by reaffirming its independence (Lacoursière 2011b).
Pharmaceutical industry funding of patient or disease interest groups raises important ethical issues related to conflicts of interest (COIs) and public trust. Of particular concern is the “subversion” or “co-opting” of patient interest groups to advance industry agendas. Using the Quebec example of CPC as a case study, we will examine the ethical challenges – and in particular, the financial COIs – faced by patient interest groups, in order to reflect on the responsibilities of both these groups and industry with regard to the very problematic COIs that arise when the latter contribute to financing the activities of the former.

Background
Patient interest or advocacy groups commonly provide their members (i.e., patients and their families) with accessible information about their condition (e.g., aetiology, possible treatments) and support to live with the condition. Some of these groups also try to encourage research on their specific condition by engaging in public fundraising campaigns and calling upon policy makers to create more favourable conditions for the conduct of research and the development of treatments. These groups can also represent their patient-members in the media and before government, appearing before or even participating as members of regulatory agencies and health policy or public advisory committees (e.g., patient interest groups are represented on the Australian Pharmaceutical Benefits Advisory Committee and on committees of the UK evaluation agency, the National Institute for Health and Care Excellence [NICE]) (Allsop et al. 2004; Lofgren 2004).

Patient interest groups are largely volunteer run and often function with very limited operating funds, much of which come from private donations but also from government grants. In the last few decades, however, governments in many developing countries have significantly reduced funding to citizen groups of all sorts. In Canada, since the 1990s, a context of fiscal restraint and a changing public role of citizen groups has led to a substantial reduction in the funding of interest groups by the federal government (Jensen and Phillips 1996). As such, patient groups have increasingly chosen to turn to private organizations, including the pharmaceutical industry, to find funding for their various activities. A study by Ball and colleagues (2006) of patient interest groups in the United States, the United Kingdom, Australia, Canada and South Africa found that of 69 groups studied, 45% declared industry funding on their group websites. Similarly, Hemminki and colleagues (2010) found that 71% of groups in Finland were funded by drug manufacturers, while O’Donovan (2007) noted industry support in at least 47% of groups in Ireland.

From the perspective of the pharmaceutical industry, an association with patient interest groups has many advantages. Such collaborations enable interest groups, and thus patients, both to access and to share information regarding manufacturer products that are directly related to their conditions. In addition, because interest groups put a human face on disease, they add credibility to causes that the industry advocates (Hemminki et al. 2010; Lofgren 2004). But relations between patient interest groups and the pharmaceutical industry are extremely varied, and can be characterized by refusing funding on the one hand, and cooperation or even co-optation on the other.
1. Refusing industry funding: Some groups refuse any funding from industry, motivated by political reasons or the desire to maintain their independence and public credibility. For example, Breast Cancer Action of San Francisco explicitly refuses industry funding to safeguard its credibility and political legitimacy (Batt 2005; O'Donovan 2007). Breast Cancer Action Montreal and the Society for Diabetic Rights are examples of this type of group in Canada. Some health consumer groups, such as Women and Health Protection, PharmaWatch and the Canadian Health Coalition, also operate completely independently of industry funding.

2. Cooperation: Groups that agree to accept some industry funding may be more or less cautious in their relations. They may require different degrees of disclosure in their annual reports or on their websites (simply the names of donors, full disclosure of amounts received, program funded or percentage of total budget). In cases of project funding and activity sponsorship, Canadian Cancer Action Network's policy stipulates that “the sponsor will be acknowledged in a way that is agreed in negotiations with the company.” Unlike most groups, Epilepsy Action Australia specifies the amounts of donations from drug companies in its annual report (Ball et al. 2006). Some groups may also require “no strings attached” agreements for any funding in order to maintain their independence. For example, Fibromyalgia and Chronic Fatigue Syndrome Canada’s policy requires a written agreement “recognizing the autonomy and independence of FM-CFS Canada and its activities separate from any influence of the supporting company.” It also requires that all educational grants be unrestricted (FM-CFS Canada 2004). However, the Canadian Cancer Action Network’s policy, while maintaining its groups’ editorial control over all material, allows companies that fund specific projects to have representation on its steering committee (CCAN 2012). Other groups may be much less concerned with the problems that can result from such partnerships and not have formal guidelines or procedures.

3. Co-optation: There are some cases where organizations have been completely co-opted by industry (e.g., Society for Women’s Health Research in the United States; see Mundy 2003) or even created from scratch by the industry while still giving the appearance of being independent grassroots organizations (Herxheimer 2003; O’Donovan 2007). Yet, if these groups become seen as representing the interests of industry, they then run the risk of losing their public credibility and utility for industry (Herxheimer 2003; Jacobson 2005; Rothman et al. 2011).

The interests of patients and industry can converge on issues related to the approval and reimbursement of medications (Hemminki 2010; Jones 2008). Patients and interest groups legitimately desire access to better and more effective medicines, while the industry is interested in expanding its market share or getting a new medication reimbursed by health insurers. When such interests align, it may be very advantageous for manufacturers to finance...
the activities of patient interest groups.

In lobbying governments and intervening in the media, patient groups can be very effective at advancing certain agendas. These groups can influence the decisions of evaluation agencies (and have done so in the past) in favour of certain medications, or even contribute to overturning decisions regarding inclusion in drug insurance plans (Ferner and McDowell 2006). For example, the UK Alzheimer’s Society’s campaign against a NICE decision contributed to widened access to Aricept, Exelon, Reminyl and Ebixa (Alzheimer’s Society 2011). In addition, Carpenter (2004) has shown that the time required for the US Food and Drug Administration (FDA) to review and approve a drug was shorter when the medical condition in question was represented by advocacy groups that were well organized and funded. However, this type of relationship can lead to important pitfalls. For example, a study among European patient and consumer organizations has revealed an association between receiving drug company funding and supporting an expanded role for these companies as information providers (Perehudoff and Alves 2011). Potential problems are even explicitly recognized by Canada’s Research-Based Pharmaceutical Companies, the association that represents the pharmaceutical industry: “Given the range of issues in common, it is natural that the pharmaceutical industry and stakeholder groups should work together. However, the industry also recognizes that there exists the potential for conflict of interest, either real or perceived, in the relationship” (Rx&D 2009a).

In this paper, we focus on the case of Coalition Priorité Cancer (CPC), a Quebec-based patient interest group that is very active on issues of oncological drug reimbursement. While likely an outlier among the diverse patient interest groups in Quebec in terms of its industry funding (which is substantial), its influence with provincial decision-makers makes it an important actor to study, and a notable example of the challenges both for patient groups and for the pharmaceutical industry in managing potentially very problematic COIs.

Methods

For this study, we followed three general steps. First, we conducted a broad, non-systematic literature review on the relationship between patient groups and drug companies to identify key analytical elements and main problems related to such relationships. Second, we collected all the information publicly available on the history and activities of CPC (Appendix 1 available online at longwoods.com/content/23466) from its creation in 2001 to the end of 2011, as well as a list of its members (Appendix 2 available online at longwoods.com/content/23466). Information sources on the CPC included:

1. the CPC website (http://www.coalitioncancer.com);
2. newspaper stories (La Presse, Le Devoir);
3. comments in the Quebec National Assembly (http://www.assnat.qc.ca);
4. publicly available documents related to forums, symposia and conferences organized by the CPC (event programs, presentations, etc.);
5. two special sections (“cahiers spéciaux”) published by the CPC in the newspaper Le Soleil (2009 and 2011); and
6. studies, polls and petitions ordered by the CPC.

Most of the information was obtained directly from the CPC website, but also by searching Google and the Quebec National Assembly’s website for the keywords “Coalition Priorité Cancer.” To select newspaper articles, we searched the Eureka database (www.biblio.eureka.cc) for the keywords “Coalition Priorité Cancer” to identify relevant articles in the French-language press in Quebec. (French in-text citations are translated into English, and newspaper stories are referenced: D = Le Devoir and P = La Presse, followed by date of publication).

Third, CPC’s organization, activities and interventions were analyzed deductively, based on the elements identified in the literature review. The content of newspapers was not inductively and independently analyzed. It was used just as were other sources of information on CPC. All three appendices were compiled by the authors. The information on evaluation status of drugs in Appendix 3 (available online at longwoods.com/content/23466) was obtained from the INESSS evaluation reports available on that agency’s website (www.inesss.qc.ca).

Results and Discussion
The main analytical elements and potential issues that were identified in the literature were:

1. the portion of a patient interest group’s income that comes from industry;
2. the fact that manufacturers tend to support groups working in their particular therapeutic areas – this provides a clue to the interested nature of their donations;
3. the influence of donors on the orientation of groups through funding certain activities rather than others;
4. the tendency of patient interest groups that receive industry funding to defend the industry’s position that the drug assessment and approval process is too long and too strict – a position that focuses on access and may downplay other criteria, such as safety and efficient use of resources;
5. neglect by patient groups of questions about drug pricing and drug price policies; and
6. conflict of interest management and disclosure practices.

In the following discussion, we develop each point and explore points in relation to the case of CPC and to interest groups in general.

The CPC brings together 40 organizations (e.g., interest groups, professional organizations, university research chairs), and was established in 2001 to “defend and give a voice to those affected by cancer (patients, survivors, their families and their relatives) and to strengthen the organization of the fight against cancer” (CPC 2012a). The group’s main declared objectives are:
• to develop – in partnership with various actors in the fight against cancer, including civil society leaders and political decision-makers – a provincial plan to fight cancer;
• to promote the creation of an agency to better coordinate and strengthen the fight against cancer;
• to propose and support any measure that improves services to all people affected by cancer;
• to develop partnerships between community organizations, the healthcare system and government;
• to ensure a continuous surveillance of the fight against cancer; and
• to educate, raise awareness and mobilize the public (CPC 2012a).

The CPC’s activities include the production of surveys, petitions, forums, conferences, press conferences and press releases (Appendix 1). It is funded by contributions from member organizations (Appendix 2) on an annual basis or for a specific activity, individual registrations in the various CPC activities, and financial assistance from the public and private sectors, including 13 drug manufacturers (Appendix 3).

The portion of a patient interest group’s operating funds that comes from industry, as compared with individual donations or government support, is a key issue raised in the literature. In some cases, the percentage of operating funds from industry may be relatively limited, such as 6% to 7% for the Canadian Arthritis Society or 9% in the case of Cancerbackup (Mintzes 2007). But industry funding may be more substantial in some cases, reaching 30% for the Diabetes Federation of Ireland (O’Donovan 2007). In their study of 39 Finnish organizations that reported receiving funding from industry, Hemminki and colleagues (2010) noted that for four groups, this funding represented more than 20% of their annual budgets. In the case of the CPC, 60% to 65% of its budget came from the pharmaceutical industry in 2011 (Daoust-Boisvert 2011), a figure that is extremely high when compared to other cases cited in the literature. Although the relative portion of an operating budget is one indicator of the importance of the financial COI, the absolute value of funding is also meaningful, as even a small percentage of a very large budget may represent a considerable amount of money.

A study by Rothman and colleagues (2011) suggests that manufacturers tend to support groups working in their particular therapeutic areas. This implies, not surprisingly, that the industry’s support of patient interest groups is not purely altruistic, but interested. Of the 13 pharmaceutical companies financially supporting the CPC in 2011–2012, all have an interest in oncology. Moreover, in 2011–2012, the 13 manufacturers all had products either rejected in evaluation or not yet evaluated (Appendix 3). All these companies had a clear interest in seeing the CPC support their cases before decision-makers and regulators, especially concerning the approval and reimbursement of their drugs.

In the absence of “no strings attached” agreements, donors may have some influence on the orientation of groups by funding some activities rather than others. It should be noted that most CPC activities known to be specifically funded by drug companies deal with the issue of reimbursement of cancer drugs (conferences in 2010 and 2011; “cahiers spéciaux” in 2009 and 2011). From 2009 onwards, the issue of drug reimbursement assumed greater prominence in the CPC’s activities, and in 2011 it became predominant.
Evaluation agencies such as INESSS in Quebec have the responsibility to make recommendations regarding the approval and reimbursement of pharmaceutical drugs based on their safety, effectiveness and efficiency (cost–benefit), and the fairness and sustainability of the drug offer. Batt (2009) noted that Canadian health interest groups receiving industry funding (e.g., Best Medicine Coalition) tend to defend the industry’s position that the drug assessment and approval process is too long and too strict. Conversely, those groups receiving no funding from industry (consumer groups such as Women and Health Protection, PharmaWatch and the Canadian Health Coalition) tend to advocate for greater drug regulation and safety standards, both before and after marketing. While patient interest groups are heterogeneous in their constitution, membership, mission and functioning, such a dichotomy between those groups that receive and those that do not receive industry funding can lead one to hypothesize that significant financial interests could have an important impact on or even shape the behaviour of these groups. The CPC fits the pattern because it has taken the industry’s position on numerous occasions: e.g., “The Coalition therefore urges Quebec to review the functioning of the Conseil [du médicament] that it considers too slow and too severe” (D.2010.12.09).

However, accelerating and easing the evaluation process is often associated with less evidence and more risk to patients (Abraham and Davis 2002). In this respect, the position of the CPC on Avastin, for metastatic breast cancer, appears problematic. Avastin was approved for this indication by the FDA in 2008 and by Health Canada in 2009, but these approvals were conditional on obtaining additional data, as efficacy and safety had not been clearly established. In June 2011, with no study having yet demonstrated the effectiveness and safety of Avastin for breast cancer, a study committee of the FDA recommended revoking the approval of the drug for this indication (Mai-Duc 2011); in November, the FDA and Health Canada followed this recommendation (Pollack 2011). Yet, in October, although the FDA had already recommended the withdrawal of Avastin, the CPC denounced INESSS’s rejection of eight cancer drugs for metastatic breast cancer, including Avastin (CPC press release 2011.10.04; Derfel 2011). In its interventions, the CPC never mentioned the questions raised by the FDA study committee surrounding Avastin’s safety and effectiveness for treating breast cancer.

The CPC’s opinion on the unreasonable severity of the drug evaluation process not only concerned the criterion of therapeutic value, but also the criterion of efficiency (cost–benefit ratio): “The process of approval of these drugs is very long and, in cases of refusal, financial arguments take too much space, also deplores Dr. Audet-Lapointe” (P.2010.12.09). From our analysis and based on the information we collected, the evaluation criterion of efficiency does not appear to be relevant for the CPC. In fact, it often asks: “What is the cost of life in Quebec?” (CPC press release, 2011.10.04; P.2011.10.05). The underlying idea seems to be that life has no price. However, drug reimbursement without regard to costs is not a responsible and efficient use of resources and can threaten the sustainability of drug insurance plans (Ferner and McDowell 2006). In addition, any inclusion of a new drug has an opportunity cost, that is to say, it necessarily implies the abandonment of or reduction in access to another
service (Drummond et al. 2005). It is thus important to consider whether the reimburse-
ment of these expensive, low-efficiency drugs constitutes the best use of resources in the fight
against cancer (Hughes 2012).

Besides putting pressure on agencies and policy makers to approve and pay for certain
drugs, patient interest groups could also put pressure on industry and governments to lower
drug prices. However, as noted by Batt (2005), “drug pricing in itself has been a neglected area
for direct lobbying by patient and health advocacy groups in Canada” (p. 12). This choice of
target is probably not unrelated to the fact that many interest groups receive industry funding.
But it might also be due to the fact that these groups have been less able to leverage the scien-
tific (health economics) expertise necessary to push for reduced pricing. When the challenge
was simply gaining access to needed medications for their members (i.e., reimbursement on
drug plans), the actual cost of the drug was a secondary or subsidiary consideration.

While the CPC is constantly urging the INESSS and health insurers to make con-
cessions on the price of anticancer drugs, we found no evidence that it similarly calls on
manufacturers to reduce those prices (Gagnon 2012). Nor did we find any evidence of the
CPC’s denouncing the failure by the pharmaceutical industry to respect agreements with the
Government of Quebec to ensure the lowest price paid in Canada (BAP rule: Best Available
Price). Indeed, manufacturers concluded secret agreements with other provinces on the price
of anticancer drugs, agreements that contravene the Quebec BAP rule (Gagnon 2011).

A first step towards better management of conflict of interest is transparency and dis-
closure (Hurst and Mauron 2008). The Association of the British Pharmaceutical Industry
(ABPI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA)
have codes of practice that require member companies to make public a list of organizations
to which they provide support. The list must include the amount of financial assistance and
a detailed description of non-financial support (ABPI 2012; EFPIA 2011). In Canada, the
Rx&D’s “Guidelines for Transparency in Stakeholder Funding” recommend to members the
disclosure, by means of their websites and annual reports, of all stakeholders to which they
provide direct funding; but they do not require disclosure of the value of the support. The
Rx&D code is voluntary, but membership in the organization requires companies to abide by
the code (Rx&D 2009b). There is no equivalent to the ABPI or EFPIA for patient interest
groups that sets standards of practice or offers guidelines for this community.

A UK study found that only 26% of the 246 patient advocacy groups receiving funding
from the industry declare such information on their website: 22 groups name companies, 18
provide information on the type of activity funded, 14 on the amounts and 4 on the portion
of their budget coming from industry (Jones 2008). Ball and colleagues (2006) analyzed 69
websites of national and international patient organizations based in the United States, the
United Kingdom, Australia, Canada and South Africa, and found that only one-third speci-
fied the source of their funding and the donor’s name, but without necessarily specifying the
amount of funding. Similarly, Rothman and colleagues (2011) found that among 161 US
groups receiving funding from Eli Lilly, 25% reported receiving funding from this manufac-
turer and 10% stated the use of funds, but none disclosed the amounts received.

On the disclosure of funding sources, the practices of CPC are minimal. On its website, the group provides a list of pharmaceutical industry donors but without specifying the amounts or the use of donations; nor does the CPC provide a public annual report. However, for some specific activities, donors’ logos appear on official documents (“états généraux,” national conferences; “cahiers spéciaux”). The CPC website states that “[f]inancial contributions of our partners, whether from public institutions or private companies, are governed by a Policy on Partnerships from the Board of Directors of the Coalition and prevents any interference in the Coalition’s governance” (CPC 2012b). And as quoted in an article in Le Devoir, according to the spokesman for the CPC, “[t]he Coalition does not depend on pharmaceutical companies in its decision-making” (D.2011.12.03). But no details concerning the Policy on Partnerships are given, nor is the policy available online. This omission clearly raises important questions. Even if industry donors are not directly involved in a group’s decision-making processes – especially if the percentage of operating funds that come from industry is substantial – one can reasonably question whether the group is actually able to make decisions or take positions that go against the interests of their major donors.

Conclusion
Patient interest or advocacy groups play a significant role in raising awareness about specific illnesses, in supporting patients and in contributing to decision-making about the development and financing of new and existing drugs. In order to play this role effectively, these groups need financial support. In the context of scarce public resources, these groups have increasingly turned to the private sector for financing. With 60% of its funding coming from the pharmaceutical industry, the CPC is an example of a group that is particularly vulnerable to influence.

The interests of patients and industry can converge on issues related to the approval and reimbursement of medications. But even on issues of drug reimbursement, these interests do not always align perfectly. From our analysis and based on the available information, the CPC’s commitment to its patient-members does not appear to be optimal on a number of different occasions. For example, the absence of a clear position or warning against Avastin for breast cancer raises some serious questions about the agency’s role as a watchdog or source of reliable advice to its patient community. Moreover, the CPC’s focus on the issue of reimbursement of expensive, low-efficiency drugs also raises questions, because such reimbursement has an important opportunity cost and does not appear to be the best way to use scarce resources to fight cancer. Finally, we found no evidence that the CPC has called for manufacturers to reduce prices, or lobbied the Quebec government to negotiate for lower drug prices, as do other provinces. Similarly, we found no evidence that the CPC has denounced the failure by the industry to respect agreements with the Quebec government in ensuring the lowest price paid in Canada.

In order for patient interest groups to manage the problematic financial COI in which they find themselves when they take funding from the private sector (e.g., pharmaceutical or
medical device industries), these groups should be, at a minimum, required to disclose donors’ names publicly, as well as the amount, the nature and the use of the support they receive from public or private donors. They should also include details of COI of any advisers to the group, and disclosure material needs to be prominent and accessible. Furthermore, general donation should be preferred, and specific funding of activities discouraged, in order to limit the capacity of donors to subtly orient the groups’ activities. Above all, more public funding would make advocacy groups less dependent on private industry sources. But in the current economic context of reduced public funding to patient interest groups, and given the evident difficulty in funding activities through individual private donations, many groups will choose to turn to the private sector for support. It then becomes essential that patient interest groups aim at full transparency regarding their fundraising activities, their operating budgets and their governance policies if they are to protect the trust that they have developed with their members and civil society. Such transparency would enable appropriate public scrutiny on the functioning of interest groups, making them less effective vectors of industry messages and thus less open to and less interesting for manipulation. Finally, an increased role for advocacy groups without industry funding may help to make debate about drug reimbursement and eventual policy decisions more credible and accountable.

Limitations
This study has several limitations. First, the information on CPC is limited to what was publicly available on the Internet and in the newspapers. For example, a spokesperson of the group mentioned that its relations with donors are regulated by a Policy of Partnership, but we did not contact CPC to obtain this document and so did not include it in our analysis. This approach reflects our normative stance that such information should be public and easily accessible if a group is to be both transparent and thus accountable. Second, our study did not allow us to make causal inferences, although we could nonetheless draw reasonable conclusions from the associations between company sponsorship and group positions and actions. Finally, while a case study does not allow any generalization to the practice of other patient groups, it does point to important issues of concern that are generalizable.

ACKNOWLEDGEMENTS
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Coalition Priorité Cancer and the Pharmaceutical Industry in Quebec:
Conflicts of Interest in the Reimbursement of Expensive Cancer Drugs?

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NOTE
1. Because the mission of most consumer groups is to protect consumers from corporate
abuse (e.g., misleading advertising), they are much less likely than other advocacy groups
(e.g., patient groups) to accept funding from drug companies.

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Abstract
Product listing agreements (PLAs) with pharmaceutical manufacturers are increasingly viewed as an innovative and useful tool in the effort to control drug expenditures. To date, Quebec is the only province that has been reluctant to enter into such agreements, arguing that their confidential nature may lead to a disparity in coverage between individuals covered by the public plan and those covered by private insurance. While PLAs may, in fact, present such a risk, in this paper we will argue that when used correctly, these agreements are actually tools that could help attain all four of the objectives set out in Quebec’s policy on medications, namely: (a) improved access to drugs, (b) fair and reasonable drug pricing, (c) optimal drug use and (d) maintaining a dynamic biopharmaceutical industry in Quebec.
Résumé
Les ententes relatives à l’inscription des produits (EIP) avec les fabricants de médicaments sont de plus en plus considérées comme des outils pratiques et novateurs pour le contrôle des dépenses pour les médicaments. À ce jour, le Québec est la seule province qui s’est montrée réticente à prendre part à de telles ententes, sous prétexte que leur caractère confidentiel peut mener à des inégalités entre les personnes qui bénéficient d’un régime public et celles qui ont un régime d’assurance privé. Bien que les EIP puissent effectivement présenter un tel risque, nous soutenons dans cet article que si elles sont employées correctement, ces ententes constituent des outils qui peuvent aider à atteindre les quatre objectifs formulés dans la politique québécoise du médicament, c’est-à-dire (a) l’accessibilité aux médicaments, (b) un prix juste et raisonnable, (c) une utilisation optimale des médicaments et (d) le maintien d’une industrie biopharmaceutique dynamique au Québec.

Over recent decades, the exponential increase in drug spending has led governments to implement traditional cost-saving policies, such as direct and indirect price controls, health technology assessment and reference pricing. However, in the last few years, an increasing number of public payers (Canadian provinces, the United Kingdom, France, Australia, Germany, Sweden, Italy and other jurisdictions) are now also relying on product listing agreements (PLAs, or “risk-sharing agreements”) with pharmaceutical manufacturers as a means of limiting the clinical and financial risks linked to drug coverage (Bourassa Forcier and Noël 2012).

Adamski and colleagues (2010) describe PLAs as “agreements concluded by payers and pharmaceutical manufacturers to diminish the impact on the payer’s budget of new and existing medicines brought about by either the uncertainty of the value of the medicine and/or the need to work within finite budgets.” Usually, in a PLA, the payer agrees to list a new medication on its drug formulary in exchange for a commitment from the pharmaceutical manufacturer. For example, a clinical PLA could involve a commitment, by the manufacturer, to conduct a post-marketing clinical study to further assess the clinical efficiency and effectiveness of the drug. In a financial PLA, the manufacturer could commit to providing a financial discount to the payer (i.e., the insurer) in order to create a positive cost-effectiveness ratio or to limit the impact on its budget of the coverage of the medication. (See Table 1 for a comparison of the advantages and disadvantages of the different types of PLAs and Table 2 for details on PLA policies and practices in other provinces.)
TABLE 1. Types of PLAs

<table>
<thead>
<tr>
<th>Type of Agreement</th>
<th>Groups</th>
<th>Definition/Use</th>
<th>Advantages [+]/ Disadvantages [-]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Financial Agreements</strong></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
| a) Rebate Agreements |                                | Create two different prices for the same medication: a confidential reduced price for the payer and an official public price (higher) for insurees (Ministry of Health and Long-Term Care 2010; widely used in Ontario). | [+ Simple to implement.  
[+] Generate savings for the payers.  
[-] High opacity.  
[-] Create artificial marketed medication prices.  
[-] Disparity between public and private insurees. |
| b) Price–Volume Agreements |                                | The first simple form of a “risk-sharing” agreement.  
The price of the medication is reduced according to drug utilization.                                | [+ Improve budget certainty.  
[+] Greater transparency compared to rebate agreements.  
[+] Simple to implement.  
[-] Disparity between public and private insurees. |
| **Clinical Agreements** |                               |                                                                                               |                                                                                                   |
| a) Conditional Coverage Agreements | | The coverage of a medication is conditional upon positive post-marketing clinical data.  
(i) Coverage with evidence development agreements (CED): Clinical studies required differ from traditional post-marketing studies, their aim being the reduction of the payer’s uncertainty about the clinical effectiveness of the medication.  
[+] Option for obtaining optimal drug therapy and “value for money.”  
[+] Provide improved access to a new, promising drug in a timely manner.  
[+] Reduce any uncertainty that may remain following the drug’s clinical evaluation.  
[-] Risk that the drug be removed from the list owing to lack of strong clinical evidence.  
[-] Difficulty in assessing clinical outcomes.  
[-] Lack of transparency. |
| b) Performance-Linked Reimbursement Agreements | | Drug coverage is tied to a specific clinical aspect of the drug.  
(i) Outcome guarantee agreements: “schemes where the manufacturer provides rebates, refunds, or price adjustments if their product fails to meet the agreed upon outcome targets” (Carlson et al. 2010: 184).  
Two principal components: a data collection process to assess the performance of the medication for each patient treated and a formula that links the reimbursement or the rebate to the data collected.  
(ii) Process of care agreements: “schemes where the reimbursement level is tied to the impact on clinical decision-making or practice patterns.” | [+ Link the price of a medication to its effectiveness for each patient.  
[-] Clearly defined evidence-based parameters for measuring success of the therapy are often missing.  
[+] Limit uncertainty concerning the drug’s impact on clinical decisions. |
**Mélanie Bourassa Forcier and François Noël**

### TABLE 2. PLAs in other provinces

<table>
<thead>
<tr>
<th>Province</th>
<th>PLA Policies</th>
<th>Mechanism</th>
<th>Types of Agreements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ontario</td>
<td>PLAs are negotiated and concluded since the adoption, in 2006, of An Act to Amend the Drug Interchangeability and Dispensing Fee Act and the Ontario Drug Benefit Act (Bill 102) (Government of Ontario 2006). In 2011, the government of Ontario introduced a policy specifically for cancer drugs, allowing the conclusion of CED agreements, called the Evidence Building Program, that aims to “develop and collect real-world data on cancer drugs where evolving evidence demonstrates clinical benefit beyond the current reimbursement criteria” (Cancer Care Ontario 2011).</td>
<td>No official mechanism. Listing recommendations may be conditional based on different commitments from pharmaceutical manufacturers (e.g., commitment to the advertisement of the appropriate use of the medication if concerns exist about “off-label” use or specific evidence to identify clinical or economic uncertainties).</td>
<td>• Mostly confidential agreements on prices (98%).</td>
</tr>
<tr>
<td>Alberta</td>
<td>Policy that stipulates comprehensive parameters for establishing and executing PLAs through a clear, collaborative, predictable and sustainable process. Four different types of PLAs: (1) price/volume agreements, (2) health research capacity agreements, (3) utilization management agreements and (4) coverage with evidence development agreements (Alberta Health and Wellness 2011).</td>
<td>The Ministry invites manufacturers, via a request for PLA (RFPLA), to submit a PLA proposal. In the RFPLA, the Minister indicates the type of drugs targeted for PLAs and the preferred type of PLA for these drugs. On the basis of the RFPLA response, a pharmaceutical manufacturer can submit a PLA proposal to be evaluated by the Alberta authorities. In their decision on whether or not to recommend the proposed agreement, the authorities take into account the priority status of the pathology, the therapeutic benefits of the medication compared to the comparator, the existence of equivalent drugs, the difficulty of the proposed agreement and the societal benefits that may result from the drug coverage.</td>
<td>PLAs that: • Facilitate improved access to innovative drugs in a timely manner. • Ensure the financial sustainability of the drug plan.</td>
</tr>
<tr>
<td>Other provinces</td>
<td>No formal PLA policies. Pan-Canadian agreements (in which Quebec has not participated) have been concluded for bulk purchasing, e.g., Soliris (IMS Brogan 2011). Canadian provinces, except Quebec, concluded an agreement on bulk purchasing for six generic drugs after April 1, 2013: Atonavastatin, Ramipril, Venlafaxine, Amlodipine, Omeprazole and Rabeprazole (Lunn 2013).</td>
<td>Willingness of some provinces to implement clear guidelines in order to regulate this process.</td>
<td>Atlantic provinces are currently working on a common PLA policy draft that should be similar to the Alberta PLA policy, except that no “health research capacity agreement” will be included in the guidelines. This is due to the fact that the biopharmaceutical industry is not developed in these provinces and thus, is not a priority.</td>
</tr>
</tbody>
</table>
Interestingly, unlike most Canadian provinces— and although section 52.1 of An Act Respecting Prescription Drug Insurance, RSQ (Government of Quebec 1996), c. A-29.01 (“the Act”) allows the Minister of Health (“the Minister”) to enter into PLAs – the government of Quebec has, to date, been reluctant to enter into such agreements (Pelchat 2012). One reason may be that clinically based agreements are difficult to implement (Neumann et al. 2011). Another reason may be that because financial PLAs are confidential, private insurers, and consequently the individuals they insure, do not benefit from the discount granted by the manufacturer to the government. According to Gagnon (2012), this situation contravenes the objective of fairness in Quebec’s pharmaceutical policy and therefore, PLAs should be considered illegal.

In this paper, we will argue that not only are PLAs legal in Quebec, but they have the potential to reduce drug expenditures, to improve accessibility to medications and reasonable pricing, to improve drug utilization and to foster innovation. In particular, we will explain why both clinical and financial PLAs are actually a means of reaching all the objectives in Quebec’s pharmaceutical policy (“the Policy”).

Objectives of Quebec’s Pharmaceutical Policy
The Act defines what is referred to as the “Basic Plan” and sets out all the conditions and guarantees required for both public and private prescription drug insurance in Quebec. The current Basic Plan, which came into effect in 1997, is unique in Canada because it requires all Quebec residents to be covered by a prescription drug insurance plan (mandatory Basic Plan) (Pomey et al. 2007).

Section 51 of the Act requires the Minister to implement a policy on pharmaceuticals. This policy, which was amended for the last time in 2007 (MSSS 2007), sets out four main objectives that the government must strive to achieve: (a) ensure access to prescription drugs, (b) fair and reasonable drug pricing, (c) optimal drug use, and (d) maintain a thriving biopharmaceutical industry in Quebec. For the purpose of this paper, we combined the first two objectives under the title “Fair and reasonable access,” below.

**Fair and reasonable access**
The objective in the Policy relating to fair and reasonable access is reflected in the Act and the regulations to it. The main elements in the Basic Plan that contribute to reaching these objectives are its mandatory nature; the fact that private insurers are required to cover, at least, the same medications as those covered under the Basic Plan; and the limited financial contribution required of individuals covered by the plan.

The mandatory nature of the Basic Plan was introduced in 1997 in order to guarantee accessibility to prescription drugs in the province. In particular, the plan guarantees all residents coverage of the cost of medications and pharmaceutical services provided in Quebec (the Act, s. 2), regardless of the risk related to the state of health of the patient (the Act, s. 7). In Quebec, a resident who is not covered by private group insurance is automatically covered by...
the public plan (the Act, ss. 7, 15–18.1). In 2011–2012, 3.4 million residents, out of a total of 7.7 million (4.3 million being covered by private group insurance), were covered by the public plan (RAMQ 2012: 90).

In order to encourage fair and reasonable access to prescription drugs, both the government and private insurers are required, under the Basic Plan, to provide minimum coverage for medications and pharmaceutical services. The guaranteed minimum coverage involves a defined maximum financial contribution (the Act, s. 10 et seq.) from the individuals covered by the plan and the reimbursement of all drugs listed under section 60 of the Act. Private insurers are required to provide the individuals who are covered by their plans at least the same coverage as that provided by individuals protected by the public plan (the Act, ss. 35 and 60, par. 1).

In Quebec, the Minister is required to first recognize a manufacturer before a drug can be listed. To be recognized, the manufacturer must enter into an agreement by signing the form found in Schedule I of A Regulation Respecting the Conditions Governing the Accreditation of Manufacturers and Wholesalers of Medications, c. A-29.01, R.2 (“the Regulation”) (Government of Quebec 2013). One of the more interesting aspects of this agreement is a guaranteed pricing policy that requires the manufacturers to sell their medications at a price no higher than any price granted for the same drug under any other provincial drug insurance program in Canada (the “lowest price” rule) (the Regulation, s. 1(4)). The Policy considers the lowest price rule to be an effective tool in ensuring reasonable drug pricing. Necessarily, the effectiveness of this rule is viewed with scepticism now that other provinces are entering into confidential PLAs in which discounts are actually granted in exchange for drugs being listed (Bourassa Forcier and Noël 2012).

It is feared that confidential PLAs between the government of Quebec and manufacturers could result in disparities between individuals covered by the public plan and those covered by private plans. This risk is related to the confidentiality of the prices agreed to for listed drugs. Private insurers, and therefore individuals who are covered by their plans, would not benefit from the discounted prices. The government of Quebec’s refusal to enter into PLAs for fear of creating disparity is certainly not the solution. Encouraging private insurers to follow the government’s lead would be a better alternative. Actually, it is the private insurers’ lack of interest in this option that would ultimately lead to such disparities.

The fact that PLAs between the government of Quebec and pharmaceutical manufacturers represent the potential to create inequalities between the insured does not mean that such agreements are illegal. Actually, a perusal of the Act and the regulations related to it clearly reveals that the fairness objective is highly relative and is more an ideal to be strived for than a legal requirement. In its application, the Act itself creates certain disparities between the individuals covered by the public plan and those covered by private plans. First, the objective related to “fair and reasonable access” contained in the Policy may be disputed owing to the large disparity between the financial contribution required of residents covered by the public plan as opposed to those paid by individuals covered by private plans. As mentioned above,
the minimum coverage under the Basic Plan requires a financial contribution from those seeking coverage. This participation varies depending on whether a person is covered by a private group insurance plan or by the public insurance plan. The financial contribution paid by an individual covered by the public plan includes a defined annual premium (the Act, s. 28), while no such defined amount exists for those covered by a private plan. Furthermore, the price of pharmaceutical services provided to residents covered by the public plan is negotiated between the Minister and the association representing the owner pharmacists of Quebec (Association québécoise des pharmaciens propriétaires du Québec). In 2012, the negotiated price under the public plan was, on average, $8.44 per prescription, while its counterpart under private insurance plans was variable and could reach as high as $50 per prescription (Gazaille 2010).

Finally, Quebec is recognized as the province with the most comprehensive list of covered prescription drugs (Gagnon 2011). Nevertheless, a few years ago, Quebec was criticized for not covering certain cancer drugs (Lacoursière 2011). This criticism was based on a cross-national comparison of access to these drugs (Hughes 2012), which concluded that in 2011, Quebec was not covering certain cancer drugs while other provinces, such as Ontario and Alberta, were (Bourassa Forcier and Noël 2012; Cancer Care Ontario 2011; Hughes 2012). This situation led to a major criticism from the Institut d’excellence en santé et en services sociaux (INESSS) (IHS 2011; INESSS 2011). In response, the province agreed to list these drugs without negotiating PLAs, even though INESSS had recommended they do so (INESSS 2011).

At this point, it can be argued that by not negotiating the price of these drugs, the government failed to fully respect and guarantee the sustainability of the Policy’s access and pricing objectives. It is quite probable that in this situation, PLAs would have represented a useful tool for promoting these objectives.

Optimal use of medication

Non-optimal drug therapy, or non-optimal drug utilization, refers to a number of undesirable events, including improper drug selection, inappropriate dosage, adverse drug reactions, drug interactions, therapeutic duplication and patient non-compliance.

In the United States, the costs associated with patient non-compliance are estimated at over US$290 billion, irrespective of costs related to morbidity and mortality (Hubbard and Daimyo 2010). According to the World Health Organization’s report on adherence to long-term therapy, “adherence to long-term therapy for chronic illnesses in developed countries averages 50%” (WHO 2003).

In light of its clinical and financial benefits, optimal drug use is a key objective of the policy of the government of Quebec. In 2002, in order to better meet this objective, the government entered into three financial partnerships with pharmaceutical manufacturers and their association, in which it was agreed to create optimal use programs. These encompass a wide range of programs that can vary in name and by the clauses they contain. Different
optimal use programs are aimed at different targets, ranging from doctors to pharmacists or patients. Such programs may, for instance, include the training of healthcare professionals, patient education, monitoring or some combination of these. Haynes and colleagues (2008) suggest that a patient adherence program may involve counselling services for the patient about the targeted disease, as well as group meetings, follow-ups, simplified dosing, reminders, different medication formulations, increased pharmacy services, mailed communications and appointment and prescription refill reminders.

Unfortunately, all three partnerships failed to reach their objectives because of various shortcomings within the contracts. In our opinion, one of the shortcomings lies precisely in the fact that they did not make the listing of medications conditional upon the manufacturers’ investing in optimal use programs and on the collection of new clinical and financial data related to their medications. Clinical PLAs are a new way to create a real incentive for manufacturers to ensure that their medications are properly prescribed and used. Indeed, non-conclusive post-marketing studies may bring about the risk that medications be removed from the formulary or that their listed price are reduced.

However, we wish to emphasize that to date, very few countries have implemented clinical PLAs (Bourassa Forcier and Noël 2012) because of the complexity of their implementation (numerous actors being involved, such as doctors and pharmacists, with the ensuing need of a data register) and the difficulty in quantifying the societal value associated with drug use programs. Indeed, clear guidelines on how to evaluate the health outcomes and economic aspects of such drug use programs would certainly render the economic evaluation process easier and more predictable, both for manufacturers and for the public.

A strong biopharmaceutical industry

Until recently, the policy of the government of Quebec had, as its fourth objective, the development of a strong biopharmaceutical industry in the province. In order to reach this goal, the 2007 policy allowed an annual indexing of drug prices. This new policy brought an end to the “price-freeze” policy that had been in place since 1994 (MSSS 2007: 7). At the same time, in order to limit the negative impact of annual price increases on the sustainability of Quebec’s public plan, the government began to enter into confidential compensatory agreements with manufacturers. As of March 31, 2011, 60 compensatory agreements, covering 648 products, were concluded with 59 pharmaceutical manufacturers (RAMQ 2012: 65).

On April 1, 2013, the new government announced a resumption of the price-freeze policy until March 31, 2015.

In addition to the price indexing policy of 2007 and in order to advance research and development (R&D) in Quebec, the government also confirmed, the same year, that it would continue to implement the “15-year rule” (BAP 15). The BAP 15 was an exception to Quebec’s “lowest price” policy (the Act, s. 28.2). Under this rule, a brand-name medication was reimbursed at its original price for the first 15 years following its inclusion in the formulary, even if a generic version was available in Quebec (the Act, s. 9). This rule was abolished in January 2013.
The government’s reasons for abolishing BAP 15 were the high level of expenditures related to medications resulting from the application of this rule, which reached approximately $25 million in 2005 (MFQ 2005) and $193 million in 2011–2012 (Lacoursière 2012), in combination with a growing scepticism regarding its efficiency in encouraging R&D, particularly in view of the closing of several pharmaceutical research laboratories in the province over recent years (Babad 2012).

We believe that it is not too late for the Province of Quebec to find a new and effective alternative to promote innovation and the development of a strong Quebec-based biotechnology industry. Through the negotiation of PLAs, the government could actually provide recognition of the value of a manufacturer’s investments in R&D in the province, as is the case in Alberta through its PLA policy (Alberta Health and Wellness 2011; see also Table 2). Through the negotiation of PLAs, the government could also emphasize particularly innovative medications. If PLAs were negotiated to recognize and reward R&D investments made in Quebec and innovation, all residents of Quebec would benefit in the long term.

Conclusion
Undoubtedly, PLAs have considerable advantages. Payers are relying more and more on PLAs to expand drug coverage and to control their drug expenditures. These agreements can also promote the collection of post-marketing clinical and economic data to help support the introduction of new drugs. Finally, through PLAs, the government of Quebec could find a new means of promoting R&D investments and innovation in the province. However, because they may rapidly become an administrative burden for the government, PLAs should be the exception. In particular, these agreements should not supplant traditional pharmaco-economic evaluations, but rather form part of a wide array of tools that can be useful in dealing with clinical or financial uncertainties.

Considering their advantages, the government of Quebec, i.e., the Minister of Health, should consider PLAs when striving to meet each of the four pharmaceutical objectives set out in its policy. However, in doing so, the Minister must not forget the lack of transparency of PLAs and the ensuing risk of creating disparities between individuals covered by the public plan or by private insurance plans. This risk must not be overlooked.

However, in view of the advantages of PLAs, rather than entirely shy away from such partnerships with drug manufacturers, the government should implement a transparent policy that would regulate their use. This policy could, for example, promote transparent agreements where only commercial and financial information would be confidential, all other information being public and accessible online. In implementing such a policy, Quebec would become a pioneer in the field of transparent PLAs and would certainly provide an incentive to other jurisdictions to follow in its footsteps.

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NOTE
1. Alberta and Ontario are the only two provinces with formal PLA policies (see Table 2).

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Product Listing Agreements (PLAs): A New Tool for Reaching Quebec’s Pharmaceutical Policy Objectives?


Adverse Events Associated with Hospitalization or Detected through the RAI-HC Assessment among Canadian Home Care Clients

Événements indésirables associés à l’hospitalisation ou détectés à l’aide du RAI-HC chez les clients qui reçoivent des soins à domicile au Canada

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On behalf of the authors (see Acknowledgements)
Abstract

Background: The occurrence of adverse events (AEs) in care settings is a patient safety concern that has significant consequences across healthcare systems. Patient safety problems have been well documented in acute care settings; however, similar data for clients in home care (HC) settings in Canada are limited. The purpose of this Canadian study was to investigate AEs in HC, specifically those associated with hospitalization or detected through the Resident Assessment Instrument for Home Care (RAI-HC).

Method: A retrospective cohort design was used. The cohort consisted of HC clients from the provinces of Nova Scotia, Ontario, British Columbia and the Winnipeg Regional Health Authority.

Results: The overall incidence rate of AEs associated with hospitalization ranged from 6% to 9%. The incidence rate of AEs determined from the RAI-HC was 4%. Injurious falls, injuries from other than fall and medication-related events were the most frequent AEs associated with hospitalization, whereas new caregiver distress was the most frequent AE identified through the RAI-HC.

Conclusion: The incidence of AEs from all sources of data ranged from 4% to 9%. More resources are needed to target strategies for addressing safety risks in HC in a broader context. Tools such as the RAI-HC and its Clinical Assessment Protocols, already available in Canada, could be very useful in the assessment and management of HC clients who are at safety risk.

Résumé

Contexte : L’occurrence d’événements indésirables (EI) dans les établissements de soins est une préoccupation en matière de sécurité des patients qui a des répercussions significatives dans les systèmes de services de santé. Les problèmes touchant la sécurité des patients sont bien documentés pour les établissements de soins de courte durée; cependant, de telles données pour les clients qui reçoivent des soins à domicile au Canada sont plus rares. Cette étude canadienne a pour objet d’examiner la question des EI dans le contexte des soins à domicile, particulièrement ceux qui sont associés à l’hospitalisation ou qui sont détectés à l’aide du Resident Assessment Instrument for Home Care (RAI-HC).

Méthode : Nous avons effectué une étude rétrospective de cohorte. La cohorte était formée de clients recevant des soins à domicile en Nouvelle-Écosse, en Ontario, en Colombie-Britannique et sur le territoire de l’Office régional de la santé de Winnipeg.

Résultats : Le taux d’incidence général des EI associés à une hospitalisation variait de 6 % à 9 %. Le taux d’incidence des EI déterminés à l’aide du RAI-HC était de 4 %. Les EI les plus fréquemment associés à l’hospitalisation sont les blessures causées par une chute, les autres types de blessures et les événements liés à la prise de médicaments, tandis que l’EI le plus fréquemment détecté à l’aide du RAI-HC est la détresse des nouveaux soignants.

Conclusion : L’incidence des EI provenant de toutes les sources de données varie de 4 % à 9 %. Il faut davantage de ressources pour concevoir des stratégies afin de traiter les risques liés à la sécurité dans le contexte général des soins à domicile. Des outils tels que le RAI-HC et
ses protocoles d’évaluation clinique, déjà disponibles au Canada, peuvent être très utiles pour l’évaluation et la gestion des clients de soins à domiciles pour lesquels il existe un risque lié à la sécurité.

Home care (HC) has been a critical part of healthcare restructuring and has played a key role in primary healthcare, chronic disease management and aging-at-home strategies across Canada (Canadian Home Care Association 2013a). Current demographic changes in Canada suggest that the utilization of HC services will escalate significantly over the next two decades. Home care programs across Canada have already experienced a 51% increase in the number of recipients since 2008 (Canadian Home Care Association 2013b). The Canadian Home Care Association (2013a) estimates that 1.8 million Canadians receive publicly funded HC services annually at an estimated cost of $5.8 billion.

Patient safety problems have been well documented in acute care settings (Baker et al. 2004); however, similar data for clients in HC settings in Canada are limited. This paper presents findings that compare adverse events (AEs) in HC that are associated with hospitalization or determined by the Resident Assessment Instrument for Home Care (RAI-HC) for four jurisdictions in Canada: Nova Scotia, Ontario, British Columbia and the Winnipeg Regional Health Authority (WRHA).

While the paper focuses on the aspects of HC delivery that need reform and improvement, it is important to recognize the impressive contributions and positive impacts of those who are engaged each day in providing safe care to the hundreds of thousands of Canadians who benefit from HC services.

The purpose of our study was to investigate the incidence, magnitude and types of AEs associated with hospitalization or determined through the RAI-HC instrument for Canadian HC clients.

Two previous North American studies (Madigan 2007; Sears et al. 2013) reported that 13% of HC clients experienced an AE each year. The types of AEs reported were falls, adverse drug events, urinary tract infections, accidents at home, wound deterioration, unexpected nursing home admissions and an increase in the number of pressure ulcers. Clients who experienced such events were generally older. These two studies were limited with regard to the population studied and sample size. For example, the study by Sears and colleagues (2013) included 430 Ontario HC clients; Madigan’s (2007) study was limited to HC clients who qualified for Medicare or Medicaid in the United States.

Doran and colleagues (2009a) described the prevalence of patient safety problems in a study of 238,958 HC clients from Ontario, Nova Scotia and the WRHA. That study determined that new falls, unintended weight loss, new emergency department (ED) visits and new hospital visits were the most common of the AEs. Significant variations in the prevalence
of patient safety problems were found between regions of the country. Variation can occur because of differences in client population served, jurisdictional factors such as delivery modes (e.g., interdisciplinary coordination) and care processes (e.g., differences in service) (Canadian Home Care Association 2013a). It is important to understand the factors that contribute to such variation because they have implications for policy or practice change. A follow-up paper was designed to generate this knowledge by investigating the extent to which safety risk factors explained variation in regional rates of AEs, focusing specifically on unplanned ED visits (Doran et al. 2009b). A history of falls, a cancer diagnosis, polypharmacy, anxiolytic medication use and antidepressant medication use were associated with increased risk of an ED visit. A limitation of these studies was that only HC clients who qualified for a RAI-HC assessment were included, so findings may not be representative of all types of HC clients.

Our current study attempted to address the limitations identified in previous literature by focusing on HC clients from regions in Canada where comparative data were available and by including short- and long-stay clients. By linking RAI-HC (Hirdes et al. 2004) data from the Home Care Reporting System (HCRS) and the hospital Discharge Abstract Database (DAD), we were able to determine pre-admission conditions associated with hospital admission and construct a profile of the types of AEs that HC clients experience.

The study questions included the following:

1. What is the incidence of AEs associated with hospitalization or determined through the RAI-HC assessment among Canadian HC clients?
2. What are the types of AEs that HC clients experience?
3. What are the factors associated with increased risk of experiencing an AE during hospitalization?

Methodology
The World Health Organization (WHO 2008) framework guided the conceptualization of the patient safety variables, and we adapted its definitions to the HC context. The WHO defines patient safety as “freedom, for a patient, from unnecessary harm or potential harm associated with healthcare” (WHO 2008: 7). Adapting this definition for HC, we defined patient safety as the absence of harm to clients and their family, and to unpaid caregivers from healthcare provided in the client’s home, as well as the actions taken to prevent or reduce this harm. Client safety is usually assessed by measuring the incidence of AEs. An adverse event is defined by the WHO as an injury caused by medical management or complication rather than by the underlying disease itself, and one that results in either prolonged healthcare, disability at the time of discharge from care or both. An adverse outcome is defined as a consequence of an AE and generally includes prolonged healthcare, a resulting disability or death. The adverse outcome may be partially or totally attributable to healthcare received. Attribution is often difficult to determine because much of the care provided is unobserved and is provided by unpaid caregivers. To minimize the threat of detection bias, we developed
specific operational definitions and inclusion/exclusion criteria for AE incidence rates (see Appendix 1 available online at http://longwoods.com/content/23473).

**Study design, setting and cohort**
A retrospective cohort design was used to determine the incidence and types of AEs among Canadian HC clients. The cohort consisted of the population of HC clients who received publicly funded HC services between January 1, 2008 and December 31, 2009 from the provinces of Nova Scotia, Ontario and British Columbia, and the WRHA. The WRHA is responsible for providing healthcare to more than 700,000 people living in the city of Winnipeg as well as the surrounding rural municipalities of East and West St. Paul and the town of Churchill, located in northern Manitoba (WRHA 2013). It is the only jurisdiction in Manitoba currently collecting RAI-HC data. In British Columbia, data were available for Fraser Health region, Vancouver Island and Northern Health. All patients aged 18 or older admitted for HC services classified as acute, maintenance, rehabilitation and long-term support were included. We excluded palliative clients because we expected the clinical course of their medical condition to be different from these other types of HC clients, and this difference could have had an influence on the AE incidence rates in our study. Exclusion of palliative clients is also consistent with the approach taken by Hirdes and colleagues (2004) in the development of HC quality indicators and is routinely done for quality indicators using the MDS 2.0 in nursing homes (Jones et al. 2010).

RAI-HC data were used to identify the occurrence of AEs for long-stay HC clients who were eligible for a RAI-HC assessment, and the DAD was used to identify the occurrence of AEs associated with hospitalization for short- and long-stay clients. RAI-HC data were available for the WRHA, Ontario and Nova Scotia, but not for British Columbia; the DAD was available for British Columbia, the WRHA and Ontario, but not for Nova Scotia.

**Ethical issues, data access and linkage**
The study received ethics approval from the University of Toronto Research Ethics Review Board. The HC population was identified from the HCRS data. The HCRS consisted of three parts: episode information, RAI-HC assessment (for long-stay clients) and health service utilization data (e.g., the number of scheduled visits). The episode data provide information on the case open date, discharge date and client region for short- and long-stay clients. The RAI-HC (Hirdes et al. 2004) assessments are completed on a periodic basis, including at admission for clients expected to be on service for 60 days or longer, then annually or biannually depending on the jurisdiction, and also when the client’s condition changes. The RAI-HC, including its psychometric properties, has been well described (Landi et al. 2000; Morris et al. 1997). All HC clients were identified from the episode data in HCRS, and their records were linked to the DAD to identify AEs associated with hospitalization.
DATA LINKAGE
De-identified client-level data were obtained from the Canadian Institute for Health Information (CIHI) and from the WRHA through linkable data cuts. At CIHI, the health card number, the province issuing the number, the birth year and the birth month were used to do the linkage. The data were prepared by identifying HC clients in jurisdictions where there were available HCRS data sources in 2008 and 2009, and the health card numbers were then used to identify health service records in the DAD for 2008 and 2009. All assembled records then had a common encryption algorithm applied to the health card numbers so that person-level linkage could be done by our researchers without any real-world identifiers being released. A similar record linkage procedure was used for the WRHA data.

DETERMINATION OF AEs AND INCIDENCE RATES
Case screening for AEs was based on previous literature (Doran et al. 2009a; Madigan 2007; Sears et al. 2013; Zed et al. 2008). The cohort for determining an AE was operationally defined as HC clients who were in a HC program during 2008 or 2009 either with or without a RAI-HC assessment. This number was used as the denominator for the calculation of an incidence rate. Two methods were used to identify clients with an AE to be included in the numerator of the incidence rate: (a) clients were followed forward from their case open date until an AE was identified in the DAD and (b) RAI-HC clients with specific RAI-HC AE items were used. The ICD-10 codes in the DAD data were used to identify AEs associated with hospitalization. We restricted the analysis to pre-admission conditions for all indicators except suicide/attempted suicide, where numbers were small and post-admission conditions were also examined. The case-screening period included 30 days after discharge from the HC program. For incidence rate calculation, multiple occurrences of the same incident type were counted only once during the same reporting period. This approach is consistent with that of the Canadian AE hospital study (Baker et al. 2004).

Analysis
Two incidence rates were calculated for AEs: (a) the percentage of clients experiencing a new AE associated with hospitalization per year and (b) the percentage of clients experiencing a new AE determined by the RAI-HC assessment data per year. For each rate, the unadjusted, age- and sex-standardized incidence rates of AEs were calculated. The Ontario HC population was used as the reference population to standardize for age and sex. For each rate, the overall incidence rate was calculated by determining the number of clients with at least one AE of any type divided by the number of clients who were in the HC program during the calendar year. Logistic regression analysis was used to determine the association between risk factors and the likelihood of experiencing any AE. Risk factors were identified from previous literature (Doran et al. 2009b; Madigan 2007; Sears et al. 2013). The variables entered into the regression model are summarized in Table 1. These variables were determined from the RAI-HC, which restricted this part of the analysis to long-stay clients who were eligible for a RAI-HC assessment from Ontario and the WRHA.
Results

Characteristics of the population of home care clients
The demographic characteristics of the HC population for Ontario, the WRHA, British Columbia and Nova Scotia are summarized in Table 2 (shown online at http://longwoods.com/content/23473). Ontario HC clients were on average younger than those in the other jurisdictions. The majority of HC clients in all regions were female, and the average number of months in the HC program in 2009 ranged from 4.9 in Ontario to 7.3 in British Columbia.

Adverse events
The unadjusted and standardized incidence rates for AEs associated with hospitalization for the three regions are reported in Table 3 (shown online at http://longwoods.com/content/23468). Injurious falls, injuries from other than falls and medication-related incidents were the most frequent AEs associated with hospitalization. Examples of injuries from other than falls include burns and contusions, exposure to inanimate force, exposure to animate mechanical force, accidental drowning, exposure to electrical current and contact with heat and hot substances. Examples of medication-related incidents include accidental poisoning, adverse effect at therapeutic dose, overdose and haemorrhagic disorder due to circulating anticoagulants. Sepsis/bacteraemia and delirium were ranked among the top five events. There were slightly higher overall rates for the WRHA and British Columbia compared to Ontario.

Table 4 presents the unadjusted and age- and sex-standardized rates of AEs determined from the RAI-HC assessments for Nova Scotia, Ontario and the WRHA. New caregiver distress was the most frequent of the AEs. Ontario clients experienced higher incidence

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**TABLE 1.** Client safety risk factors entered into the regression model

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>Safety Risk Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Client characteristics</strong></td>
<td>Decline in activities of daily living</td>
</tr>
<tr>
<td></td>
<td>CHESS</td>
</tr>
<tr>
<td></td>
<td>Depression Rating Scale (DRS)d</td>
</tr>
<tr>
<td></td>
<td>Age at assessment</td>
</tr>
<tr>
<td></td>
<td>Sex (female)</td>
</tr>
<tr>
<td></td>
<td>Number of medical illnesses</td>
</tr>
<tr>
<td></td>
<td>Caregiver distress</td>
</tr>
<tr>
<td><strong>Current medical diagnoses</strong></td>
<td>Congestive heart failure (CHF); peripheral vascular disease; dementia or Alzheimer’s disease; Parkinsonism; psychiatric diagnosis; cancer diagnosis; emphysema, chronic obstructive pulmonary disease (COPD), asthma; renal failure; urinary tract infection in last 30 days</td>
</tr>
<tr>
<td><strong>Client living situation</strong></td>
<td>Lives alone</td>
</tr>
<tr>
<td></td>
<td>Unsafe housing</td>
</tr>
<tr>
<td><strong>Healthcare management factors</strong></td>
<td>Polypharmacy</td>
</tr>
<tr>
<td></td>
<td>Nursing service intensity in last 7 days</td>
</tr>
<tr>
<td></td>
<td>Personal support worker (PSW) service intensity in last 7 days</td>
</tr>
<tr>
<td></td>
<td>Home care days</td>
</tr>
<tr>
<td></td>
<td>Anxiolytic/hypnotic in last 7 days</td>
</tr>
<tr>
<td></td>
<td>Hospital discharge within 30 days before RAI assessment</td>
</tr>
</tbody>
</table>

* The CHESS score is Changes in Health, End-Stage Disease, Signs and Symptoms (Hirdes et al. 2003).
* The Depression Rating Scale (Burrows et al. 2000).
of new pressure or stasis ulcers or stage worsening compared to Nova Scotia and WRHA clients, while Ontario clients experienced lower incidence of any new injury. The overall incidence rate for AEs determined from RAI-HC data was approximately 4% for the three regions (see Table 4 online at http://longwoods.com/content/23473).

**Risk factors**

The risk factors that were found to be significantly associated with experiencing any AE associated with hospitalization are summarized in Table 5. Age and sex, although not significant, were included in the model because previous research has indicated association between these variables and prevalence of AEs (Baker et al. 2004; Doran et al. 2009b). The adjusted odds ratios (OR) are presented, which take into account the other variables in the model. Hospital discharge within the past 30 days was associated with significantly increased odds of experiencing an AE. Polypharmacy, nursing service intensity in last seven days, peripheral vascular disease, CHF, ADL decline and number of medical illnesses were also associated with increased odds of experiencing an AE.

**TABLE 5.** Risk factors associated with any AE during hospitalization in 2009 for Ontario and WRHA HC clients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Without any AE</th>
<th>With an AE</th>
<th>OR</th>
<th>CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Female (y vs. n)</td>
<td>89,647</td>
<td>66.8</td>
<td>9,092</td>
<td>63.8</td>
</tr>
<tr>
<td>Age at assessment (≥ 75 vs. &lt;75 years)</td>
<td>89,530</td>
<td>66.7</td>
<td>9,539</td>
<td>66.9</td>
</tr>
<tr>
<td>No. with illnesses (2/3/4 vs. 0/1)</td>
<td>77,594</td>
<td>57.8</td>
<td>7,524</td>
<td>52.8</td>
</tr>
<tr>
<td>No. with illnesses (5+ vs. 0/1)</td>
<td>36,794</td>
<td>27.4</td>
<td>5,154</td>
<td>36.2</td>
</tr>
<tr>
<td>ADL hierarchy (≥1 vs. 0)</td>
<td>43,682</td>
<td>32.5</td>
<td>5,573</td>
<td>39.1</td>
</tr>
<tr>
<td>Congestive heart failure (y vs. n)</td>
<td>15,106</td>
<td>11.3</td>
<td>2,359</td>
<td>16.6</td>
</tr>
<tr>
<td>Peripheral vascular disease (y vs. n)</td>
<td>9,261</td>
<td>6.9</td>
<td>1,433</td>
<td>10.1</td>
</tr>
<tr>
<td>Nursing service intensity in last 7 days (&gt; 0 vs. = 0 hours)</td>
<td>34,306</td>
<td>25.6</td>
<td>5,505</td>
<td>38.6</td>
</tr>
<tr>
<td>Polypharmacy (≥9 vs. &lt;9 meds)</td>
<td>64,126</td>
<td>47.8</td>
<td>8,208</td>
<td>57.6</td>
</tr>
<tr>
<td>Hospital discharge within 30 days before RAI (y vs. n)</td>
<td>17,592</td>
<td>13.1</td>
<td>4,137</td>
<td>29.0</td>
</tr>
</tbody>
</table>

Note: After backwards selection, p-value=0.3 for goodness-of-fit test.
Discussion

The overall incidence rate of AEs associated with hospitalization ranged from 6% in Ontario to almost 9% in British Columbia and the WRHA. The overall incidence for AEs determined through the RAI-HC data was approximately 4% for all regions. Caution should be exercised in comparing rates between regions for a variety of reasons. Some of the variations observed could be explained by differences in the HC populations that were not accounted for by age and sex standardization. There are differences in how HC is defined or operationalized in different jurisdictions in Canada (Canadian Home Care Association 2013a). Eligibility and types of services can differ from province to province, which may affect the risk profile of the HC clients from region to region. Availability of community services may have influenced hospital utilization rates and affected whether AEs were treated in hospital or in the community, thus influencing our ability to detect AEs in this study.

The subgroup of clients who contributed RAI-HC data represents long-stay clients, those expected to be on service for 60 days or longer. Comparing rates for RAI-HC data yielded similar rates for the three regions included in this analysis.

We found that injurious falls, injuries from other than fall and medication-related incidents were the most frequent types of AEs associated with hospitalization. Between 2% to 3% of HC clients had falls that resulted in injuries associated with hospitalization. Approximately one in three Canadians aged 65 and older will fall each year (Health Canada 2002), and unintentional falls will account for 84% of all hospitalizations due to injury in this population (CIHI 2009). Effective policies and strategies are needed to target the prevention of falls that could result in injuries. In Canada, resources such as the interRAI Clinical Assessment Protocol (CAP) (CIHI 2008) and the Registered Nurses’ Association of Ontario best practice guidelines (RNAO 2005, 2011) are available and should be integrated into clinical practice. The interRAI CAPs and RNAO best practice guidelines provide clinicians with evidence-based recommendations for planning and delivering care. For example, the CAPs that have been developed for HC provide guidance in the assessment of, and care planning for, functional performance, cognition, mental health, social life and clinical issues (e.g., falls, pain, pressure ulcers). Each CAP has goals for care that include the possibility of problem resolution, reducing risk or increasing potential for improvement.

In our study, the incidence of medication-related AEs associated with hospitalization was 2%. Although comparative data for hospitalization rates were not found in other published sources, a prospective study of medication-related ED visits reported a 12% rate (Zed et al. 2008), and another study reported a 4.7% rate (Hohl et al. 2010). Improvement in medication management in HC is clearly a high-priority safety issue.

The incidence of new caregiver distress ranged between 6% and 11%, and this rate is within the range of the 6% rate reported by CIHI (2004). In the context of the RAI-HC, caregiver distress reflects caregivers’ inability to continue their caregiving activities and their expressions of distress, anger or depression. As HC clients and unpaid caregivers do whatever it takes to keep the client at home, the challenges become more stressful for both. If the needs
of the caregivers are not adequately addressed, the clients are at risk for re-admission to acute or long-term care facilities at increased cost (Bryan 2010).

One of the recommendations from a Canadian symposium on AEs in community care was the need for improved understanding of the variables associated with the occurrences of AEs, including assessing patient risk (Masotti et al. 2009). This study helps to advance such understanding. The first 30 to 60 days following admission to HC is a post-acute period in which there is a transition of care from hospital to HC. CIHI (2012) reported that one in 12 patients is readmitted to hospital within 30 days of discharge. Our study confirms that the first 30 days post–hospital discharge is a high-risk period for HC clients. This transition is the point at which HC personnel should screen for risk and intervene to reduce risk of AEs for HC clients. We also observed that clients with more medical illnesses and those requiring increased service intensity over the past seven days were at increased risk of experiencing an AE. The relationship between service intensity and AEs likely reflects instability in the client’s medical condition resulting in increased risk.

Our study found that polypharmacy was associated with increased risk of AEs. The incidence of potential drug interactions increases with increased drug use, and these interactions have been associated with hospitalizations in previous research (Delafuente 2003; Hanlon et al. 1997). Drug interactions have also been shown to cause a decline in functional abilities in older people (Delafuente 2003), compounding the risk of AEs such as falls. Prudent use of medications and vigilant drug monitoring are essential to avoid AEs among elderly HC clients.

ADL decline is an indicator of frailty, and it was associated with increased risk of AEs in this study. A systematic review of home-based nursing health promotion for older people found that preventive home visits were most effective for individuals who were not limited in basic ADL (Markle-Reid et al. 2006). The authors of that review suggested that a preventive intervention may work best at early and reversible stages in the continuum of health to disability. Our study underscores the importance of instituting such interventions in order to reduce the risk of AEs in HC.

**Strengths and limitations**

The present study was a large, population-based investigation of AEs among HC clients in Canada. The data in this study were obtained from a well-established secondary health data-base and the RAI-HC instrument, a highly reliable and validated assessment tool (Landi et al. 2000). Although there are a few published studies pertaining to HC safety, to our knowledge this is the first study of HC settings that investigated AEs associated with hospitalization.

Because periodic assessment with the RAI-HC does not allow all events to be detected, our results likely underreport actual experience. It was particularly challenging to capture data for some types of events of interest, for example, non-recognition or non-reporting of medication errors (Hohl et al. 2010). Injuries that do not leave visible marks, or pressure ulcers that require personal examination, are examples of AEs in HC that are likely to be underreported, both through RAI-HC assessment and by encounters with hospitals. There were differences
in the data sources available for provinces/regions in Canada, which limited our ability to include Nova Scotia in the hospitalization rates and British Columbia in the RAI-HC rates. Our study did not include AEs associated with an ED visit because of lack of comparative data for the provinces/regions. There was no way to determine from the DAD whether an AE we identified as a pre-admission condition to hospitalization was the primary reason for the hospitalization. Furthermore, there was no way to determine from the data whether the AEs observed were due to the “plans or actions taken during the provision of health care” or if they were due to underlying disease, client behaviour, injury or other causes. Lastly, it is important to note that AEs do not always demonstrate inappropriate or inadequate home care.

Implications for healthcare leaders and health policy
Injurious falls, injuries from other than fall and medication-related events were the most frequent AEs associated with hospitalization. New caregiver distress was the most frequent AE identified through the RAI-HC data. Strategies designed to improve the safety of the HC environment need to focus on reducing the risk of falls and other injuries, improving the management of medications in the home, promoting recognition of early signs and symptoms of sepsis/bacteraemia and delirium followed by prompt intervention. We need to strengthen supports and resources for informal caregivers through education and assessment of their risk for caregiver distress. The RAI-HC, which has Clinical Assessment Protocols based on practice guidelines, could be used to help manage HC clients and their caregivers who are at risk of AEs (CIHI 2008). That tool was designed to be an assessment system to inform and guide care planning in the HC environment (Landi et al. 2000), and it can be used to guide a comprehensive assessment of safety risks such as physical and cognitive functioning, informal support services, environmental assessment and medications (Morris et al. 1997). Implementation of the full clinical capabilities of the RAI-HC in Canada should be a priority.

Patient outcomes are influenced not only by formal healthcare providers but also, to a significant extent, by the quality of care that is provided by informal caregivers. A significant proportion of caregivers were found to have new caregiver distress, with notable differences in rates across the country. In order to build a safe and sustainable HC system, HC needs to encompass care for the informal caregivers because they are the people on whom the system relies for much of the care delivered to clients.

Conclusion
The overall incidence rate of AEs associated with hospital visits for the HC client population ranged from 6% to 9%, and the rate was 4% for AEs determined from the RAI-HC data. This study provides new data about safety outcomes detected through the RAI-HC assessment and the potential role of the RAI-HC with regard to its use in detecting AEs among HC clients.

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The Association between Health Information Technology Adoption and Family Physicians’ Practice Patterns in Canada: Evidence from 2007 and 2010 National Physician Surveys

Relation entre l’adoption des technologies de l’information sur la santé et les schémas de pratique des médecins de famille au Canada : données provenant des sondages nationaux des médecins de 2007 et de 2010

SISIRA SARMA, MOHAMMAD HAJIZADEH, AMARDEEP THIND AND RICK CHAN

Abstract

Objective: To describe the association between health information technology (HIT) adoption and family physicians’ patient visit length in Canada after controlling for physician and practice characteristics.

Method: HIT adoption is defined in terms of four types of HIT usage: no HIT use (NO), basic HIT use without electronic medical record system (HIT), basic HIT use with electronic medical record (EMR) and advanced HIT use (EMR + HIT). The outcome variable is the average time spent on a patient visit (visit length). The data for this study came from the 2007 and 2010 National Physician Surveys. A log-linear model was used to analyze our visit length outcome.

Results: The average time worked per week was found to be in the neighbourhood of 36 hours in both 2007 and 2010, but users of EMR and EMR + HIT were undertaking fewer patient visits per week relative to NO users. Multivariable analysis showed that EMR and EMR + HIT were associated with longer average time spent per patient visit by about 7.7% (p<0.05) and 6.7% (p<0.01), respectively, compared to NO users in 2007. In 2010, EMR was not statistically significant and EMR + HIT was associated with a 4% (p<0.1) increased visit length. A variety of practice-related variables such as the mode of remuneration, work setting and interprofessional practice influenced visit length in the expected direction.

Conclusion: Use of HIT is found to be associated with fewer patient visits and longer visit length among family physicians in Canada relative to NO users, but this association weakened in the multivariable analysis of 2010.

Résumé

Objectif : Décrire la relation entre l’adoption des technologies d’information sur la santé (TIS) et la durée des consultations chez les médecins de famille au Canada, après avoir contrôlé les caractéristiques des médecins et des pratiques.

Méthode : L’adoption des TIS se définit en fonction de quatre types d’usage des TIS : aucun usage des TIS [NO], un usage rudimentaire des TIS sans système de dossiers médicaux informatisés (DMI) [TIS], un usage rudimentaire des TIS avec système de DMI [DMI] et un usage étendu des TIS [DMI+TIS]. La variable dépendante est la moyenne du temps de

*Résultats*: Le temps de travail moyen est d’environ 36 heures par semaine tant en 2007 qu’en 2010, mais les usagers DMI et DMI+TIS effectuent moins de consultations par semaine comparativement aux usagers NO. L’analyse multivariable montre que les usagers DMI et DMI+TIS sont associés à un plus long temps moyen de consultation de l’ordre de 7,7 % (p<0,05) et 6,7 % (p<0,01), respectivement, comparativement aux usagers NO en 2007.

Les données de 2010 sur les usagers DMI ne sont pas statistiquement significatives, alors que celles des usagers DMI+TIS sont associées à une plus grande durée de consultation de l’ordre de 4 % (p<0,1). Un certain nombre de variables liées à la pratique, telles que le mode de rémunération, le cadre de travail et la pratique interprofessionnelle influencent la durée de consultation dans le sens escompté.

*Conclusion*: Il semble y avoir, chez les médecins de famille au Canada, un lien entre l’usage des TIS et un moindre nombre de consultations par semaine ainsi qu’une plus grande durée de consultation, comparativement aux usagers NO, mais ce lien est moins marqué dans l’analyse multivariable des données de 2010.

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