HEALTHCARE

POLICY

Politiques de Santé

Health Services, Management and Policy Research
Services de santé, gestion et recherche de politique

Volume 6 • Number 2

Data Matters • Discussion and Debate • Research Papers
Knowledge Translation, Linkage and Exchange

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Politiques de Santé

Health Services, Management and Policy Research
Services de santé, gestion et recherche de politique

VOLUME 6 NUMBER 2 • NOVEMBER 2010

Healthcare Policy/Politiques de Santé seeks to bridge the worlds of research and decision-making by presenting research, analysis and information that speak to both audiences. Accordingly, our manuscript review and editorial processes include researchers and decision-makers.

We publish original scholarly and research papers that support health policy development and decision-making in spheres ranging from governance, organization and service delivery to financing, funding and resource allocation. The journal welcomes submissions from researchers across a broad spectrum of disciplines in health sciences, social sciences, management and the humanities and from interdisciplinary research teams. We encourage submissions from decision-makers or researcher–decision-maker collaborations that address knowledge application and exchange.

While *Healthcare Policy/Politiques de Santé* encourages submissions that are theoretically grounded and methodologically innovative, we emphasize applied research rather than theoretical work and methods development. The journal maintains a distinctly Canadian flavour by focusing on Canadian health services and policy issues. We also publish research and analysis involving international comparisons or set in other jurisdictions that are relevant to the Canadian context.

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Healthcare Policy/Politiques de Santé cherche à rapprocher le monde de la recherche et celui des décideurs en présentant des travaux de recherche, des analyses et des renseignements qui s'adressent aux deux auditoires. Ainsi donc, nos processus rédactionnel et d'examen des manuscrits font intervenir à la fois des chercheurs et des décideurs.

Nous publions des articles savants et des rapports de recherche qui appuient l'élaboration de politiques et le processus décisionnel dans le domaine de la santé et qui abordent des aspects aussi variés que la gouvernance, l'organisation et la prestation des services, le financement et la répartition des ressources. La revue accueille favorablement les articles rédigés par des chercheurs provenant d'un large éventail de disciplines dans les sciences de la santé, les sciences sociales et la gestion, et par des équipes de recherche interdisciplinaires. Nous invitons également les décideurs ou les membres d'équipes formées de chercheurs et de décideurs à nous envoyer des articles qui traitent de l'échange et de l'application des connaissances.

Bien que *Healthcare Policy/Politiques de Santé* encourage l'envoi d'articles ayant un solide fondement théorique et innovateurs sur le plan méthodologique, nous privilégions la recherche appliquée plutôt que les travaux théoriques et l'élaboration de méthodes. La revue veut maintenir une saveur distinctement canadienne en mettant l'accent sur les questions liées aux services et aux politiques de santé au Canada. Nous publions aussi des travaux de recherche et des analyses présentant des comparaisons internationales qui sont pertinentes pour le contexte canadien.

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The Canadian Institutes of Health Research (CIHR)
is a proud supporter of *Healthcare Policy/Politiques de Santé*.

CIHR provides financial and in-kind support for the publication of *Healthcare Policy/Politiques de Santé*, and has played a key role in the journal's inception and development.

Longwoods Publishing gratefully acknowledges the financial support of the following organizations:

Canadian Health Services Research **Foundation**
Fondation canadienne de la recherche sur les services de santé

Institute of Aging
Institute of Infection and Immunity

Canadian Association for Health Services and Policy Research

l'Association canadienne pour la recherche sur les services et les politiques de la santé

HEALTHCARE
POLICY
Politiques de Santé

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For deliveries to our studio: 54 Berkeley St., Suite 305, Toronto, Ontario M5A 2W4, Canada.

SUBSCRIPTIONS
Individual subscription rates for one year are [C] $108 for online only and [C] $160 for print + online. For individual subscriptions contact Barbara Marshall at telephone 416-864-9667, ext. 100 or by e-mail at bmarshall@longwoods.com.

Institutional subscription rates are [C] $473 for online only and [C] $579 for print + online. For institutional subscriptions, please contact Rebecca Hart at telephone 416-864-9667, ext. 114 or by e-mail at rhart@longwoods.com.

Subscriptions must be paid in advance. An additional tax (GST/HST) is payable on all Canadian transactions. Rates outside of Canada are in US dollars. Our GST/HST number is R138513668.

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Single issues are available at $45. Includes shipping and handling. Reprints can be ordered in lots of 100 or more. For reprint information call Barbara Marshall at 416-864-9667 or fax 416-368-4443 or e-mail to bmarshall@longwoods.com.

Return undeliverable Canadian addresses to: Circulation Department, Longwoods Publishing Corporation, 260 Adelaide Street East, No. 8, Toronto, Ontario M5A 1N1, Canada.

EDITORIAL
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PUBLISHING
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Healthcare Policy/Politiques de Santé is published four times per year by Longwoods Publishing Corp., 260 Adelaide St. East, No. 8, Toronto, ON M5A 1N1, Canada. The journal is published with support from the Canadian Institutes of Health Research's Institute of Health Services and Policy Research. Manuscripts are reviewed by the editors and a panel of peers appointed by the editors. Information contained in this publication has been compiled from sources believed to be reliable. While every effort has been made to ensure accuracy and completeness, these are not guaranteed. The views and opinions expressed are those of the individual contributors and do not necessarily represent an official opinion of *Healthcare Policy* or Longwoods Publishing Corporation. Readers are urged to consult their professional advisers prior to acting on the basis of material in this journal.

Healthcare Policy/Politiques de Santé is indexed in the following: PubMed Central, CINAHL, CSA (Cambridge), Ulrich's, Embase, IndexCopernicus, Scopus and is a partner of HINARI

No liability for this journal's content shall be incurred by Longwoods Publishing Corporation, the editors, the editorial advisory board or any contributors. ISSN No. 1715-6572

Publications Mail Agreement No. 40069375

EDITORIAL

Understanding the Mosaic: Health Services and Policy Research in Canada

I opened my e-mail recently to find a message reminding me about the birthday of a relative that I didn't know I had. The message came from the online genealogy service that a relative recently added me to, an example of the combined power (and inbox-filling potential) of social networking and commons-based peer production.

In this issue of *Healthcare Policy/Politiques de Santé*, Mark Dobrow, Sarah Costa, Saadia Israr and Roger Chafe use several different approaches to map Canada's health services and policy research family, uncovering some surprises in the process. Their research covered both traditional research settings (universities, hospitals and research institutes) as well as those with pockets of research capacity that are less recognized (government agencies, regional health authorities and charitable organizations). As they point out, we don't often think of the full range of research settings as part of our overall research capacity, but it may be broader and more complex than we realize, just as my family tree was.

This diversity presents interesting challenges. For example, what types of settings need graduates of training programs in health services and policy research? How will the skills that these trainees need vary depending on the environments in which they will work during the course of their careers? Similarly, measuring the success of capacity building efforts is difficult without understanding the various places in which that capacity might be found.

This issue of the journal provides examples of the extent and depth of our capacity in health services and policy research. In it, we feature papers from different regions, a range of institutions and widely varying disciplines. Whichever part of the mosaic you come from, I hope that you will find the insights in these pages valuable to your work, and I encourage you to contribute your perspectives to future issues.

In those future issues, you will see some changes in the journal. Chris Woodward is moving on after completing a five-year term on the editorial board. During her tenure, Chris has been responsible for working with authors to shepherd dozens of

research papers through the editorial process. Both the journal and the health services and policy research community more generally are much richer for her efforts. Please join me in thanking Chris for her superb service over the last five years.

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

ÉDITORIAL

Comprendre la mosaïque : recherche sur les services et les politiques de santé au Canada

Récemment, j'ai reçu dans mes courriels un message qui me rappelait l'anniversaire d'un parent dont j'ignorais jusque-là l'existence. Le message venait d'un service de généalogie en ligne auquel m'avait inscrite un autre parent. Il s'agit là d'un exemple du pouvoir combiné (et du potentiel de congestion des boîtes de réception) du réseautage social et de la production de biens communs par les pairs.

Dans ce numéro de *Politiques de Santé/Healthcare Policy*, Mark Dobrow, Sarah Costa, Saadia Israr et Roger Chafe font appel à différentes démarches pour cartographier la recherche sur les services et les politiques de santé au Canada; et ils nous dévoilent quelques surprises. Leur recherche a porté sur les établissements traditionnels de recherche (universités, hôpitaux et instituts de recherche) ainsi que sur d'autres types d'établissements où existe une certaine activité de recherche qui est moins reconnue (organismes gouvernementaux, régies régionales de la santé et organismes de bienfaisance). Comme ils l'indiquent, l'éventail complet des établissements de recherche ne vient pas toujours à l'esprit quand on pense à l'ensemble de la capacité de recherche, cependant cette dernière est peut-être plus importante et plus complexe qu'on ne le pense; un peu comme les surprises que peut nous réserver notre arbre généalogique.

Cette diversité présente des défis intéressants. Par exemple, quels types d'établissements pourraient bénéficier de stagiaires provenant des programmes d'études

supérieures en recherche sur les services et les politiques de santé? Quelles seront les compétences nécessaires à ces stagiaires pour évoluer dans l'environnement de travail qu'ils rencontreront au cours de leur carrière? De même, si on ne connaît pas bien les divers endroits où se trouvent les capacités de recherche, il sera difficile de mesurer le succès des efforts de renforcement des capacités.

Le présent numéro fournit des exemples de l'étendue et de la profondeur de notre capacité de recherche sur les services et les politiques de santé. Les articles présentés proviennent de différentes régions, de diverses institutions ainsi que d'un éventail de disciplines. Quelle que soit votre place dans la mosaïque, j'espère que les pistes offertes dans ces pages vous seront utiles et vous inciteront à partager votre point de vue dans les numéros à venir.

D'ailleurs, les prochains numéros de la revue s'accompagneront de changements. En effet, Chris Woodward s'oriente vers d'autres projets après avoir terminé un mandat de cinq ans comme membre du comité de rédaction. Dans le cadre de son mandat, elle était responsable de travailler avec les auteurs pour parachever des douzaines de rapports de recherche pour leur publication. Ses efforts ont permis d'enrichir la revue ainsi que le milieu de la recherche sur les services et les politiques de santé. Nous souhaitons tous lui exprimer notre gratitude pour l'excellent service dont elle a fait preuve au cours des cinq dernières années.

JENNIFER ZELMER, BSC, MA, PHD
Rédactrice en chef

The TSX Gives a Short Course in Health Economics: It's the Prices, Stupid!

Le TSX donne un cours d'appoint en économie de la santé : C'est une question de prix, ignorant!

by ROBERT G. EVANS

Abstract

The fall in Shoppers Drug Mart shares last April 8 gave a crystal-clear demonstration of the link between health expenditures and health incomes. Reacting (finally) to the excessive retail prices of generic drugs, the Ontario government effectively halved the rate of reimbursement of ingredient costs and banned the "professional allowances" (kickbacks) paid to pharmacies by generic manufacturers. Taxpayers and private payers will save hundreds of millions of dollars, and pharmacy revenues will fall by an equivalent amount. Patients will still get their drugs, with no loss of quantity, quality or even convenience; no one's health is threatened. But investor profits will fall. There are similar savings opportunities throughout the health system. Health costs are primarily a political, not an economic, problem.

Résumé

La baisse des actions de Pharmaprix, le 8 avril dernier, a été une démonstration claire du lien entre les dépenses de santé et les résultats en matière de santé. Réagissant (finalement) aux prix de détail excessifs des médicaments génériques, le gouvernement ontarien a réduit de moitié le remboursement du coût des ingrédients et a interdit les « ristournes » (ou pots-de-vin) accordées aux pharmacies par les fabricants de produits génériques. Les contribuables et les tiers payant privés économiseront des centaines de millions de dollars tandis que le revenu des pharmacies baissera proportionnellement. Les patients continueront d'obtenir leurs médicaments, sans perte de qualité, de quantité ou même de commodité; nul ne verra sa santé mise en danger. Cependant, les bénéfices des investisseurs chuteront. Il existe des possibilités d'économies semblables dans tout le secteur de la santé. Les dépenses de santé sont d'abord et avant tout un problème politique, non pas économique.

Wednesday, April 7, 2010. The shares of Shoppers Drug Mart (SC-T) closed on the Toronto Stock Exchange at just under $44. The next morning they were trading below $37. Nearly a fifth of the company's market value, about $1.6 billion, had vanished literally overnight. It got worse. On June 29, Shoppers bottomed at $32.57 a share. The company had lost a quarter of its market value since the evening of April 7. (Shoppers has since recovered somewhat; on October 1, it closed at $38.82.)

Lesson One: *Every dollar of expenditure on health services (or anything else) is a dollar of someone's income.*

There is no mystery about where the money went. The Minister of Health of Ontario announced, on that Wednesday evening, that as of July 1 the Ontario Drug Benefit (ODB) Plan would change the rate at which pharmacies were reimbursed for the ingredient costs of generic drugs dispensed to beneficiaries. By June 29, it was clear that they were going ahead as planned. Pharmacies had previously been receiving 50% of the price of the corresponding branded and originally patented drug; henceforth they would receive only 25%. At the same time, the "professional allowances" (less politely, kickbacks) paid by generic manufacturers to pharmacies would be banned. Shoppers, the largest chain pharmacy in Canada, would see this change come straight off its bottom line – as indeed would every other pharmacy in Ontario – and the stock market reacted accordingly.

The Ontario government estimated that this change would reduce ODB outlays by about $500 million per year, or 12% of the estimated $4.1 billion that the Ontario

government spent on drugs in 2009 (CIHI 2009). But private payers in Ontario, both insurers and individual patients, spent another $7.6 billion, and as of April 1, 2012, they too will be paying no more than 25% of the price of the originally patented drug.

Nationally, about a quarter of private spending is for non-prescription drugs and related items. So if one assumes an equivalent 12% saving on generics for private payers, that would amount to 7.6 x 0.75 x 0.12 = $684 million. The numbers are rough, but the total savings look "not unadjacent to" $1.2 billion per year.[1]

That's an average of nearly $100 for every resident of Ontario. It is also an estimate of the annual revenue lost by Ontario pharmacies. The savings and the loss are opposite sides of the same coin. And the savings/lost revenue will increase over the next few years as several high-volume "blockbuster" drugs come off patent and more generic alternatives become available (Picard 2010; Cutler 2007). The fall in Shoppers' capitalization represents Bay Street's (rather unstable) guesstimate of the present value of its share of that lost stream of future revenue. No wonder Jürgen Schreiber (CEO of Shoppers) was upset.

Lesson Two: *Winners and losers are always unevenly distributed.*

The gainers from this policy change are Ontario taxpayers, patients and (eventually) privately insured workers and their employers. Patients benefit immediately, taxpayers will gain as the debt burden is lessened and workers/employers will gain as, if and when, private insurance premiums fall (or rise less rapidly), leaving more cash on the table to be divided between them.

Investors, in and out of Canada, will lose; the market has already made a preliminary calculation of their loss. Shoppers Drug Mart is a blue-chip stock, popular with mutual funds and exchange-traded funds offering steady growth with good dividends. (It has a beta of 0.40.) These folks have had a nasty surprise. Overall, the net effect has probably been to shift wealth down the income distribution because stock ownership is highly correlated with income and pharmaceutical use is not.

Pharmacists, *qua* pharmacists, will probably be little affected. The steady up-trend in prescriptions to be filled will not change, and failing significant technical changes in the dispensing process, pharmacists will be needed to fill them. Assuming that the market for pharmacists' services is reasonably competitive, and chains like Shoppers pay no higher wages and hire no more pharmacists than they have to (they are, after all, for-profit corporations, not charities), then pharmacists' wages and employment are unlikely to change.[2]

Those pharmacists who own their own stores, however, definitely will lose – their profits will fall along with those of corporate pharmacies. They are, in a sense, their own shareholders. But it is the return to store ownership, not the wages of pharma-

cists, that will fall.[3] Expressions of distress by pharmacists' organizations will reflect this impact on pharmacy owners.

Lesson Three: *It's the prices, stupid!*

Health expenditures are driven by prices as well as quantities: E = P x Q. Q is unchanged; Ontarians are still getting their prescriptions filled. The reforms have cut the prices paid for generic prescriptions, not the quantity provided. Pharmacies have had their profits cut but have not gone out of business, and it appears that Bay Street has significantly reduced its June 29 estimates of the impact of the reforms. As the price cuts are extended to private payers, there could be some reduction in the numbers of pharmacy outlets, but Ontario is heavily over-endowed with pharmacies, especially in urban areas.[4] Indeed, this density is likely a consequence of the overpricing of generic drugs.

The ODB reforms do contain provisions to protect access to pharmacy services in regions with low dispensing volumes, where lower reimbursement might really threaten patients' access to drugs, but this is a small fraction of the Ontario population. Because the vast majority of prescriptions are filled in markets densely populated with pharmacies, there seems no good reason to let the rural tail wag the urban dog.

Shoppers initially threatened to terminate free delivery services and other benefits to patients, but this move seems questionable. Providing such services is a marketing decision, not an act of charity. If they add to profits, they continue. If not, well, the pharmacy can always offer these services for a price to those willing to pay.[5]

Lesson Four: *Rising health costs are not a law of nature, like the tides. They are responsive to well-crafted policy.*

This episode gives the lie to those who allege that containing health costs must necessarily impose unacceptable cuts to the quantity and/or quality of health services, threatening Canadians' health. Such claims are the basis for the argument that universal public health insurance is "fiscally unsustainable." They are also false.

The interests driving these claims are not difficult to discern; see Lesson One, above. But the implicit assumptions are twofold, and both are wrong. First, they assume that the prices currently paid for health services are determined through some market or other process such that they reflect the real costs of production. Imposed reductions must therefore result in reduced quantity or quality of services. The Ontario reform demonstrates that this is incorrect. The second assumption is that the services currently being provided are all necessary and effective in promoting patients' health. This assumption flies in the face of a vast literature on prescribing appropriateness and clinical variations; for the merest scratch on the surface of the latter, see Evans (2009).

Lesson Five: *Cost containment is primarily a political, not an economic, problem.*

The shares of Jean Coutu, the large Quebec pharmacy chain, also fell on April 8, from $10 to $9, and bottomed on June 29 at $7.88. Investors expected Quebec to follow Ontario's lead. More generally, Ontario is only about 40% of Canada. If its reforms rolled across the country, could we be seeing national savings – pharmacy revenue losses – in the $2–$3 billion range? The answer appears to be no, not so much, and the reasons are quite instructive.

The government of British Columbia did react, very quickly. Health Minister Kevin Falcon announced that PharmaCare would negotiate a mutually acceptable agreement with pharmacies to reduce the reimbursement rate for generic drugs. Reductions will apply to private payers as well. But the reimbursement rate was reduced only to 35% of the corresponding previously patented drug, phased in over three years. There would also be additional payments to pharmacists for various other services, of possible value to patients but of clear benefit to pharmacies.

Alberta had, in fact, acted earlier to reduce payments for generic drugs, first for new generics and then, effective April 1, 2010, all generic drugs. But the cuts were from 75% to 56% of the corresponding branded product (45% for new generics), so that Albertans after their reform are still paying higher prices than the ODB was paying before July 1, 2010.

As the Alberta government's press release notes, disingenuously: "The pharmacy industry indicated it had some concerns with reductions to generic drug prices. … Government recognizes that reducing the price of generic drugs will impact revenues of pharmacy businesses" (Alberta 2010). Well, duh! (Yet again, see Lesson One, above.)

Unlike Ontario, neither Alberta nor British Columbia eliminated kickbacks from generic manufacturers to pharmacies. And both left in place maximum dispensing fees well above Ontario's rate of $8.50 (Alberta, $11.93; BC, $10.50). In short, while recognizing that generic drug prices were too high, both Alberta and British Columbia struck a political compromise between the financial interests of taxpayers and private payers on the one hand, and pharmacies on the other.

There is no economic reason why governments in both Alberta and British Columbia could not have followed Ontario and gone for 25% or even less. The government of British Columbia, in particular, seems proud that they achieved a "negotiated" rather than an imposed settlement. But pharmacies negotiated with a gun at their heads. By leaving so much money on the table, these governments in effect bought ideological comfort and, presumably, political advantage with other people's money. (In BC, some of mine.)

Well, it isn't the first time *that* has happened. The point that comes through loud and clear, however, is that had they wanted to cut drug costs still further, they could easily have done so. Both the previous and the new lower costs of generic drugs are the result of political choices, not economic forces.

Quebec is more involved. Current legislation requires the provincial government to pay no more for a drug than the lowest price available in any other province. That would force them to match Ontario's 25%, and the government says they will. But:

> This same law prohibits private plans from adopting the same control approach as the RAMQ [Quebec's health insurance plan]. Indeed, private plans are obligated to reimburse an original drug at a minimum of 68% of the amount claimed, even if the generic drug is sold to the pharmacist at a maximum of 25% of the price of the original. (Tagsa 2010)

In effect, the government of Quebec is trimming its own costs while leaving private payers exposed to higher charges. And in Quebec, employer-based insurance is *de facto* compulsory. Employers and employees are thus being milked to subsidize pharmacies – a distinctly perverse approach to cost control!

Nonetheless, pharmacy owners are said to be outraged that they were not consulted. (What, exactly, might they have said? It's a zero-sum game.) They have demanded various forms of compensation, and have taken a page from the Big Pharma playbook. Current or planned generic production in the province will be suspended if their prices fall.

That argument makes no economic sense. Generics are an internationally traded commodity. What possible benefit would there be to Quebeckers at large from paying a premium, directly or indirectly, for local production – and supporting the price of Jean Coutu shares?

But that is an economist talking. The political calculation is likely to be different – as it was in Alberta and British Columbia. At time of writing, the Quebec poker game was still in session. The important point is that it *is* a political poker game. Whatever emerges, any suggestion that Quebeckers will pay prices for generic drugs that approximate their real economic costs, or are determined by competitive market forces, would be incredibly naïve or simply dishonest.

Lesson Six: *In the health services sector, regulation works. Markets don't.*

In October 2007, the Canadian Competition Bureau released a report on generic drug prices (Canada 2008). Bay Street analysts are paid to assess the profit potential of publicly traded corporations. They ignored the Competition Bureau report, if they noticed it at all. A small prize will be given to the reader who can find a response in Shoppers Drug Mart share prices during October 2007.

Yet, the Bureau clearly stated that retail prices for generic drugs were too high. Competition among generic suppliers was effective in holding down prices paid by pharmacies, but not prices charged by pharmacies; the benefits of competition were

being appropriated before reaching the retail payer (and hence were capitalized in, e.g., Shoppers share prices). The Competition Bureau's report contains thoughtful discussion of the ways in which the competitive market forces of the economic textbooks have been subverted in this market, and hopeful suggestions as to how they might be strengthened and made more effective. The TSX apparently did not fancy their chances.[6]

The report ends on a rather wistful note:

> Individual plan members and persons paying out of pocket can also play a key role in helping to obtain the benefits from competition by being effective shoppers. The more that consumers compare prices and services when shopping for drugs, the more incentive the pharmacies will have to make lower prices and better services available to patients. (Canada 2008)

Indeed. And if wishes were horses, beggars might ride. In the real world:

> it is the cash-paying customer without a drug plan who typically pays the highest price for prescription drugs. Sullivan says many pharmacy computers are set up so that if a regular pharmacy client loses their employer-paid benefits, and that information is entered on the screen, "a completely different" higher price for the prescription automatically pops up. (Silversides 2009)

The central point is that over half of prescription drug costs (55% in 2009), generic and patented, are paid privately and always have been. Yet, this private market has not restrained prices. Conceivably, an activist provincial government might try to restructure the drug dispensing process to create genuine market competition, but such restructuring would have to be extensive, complex, politically costly and highly uncertain of outcome.

Why would any rational government take on such a dubious task when regulatory alternatives are ready to hand? Such a quixotic enterprise might please ideological marketophiles and congenital economists, but the more realistic folk who decry regulation and champion "the market" in health services typically do so precisely because they understand how little threat markets pose to existing price and income patterns.[7] The Ontario government has instead chosen to cut the Gordian Knot. Its example has forced other provinces, perhaps half-heartedly and despite ideological reservations, to follow along.

Lesson Seven (extra credit): *All six of these lessons apply across the whole health system.*

Prescription drugs account for only 13.9% of Canadian health spending, and generics for less than half of that. Even if provinces could pick up, for their residents, all of the

$2–$3 billion in annual savings that might be on the table, that is small change compared to last year's estimated total of $183.1 billion, increasing about $10 billion a year.

But wait! There's more!

When Canada's Medicare was extended to cover physicians' services in the late 1960s, the rate of escalation of physician and hospital costs was dramatically reduced. The universal public system both avoids the very large administrative overheads generated by private insurance (Woolhandler et al. 2003) and possesses a significant degree of bargaining power in negotiating with providers. The sectoral price inflation endemic to private or mixed financing systems – over and above general inflation rates – is substantially reduced. A universal pharmacare program could do the same.

But in Canada, we still finance prescription drugs on the American Plan – multiple public and private payers, very expensive and highly inequitable. Commentators have noted for years that we incur substantially higher costs as a result. Most recently, Gagnon (2010) calculates that a true pharmacare system similar to medicare – universal, first-dollar, tax financed, with a single public payer – could reduce total drug costs by as much as $10.7 billion per year, even assuming a 10% increase in utilization. That begins to sound like serious money.

About $1.5 billion could be saved by eliminating most of the administrative overhead, the extra paper pushing (and the tax-expenditure subsidies) associated with private insurance. But the big money comes from aggressive price negotiating with the pharmaceutical industry. When governments are themselves on the hook for drug costs – directly accountable – it concentrates the political mind wonderfully. Promoting industrial policy by giving away their citizens' money to Big Pharma is likely to look less attractive.

These savings are not imaginary; examining New Zealand's Pharmac program for drug purchasing, Morgan (in Evans et al. 2007) has calculated potential savings for Canada of a similar magnitude. So fierce opposition to a medicare-type Pharmacare program from Big Pharma and the private insurance industry is a given. The potential savings are their revenues – once more, see Lesson One, above.[8]

But there is another source of resistance. In cutting about $10 billion from Canadians' total drug bill, genuine pharmacare would also double the public share. Opposition thus comes not only from anti-tax ideologues and assorted libertarian loonies, but also from quite clear-eyed occupants of the upper income brackets. Tax-financed pharmacare, like medicare, would transfer some of the overall payment burden from the unhealthy and unwealthy to the healthy and wealthy. The latter are thus natural allies of Big Pharma and the private insurers in protecting our high-cost drug financing system. And they make their dollars count, politically.

Pharmaceuticals are not the only sector where prices are out of line. Payments to physicians account for the same share of health spending ($25.6 billion in 2009) as pharmaceuticals ($25.4 billion), and they have been on a bit of a tear lately. According

to the Canadian Institute for Health Information (2009), per capita expenditures have risen 45% in the last 10 years, after adjusting for general inflation. This increase is second only to pharmaceuticals (a whopping 74%). But in the last five years, the escalation of payments to physicians has accelerated – 24% above inflation and population growth since 2004, compared with 16% in the previous five years – while in all other major expenditure categories the growth, while still very significant, has slowed. (Pharmaceuticals fell from 46%, 1999–2004 to 19%, 2004–2009; hospitals are down to a mere 11%.)

These are very big numbers. If payments to physicians had merely kept pace with inflation and population growth over the last decade, our annual doctor bill would now be $7.9 billion lower. Similar restraint in prescription drugs would have saved us $11.0 billion.[9]

Research currently nearing completion at the Centre for Health Services and Policy Research at UBC suggests that the growth in physician expenditures is, like that of pharmaceuticals, largely a consequence of increasing relative prices – sector-specific inflation. There is thus considerable scope for cost containment in physicians' services, as in prescription drugs, by focusing on the prices being paid. The real problem is, as always, the political difficulty of containing the income aspirations of powerful actors on the supply side.

The economics is, by comparison, easy.

ACKNOWLEDGEMENTS

With thanks to Michael Law for helpful comments.

NOTES

[1] The cut to 25% is not the whole story; there are to be a variety of other compensatory payments to pharmacies to cushion the shock. On the other hand, the proportionate savings to private payers may be even greater than those to the ODB.

[2] This prediction assumes that because the overall volume of dispensing work will not be reduced, requirements for pharmacists will not change, i.e., the average number of prescriptions filled per pharmacist will remain constant. Conceivably, however, efforts to restore the profitability of pharmacies could lead to fewer pharmacies and higher dispensing rates per pharmacist – reducing the demand for pharmacists. Introduction of "robo-pharmacy" could have even more dramatic effects.

[3] If the option of opening one's own pharmacy enables pharmacists to bargain for higher wages than the market would otherwise provide for work of similar effort and knowledge, then any such premium would be reduced as store ownership becomes less attractive.

[4] A recent analysis of the supply and geographic distribution of pharmacies in Ontario (Law et al. 2010) shows that the majority of the population (63.6%) live within an 800-metre walk of one or more pharmacies, and nearly all (90.7%) live within a five-kilometre driving distance. A randomly

distributed cut of 20% in the number of outlets (conservative, since closures would be more likely in pharmacy-dense areas) would have virtually no impact on these access measures.

[5] The announcement by Loblaws that they were considering opening dispensaries in their stores took some of the wind out of Shoppers PR sails, though that may have been just a shot across the bow in response to Shoppers' intrusion into the grocery market.

[6] Still, the clear message, from a disinterested public agency, that Canadians were paying too much for generic drugs can only have strengthened the political position of the Ontario government.

[7] There are examples of successful cost containment through competition – New Zealand's Pharmac and Medicaid in the United States, or, for that matter, hospital or pharmacy purchasing in Canada. But these are competitive tendering processes at wholesale, by a single buyer or a coordinated group, not a fragmented retail market. Even very large private insurers have been remarkably ineffective, worldwide, in mobilizing their potential market power to restrain price inflation in the health sector.

[8] When the United States introduced the Medicare Part D coverage of prescription drugs for the elderly, the pharmaceutical industry lobbied successfully to have the legislation specifically prohibit the Social Security Administration from negotiating drug prices with suppliers. They were well aware of the potential impact on prices of a large public buyer.

[9] Of course, the population is also aging. Demography would account for an increase of about 5%.

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DISCUSSION AND DEBATE

The Commercialization of Genomic Research in Canada

La commercialisation de la recherche en génomique au Canada

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Abstract

The commercialization of academic research has been promoted by North American policy makers for over 30 years as a means of increasing university financing and to ensure that promising research would eventually find its way to the marketplace. The following issues paper constitutes a reflection on the impact of the Canadian commercialization framework on academic research in the field of genomics. It was written following two workshops and two independent studies organized by academic groups in Quebec (Centre of Genomics and Policy) and Alberta (Health Law Institute). The full sets of recommendations are available upon request to the authors.

Résumé

Depuis 30 ans, en Amérique du Nord, les decideurs de politiques favorisent la commercialisation de la recherche universitaire comme moyen de financement et pour assurer que les recherches prometteuses se taillent éventuellement une place sur le marché. Cet article de discussion est une réflexion sur l'impact, au Canada, du cadre de commercialisation de la recherche universitaire dans le domaine de la génomique. Il a été écrit suite à deux ateliers et deux études indépendantes organisées par des groupes universitaires au Québec (Centre de génomique et politique) et en Alberta (Institut du droit de la santé). L'ensemble des recommandations est disponible sur demande auprès des auteurs.

This policy paper is intended to encourage policy makers and academic institutions to reflect on how commercialization, intellectual property (IP) and public–private partnerships in genomic research should be managed in the Canadian context. By way of IP rights and the creation of public–private partnerships, commercialization aims to convert academic research into a variety of commercial products. Commercialization could be viewed as the process of extracting economic value out of new products, processes and knowledge through the use of IP rights, the creation of spin-off companies or both (Gault and McDaniel 2005). In Canada, as in the United States and Europe, there has been a considerable push to commercialize university-based research in order to improve technology transfer,

facilitate economic growth, stimulate research collaboration and boost university financing (Joly et al. 2007). This activity has sparked debates on the impact of research commercialization within these countries/regions.

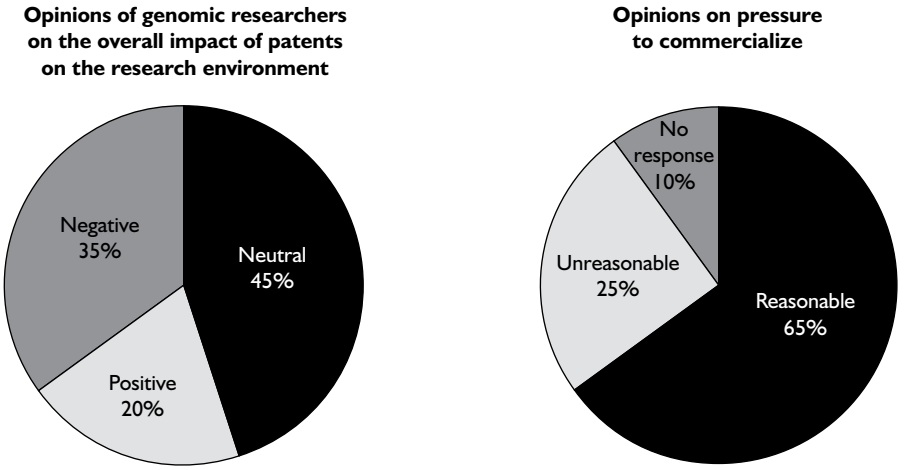
In late 2008, at the launch of the Centre of Excellence for the Commercialization of Research, Canada's Minister of Science and Technology, Gary Goodyear, stressed that in these times when many are concerned about the global economy, commercialization should become a greater priority. This commercial bent is no recent trend: the enabling legislation of the Canadian Institutes of Health Research (CIHR) stipulates that the objectives of the agency are to "encourage innovation, facilitate the commercialization of health research in Canada and promote economic development through health research in Canada." Likewise, many Canadian National Centres of Excellence projects have a strong commercial focus (e.g., the Stem Cell Network). To date, no real attempt has been made to situate the debate over commercialization in the broader context of academic research promotion.

Genomic research is an exciting new field of study that offers the prospect of new technologies and new cures. It aims to unravel the complexity of an organism's full complement of genes and how they interact – it links physiology with complete genetic make-up. By focusing on genetic networks rather than individual genes, genomic research has the potential to aid in the elucidation of the etiology of complex diseases or drug responses by surveying patterns of gene expression.

In 2000, the non-profit organization Genome Canada was established in order to develop and implement a national strategy in genomic research in areas such as agriculture, health and new technology development. Génome Québec, an investment arm of Genome Canada, has implemented specific measures to stimulate the integration of genomic research within industry. One example is the PRIVAC financing program of Génome Québec, which requires that at least a third of a project's funds be derived from the private sector. Given this shift to a more entrepreneurial approach, it seems essential to consider the effects of commercialization on genomic researchers, as well as on the organization and direction of genomic research in Canada.

In spite of two decades of commentary on the impact of commercialization on the field of genetic/genomic research, evidence on the trade-offs inherent in the push towards commercialization and the entrepreneurial university paradigm, specific to the Canadian context, is still lacking (Herder and Gold 2007). Outside of the general ethical framework of the *Tri-Council Policy Statement* (TCPS), no practical guidance exists for Canadian researchers or policy makers. In 2008, two groups of Canadian researchers, one based at the Centre de recherche en droit public in Montreal and the other at the Health Law Institute in Edmonton, undertook a series of in-depth qualitative interviews of genomic researchers concerning the commercialization environment (Silverstein et al. 2009; Murdoch and Caulfield 2009). Their research was financed by Génome Québec, Genome Alberta and Genome Canada.

FIGURE 1. Opinions of genomic researchers on the impact of patents and commercialization (based on results from Murdoch and Caulfield 2009)



Although the survey was conducted on a small sample of researchers (30 Canadian researchers), the results do not suggest that commercialization has had an overwhelmingly negative impact on their work or has created overt conflicts of interest. While interviewees mostly viewed patents in a neutral light, they identified secrecy, the proliferation of material transfer agreements (MTAs) and publication delays as causes for concern. Moreover, researchers often felt disconnected from the imperatives of the commercialization agenda. The results of these two qualitative studies, as well as additional evidence from the literature, inform the points to consider listed in Table 1.

Conflicts of Interest

Conflicts of interest (COIs), arising from undue influence of industry, call into question the objectivity and trustworthiness of research (Bekelman et al. 2003). The 2008 federal government's draft second edition of the *Tri-Council Policy Statement* notes that "[a]lthough the potential for such conflicts has always existed, pressures to commercialize research or suspend dissemination of research outcomes heighten concerns" (Panel on Research Ethics 2010). With genomic research, it has been suggested that the need to commercialize new research findings and to secure private partners could conflict with more traditional values of scientific integrity, academic freedom and the vocation of the academy (Joly et al. 2007; Bekelman et al. 2003). According to this position, traditional academic values are being neglected in favour of new commercial imperatives: it has been suggested that commercial agreements could negatively affect the mentorship of graduate students by faculty researchers and reduce the ability of these students to publish their research results (Behrens and Gray 2001). This pessimistic vision of the academic–industrial relationship thrives owing to a lack of trans-

parency, accessibility, harmonization and readability of institutional policies on COIs (Williams-Jones and MacDonald 2008). Furthermore, public trust can be eroded by highly publicized commercial controversies or theoretical arguments stressing the potential for conflicts in the fields of genetics and genomics, irrespective of the actual evidence (Caulfield et al. 2007).

TABLE 1. Commercialization of genomic research: Points to consider

Conflicts of interest Ethics committees should require a declaration of COIs from principal investigators whose research projects involve the private sector before approving their protocols.
Secrecy Researchers should conduct additional studies to pinpoint the sources of secrecy in the context of genomic research and to clearly delineate the respective roles played by MTAs, public–private partnerships and IP in this problematic area.
MTAs Canadian institutions should consider moving towards a simple standardized model of MTAs for non-commercial genomic research.
Intellectual property Funding bodies should encourage comprehensive empirical studies on the direct and indirect effects that the patent system has on academic genomic research in Canada.
Harmonization Canadian research institutions should promote transparency in three ways: (a) provide standard MTA forms online, (b) facilitate public access to COI and commercialization policies via websites and (c) develop open science data-sharing practices.
Overall Policy makers should recognize the structural limits of the commercialization framework and begin discussions on the promotion of university-based research in a broader context.

Secrecy

One of the most disturbing claims concerning the commercialization of genomic research is that it could possibly contribute to an increase in secrecy among university scientists and administrators. According to a growing body of evidence, researchers are not sharing data, materials and research tools as freely as they used to and are often publishing at a later stage in the research process (Blumenthal et al. 2006; Campbell et al. 2002). It has so far been difficult to attribute this problematic situation to a single element, although the proliferation of MTAs in academic research is believed by many to be a contributing factor. As recently suggested by Hong and Walsh (2009), it would be beneficial to "unpack the various dimensions of commercialization, sharing and secrecy to see what aspects are affected by what." If allowed to develop, the climate of secrecy in genomic research could limit the capacity of researchers to review and validate the work of other research groups by reproducing it independently. It

could also restrict the academic freedom of researchers in two ways: first, in pursuing research in the direction of their choosing, and second, in choosing their collaborators, and so hindering collaboration and delaying scientific progress. However, in limited circumstances a certain degree of secrecy could be justified by the need to protect the personal information of research participants.

Material Transfer Agreements

As genomic projects expand in size and ambition, researchers increasingly depend on the use of research tools and materials from outside their institutions to carry out research. However, because of the promise of obtaining IP rights, materials are often transferred by means of detailed agreements delineating the precise rights and obligations applicable to the transfer. Such MTAs are a direct consequence of the commercialization of academic research and of the rapid development of new scientific fields. These private legal agreements, variable in scope and complexity, are now extensively used in academia to clarify the rights of providers and recipients of genomic materials, tools or data. In fact, one could even argue that MTAs are used in situations where there is no real necessity for them (e.g., when the material to be transferred is of little commercial value or is meant to be openly disseminated). MTAs are a growing source of secrecy, reach-through rights and communication delays. They are also perceived as creating a significant hurdle to open collaboration among researchers (Bennett et al. 2007; Campbell et al. 2002). Conversely, it could also be argued that MTAs have become a necessary evil in protecting the potential of genomic research at a time when patenting research tools and private–public partnerships have become common practice.

Intellectual Property

IP gives power to an individual or entity (the IP holder) to control how knowledge will be used. In the field of genomics, IP protection is usually ensured through the patent system. Patents are exclusive IP rights, granted on eligible inventions for a period of 20 years. The patenting of genetic "inventions" has generated a considerable amount of controversy in recent years. It has been criticized for slowing down the pace of innovation, fostering secrecy, biasing the choice of research projects and obstructing the clinical uptake of valuable research (Joly 2009). Emerging evidence questions the veracity of many of these critiques (Walsh et al. 2003). Nevertheless, it is still possible that the growing importance of securing patent rights within academia is, directly or indirectly, encouraging the proliferation of MTAs, publication delays, secrecy and other sources of conflicting interests among genomic researchers. Patenting practices may exacerbate these concerns in the future (Mills and Tereskerz 2007). OECD member countries have taken the position that licence agreements that give licensors

exclusive control over human genetic information should be avoided. The OECD guidelines on good licensing practices are a proactive mechanism to streamline the patent system (OECD 2006; Canadian Biotechnology Advisory Committee 2005).

Harmonization

The new era of "big science" genomics involves the collaboration of multiple centres, often across national boundaries, and the creation of large biobank projects, such as the International Cancer Genome Consortium and the Canadian Partnership for Tomorrow Project. However, a major obstacle to achieving interoperability, large-scale collaboration and database networking is the dearth of socio-ethical or legal norms at the global and national levels that could guide such endeavours. Discrepancies in the policies that apply at the institutional level also impede the success of networking efforts. If commercialization remains a priority, some level of policy harmonization is necessary. Otherwise, policies meant to alleviate some of the potentially adverse effects of commercialization could end up doing more harm than good, leaving researchers mired in conflicting obligations, the reconciliation of which will require time and effort. Arguably, some of the issues associated with commercialization may derive from the difficulty of researchers and administrators to navigate through the numerous diverging institutional policies and identify a clear and comprehensive picture of trends, obligations and obstacles in policy work on this topic.

Conclusion: Towards a More Coherent Framework?

The issues associated with commercialization would be better managed if we were to view commercialization as one of many vectors in the broader context of the promotion of genomic research. In its 2001 *Policy on Science and Innovation*, the government of Quebec decided to avoid the general use of the term commercialization, replacing it instead by the French word *valorisation*. This word is sometimes translated in English as "development" or "promotion." This expression would seem to convey a much richer content than the word *commercialization*. The *Policy on Science and Innovation* confirms this by specifying that *valorisation* "refers globally to a group of activities that introduces the world of research to the economic and social sphere" and by adding the following:

> All research results will not produce commercial applications and lead to financially profitable businesses. Obviously, the promotion of research cannot be limited to the commercial exploitation of research results; generally, it rests on the demonstration and exchange of knowledge, and this, in all fields of knowledge development. (Translated from the French)

Nevertheless, in more recent documents – for example, in its *Action Plan: Managing Intellectual Property* – the Quebec government seems to have increasingly equated *valorisation* with *commercialization* alone and forgotten the other meanings conveyed. This is regrettable; the time has now come for policy makers to recognize the structural limit of the commercialization framework and to begin discussions on the promotion of university-based research in a broader context. This new framework should go beyond commercialization to consider also the implementation of research knowledge (the conversion of knowledge into tangible applications) along with its impact on health services. By better linking research with action, *valorisation* could enable stakeholders to bridge the pervasive disconnect between discovery and application in genomic research, thus finally enabling the population to enjoy concrete health benefits from the "genomic revolution."

ACKNOWLEDGEMENTS

The authors would like to acknowledge the financial contribution of the GRID Project (Genome Canada, Genome Quebec), and Genome Alberta. They would also like to thank Tina Silverstein, Flora Wahnon, Michael Huynh and Maria Braker (Centre of Genomics and Policy, McGill University) for their research and editorial assistance.

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Understanding the Unattached Population in Ontario: Evidence from the Primary Care Access Survey (PCAS)

Mieux comprendre la population sans médecin de famille en Ontario : données provenant du sondage sur l'accès aux soins primaires

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Abstract

To measure primary care access on an ongoing basis, the Ontario Ministry of Health and Long-Term Care implemented the Primary Care Access Survey (PCAS) in 2006. The PCAS, a cross-sectional telephone survey, samples approximately 8,400 Ontario adults each year. It collects information on access to a family doctor, use of services, health status and socio-demographics. Analysis of the 2007–2008 PCAS (n=16,560) shows that 7.1% of Ontario's adults were without a family doctor (i.e., unattached). The attached and unattached populations differed on socio-demographic and health characteristics. Emergency department use was similar between the two groups, but walk-in clinic use was higher among the unattached. The unattached were less likely to have used care for immediate issues but accessed care in a more timely fashion than the attached. This initial exploration of the PCAS provides a better understanding of some of the differences between the attached and unattached populations in Ontario.

Résumé

En 2006, le ministère ontarien de la Santé et des Soins de longue durée mettait en place le sondage sur l'accès aux soins primaires (Primary Care Access Survey, ou PCAS) pour mesurer de façon continue l'accès à ce type de soins. Le PCAS est une enquête téléphonique transversale dont l'échantillon annuel est d'environ 8 400 Ontariens adultes. Elle permet de recueillir des renseignements sur l'accès au médecin de famille, l'utilisation des services, l'état de santé et la situation sociodémographique. L'analyse des données du PCAS de 2007–2008 (n=16 560) montre que 7,1 % des Ontariens adultes n'ont pas de médecin de famille. Les populations avec et sans médecin de famille présentent différentes caractéristiques sociodémographiques et sanitaires. L'utilisation du service des urgences est semblable entre les deux groupes,

mais l'utilisation des cliniques sans rendez-vous est plus élevée chez ceux qui n'ont pas de médecin de famille. Ces derniers sont moins enclins à utiliser les services pour des besoins immédiats, cependant ils jouissent d'un accès en temps plus opportun que ceux qui ont un médecin de famille. Cette première exploration des données du PCAS permet une meilleure compréhension de certaines différences entre la population ontarienne qui a un médecin de famille et celle qui n'en a pas.

Access to family doctors is a concern to a large number of Ontario residents and has become part of the public discourse on primary care. Having a family doctor has many important benefits, including earlier treatment for potentially difficult conditions, more preventative care (such as blood pressure checks, mammograms and Pap smears) and better management of chronic disease (Lambrew et al. 1996; DeVoe et al. 2003; McIsaac et al. 2001; Xu 2002). Having an established physician–patient relationship also contributes to better continuity and improved patient satisfaction (Hjortdahl and Laerum 1992; Schoen et al. 2004).

Patients without family physicians may use other services such as walk-in clinics or emergency departments as a substitute for primary care (Baker et al. 1994; Rask et al. 1994; Schoen et al. 2004). However, the use of such services is viewed as an inadequate substitute because it may disrupt coordination of care and leave patients at higher risk for drug interactions and delays in receiving results of lab or diagnostic tests (Lowe et al. 2005; Schoen et al. 2004). While the majority of patients using walk-in clinics have regular family doctors, there is some suggestion of lower attachment rates among visitors to clinics (Jones 2000). As with emergency departments, the substitution of walk-in clinics is related to patients' perceptions of timely primary care (Szafran and Bell 2000).

Although the vast majority of Ontario residents have regular medical doctors (Ontario Health Quality Council 2009), those without family doctors are an important concern for health jurisdictions from both population health and policy perspectives. Lower likelihood of having a family doctor has been associated with certain demographic characteristics such as younger age and being male (Merzel 2000; Viera et al. 2006; Talbot et al. 2001; DeVoe et al. 2003), as well as social factors such as single marital status, lower educational attainment and lack of English language skills (Talbot et al. 2001; Sanmartin and Ross 2006; Ponce et al. 2006; McIsaac et al. 2001). There is some evidence that those without family doctors tend to be in better health (Hayward et al. 1991; Viera et al. 2006; Nabalamba and Millar 2007; Talbot et al. 2001). Urban/rural differences in access and use of primary care have been found in some studies (DeVoe et al. 2003; Finkelstein 2001; Nabalamba and Millar 2007; Sanmartin et al. 2006; Wellstood et al. 2006), but this relationship is likely highly contextualized and

partially dependent on variations in physician supply (Chaix et al. 2005).

Existing data sources such as the Canadian Community Health Survey (CCHS) can be used to determine the number of Ontarians without family doctors and their socio-demographic characteristics. However, the data are not always timely and do not capture some of the salient information needed for provincial planning. In order to inform policy, planning and management, to measure health system performance and to further research on primary care issues in Ontario, it was determined that a data source focused specifically on primary care physician access in Ontario was needed. In 2006, the Ontario Ministry of Health and Long-Term Care, in consultation with the Ontario Medical Association, the Ontario College of Family Physicians and the Institute for Clinical Evaluative Sciences, developed the Primary Care Access Survey (PCAS). Key to this initiative was the need for timely information on access, regional variation and utilization trends and the need to monitor the impact of significant primary care reforms underway in Ontario. Additionally, and perhaps more critically, there was an implicit assumption that the perceived challenges in access to care for those without a regular doctor were not being adequately examined and documented. The PCAS was designed to measure, on an ongoing basis, access to family doctors in Ontario and thus better understand the factors that may contribute to having a family doctor and accessing primary care. Measuring primary care access includes determining both the number of people who do and do not have regular family doctors, known as the attached and unattached populations, respectively, along with their experiences in attaining care, and their health and socio-demographic characteristics.

The purpose of this paper is to introduce readers to the PCAS and to use these survey data to describe the characteristics and patterns of access to primary care in Ontario by comparing the unattached and attached populations.

Methods

Data source

The PCAS began in January 2006. The survey is administered by telephone by the Institute for Social Research (ISR) at York University. Respondents are asked about their perceptions of the healthcare system in Ontario, their health status, family doctor status, reasons for not having a family doctor, their family doctor's practice setting, utilization of primary care services, socio-demographics and household composition, and coverage under the Ontario Health Insurance Plan. Each interview, conducted in either English or French, takes approximately 15 to 20 minutes to complete.

The survey covers the household population age 16 and older in Ontario. The sample is allocated equally among the 14 Local Health Integration Networks (LHINs) in Ontario, maximizing the ability to compare primary care access among the LHINs. Data are collected over the course of the year but use a quarterly sampling frame to

facilitate trending over time. A minimum of 150 interviews are completed per quarter per LHIN, for a total provincial sample of approximately 2,100 every three months.

Sample design

A modified random digit dialling (RDD) sample, designed by ISR, used the following steps. First, an inventory of known telephone numbers was developed from published sources such as telephone books, street directories and subscribers' lists. These numbers were included in the sampling frame and a random list of numbers was subsequently generated to create the sample. When interviewers dial a number, they determine whether it is in service and whether it is a household number. Interviewers then randomly select an adult respondent aged 16 or older, living in the household, who is able to speak either English or French. Up to 12 call attempts are made, and if there is good reason to believe an interview will be obtained, more calls are completed. Calls are made during the day, evenings and on weekends. Computer-assisted telephone interviewing (CATI) is used in data collection. Households without telephones and some households that use only cellular phones are not included in the sample design. Of the estimated number of eligible households in the sample, 59% completed the survey.

Measures

The variables collected by the PCAS and described in this paper provide information on predisposing, enabling and need characteristics, consistent with the framework for examining access to healthcare services developed by Andersen (Andersen and Newman 1973; Andersen 1995). Seven measures of primary care access were examined: attachment to family doctors; family doctor utilization for routine care, immediate care and overall care; walk-in clinic utilization; emergency department utilization; and the time to see family doctors for immediate care. All utilization measures were based on one or more visits to a family doctor in the 12 months preceding the interview. The reference period for questions related to use and access of care was also the past 12 months. These measures and some key terms are defined in Table 1. More detailed descriptions of the social, demographic and health status variables presented in this paper are available from the authors.

Analyses

Seventeen thousand, one hundred thirty-seven respondents were interviewed in 2007 and 2008. Sampling weights were used to correct for the unequal probability of selection with respect to household size (i.e., the number of adults aged 16 and older in the household) and the LHIN in which the respondent resided. Post-stratification adjust-

ments were subsequently applied to the weighted sample so that the total age and sex categories reflected the 2007 Ontario population structure.

TABLE 1. Key definitions

Terms	Definitions
Family doctors	Refers to the doctor whom respondents typically see for routine care and non-emergent problems; includes family doctors, family physicians, general practitioners or medical doctors but does not include dentists, eye doctors, gynaecologists or obstetricians.
Attached patients	Respondents who have family doctors.
Unattached patients	Respondents who do not have family doctors.
Routine care	Refers to regular check-ups or monitoring of ongoing health issues.
Immediate care	Refers to urgent health problems that require immediate attention, for example, when sick.
Overall care	Includes routine care, immediate care, care to obtain health information, or for advice regarding whether care is necessary.
Walk-in clinic visits	Refers to any visits to walk-in clinics for a health-related reason.
Emergency department visits	Refers to any visits to emergency departments for any health-related problems.
Time to see family doctor for immediate care	Based on the number of days it took respondents to obtain an appointment from a family doctor when they were sick.
Urban/rural geography	Urban refers to continuously built-up areas with a minimum population of 1,000 and a minimum population density of 400 per square kilometres. All other areas are defined as rural. Derived from respondent's postal code using the Postal Code Conversion File (Statistics Canada 2009).

Respondents who did not report their age (n=577) were excluded from analysis (all respondents must be assigned to an age group to post-stratify the data), leaving a sample of 16,560 respondents. For each question, respondents reporting "don't know" or "refused" were excluded from the analysis of that item. The "don't know" and "refused" categories accounted for less than 2.2% of responses for each item, with the exception of geography. Ten per cent of respondents were not assigned to urban/rural geography because of missing or invalid postal codes.

All analyses were based on the post-stratified weighted sample, which is representative of the Ontario population aged 16 or older. Analyses were conducted using Stata Version 10.1 (StataCorp. 2008) using the program's complex survey analysis module to calculate estimates and confidence intervals at the 95% level. Weighted frequency estimates were produced to describe the characteristics of the study population. Bivariate analyses were performed to determine the association between attach-

ment and socio-demographic characteristics, family doctor utilization, walk-in clinic and emergency department utilization, and the length of time to obtain immediate care. Differences between estimates were tested for statistical significance at the level of $p<0.05$, using chi-square tests.

Results

Table 2 shows selected characteristics of the Ontario population based on responses from PCAS respondents. A total sample of 16,560 was weighted to represent 10.4 million Ontarians aged 16+. According to the 2007 and 2008 PCAS data, almost 93% of Ontario residents, aged 16 or over, reported they have a family doctor (i.e., are attached).

TABLE 2. Characteristics of study population aged 16 or older, Ontario (2007 and 2008)

	Unattached (no family doctor)		Attached (has family doctor)		Total		
PCAS sample	**(n=1,260)**		**(n=15,300)**		**(n=16,560)**		
Estimated population (weighted sample)	**(N=733,566)**		**(N=9,658,311)**		**(N=10,391,877)**		
	% of estimated population[§]	**95% CI**	**% of estimated population[§]**	**95% CI**	**% of estimated population[§]**	**95% CI**	***p* value[†] (unattached vs attached)**
Total population, aged 16+	7.1	6.6, 7.5	92.9	92.5, 93.4	100.0		
Gender[‡]							
Male	58.7	55.4, 62.0	48.2	47.9, 48.4	48.9	-	$p<0.01$
Female	41.3	38.0, 44.6	51.8	51.6, 52.1	51.1	-	
Age[‡]							
16–24	17.2	14.2, 20.1	14.9	14.7, 15.2	15.1	-	$p<0.01$
25–34	25.1	21.9, 28.2	16.1	15.9, 16.4	16.8	-	
35–64	49.4	46.0, 52.8	52.1	51.9, 52.4	51.9	-	
65+	8.4	6.8, 9.9	16.8	16.7, 16.9	16.2	-	
Education							
Less than high school	10.9	8.8, 12.9	13.2	12.6, 13.8	13.1	12.5, 13.6	
High school or some post-secondary	35.2	31.8, 38.6	35.6	34.7, 36.5	35.6	34.7, 36.4	
Post-secondary or higher completed	54.0	50.5, 57.5	51.2	50.3, 52.1	51.4	50.5, 52.2	

TABLE 2. Continued

	Unattached (no family doctor)		Attached (has family doctor)		Total		
Employment							
Employed	67.0	63.7, 70.3	62.1	61.3, 62.8	62.4	61.7, 63.1	$p<0.01$
Unemployed	6.8	5.0, 8.7	3.2	2.9, 3.6	3.5	3.1, 3.8	
Student	11.8	9.2, 14.4	9.0	8.4, 9.5	9.2	8.6, 9.7	
Retired	9.7	8.1, 11.3	20.0	19.6, 20.4	19.3	18.9, 19.6	
Other	4.7	3.4, 6.0	5.7	5.3, 6.1	5.7	5.3, 6.1	
Family size							
2 or more children	10.5	8.5, 12.5	13.8	13.2, 14.4	13.6	13.0, 14.1	$p<0.05$
1 child	14.1	11.5, 16.7	13.4	12.7, 14.0	13.4	12.8, 14.1	
0 children	75.4	72.3, 78.5	72.9	72.1, 73.6	73.0	72.3, 73.8	
Immigrant status							
Non-immigrant	76.8	73.7, 79.8	73.1	72.2, 73.9	73.3	72.5, 74.2	$p<0.01$
Established immigrants (10+ yrs in Canada)	14.7	12.2, 17.1	21.4	20.6, 22.2	20.9	20.1, 21.7	
Recent immigrants (<10 yrs in Canada)	8.6	6.4, 10.8	5.6	5.1, 6.1	5.8	5.3, 6.3	
Geography							
Urban	81.3	78.7, 84.0	79.6	78.9, 80.4	79.7	79.0, 80.5	
Rural	18.7	16.0, 21.3	20.4	19.6, 21.1	20.3	19.5, 21.0	
Healthcare system system confidence							
Very/somewhat confident	59.5	56.1, 63.0	67.3	66.4, 68.2	66.8	65.9, 67.7	$p<0.01$
Not very/not confident	40.5	37.0, 43.9	32.7	31.8, 33.6	33.2	32.3, 34.1	
Has medical training							
Yes	10.2	8.1, 12.2	11.3	10.7, 11.9	11.2	10.6, 11.8	
No	89.8	87.8, 91.9	88.7	88.1, 89.3	88.8	88.2, 89.4	
Number of chronic diseases[2]							
None	66.0	62.7, 69.3	56.1	55.2, 57.0	56.8	56.0, 57.6	$p<0.01$
1	22.7	19.7, 25.8	24.9	24.1, 25.7	24.7	23.9, 25.5	
2 or more	11.3	9.4, 13.1	19.0	18.4, 19.6	18.5	17.9, 19.0	

TABLE 2. Continued

	Unattached (no family doctor)		Attached (has family doctor)		Total		
Health status							
Excellent/Very good	59.6	56.2, 63.1	58.7	57.7, 59.6	58.7	57.8, 59.7	
Good	27.3	24.1, 30.5	26.7	25.8, 27.6	26.8	25.9, 27.6	
Fair/Poor	13.0	10.8, 15.3	14.6	13.9, 15.3	14.5	13.9, 15.2	

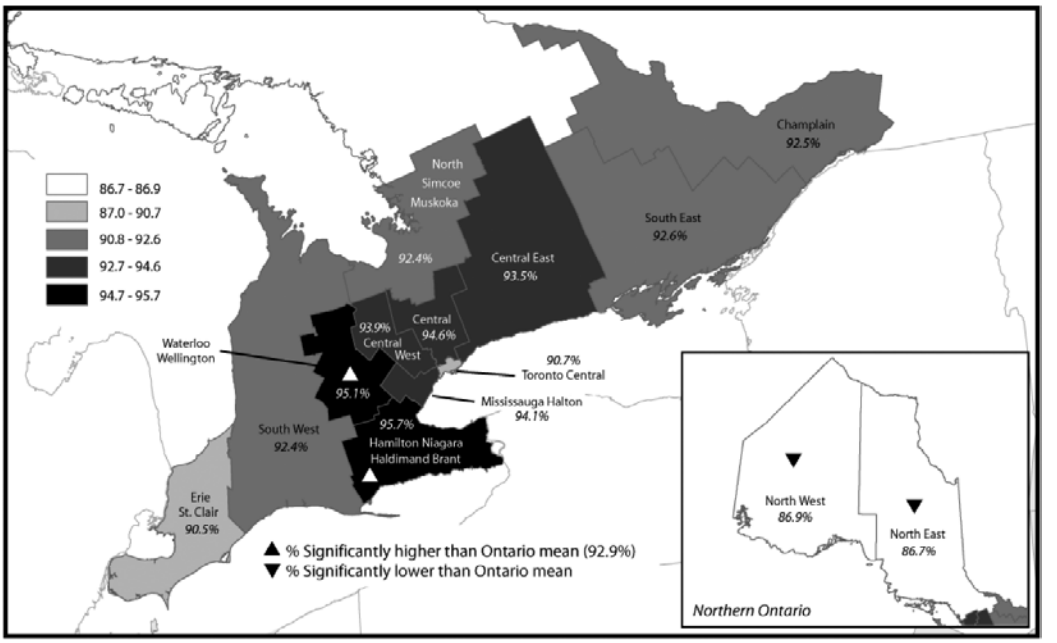
[§] Percentages are based on the weighted number of survey respondents to ensure estimates are representative of the population.
[†] Test for significance between Unattached and Attached groups based on χ^2 test.
[1] PCAS data are post-stratified by age and gender and thus no confidence intervals are available.
[2] Refers to selected chronic diseases including arthritis, asthma, cancer, chronic respiratory problems, diabetes, heart disease/stroke or high blood pressure.

The attached and unattached populations were significantly different with respect to socio-demographic and health characteristics including gender, age, employment, family size, immigrant status, healthcare system confidence and chronic diseases. Those without a family doctor were more likely to be male, younger or recent immigrants. Their employment status was more likely to be employed or unemployed, and they were less likely to report chronic conditions. Ontarians with a family doctor were more likely to be retired, have two or more children or be established immigrants. They were more likely to report they have confidence in the healthcare system and also more likely to have multiple chronic conditions.

Figure 1 illustrates the geographic variation in the proportion of the population with a family doctor across Ontario's 14 LHINs. In six LHINs (those surrounding the Toronto Central LHIN), between 93% to 95% of the population were attached to a family doctor. The proportion was only slightly lower in the South West, South East, Champlain and North Simcoe Muskoka LHINs (between 92% to 93%). Compared to the provincial average, Hamilton Niagara Haldimand Brant and Waterloo Wellington LHINs had significantly higher proportions of residents attached to a family doctor, whereas North East and North West LHINs had a significantly lower proportion.

The relationship between attachment and access to primary care services is presented in Table 3. Unattached residents were less likely to report they received care in the past year. In comparison to the unattached population, those with a family doctor were almost three times more likely to report they received routine care such as monitoring of health issues or check-ups (73% versus 26%). They were also more likely than unattached residents to report having received immediate care, but the difference was less pronounced (36% versus 26%). Although the use of walk-in clinics was almost twice as high among the unattached population compared to the attached, the use of emergency departments was similar between the two groups.

FIGURE 1. Percentage of attached patients, population aged 16 or older, by Ontario LHINs (2007 and 2008)



Those who had sought care for an urgent health issue were asked how long it took them to receive immediate care. The relationship between attachment and the length of time (in days) it took to see family doctors for immediate care is presented in Table 4. Compared to attached residents, a much larger percentage of unattached residents reported they were able to see a family doctor on either the same day or within one day from when they first tried to obtain care.

TABLE 3. Use of primary care services by unattached and attached persons, Ontario (2007 and 2008)

	Unattached (no family doctor)		Attached (has family doctor)		Total population		*p* value† (unattached vs attached)
	Per cent	95% CI	Per cent	95% CI	Per cent	95% CI	
Overall care	50.1	46.5, 53.6	84.1	83.3, 84.8	81.7	80.9, 82.4	$p<0.01$
Routine care	25.9	22.8, 29.0	73.1	72.2, 73.9	69.7	68.9, 70.6	$p<0.01$
Immediate care	25.7	22.5, 28.9	36.0	35.0, 37.0	35.3	34.4, 36.2	$p<0.01$
Use of walk-in clinic	47.9	44.4, 51.5	24.6	23.7, 25.4	26.2	25.4, 27.1	$p<0.01$
Emergency department use	20.8	18.0, 23.6	20.5	19.7, 21.3	20.6	19.8, 21.3	

Percentages are based on the weighted number of survey respondents to ensure estimates are representative of the population.
† Test for significance between Unattached and Attached groups based on χ^2 test.

TABLE 4. Amount of time (in days) to access immediate care by unattached and attached persons, Ontario (2007 and 2008)

	Unattached (no family doctor)		Attached (has family doctor)		Total population		*p* value† (unattached vs attached)
	Per cent	95% CI	Per cent	95% CI	Per cent	95% CI	
Same day	59.5	52.9, 66.1	26.4	25.4, 29.5	28.1	26.6, 29.6	p<0.01
Within 1 day	66.3	59.9, 72.8	46.1	44.9, 49.6	47.1	45.5, 48.7	p<0.01
Within 2 days	71.5	65.3, 77.7	62.8	60.9, 65.5	63.2	61.6, 64.8	p<0.05

Percentages are based on the weighted number of survey respondents to ensure estimates are representative of the population.
† Test for significance between Unattached and Attached groups based on χ^2 test.

Discussion and Conclusion

In 2007 and 2008, approximately 734,000 Ontario residents (aged 16+), representing 7.1% of the provincial population, did not have a family doctor. This figure is lower than estimates from national surveys, which had reported that 9.0% of Ontarians are without a regular medical doctor (CCHS 2007). The PCAS results show substantial geographic variation in attachment rates within Ontario, with lower attachment rates in northern regions of the province relative to the south.

The PCAS results suggest that the unattached and attached populations are not homogenous with respect to their socio-demographic characteristics nor in their use of primary care services. The unattached population was more likely to be male, younger, recent immigrants and healthier in terms of the number of chronic conditions. These differences are consistent with previous findings showing that those with and without family doctors differed with respect to health status and demographic characteristics (Talbot et al. 2001; McIsaac et al. 2001; Viera et al. 2006; Nabalamba and Millar 2007).

A previous study of Canadians had shown that those without a regular medical doctor were more likely to report difficulties accessing routine care but not immediate care (Sanmartin and Ross 2006). Although we did not look at difficulties in accessing care, we did find that unattached persons were much less likely to have used routine care in the past year. Because the unattached population is younger and healthier than those who are attached, the lower use of routine care may reflect either a self-perceived lack of need for these services, a potential lack of access to the services or a combination of the two.

The findings on the use and timing for immediate care services suggest that although those without a family doctor were less likely to have used care for an urgent problem, when they did access care they were able to do so in a more timely fashion than those with a family doctor. This may be because of the higher use of walk-in clinics among residents without a family doctor. Interestingly, approximately 20%

of the attached still made use of walk-in clinics, a finding that is perhaps due to less timely access from their regular family doctors. This finding is consistent with other studies that have shown that those with a regular doctor may still experience challenges in timely access (Szafran and Bell 2000; Sanmartin et al. 2004; Wellstood et al. 2006), and that those with a family doctor may also substitute these services when timely access is not available (Rust et al. 2008; Matthews and Barnsley 2003). It is noteworthy that use of emergency departments is similar for attached and unattached Ontarians, suggesting that the unattached population does not place an overt burden on emergency services.

The limitations that typically apply to cross-sectional survey data (e.g., validity and reliability of self-reported data, generalizability of the sample) and its analysis (causal relationships between variables cannot be inferred) apply here. More specifically, PCAS household telephone survey methodology does not capture households without a telephone and may not include those that use cellular telephones exclusively. Because 92.5% of Ontario households have a land line phone and only 5% use a cellphone exclusively, this limitation is unlikely to bias our results (Statistics Canada 2007). Nonetheless, the PCAS has been instrumental in providing up-to-date estimates of unattachment rates at the provincial and LHIN levels because the continuous data collection permits ongoing monitoring. Physician attachment has been improving in Ontario (MOHLTC 2009), and the results from the PCAS suggest that fears of a burgeoning physician access problem may have been overstated. Regardless, a substantial number of Ontarians are without regular doctors and are therefore not able to receive comprehensive primary care. PCAS results show that despite this situation, primary care is being accessed by the unattached population, and their needs for immediate care are met within the same or better time frame as those with regular doctors. The unattached use walk-in clinics rather than emergency departments, but because the distribution of such clinics is greatest in urban areas, attention must be paid to those areas where alternative primary care is not readily available – notably, in rural and northern communities.

In Ontario, PCAS findings have been instrumental in shifting the policy emphasis from physician supply to strategies to promote attachment. For example, the PCAS identified the need for the Health Care Connects program, which helps Ontarians who are unattached find healthcare providers. Eligible registrants are prioritized for attachment, and physicians receive incentives to roster new patients. The ministry has also created a medical services directory for Ontarians seeking care to reduce reliance on emergency rooms. This directory includes information on walk-in clinics, acknowledging the role these clinics play in meeting the needs of unattached residents.

There is considerable scope for future research using the PCAS data, and some of this analysis is under way. While this initial exploration of the PCAS data provides a better description of some of the major differences between the attached and

unattached populations in Ontario, more nuanced multivariate analyses will provide a better understanding of the relationship between demographic, social and health status characteristics and unattachment. From a research perspective, a more thorough understanding of the dynamics of unattachment in Ontario is required. PCAS results (not shown here) show that almost a third report that they are unattached because they have moved, suggesting that 100% attachment rates are an unrealistic goal. Identifying what would be a reasonable target requires understanding of such dynamics. Furthermore, the incorporation of the PCAS with data on the supply side, and a greater exploration of factors influencing geographic differences, will better inform policy and, in the long run, help improve access for Ontario residents.

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RESEARCH PAPER

Listening for Prescriptions: A National Consultation on Pharmaceutical Policy Issues

Ordonnance à l'écoute : consultation nationale sur les enjeux politiques sur les produits pharmaceutiques

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Abstract

Objectives and Methods: Pharmaceutical policy is an increasingly costly, essential and challenging component of health system management. We sought to identify priority pharmaceutical policy issues in Canada and to translate them into research priorities using key informant interviews, stakeholder surveys and a deliberative workshop.

Results: We found consensus on overarching policy goals: to provide all Canadians with equitable and sustainable access to necessary medicines. We also found widespread frustration that many key pharmaceutical policy issues in Canada – including improving prescription drug financing and pricing – have been persistent challenges owing to a lack of policy coordination. The coverage of extraordinarily costly medicines for serious conditions was identified as a rapidly emerging policy issue.
Conclusion: Targeted research and knowledge translation activities can help address key policy issues and, importantly, challenges of policy coordination in Canada and thereby reduce inequity and inefficiency in policy approaches and outcomes.

Abstract

Objectifs et méthodologie : La question des politiques sur les produits pharmaceutiques constitue un des aspects de la gestion du système de santé qui présente de plus en plus de défis et qui est de plus en plus coûteux et important. Nous avons cherché à déterminer les enjeux prioritaires en matière de politiques sur les produits pharmaceutiques au Canada et à les transposer en priorités de recherche, et ce, au moyen d'entrevues auprès d'informateurs clés, de sondages auprès des intervenants et d'un atelier de discussion.
Résultats : Nous avons observé qu'il y a consensus sur les objectifs principaux en matière de politiques, soit fournir à tous les Canadiens un accès équitable et durable aux médicaments nécessaires. Nous avons également observé un sentiment de frustration générale quant au fait que plusieurs enjeux essentiels de politiques sur les produits pharmaceutiques au Canada – notamment l'amélioration du financement et des coûts des médicaments sur ordonnance – constituent des défis constants qui découlent d'un manque de coordination des politiques. La couverture des médicaments exceptionnellement onéreux pour les états de santé graves a été désignée comme un enjeu qui émerge rapidement.
Conclusion : La recherche ciblée et les activités de transposition de connaissances peuvent aider à cerner les principaux enjeux politiques et, ce qui est primordial, à affronter les défis en matière de coordination des politiques au Canada, permettant ainsi de réduire les iniquités et l'inefficacité des démarches politiques et de leurs résultats.

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With increased use and cost of medicines over the past half-century, pharmaceutical policy has become a key component of health system management. We believe a pharmaceutical policy research strategy is needed because of the prominent political and economic challenges faced in the sector and because specific features of the Canadian regime have resulted in disappointing progress towards previously identified pharmaceutical policy goals. Research

aligned with priority policy issues and related challenges may help Canada's pharmaceutical policy makers better address current and emerging challenges in this sector.

Government commissions have studied pharmaceutical policy in Canada almost every 10 years since the 1960s with the intent to make recommendations concerning priority policy actions (Canada 1963, 1965, 1985, 1998, 2002). While some of these have been extensively consultative, none has focused on identifying underlying policy issues and ways in which health research can inform pharmaceutical policy development (even the identification of pharmaceutical policy problems) in the same way that the Listening for Directions consultations of the Canadian Health Services Research Foundation and partners have done for health services and policy research more generally (CHSRF 2001; Dault et al. 2004; Law et al. 2008). We therefore set out to identify priorities for research in support of pharmaceutical policy in Canada using an interpretative priority-setting process similar to the Listening for Directions consultations (Lomas et al. 2003). With input from policy makers, researchers, health professionals, patient advocates and industry representatives, we identified the key pharmaceutical policy issues facing Canadians in the short and medium term and translated these issues into priority areas for policy research.

Methods

Our priority-setting process involved several stages of expert consultation, analysis and interpretation. As Lomas and colleagues (2003) have recommended for policy research priority-setting, we deliberately oversampled decision-makers at each consultation stage. Each stage of primary data collection was approved by the Behavioural Research Ethics Board at the University of British Columbia.

Telephone interviews

In February 2009, we conducted a series of telephone interviews with individuals identified as important potential users of pharmaceutical policy research. Potential interviewees were purposively selected from federal and provincial government branches directly related to general health policy, pharmaceutical policy and industry policy; public agencies in health and the pharmaceutical sector; professional associations of pharmacy, medicine and nursing; patient advocacy organizations; private sector consultancies; the generic and brand-name pharmaceutical industries; and the private health insurance industry. Aiming for representation across stakeholder groups and geographic regions, we invited 42 key informants to participate in a telephone interview. A total of 24 participated (57% response rate): 14 government decision-makers; three employees of public agencies; four representatives of health professions; three patient/consumer advocates; one private consultant; and one pharmaceutical indus-

try representative. Interviews involved open-ended questions organized around three themes: (a) leading pharmaceutical policy issues today and in the near future, (b) areas where new policy research would have the greatest impact and (c) recommendations on how to improve pharmaceutical policy research in Canada. Interviews were conducted by both authors, lasted from 20 to 40 minutes and were digitally recorded and professionally transcribed.

Online survey

Also in February 2009, we e-mailed invitations to participate in an online survey to 225 purposively selected individuals from across stakeholder groups and regions. The survey consisted of short-answer questions organized around the same themes as the telephone interviews. We received 82 completed surveys (~33% response rate): 26 from university-based researchers; 22 from policy makers and employees of public agencies; 13 from health professionals; seven from private consultants; five from patient advocates; three from the pharmaceutical industry; three from drug plan sponsors; and three from persons who did not identify their role in the sector.

Deliberative workshop

In November 2009, we hosted a workshop with 10 policy makers, seven employees of public agencies and 13 university-based researchers to refine and prioritize findings. The meeting involved presentations and discussions around leading themes from the initial stages of our consultation. In small groups, participants reviewed a summary of consultation themes and identified what they viewed as priority areas for new pharmaceutical policy research. After small-group work and large-group discussions, participants were given six stickers to use as "votes" for what they believed were the top priorities (and allowing them to cast multiple votes for a single research area). Stickers were colour-coded so that researcher and policy maker/analyst votes could be tallied separately.

Interpretive analysis and final review

We independently read all interview transcripts to develop draft theme codes, which we revised based on discussion and review of online survey data. We sent initial themes to workshop participants and then finalized a draft set of research priorities based on grouping and prioritizing themes from all stages of consultation. In February 2010, we sent a draft of the findings for validation and comment to the 48 people who participated in the telephone interviews, the deliberative workshop or both. Thirteen (27%) responded with comments and suggestions, all of which were taken into consideration when preparing this manuscript.

Results

Emergence of themes

We began to see saturation of themes related to overarching policy goals and key policy challenges early in the interview process and observed remarkable consensus on these overarching themes throughout our consultation stages. Specifically, participants from all stakeholder groups suggested that a central policy goal is to provide all Canadians with equitable and sustainable access to safe and effective treatments when needed. However, this suggestion was often expressed in terms of frustration with the status quo: that access to medicines is not equitable within and across provinces, and that existing systems for drug pricing, financing and coverage are not adequate for dealing with financial pressures in a sustainable way. This was put most clearly by a provincial decision-maker in a telephone interview: "until we have a consistent approach to how we deal with pharmaceuticals across the country, until we have a reimbursement system that is consistent across the country, until we have an eligibility criteria and product selection across the country that's consistent, our pharmaceutical programs will never be sustainable."

From our telephone interviews, three specific policy issues and one cross-cutting challenge emerged as dominant. The first dominant issue was the pricing of both new and generic medicines given the increased availability of generic versions of blockbuster drugs and the trend towards extraordinarily high prices for new, specialized medicines. The second dominant issue was equity and sustainability of prescription drug financing systems given historically rapid growth in costs and concerns about the effects of population aging. The third dominant issue was a concern about inter- and intra-provincial disparities in drug coverage given the challenges in assessing extraordinarily costly medicines for serious and often-rare diseases. A further cross-cutting theme raised by all types of stakeholders interviewed was concern about the lack of pharmaceutical policy coordination and cooperation in Canada.

Survey results were largely consistent with telephone interview themes. Table 1 lists the frequency with which specific themes were identified as priority challenges or priority areas for future policy research in our online survey. Recognizing that some of the narrow themes in our coding system related to others – e.g., a theme of "value for money" is related to the themes of pricing policy and coverage decisions – the general themes of financing, coverage and pricing were among the most commonly mentioned in the online survey. Results from our deliberative workshop – summarized in Table 2 – were also comparable to those of the telephone interviews and online survey, with financing- and pricing-related policy research receiving the most "votes" as priority areas for policy research.

TABLE 1. Frequency of policy issue themes identified in an online survey of stakeholders, by question posed

	Most pressing pharmaceutical policy issues/ challenges	Area where new pharmaceutical policy research would have the greatest impact
Financing: providing an equitable and sustainable system of financing necessary medicines	39	9
Regulation: ensuring that available medicines are safe and effective	32	5
Value: ensuring that pharmaceuticals purchased produce benefits to patient and population health that are commensurate with benefits from alternate uses of equivalent resources	23	9
Expensive drugs for rare diseases (EDRD): appropriately managing evaluations, expectations and costs of treatments for rare and serious diseases	20	2
Pricing: achieving fair and competitive prices for brand and generic drugs	17	5
Information: ensuring that balanced and complete information about diseases and treatment options is readily available to prescribers and patients in formats appropriate to their use	17	4
Policy coordination: effectively coordinating pharmaceutical policies within and across jurisdictions and organizations	16	5
Coverage: allocating resources in an equitable, efficient and acceptable way	15	6
Quality use of medicines (QUM): ensuring that patients seek and take pharmaceuticals in ways that are optimal by comparison to alternatives, including non-drug options	12	5
Prescribing: optimizing the quality of prescribing in primary care	12	2
Dispensing: making efficient use of pharmacists' professional skills while generating welfare-enhancing competition among retailers and distributors of prescription drugs	10	3
Innovation: promoting the development of treatments that address previously unmet needs and/or stimulate welfare-enhancing competition	10	1
Engagement: generating public understanding, engagement and ownership related to pharmaceutical policies as health system policies	5	3

Note: Based on the survey design, three items could be mentioned as pressing challenges, whereas only one could be mentioned as an area where more research would have the greatest impact.

TABLE 2. Percentage of "votes" cast for further research, by theme coding and role of voter

	University-based researchers	Policy makers and analysts at public agencies	Total
Financing: providing an equitable and sustainable system of financing necessary medicines	28%	26%	27%
Pricing: achieving fair and competitive prices for brand and generic drugs	19%	26%	23%
Prescribing: optimizing the quality of prescribing in primary care	17%	14%	15%
Coverage: allocating resources in an equitable, efficient and acceptable way	11%	12%	12%
Policy coordination: effectively coordinating pharmaceutical policies within and across jurisdictions and organizations	11%	11%	11%
Dispensing: making efficient use of pharmacists' professional skills while generating welfare-enhancing competition among retailers and distributors of prescription drugs	11%	9%	10%
Expensive drugs for rare diseases (EDRD): appropriately managing evaluations, expectations and costs of treatments for rare and serious diseases	2%	2%	2%

Final priority research areas

By synthesizing the results from all consultation stages, we identified six key issues – stated in terms of policy objectives – that form our final priority areas for pharmaceutical policy research in Canada: (1) coordinated policies within and across jurisdictions, (2) equitable and sustainable financing, (3) fair pricing for value and competition, (4) high-quality prescribing and medicine use in primary care, (5) reasonable and accountable coverage policy and processes and (6) regulation for ongoing safety and effectiveness. These are listed in terms of research priority, finalized based on deliberation and interpretation of data collected at each stage of consultation. Even though it was not singled out as frequently as some other issues, the theme of policy coordination is our top priority because it is a cross-cutting theme and because inter-jurisdictional challenges were specifically identified by participants in relation to many other key priority issues – such as financing, pricing, coverage and safety. In the sections that follow, we briefly discuss each policy objective, place it in context, and provide examples of the types of research that could help inform related policy processes.

COORDINATED POLICIES WITHIN AND ACROSS JURISDICTIONS

> One of the difficulties we have is that a lot of the patent issues are federal and are looked at from Industry Canada's perspective … whereas a lot of the pricing issues are provincial issues and looked at from a whole different perspective, and we don't always get good coordination there. [Industry representative]

> Having limited [budgets] and being beside the largest unregulated marketplace has its own challenges. But I think our bigger challenge really is for us to be consistent across jurisdictions. … The fact is there needs to be cohesion and coordination across jurisdictions, but people are just disengaged. [Government decision-maker]

Owing to the distribution of legislative powers in Canada's *Constitution Acts* (1867 and 1982), healthcare and the regulation of health professionals are provincial responsibilities while the regulation of trade, commerce and intellectual property rights are federal responsibilities. This division of jurisdictional authority is a significant challenge for pharmaceutical policy making because pharmaceutical policy is ultimately a system of interdependent policies, including commercial regulation, intellectual property law, healthcare financing, professional regulation and more (WHO 2001; Morgan, Kennedy et al. 2009). Coordination is therefore fundamental to achieving desired goals effectively and efficiently. Yet, as noted by consultation participants from all stakeholder groups, there has been no sustained mechanism for coordinating the policy efforts of different governments in Canada.

While there are examples of pharmaceutical policy collaboration in Canada around specific policy areas – such as the Common Drug Review – the National Pharmaceuticals Strategy that was launched in 2004 with the 10-Year Plan to Strengthen Health Care in Canada has not translated into an effective and coordinated policy system (Health Council of Canada 2009). With possible renewal of the 10-Year Plan fast approaching, research in this area may assist in developing plans and processes for better coordinating pharmaceutical policies in Canada. For example, comparative and historical analyses of politics, law and public opinion may illustrate ways to overcome challenges of pharmaceutical policy coordination in federations such as Canada.

SUSTAINABLE AND EQUITABLE FINANCING

> [With] the economic downturn that's happening now, the access to proper medication will be even harder for medium-to-low income groups. And that comes to the argument of having a public pharmacare program. [Health professional]

> What are the issues around equity, or lack of equity, in access … issues related to efficiency, or lack thereof, that are associated with and arise from the

> fact that we've got multiple payers and multiple benefit regimes for drugs? [Government decision-maker]

While the financing of medical and hospital care is reasonably well harmonized in Canada through federal cost-sharing arrangements that date back to the 1950s and 1960s (Taylor 2009), there is no equivalent act for coordinating prescription drug benefits in the community setting. Federal and provincial financing policies have therefore evolved independently: the federal government provides drug benefits for specific populations – status Indians, military, etc. – and provinces generally provide coverage for select groups defined by age, income, employment, health status or some combination of these (CIHI 2010). Remarkably few data regarding private drug benefits are systematically collected in Canada; however, previous research suggests that many Canadians experience financial barriers to accessing necessary medicines (Kennedy and Morgan 2009).

In provinces where public coverage is targeted towards senior citizens, the aging of the baby-boomer generation is an increasingly apparent fiscal pressure because government liability for (though not the total level of) drug costs will increase dramatically once boomers reach age 65. In provinces where public drug benefits are set based on income, economic downturns and related cutbacks in employment- and retirement-based private insurance put increasing financial strain on households and, ultimately, on public programs. As noted by many experts with whom we consulted, financing systems and financial pressures in Canada create a classic dilemma: universal pharmacare is a difficult political sell when costs are out of control, yet effective tools for controlling costs depend on such systems of financing (Evans and Williamson 1978; Evans et al. 2007). Policy research can help provide governments with a coherent and principled basis for financing reforms. As a starting point, policy makers need high-quality data on the nature, cost (both private and public) and trends of private drug coverage in Canada. Moreover, provincial pharmacare models should be carefully evaluated and compared with domestic and international alternatives. Research should aim to identify the design, expected performance and viability of financing options for Canada in light of Canadian law, politics and public expectations.

FAIR PRICING FOR VALUE AND COMPETITION

> I think there should be one [generic drug] price for the country, but that's not happening. Everybody has a different policy for generic pricing. [Government decision-maker]

> [The] lack of pan-Canadian price negotiation … means the smaller provinces never quite know what the prices are across the country, and they don't have

> access to the same prices. … I think that's fundamentally wrong. [Employee of a public agency]

Canada has relatively uncoordinated pharmaceutical pricing policies as a consequence of its fragmented financing system and past policy decisions by federal and provincial governments. To help address what were thought to be excessive drug prices in the 1960s (Canada 1963), the federal government allowed generics to compete directly with patented medicines under a policy known as compulsory licensing (Lexchin 1993). As generic versions of patented medicines were generally not available in other countries, provinces were content to pay for generics at modest discounts relative to patent-holding brands. In the late 1980s, the federal government began a process of eliminating the compulsory licensing provision for drug patents, but provinces did not update their generic pricing policies. The historic policy of covering any generic priced at specified discounts (e.g., 30% less than the brand) gives retailers little or no incentive to compete on generic prices. Because the cost of producing generics is often a small fraction of the retail price of brands, generic manufacturers still compete with one another by paying rebates to retail pharmacies; however, these rebates are not passed on to patients or drug plans (Hollis 2002; Competition Bureau 2007). With patents expiring for many of the world's blockbuster drugs in the current era (IMS 2010), provincial governments are now looking to update their policies to better capture the potential savings from generic competition.

At the other end of the pricing spectrum – involving new drugs protected by patent – policy challenges are emerging in price negotiation and the transparency thereof. Provincial drug plans (like drug plans around the world) are both considering and using contracts as mechanisms for setting prices for new medicines. These contracts may involve secret rebates, volume-based price reductions and payment based on clinical outcomes. The outcomes-based contracts raise particular scientific challenges, such as how to generate real-world effectiveness evidence strong enough for contract enforcement; however, all contract-based pricing policies pose equity and efficiency challenges in multi-payer environments. The main challenges arise because fragmentation of financing reduces the purchasing power of individual drug plans and tends to result in the highest prices being charged to those with the least ability to pay (e.g., uninsured patients). Research drawing on ethical, legal, political and economic theory and evidence can help identify pricing models – including contracting and regulatory systems – that are best suited for pharmaceuticals in the Canadian context. Moreover, specific research that draws on theory, evidence and international experience concerning generic drug pricing and retail pharmacy markets may help policy makers realize the full potential of generic competition.

HIGH-QUALITY PRESCRIBING AND MEDICINE USE IN PRIMARY CARE

> We need to figure some way of getting [the public] appropriate information because, otherwise, they're just getting everything off the Internet. [Government decision-maker]

> A challenge that has been on our plate [as health professionals] for at least 20 years now is the relationship with industry. [Health professional]

Ensuring that the right drugs are prescribed to, and used appropriately by, the right patients is both a central goal and a major challenge for pharmaceutical policy (Sansom 1999). Challenges are particularly great in the community setting, where the lack of institutional structures makes pharmaceutical management and communication more difficult than in hospitals and other care facilities. Policy aimed at optimizing the use of medicines in primary care settings requires a combination of regulation, education, remuneration and infrastructure development – policy levers that are divided between jurisdictions in Canada (MacKinnon and Canadian Pharmacists Association 2007). Although provinces have undertaken various initiatives to encourage appropriate prescribing, Canada as a whole has not coordinated the many policy instruments that affect medicine prescribing and use.

At the clinical encounter, Canadian doctors have far less access to electronic medical records, electronic prescribing and prescribing aids than doctors in other countries (Schoen et al. 2009). Moreover, the dominant model of primary care in Canada encourages high-volume, physician-only primary care practice, which increases risks of potentially inappropriate prescribing (Hutchinson and Foley 1999; Tamblyn et al. 2003; Cadieux et al. 2007). There are also growing concerns about whether the public has and uses information that is complete, balanced and accurate given increases in a variety of forms of consumer-targeted pharmaceutical marketing (Bell et al. 2000; Gahart et al. 2003; Kaphingst et al. 2004; Frosch et al. 2007). Provinces are also currently experimenting with new prescribing privileges for pharmacists that may have significant effects on the quality of medicine use. Existing research on quality improvement initiatives has been gathered together in the Rx for Change database (CADTH 2010). Findings need to be contextualized to Canadian settings based on sound behavioural and organizational theories; moreover – given the varied quality of previous studies – the body of existing evidence should be used to guide the implementation and rigorous evaluation of quality improvement initiatives that appear fit for Canadian contexts. With rapid changes in marketing activities and Web-based information seeking, there is an increased need for high-quality research on the effects of these information sources on professionals, patients and health systems. Primary care research on impacts of prescribing roles and privileges for different health professionals is also needed to inform emerging policies in this area.

REASONABLE AND ACCOUNTABLE COVERAGE POLICY AND PROCESSES

> There's got to be some way that we can capture the data and evaluate when a drug is cost-effective and when it isn't cost-effective … we don't want the drug plans wasting taxpayers' money on drugs that aren't working for people. [Patient]

> The more we move into the future, and we start looking at very, very targeted therapies … we're going to be really struggling as a society trying to figure out how to actually put a dollar value on a life or a quality of life. [Government decision-maker]

Coverage policy involves deciding what treatments will, and will not, be paid for – decisions that are challenging at the best of times (Maynard 1999). Even though a Common Drug Review coordinates the critical assessment of clinical and economic evidence for all provinces but Quebec, there is widespread concern about variation in the drugs that are covered across provinces. Research had demonstrated that virtually all of the most commonly prescribed drugs are covered by all provinces (Morgan, Hanley et al. 2009); however, the popular concerns about drug coverage pertain to those medicines used to treat more serious conditions such as cancer (Menon et al. 2005). Regardless of the drug in question, coverage decisions often must be made with limited evidence about what actual utilization levels, costs and (most importantly) health outcomes will result if a product is listed on a drug formulary. Coverage policy for expensive drugs for rare diseases is further complicated by sparse evidence, extraordinary prices and (regardless of the quality of evidence) choices that may be portrayed as life-or-death decisions (Hollis 2005; McCabe et al. 2005). These challenges will likely be heightened in coming years because many of the new drugs in development today are treatments for relatively serious conditions (including many cancers), and many are being targeted to specific populations that have specific genetic or biologic markers.

In light of the tensions in drug coverage decision-making, the process of making coverage decisions is emerging as critically important (Syrett 2003; Mitton et al. 2006; Milewa 2008). Agreement on all decisions is unlikely in a world of scarce resources and clinical uncertainty; however, a well-designed process can give decisions a form of legitimacy that, as one decision-maker noted in our telephone interviews, "is meaningful in that people can say, 'Okay, I disagree with you but I understand your reasons.'" Comparative policy research on international best practices for making resource allocation decisions – especially concerning expensive drugs for rare and serious diseases – may help make Canadian processes publicly acceptable, scientifically defensible and able to withstand various external and political pressures. Research regarding inter-provincial variations in drug coverage should specifically focus on the rationale behind such variations and the extent to which they produce measurable differences in health outcomes.

REGULATION FOR ONGOING SAFETY AND EFFECTIVENESS

> We see clinical trials being done on populations where the drugs aren't going to be used … we need systems that are better at closing those information gaps. [Health professional]

> The approval process really emphasizes the speed of drug approvals, rather than ensuring that the evidence that is submitted by manufacturers is carefully scrutinized. [Patient advocate]

With the federal government clearly responsible for consumer protection, product regulation is arguably the aspect of pharmaceutical policy in Canada that is most easily coordinated. It is not without significant challenges, however, because regulatory policies must balance the competing objectives of ensuring that drugs sold on the market are safe and effective while trying not to impede access or discourage valued innovation. The history of the pharmaceutical industry is punctuated by tragic examples of what can go wrong if protections are not in place and enforced, followed by regulatory changes implemented to prevent recurrence of such outcomes (Temin 1980; Avorn 2004). Piqued by high-profile drug withdrawals – such as the 2004 withdrawal of Vioxx® – there is increased awareness of the need for rigorous evaluations of medicines before and after market approval.

More effective post-market evaluation is sought, in part, because there are often significant differences between populations enrolled in clinical trials (the young and relatively healthy) and those who use medicines in real-world contexts (Sherr 2000; Deyo 2004; Lippman 2006). Furthermore, important information about drug safety and effectiveness emerges only when large numbers of patients have used medicines over long periods of time. Increased emphasis on post-market drug evaluation creates new opportunities and challenges in policy and new needs for inter-jurisdictional cooperation in Canada. Governments are now establishing processes for ongoing assessments of pharmaceuticals to facilitate continued evaluation. A key example is Health Canada's investment in the Drug Safety and Effectiveness Network. Research on real-world evaluation methods and systems – including research on governance and accountability – can help to inform regulatory policy development and implementation. Research also can help inform pre-market regulatory policy by addressing such questions as ways to increase the quality and transparency of drug safety and efficacy studies and by evaluating the extent to which changes in regulatory standards might alter the quantity and quality of new drugs brought to market.

Recommendations for pharmaceutical policy research

In addition to asking about key policy issues, we also asked participants about how pharmaceutical policy research and knowledge translation could be improved in

Canada. This consultation involved questions concerning what they would change about pharmaceutical policy research in Canada today and how they would invest a hypothetical $5 million per year to improve related research and knowledge translation. Respondents consistently identified a few key recommendations, some of which mirrored concerns about pharmaceutical policy making in Canada. For example, several participants argued for a more coordinated approach to research, just as in policy (see above). Coordination was seen as a means to ensure that necessary capacity is developed, that key information needs are met, and that policy experiments are evaluated in relevant jurisdictions, compared against others, and then communicated appropriately.

> It seems to us that everybody is running and doing their own thing and setting up their own studies – and sometimes it's kind of a cacophony of noise. We would like to see much better coordination in the research program. [Government decision-maker]

> The policy makers are trying very hard to come up with a national approach for certain things ... and I really do think that pharmaceutical policy researchers have got to do the same thing in this country. [Government decision-maker]

Participants from all stakeholder groups also argued for a consistent strategy for developing and utilizing databases on the use, cost and outcomes of medicines used by all persons in all provinces:

> We need to have linked data so that the physician database, the lab database, the pharmacy database are all more readily accessible to support research. [Government decision-maker]

Several participants noted that many priority issues in pharmaceutical policy cannot be effectively addressed without access to such information.

Finally, communications and knowledge translation were a commonly cited area for improvement in pharmaceutical policy research. Many participants noted that there was no "go-to" source of information on pharmaceutical policy issues – no equivalent of the Canadian Agency for Drugs and Technologies in Health with a reputation for credible expertise in pharmaceutical policy issues and timely and responsible policy analysis. Participants also argued for investments in mechanisms that would regularly get key stakeholders together to talk about what is known, what is not known and where more information is needed:

> It's the perennial issue of when and how, with what frequency do people who are in the pharmaceutical policy and research sectors get together and seri-

> ously exchange views about what's known, what would be useful to know, and what kinds of research – at what levels of intensity – would actually be worthwhile. [Government decision-maker]

Conclusion

Through the first extensive consultation of its kind, we uncovered a consensus on overarching policy objectives and priority policy issues in Canada. Several of the priority policy issues identified here – particularly those related to financing, pricing and coverage – are consistent with priority actions called for by the National Pharmaceuticals Strategy in 2004 and by government commissions dating back to the 1960s (Canada 1963, 1965, 1985, 1998, 2002, 2004). The continued prominence of key pharmaceutical policy issues highlights an overarching challenge regarding pharmaceutical policy in Canada, one that was articulated by the experts with whom we spoke: pharmaceutical policy in Canada is uniquely challenging because different levels of government are responsible for critical elements of the pharmaceutical policy system.

Although national pharmaceutical policies have been proposed as far back as the 1960s (Canada 1965), none has been implemented in a significant and sustained fashion. Pharmaceutical policies of federal and provincial governments have therefore evolved in a relatively independent and uncoordinated fashion. Meanwhile, the pharmaceutical sector also developed into an increasingly important, costly and complex component of the healthcare system. This development has resulted in a significant policy dilemma. The refrain "no cost control without pharmacare; no pharmacare without cost control" has become all too familiar in pharmaceutical policy debates, suggesting that Canada's lack of coordination may have created a negatively reinforcing policy trap: uncoordinated policies create system inefficiencies and regional inequities, and those outcomes create inter-jurisdictional tensions that, in turn, reinforce barriers to cooperation and coordination.

Effective policy reform in this sector will require political support and something perhaps overlooked in the past: a principled basis for policy action, or shared understanding of both why and how reforms should take place (Boothe 2010). There already appears to be a common understanding about the goal of reforms in Canada: providing all Canadians with equitable and sustainable access to necessary medicines. Because there are many challenges to achieving this goal, understanding the "how" of policy reform in Canada is critical. The research community can play an important role in this regard. This role will require greater efforts on the part of investigators and funders to coordinate and target research and knowledge translation activities. Researchers can and should help to identify creative policy solutions, based on sound theory and international experience; generate evidence of policy effectiveness, based on careful evaluation of policy experiences; and provide insight about the factors that

influence policy processes, based on legal, political and ethical scholarship. If well coordinated and communicated, such work may help develop a foundation of shared knowledge upon which reforms can be built to reduce inequities and inefficiencies in pharmaceutical policy approaches and outcomes in Canada.

ACKNOWLEDGEMENTS

This research was supported by a Canadian Institutes of Health Research (CIHR) Emerging Team grant and a CIHR Institute of Health Service and Policy Research Meetings, Planning and Dissemination grant.

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RESEARCH PAPER

Does Receiving Clinical Preventive Services Vary across Different Types of Primary Healthcare Organizations? Evidence from a Population-Based Survey

La prestation des services préventifs en milieu clinique varie-t-elle selon le type d'organismes offrant des soins de santé primaires? Données provenant d'une enquête auprès de la population

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Abstract

Objective: To measure the association between primary healthcare (PHC) organizational types and patient coverage for clinical preventive services (CPS).
Method: Study conducted in Quebec (2005), including a population-based survey of patients' experience of care (N=4,417) and a survey of PHC clinics. *Outcome measures:* Patient-reported CPS delivery rates and CPS coverage scores. Multiple logistic regressions used to assess factors associated with higher probability of receiving CPS. *Results:* CPS delivery rates were higher among patients with a regular source of PHC. Higher CPS score was associated with having a public (OR 1.79; 95% CI 1.35–2.37) or mixed (OR 1.22; 95% CI 1.01–1.48) type of organization as source of PHC compared to a private one, and having had a high number of visits to the regular source of PHC in the past two years (≥6: OR 1.83; 95% CI 1.41–2.38) compared to a single visit. *Conclusion:* Public and mixed PHC organizations seem to perform better. CPS delivery is strongly associated with having a regular source of care.

Résumé

Objectif : Mesurer la relation entre le type d'organisation de services médicaux de première ligne et la prestation des pratiques cliniques préventives (PCP).
Méthodologie : Étude menée au Québec (2005), comprenant une enquête auprès

de la population sur l'expérience des soins (n=4 417) et une enquête auprès des cliniques de première ligne. *Mesures des résultats :* Les taux de prestation des PCP rapportés par les patients et le score d'exposition aux PCP. Des régressions logistiques multiples ont été employées pour identifier les facteurs associés à une plus grande probabilité d'être exposé aux PCP.
Résultats : Les taux de prestation des PCP étaient plus élevés chez les patients ayant une source régulière de soins médicaux de première ligne. Un score de PCP plus élevé était associé au fait d'avoir, comme source de soins, un type d'organisation public (RC 1,79; IC 95 % 1,35–2,37) ou mixte (RC 1,22; IC 95 % 1,01–1,48), comparé à une organisation privée; et au fait d'avoir eu un nombre élevé de visites à la source régulière de soins au cours des deux années antérieures (≥ 6 visites : RC 1,83; IC 95 % 1,41–2,38), comparé à une seule visite.
Conclusion : Les organisations de soins médicaux de première ligne publiques et mixtes affichent des résultats plus favorables. La prestation des PCP est fortement associée au fait d'avoir une source régulière de soins de première ligne.

Integrating recommended clinical preventive services (CPS) into medical care is recognized as an important component of health systems' response towards chronic illness (Rothman and Wagner 2003; Glasgow et al. 2001). However, current levels of CPS have been deemed suboptimal (Wang et al. 2009; Swan et al. 2003; Ruffin et al. 2000). There are also substantial variations in rates of CPS delivery among clinics and by specific types of CPS (Vogt et al. 2007; Hershey and Karuza 1997). Moreover, there is a lack of consistency between a clinic's performance on one specific CPS and its performance on others (Solberg et al. 2001). Although patient and physician characteristics may influence CPS delivery rate (Flocke et al. 1998b; Pham et al. 2005), having a regular family physician or usual source of primary healthcare (PHC) has a greater impact on the likelihood of receiving preventive services (Schueler et al. 2008; Qi et al. 2006; Starfield et al. 2005; Swan et al. 2003; DeVoe et al. 2003; McIsaac et al. 2001; Flocke et al. 1998b; Bindman et al. 1996). Also, clinical context has an impact on preventive care delivery, CPS being delivered more often during visits for chronic than acute illnesses (Stange et al. 1998; Flocke et al. 1998a) and during visits for routine check-ups than for specific injuries or illnesses (Stange et al. 1994).

With regard to PHC organizational characteristics, studies conducted in the United States indicated that patients receiving PHC in university-based clinics (Ramsey et al. 2001), community health centres (Starfield et al. 2005) or large academic facilities with extensive training programs (Goldzweig et al. 2004) tend to receive more recommended preventive services. In addition, teamwork, common goals shared by physicians and staff, and priority given to prevention have been associ-

ated with higher CPS delivery (Carpiano et al. 2003). Group practice has also been positively associated with delivery of preventive services (Pham et al. 2005). Thus, it has been advocated that interventions aimed at promoting sustainable CPS delivery should take into account organizational characteristics of PHC settings (Stange et al. 2003; Goodwin et al. 2001).

Integrating CPS into medical practice in the context of PHC reorganization is challenging, and some types of organization may present more favourable conditions for CPS delivery. In Quebec, PHC practice settings include public clinics and privately owned (or "private") clinics. Public clinics include PHC clinics located in Local Community Health Centres (known in Quebec as CLSCs) and in teaching family medicine units (FMUs), where physicians are usually paid on a salary or time basis by the Health Insurance Board, and infrastructure and administrative costs are directly financed by the Ministry of Health (Pineault et al. 2008). In privately owned clinics (groups or solo), physicians are usually paid by the Health Insurance Board on a fee-for-service basis, and infrastructure costs are indirectly paid by the government because they are included in the fees paid to the physicians.

Recent policy reform initiatives by Quebec's Ministry of Health to increase accessibility and continuity of care include the creation of Family Medicine Groups (FMGs). The FMG policy consists mostly in developing a contractual agreement between PHC physicians and the provincial government, including complementary public funding, mostly for computerization and additional staff (nurses), in exchange for increasing services (e.g., extended opening hours). A typical FMG consists of six to 10 physicians working with two nurses to provide services for 10,000 to 20,000 registered patients, by appointment and on a walk-in basis. This new, emerging form of PHC organization can be implemented in various types of clinics (including CLSCs and FMUs). Because FMGs located in privately owned clinics receive direct public funding (e.g., for extra staff and for computerization) in addition to the infrastructure costs indirectly funded by the government through the fee-for-service payment of the physicians, they represent a "mixed" type of PHC organization based on infrastructure and administrative funding.

As Deber (2004) has correctly pointed out, boundaries between public and private are not always clear. The categories described above grossly correspond to the typology developed by Deber in her extensive work, at least for the public and private for-profit small-business types of organizations. As for the mixed type, it contains elements of these two polar cases as there is a direct yet marginal financing that comes from the government, while for the major part it maintains the characteristics of private organizations, both in terms of financing and delivery. Overall, in the two most populous regions of Quebec (Montreal and Monteregie), public clinics represent 13% of PHC organizations and reach 10% of patients; private/group type, 53% of PHC organizations and 65% of patients; private/solo type, 27% and 14% of patients; mixed, 7% of PHC organizations and 10% of patients (Pineault et al. 2008).

Given the gap in knowledge related to the influence of type of PHC organization on clinical preventive services delivery and current PHC reform, this paper focuses on the association between type of PHC organization and CPS coverage for patients.

Method

In 2005, a research project (Pineault et al. 2009) conducted in Monteregie, the second most populous region in Quebec, looked at organizational models of PHC delivery and the experience of care of users of these services, including CPS delivery. The project included two surveys: (a) a population-based telephone survey of care experience among randomly selected community-dwelling adults aged 18 and over, using the random-digit dialling method (response rate: 66%) and (b) a postal survey of all PHC clinics in the region, which focused on their goals and values; material, financial and human resources; current organizational structures; practices supporting service delivery; and inter-organizational collaboration (response rate: 81%). The surveys were linked through identification of patients' regular source of care during the past two years. Regular source of care was defined as the place a patient "usually goes to see a doctor for general medical care, excluding specialized care." When respondents did not identify a usual source of care, the place where they went most often in the past two years was designated as the regular source. Among the 4,417 respondents, 3,172 patients had a regular source of PHC (2,618 of them reporting having a family physician within their regular source of care). Respondents who did not answer the questions on CPS (n=12) and those who reported having a family physician outside their regular source of PHC (n=246) were excluded from the analyses.

For the purpose of this paper, the outcome measures were patient-reported CPS delivery rates (data from the population survey). We selected seven services recommended (category A or B) by the Canadian Task Force on Preventive Health Care and the US Preventive Services Task Force at the time of the survey (Table 1). Of the seven CPS, six are in the top 15 ranked by Partnership for Prevention and Health Partners Research Foundation in the United States (Coffield et al. 2001).

An overall CPS coverage score, defined as the proportion of CPS performed among all CPS for which the patient was eligible, was calculated for each respondent using the formula:

$$\frac{\text{Sum of recommended CPS delivered to an individual}}{\text{Sum of recommended CPS for which an individual is eligible based on age, sex* and lifestyle habits}} \times 100\% = \text{CPS score}$$

(* Women who had a hysterectomy were considered ineligible for Pap tests.)

TABLE 1. Clinical preventive services (CPS) under study

CPS	Time interval for delivery	Target groups
Physician recommended a healthy diet	past 2 years	all patients
Physician inquired about smoking status	past 2 years	all patients
Physician recommended quitting smoking	past 2 years	smokers
Physician took blood pressure	past 2 years	all patients
Physician did a Pap test	past 3 years	women aged 18–69
Patient had a mammography	past 2 years	women aged 50–69
Patient had a fecal occult blood test or sigmoidoscopy/colonoscopy	past 2 years for fecal occult blood test past 5–10 years for sigmoidoscopy/colonoscopy	patients aged 50 or over

In the calculation of CPS scores, missing data, don't know/don't remember responses and refusals for question on a CPS for which the respondent was eligible were included in the "not receiving the CPS" category. Very few of these cases were found (2–20 cases, depending on the CPS).

Four types of PHC organizations were identified from the PHC clinics survey, based on infrastructure and administrative funding as described at the beginning of this paper: two private (group; solo), one public (PHC clinic in a CLSC or FMU) and one mixed (FMG implemented in a private clinic). FMGs implemented in CLSCs or FMUs were included in the public PHC organizations.

A mean CPS score was calculated for respondents pertaining to each type of PHC organization reported as their regular source of care. For each CPS and overall CPS coverage score, multiple logistic regression was used to assess the independent contribution of the type of organization to receiving preventive care (Hosmer and Lemeshow 1989). The CPS score was dichotomized when used as a dependent variable in the logistic regression analysis. A 75% cut-off was chosen to distinguish individuals with fairly good CPS coverage from the others, based on the distribution of the score and on experts' clinical judgment. Sensitivity analyses using other cut-offs (66%, 80% and 100%) provided similar results. Adjustments were made for potential confounding variables, including socio-demographic characteristics (sex, age, education and income levels) and health status (having risk factors or health problems, smoking status). Time since last visit and number of visits to the regular source in the past two years were also included as predictors in our models. Having a family physician was not included in the regression model because it constitutes an intrinsic characteristic of the types of PHC organizations, and so was considered endogenous.

Results

Table 2 presents respondents' socio-demographic and health characteristics by affiliation with a regular source of care. Based on 2001 Canadian census data (2005 projections), our sample was representative of the general population with regard to age and sex. Having a regular source of care is associated with being female, older age, higher educational level, higher income, and having some risk factors or health problems. Among those who had a regular PHC source during the past two years, 60% had a regular source of PHC in private/group clinics, 20% in mixed/FMGs, 12% in private/solo and 8% in public/CLSC–FMU clinics. A vast majority of respondents had attended their regular source of PHC for at least two years (89%) and had a family physician within their regular source of care (81% of patients affiliated with private/group clinics, 83% with mixed/FMGs, 95% with private/solo and 78% with public/CLSC–FMU clinics). One out of four (24%) had visited their regular source of PHC six times or more during the past two years.

TABLE 2. Respondent characteristics according to their affiliation with a regular source of PHC: Monteregie, Quebec, Canada, 2005

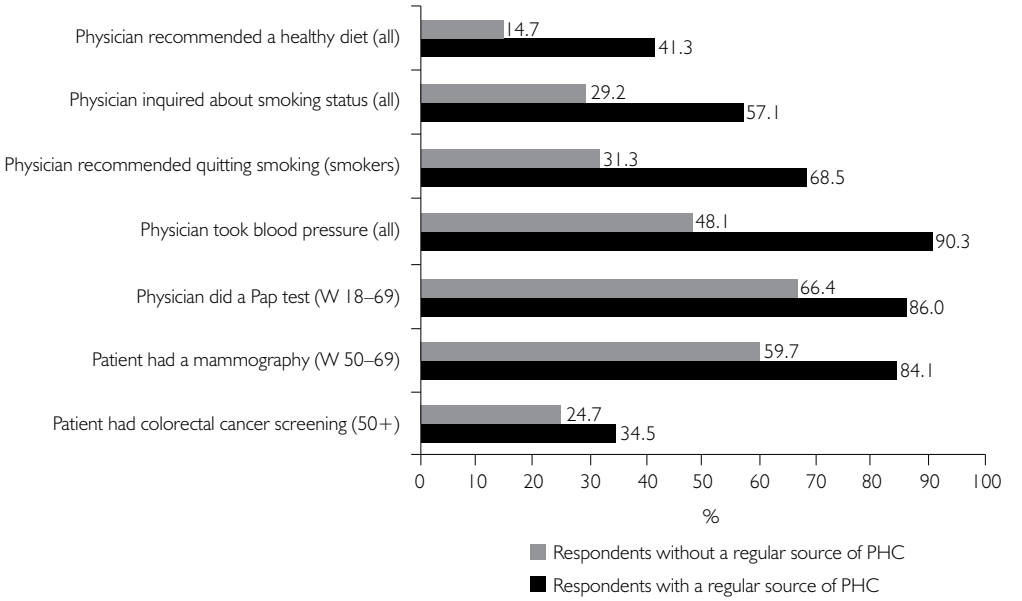
	Respondents with a regular source of PHC (N=3,172)		Respondents without a regular source of PHC (N=987)	
	N	%	N	%
Female	1,772	55.9	342	34.7
Aged 50 or over	1,451	45.8	328	33.2
Middle or high level of education	1,610	50.9	461	47.0
Upper-middle or high income, adjusted for size of household	1,734	54.7	481	48.8
At least one risk factor (HBP, diabetes, hypercholesterolemia)	1,254	39.5	199	20.2
At least one health problem (heart, respiratory, stroke, cancer)	869	27.4	151	15.3

HBP = high blood pressure

Figure 1 presents patient-reported CPS delivery rates. Rates were higher for all CPS among patients with a regular source of PHC than for those without one. Patient-reported delivery rates also varied depending on the specific CPS. For patients who had a regular source of PHC, rates ranged from 35% for colorectal cancer screening to 90% for hypertension screening, and the overall mean CPS coverage score was 63%. Figure 2 shows scores across types of PHC organizations. Scores tend to be higher for patients with a public source of PHC (68%) than for mixed (64%), private/group (61%) and private/solo clinics (65%); however, the difference was statistically significant ($p<0.05$) only between public and private/group PHC organizations.

Delivery rates of each CPS for each type of PHC clinic (Table 3) show the same pattern: usually higher for public/CLSC-FMU and lower for private/group clinics.

FIGURE 1. Patient-reported CPS delivery (%): Monteregie, Quebec, Canada, 2005



Results of logistic regression analyses (Table 4, see http://www.longwoods.com/articles/images/22025) indicate that a CPS coverage score ≥75% was associated with having a public (OR 1.79; 95% CI 1.35–2.37) or mixed (OR 1.22; 95% CI 1.01–1.48) source of PHC compared to having a private/group source, and with a high number of visits to the regular source of PHC in the past two years (two to five visits: OR 1.36, 95% CI 1.08–1.70; six or over: OR 1.83, 95% CI 1.41–2.38) compared to a single visit. Moreover, association between private/solo clinic and CPS coverage score ≥75% almost reached statistical significance (OR 1.23; 95% CI 0.97–1.56; p=0.088; reference category: private/group). Table 4 also presents the results of logistic regression models using each CPS as the dependent variable. Results show no association between type of clinic and patient-reported rates of nutrition counselling, smoking cessation counselling and mammography. On the other hand, when compared to private/group clinics, smoking status screening was associated with affiliation with public (OR 1.50; 95% CI 1.12–2.00) and mixed (OR 1.24; 95% CI 1.02–1.51) clinics; hypertension screening with private/solo clinics (OR 3.18; 95% CI 1.79–5.64); and colorectal cancer screening with public (OR 3.27; 95% CI 2.15–4.98), private/solo (OR 1.55; 95% CI 1.11–2.16) and mixed (OR 1.39; 95% CI 1.05–1.85) clinics. Association between public clinics and Pap test was near statistical significance (OR 1.85; 95% CI 0.90–3.79; p=0.09).

FIGURE 2. Mean CPS score by type of PHC organization: Monteregie, Quebec, Canada, 2005

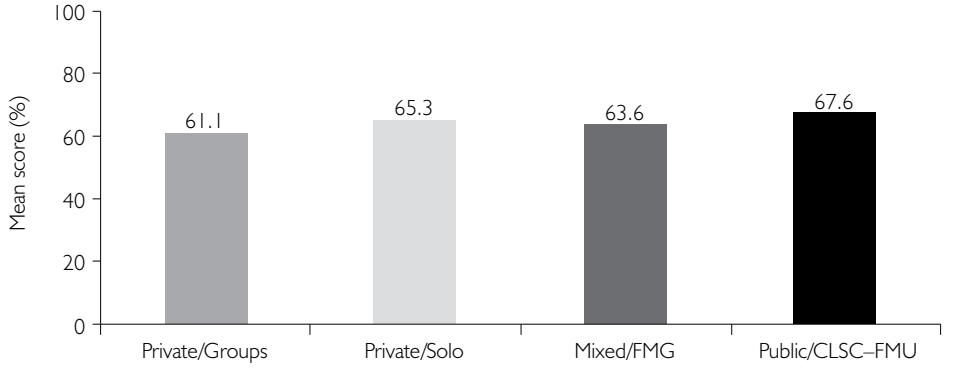


TABLE 3. Patient-reported CPS coverage by type of regular source of PHC. Patients with a regular source of PHC: Monteregie, Quebec, Canada, 2005

Regular source of PHC	Overall PCP score ≥ 75% (all)*	Healthy diet counselling (all)	Tobacco use screening (all)*	Tobacco cessation counselling (smokers)	HBP screening (all)*	Pap test (W 18–69)	Mammography (W 50–69)	Colorectal cancer screening (50+)*
Private/Group	42.0	40.3	55.1	66.8	89.4	84.7	84.1	29.4
Private/Solo	44.8	42.7	58.2	75.5	96.2	87.9	83.6	40.3
Mixed/FMG	45.3	41.9	59.4	68.6	90.5	87.1	82.8	36.6
Public/CLSC–FMU	55.1	44.5	64.1	70.7	88.3	91.6	87.0	58.3

* $p<0.05$
PCP = primary care physician,
HBP = high blood pressure

Discussion

As seen in other studies (Wang et al. 2009; Swan et al. 2003; Ruffin et al. 2000), we found CPS coverage to be suboptimal. However, it seems better for screening (except for colorectal cancer screening) than for lifestyle counselling. Among CPS studied, high blood pressure screening was most frequent, and colorectal cancer screening least frequent, as found by other researchers (Vogt et al. 2007). Variations in CPS delivery at least partly reflect differences inherent in the nature of CPS; some are easier to perform and thus more fully integrated into physicians' practices (e.g., high blood pressure screening); others require more efforts to convince patients to undergo less acceptable

and accessible procedures (e.g., colonoscopy) and may be more difficult to implement. Some CPS may also be considered closer to the field of clinical medicine (e.g., high blood pressure screening, Pap test) than counselling-type CPS (e.g., recommending a healthy diet). Also, some CPS have been recommended in the medical literature for longer (e.g., hypertension screening) than others (e.g., colorectal screening). Finally, for breast cancer screening, the role of the family physician in Quebec is mainly to reinforce the message of a provincial program that urges eligible women to undergo a mammography every two years.

Our findings confirm that CPS delivery is strongly associated with having a regular source of care, as suggested by other authors (Qi et al. 2006; DeVoe et al. 2003; Flocke et al. 1998b; Bindman et al. 1996). The type of organization of regular PHC source also influences CPS delivery, as better coverage for CPS was more often associated with having public (CLSC, FMU) and mixed (FMG) clinics as regular sources of PHC. The community orientation, greater number of resources and wider range of services in these organizations may enhance preventive services delivery. In addition, these types of organizations are known to have better information and registration systems, enabling health professionals to assess patients' needs for preventive services, and tools to remind clinicians to offer recommending them.

Our findings do not allow us to pinpoint the specific organizational characteristics that might be responsible for differences in CPS delivery across types of clinics. However, in the public PHC organizations in Quebec, physicians are more likely to be paid on a time rather than fee-for-service basis. Fee-for-service paid physicians, that is, most PHC physicians in private types of organizations, do not have separate CPS fees in their reimbursement schedule. Rather, this fee is included in payment for the visit to the PHC physician, a practice that could constitute a disincentive to providing CPS. Physicians in the mixed PHC organizations are mostly paid by fee-for-service but also receive, from the Health Insurance Board, fixed annual amounts for each enrolled patient. This per capita component of remuneration may act as an incentive for delivering CPS. As stated by Wee and colleagues (2001) and Gosden and colleagues (2001), studies are needed to examine the effects of financial incentives on quality of care, and whether quality-based incentives improve preventive care performance. Public PHC organizations are also characterized by a clinical orientation that emphasizes prevention and by family medicine training, an approach that may favour integration of CPS delivery into practice. This explanation is supported by Ramsey and colleagues (2001), who found fewer screening services delivered in a county hospital-based clinic than in university-based ones. Organizational characteristics, such as prioritizing prevention, have also been associated with higher CPS delivery rates (Carpiano et al. 2003). Moreover, in public PHC organizations, lower caseloads might free up time to provide more preventive services to fewer patients. However, the higher volume of patients seen in private-group PHC organizations may result in more CPS

performed each year, and thus could have a greater impact on the population.

Further, there is more coverage for CPS in private/solo than private/group clinics. This finding may reflect, at least in part, the importance for CPS coverage of having a family physician, because the private/solo PHC organizations have a higher percentage of patients with regular physicians (94.5% vs. 80.6% in private/groups). In our bivariate analyses, having a family physician was strongly associated with coverage for CPS ≥75% (unadjusted OR 2.20, 95% CI 1.81–2.69; data not shown).

Despite the differences we found in patient coverage for recommended CPS across PHC organizations, variations were less extensive than expected. Flocke and Litaker (2007) showed that comparable rates of preventive services delivery occurred across several distinct physician–practice configurations of physician attributes, practice processes and contexts. They suggested that striving for a single, ideal configuration may be less valuable for improving preventive care than understanding and leveraging existing characteristics within PHC practices.

A greater number of visits is also associated with better CPS coverage, presumably related to the higher number of opportunities to address the many curative and preventive concerns (Crabtree et al. 2005; Yarnall et al. 2003; McIsaac et al. 2001; Stange et al. 1998). In our study, there was an association between CPS delivery and number of visits for the overall CPS score as well as for most individual CPS. Although some studies have demonstrated that visiting a regular source of PHC for a longer time period was associated with delivery of CPS (Parchman and Burge 2004; Steven et al. 1998), others found no association (Pham et al. 2005). Our results do not suggest a clear association between these variables.

Study strengths and limitations

A major strength of our study is its capacity to establish a link between population and organization survey data, allowing us to link patient-reported CPS delivery to well-characterized PHC organization types. The sample size and relatively good response rates also allow us confidence in our results. However, despite adequate response rates, the paucity of information on non-respondents prevents us from ascertaining the magnitude of bias due to non-response.

The CPS score calculated does not cover the whole range of recommended CPS that should be offered to adult patients. Although it may blur some differences across CPS, the score provides a useful overall comparison measure, across PHC organizations, of a wide array of recommended preventive services that should be offered to the population. Other researchers have used this kind of composite measure (Flocke and Litaker 2007; Nietert et al. 2007; Carpiano et al. 2003; Lemelin et al. 2001; Flocke et al. 1998b). Nietert and colleagues (2007) have stated that the measure calculated for patients can be easily aggregated at higher levels, such as for PHC organizations.

Although the overall score may be influenced by the fact that many patients are not eligible for all measures (Nietert et al. 2007), including the number of CPS for which patients were eligible as a covariate in regression models did not change the direction or magnitude of our results. Another interesting way to study CPS delivery would be to use a "tracer CPS" that could reflect preventive care delivery as a whole. However, this approach seems unrealistic considering the wide range of preventive interventions, substantial variation among CPS rates, difficulties in selecting a CPS that might reflect differences among physicians' clienteles, and the small correlation observed between a clinic's performance on one preventive service and on others (Solberg et al. 2001). We believe that in addition to analyzing individual services, analysis of CPS delivery using a composite score is appropriate to assess preventive care delivery.

One limitation is the cross-sectional nature of our study, which does not lend itself to causal inference. The study relied on patient self-reported information, which is more susceptible to recall and social desirability biases. Aside from direct observation of medical encounters, a "gold standard" measure of CPS delivery does not exist. Each method of assessing CPS delivery has its advantages and drawbacks. On one hand, reviews tend to underestimate CPS delivery compared to physician practice reports through "standardized patient" visits and to physician responses to clinical vignettes (Peabody et al. 2000; Dresselhaus et al. 2000); on the other hand, physician self-reported CPS delivery is frequently overestimated (Montaño and Phillips 1995). Palonen and colleagues (2006) have indicated that medical record reviews and patient surveys provide similar rates of preventive interventions. Moreover, CPS do not represent a homogeneous group of services with regard to evaluation: some, like cancer screening, may be overestimated by patients compared to chart reviews (Wang et al. 2009; Howard et al. 2009; Rauscher et al. 2008; Partin et al. 2008; Khoja et al. 2007; Jones et al. 2008; Hall et al. 2004; McPhee et al. 2002; Hiatt et al. 1995), while others, like lifestyle counselling, may be entered less often in medical charts. Besides, some types of data are more difficult to obtain because of low response rates (e.g., for physician surveys), high costs and confidentiality concerns (e.g., for chart reviews). Finally, administrative data on CPS delivery are not available in Quebec because there is no separate CPS fee in the physicians' reimbursement fee schedules. Patient self-reported data were thus an acceptable proxy for measuring CPS delivery in our study.

Lack of precision in question formulation prevents us from concluding with certainty that CPS were obtained at the patient's regular PHC source. However, although patients could occasionally receive services at other clinics, we assumed that preventive services were more closely associated with their regular source of care. In addition, some CPS (e.g., mammography, sigmoidoscopy/colonoscopy, Pap test) may have been provided as diagnostic procedures rather than for screening purposes. These limitations overestimate CPS delivery rates by the regular source of PHC. Furthermore, by our limiting coverage for counselling CPS to the past two years, we

may have underestimated CPS delivery rates: it is possible that, during the past two years, physicians did not consider it pertinent to discuss lifestyle habits again with their long-standing patients. Finally, no information on CPS provided by professionals other than physicians was available in our survey. As CPS delivery may be improved through teamwork involving physicians and other health professionals (Hung 2007; Hung et al. 2006), this information would have been pertinent, because sharing a practice with these professionals is a key feature of new, emerging PHC organizations such as FMGs.

Conclusion

Our results indicate that CPS delivery in Quebec is strongly associated with having a regular source of care. Regardless of the type of regular PHC source, patient coverage for CPS is not optimal. Public and mixed PHC organizations seem to perform better. Characteristics of these organizations, such as clinical orientation and physicians' method of payment, could explain some of these differences. Further studies designed to identify more precisely the organizational characteristics associated with CPS delivery in PHC settings are needed to help integrate preventive care into practice.

The finding that CPS delivery is associated with continuous care by family physicians raises some concerns in the context of the continuously growing number of interventions expected of them. Consequently, newly emerging PHC organizational models including coordinated teamwork among various types of health professionals could be promising. Further research is needed to study integration of preventive care and reorganization of primary healthcare, taking into account the evolution of organizational models and shared work within PHC teams.

ACKNOWLEDGEMENTS

Data presented in this paper originate from a research project funded by the Canadian Institutes of Health Research (CIHR), Canadian Health Services Research Foundation (CHSRF) and Fonds de recherche en santé du Québec (FRSQ). Financial support was also provided by the Agence de la santé et des services sociaux (ASSS) de Montréal, Agence de la santé et des services sociaux de la Montérégie, Institut national de santé publique du Québec (INSPQ), Groupe de recherche sur l'équité d'accès et l'organisation des services de santé de première ligne (GRÉAS 1) and Groupe interuniversitaire de recherche sur les urgences (GIRU).

The authors wish to thank André Tremblay (Direction de santé publique de l'ASSS de Montérégie) for his contribution to the construction of the questionnaire, and Alexandre Prud'homme (Direction de santé publique de l'ASSS de Montréal and Institut national de santé publique du Québec) for his contribution to the data analysis.

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RESEARCH PAPER

Mapping Health Services and Policy Research Settings in Canada: Following the Money, the Publications and the Interest

Cartographie de la recherche sur les services et les politiques de santé au Canada : sur les traces de l'argent, des publications et des intérêts

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Abstract

While health services and policy research (HSPR) has an established footing in traditional research settings (e.g., universities, hospitals, research institutes) in Canada, its presence in other research settings (e.g., government agencies, regional health authorities, charitable organizations) is emergent and less well understood. Drawing on data from the Canadian Institutes of Health Research, the Canadian Health Services Research Foundation, two Canadian HSPR-focused journals (*Healthcare Policy* and *Healthcare Management Forum*) and the Canadian Association of Health Services and Policy Research, we mapped HSPR settings based on three different measures: (1) HSPR-related funding, (2) authorship in Canadian HSPR-focused journals and (3) membership in a professional HSPR association. Our findings suggest that while a significant proportion of HSPR is directly linked to non-traditional research settings, the nature and extent of HSPR activity in those settings are unclear.

Résumé

Bien que la recherche sur les services et les politiques de santé (RSPS) au Canada soit bien établie dans les établissements traditionnels de recherche (c'est-à-dire les universités, les hôpitaux et les instituts de recherche), sa présence dans d'autres types d'établissements de recherche (c'est-à-dire les organismes gouvernementaux, les régies régionales de la santé et les organismes de bienfaisance) est émergente et beaucoup moins bien comprise. À partir de données provenant des Instituts de recherche en santé du Canada, de la Fondation canadienne de la recherche sur les services de santé, de deux revues canadiennes sur la RSPS (*Politiques de Santé* et *Forum Gestion des soins de santé)* et de l'Association canadienne pour la recherche sur les services et les politiques de la santé, nous avons cartographié les établissements de RSPS en fonction de trois mesures : (1) le financement lié à la RSPS, (2) les publications des auteurs dans les revues canadiennes de RSPS et (3) l'adhésion à une association professionnelle de RSPS. Nos résultats suggèrent que bien qu'une proportion significative de la RSPS soit directement liée à des établissements de recherche non traditionnels, la nature et l'amplitude de l'activité de RSPS dans ces établissements demeurent imprécises.

In 1997, Jonathan Lomas warned that "efforts by researchers and by decision-makers seem to proceed largely independently. Each have their own (often misplaced) ideas about the other's environment. Opportunities for ongoing exchange and communication are few" (Lomas 1997: 1). Lomas' guidance included a call for "new organizational structures, new activities and processes, and new human resources to facilitate more ongoing communication [between researchers and decision-makers]" (Lomas 1997: 4). In the years that have followed, much of the Canadian landscape for health services and policy research (HSPR) has changed, including more opportunities for researchers and decision-makers to work together. However, despite these changes, we have surprisingly limited information regarding who is contributing to HSPR and where it is being conducted.

The Canadian Institutes of Health Research acknowledged the lack of a comprehensive "map" of HSPR in Canada as a key challenge when it established its Institute for Health Services and Policy Research (IHSPR), noting the need to develop a "database of researchers with skills and interests in HSPR" (CIHR 2001). With diverse and complex health services and policy contexts, a better understanding of the HSPR landscape in Canada will allow key stakeholders to identify more optimal approaches developing and using HSPR. To address this knowledge gap, we set out to map where HSPR is conducted and the nature and extent of contributions made in different settings.

Mapping HSPR Settings

While HSPR is established in traditional research settings (e.g., universities, hospitals, research institutes), its presence in other research settings (e.g., government agencies, regional health authorities, charitable organizations, private think tanks) is emergent and less well understood (Mitton and Bate 2007; Chafe and Dobrow 2008). The multidisciplinary and multi-professional nature of HSPR presents a number of measurement challenges, with many contributors outside of traditional research settings holding other, often primary, non-research responsibilities. A recent report on the health services research workforce in the United States suggested that the "transience of many of the practitioners of HSR [health services research] into and out of the field makes it difficult to identify who will one day be involved in HSR and which specific professions and professionals are most involved" (Ricketts 2007). Definitions of HSPR are similarly elusive, often characterized as the study of some or all aspects of how healthcare services are organized, regulated, managed, financed, utilized and delivered (CIHR 2006; CHSPR 2009; Ontario Training Centre 2009). Unsurprisingly, there is no single data source that accurately and reliably captures all HSPR activity in Canada.

Therefore, we identified three proxy measures derived from five accessible data sources to map HSPR settings. First, in terms of HSPR funding, we analyzed the organizational affiliations of individuals who received HSPR-related grants and awards

from two leading HSPR funding agencies in Canada: the Canadian Institutes of Health Research (CIHR) and the Canadian Health Services Research Foundation (CHSRF). Second, we documented and analyzed the affiliations of authors contributing to papers published in two Canadian HSPR-focused peer-reviewed journals, *Healthcare Policy* and *Healthcare Management Forum*. Finally, we examined the affiliations of members of the Canadian Association of Health Services and Policy Research (CAHSPR).

To facilitate the analysis, we have classified research settings into four categories: (1) universities, (2) hospitals and research institutes, (3) government agencies and regional health authorities and (4) other organizations. The first two categories represent traditional research settings, while the last two categories represent non-traditional research settings. Hospitals (including both teaching and community) and research institutes were combined because in many cases, research institutes are based within hospitals and it is often difficult to link HSPR activity exclusively to one setting or the other. In contrast, while the main offices of regional health authorities are often co-located with hospitals, the two settings were more clearly distinguished and therefore could be categorized separately.

Following the money: HSPR-related funding

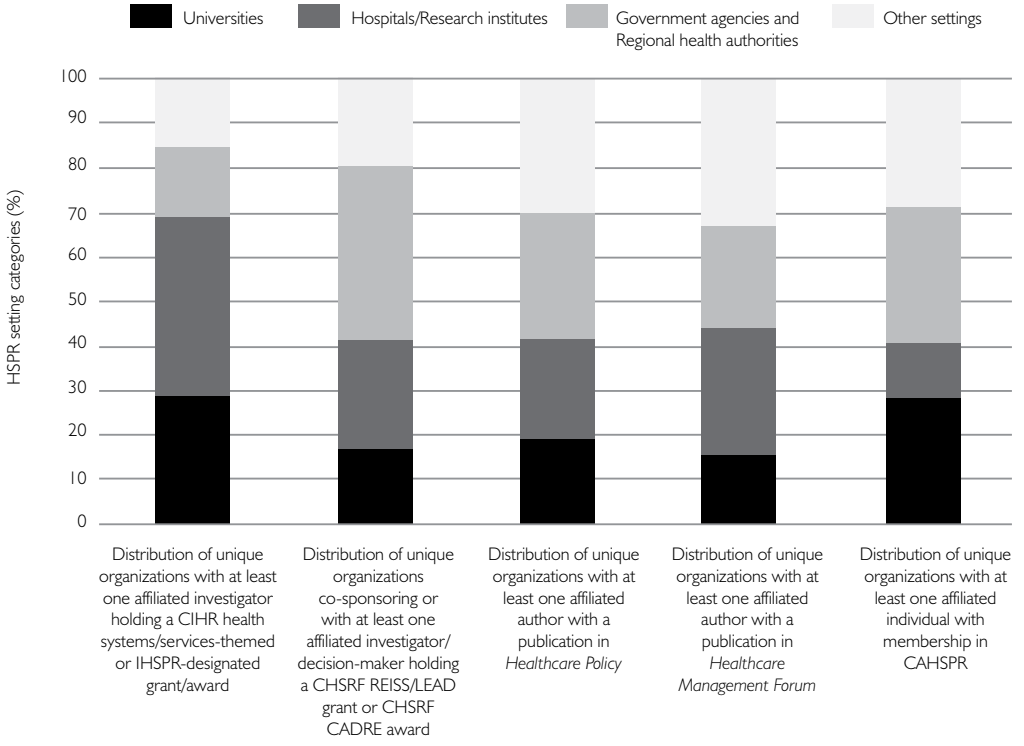
The CIHR's Funded Research Database (http://webapps.cihr-irsc.gc.ca/funding) provides publicly accessible information on grants and awards funded by that agency. The database identifies applicants and their affiliated organizations, funding program type (e.g., operating grant, personnel/training award, etc.), research project title, peer review committee, funding period, amount funded, institution paid, research theme (i.e., biomedical; clinical, health systems/services; social/cultural/environmental/population health) and the relevant CIHR institute (e.g., the IHSPR). To use this database to identify HSPR settings in Canada, we made two key assumptions. First, we assumed that each principal and co-applicant's affiliated organization represented a research setting where HSPR was conducted. While this assumption might overestimate the reach of HSPR, it ensures that multi-site studies and the role of decision-making partners that participate in CIHR's main partnership grants – e.g., Partnerships for Health System Improvement (PHSI) and Knowledge to Action (K2A) – are represented. Second, given that CIHR applicants are requested to categorize grant/award applications into one of the four research themes identified above, we assumed that health systems/services was the only theme that consistently represented HSPR. However, as some clinical and social/cultural/environmental/population health-themed grants also represent HSPR, we cross-referenced our search to identify any grant/award designating the IHSPR as the primary CIHR institute. This approach allowed us to include CIHR grants/awards not thematically identified as health systems/services research.

Based on these assumptions, we searched the CIHR Funded Research Database for health systems/services-themed or IHSPR-designated grants/awards funded over the period 2006/07 to 2008/09. We identified 1,134 health systems/services-themed or IHSPR-designated grants/awards funded by CIHR to organizations distributed across every province in Canada. In terms of exposure (i.e., organizations with an affiliated applicant holding at least one grant/award), hospitals and research institutes represented 42% of HSPR settings, universities represented 28%, government agencies/regional health authorities represented 15% and other organizations (e.g., charitable agencies) represented 16% (Figure 1). When focusing on intensity (i.e., total number of affiliated applicants holding grants/awards per organization), traditional research settings accounted for the vast majority of these grants/awards (70% held by universities and 25% held by hospitals/research institutes), with government agencies, regional health authorities and other organizations accounting for less than 6% (Figure 2).

We also examined the CIHR data by institution paid. The five institutions that received the largest number of health systems/services-themed or IHSPR-designated grants/awards – 34% of those funded by CIHR during the period analyzed – were all universities: University of Toronto (104), University of British Columbia (90), University of Alberta (67), McMaster University (66) and McGill University (58) (Table 1). A more focused examination of these five universities' grants/awards revealed both inter- and intra-university variation regarding the types of departments where the funds were held. For four of the five universities, the majority of these grants/awards were held within departments with focused interest in healthcare policy, management and/or clinical epidemiology/biostatistics. Many other departments holding these grants/awards primarily represent typical health-related fields (e.g., public health, medicine, nursing, pharmacy, etc.). However, each university's distribution of grants/awards across these departments varied. There were also examples of health systems/services-themed or IHSPR-designated grants/awards held in less typical departments (e.g., architecture, English, history), while a number of the grants/awards did not specify a university department.

Based on the institution paid, traditional research settings (i.e., universities, hospitals and research institutes) accounted for all CIHR health systems/services-themed or IHSPR-designated grants/awards in three of the 10 provinces (Table 2). The relatively small number of government agencies (e.g., public health agencies and provincial cancer agencies/boards) or regional health authorities that held these grants/awards were dispersed across six provinces. The remaining organizations holding CIHR health systems/services or IHSPR-designated grants/awards were also dispersed across six provinces. These organizations were mainly not-for-profit organizations that serve specific communities, such as HIV/AIDS networks or community organizations serving Aboriginal populations.

FIGURE 1. Exposure by HSPR setting: Distribution of unique organizations (1) with at least one affiliated investigator holding a CIHR health systems/services-themed or IHSPR-designated grant/award[a], (2) co-sponsoring or with at least one affiliated investigator/decision-maker holding a CHSRF REISS/LEAD grant or CHSRF CADRE award[b], (3) with at least one affiliated author with a publication in *Healthcare Policy*[c], (4) with at least one affiliated author with a publication in *Healthcare Management Forum*[d] and (5) with at least one affiliated individual with membership in CAHSPR[e].

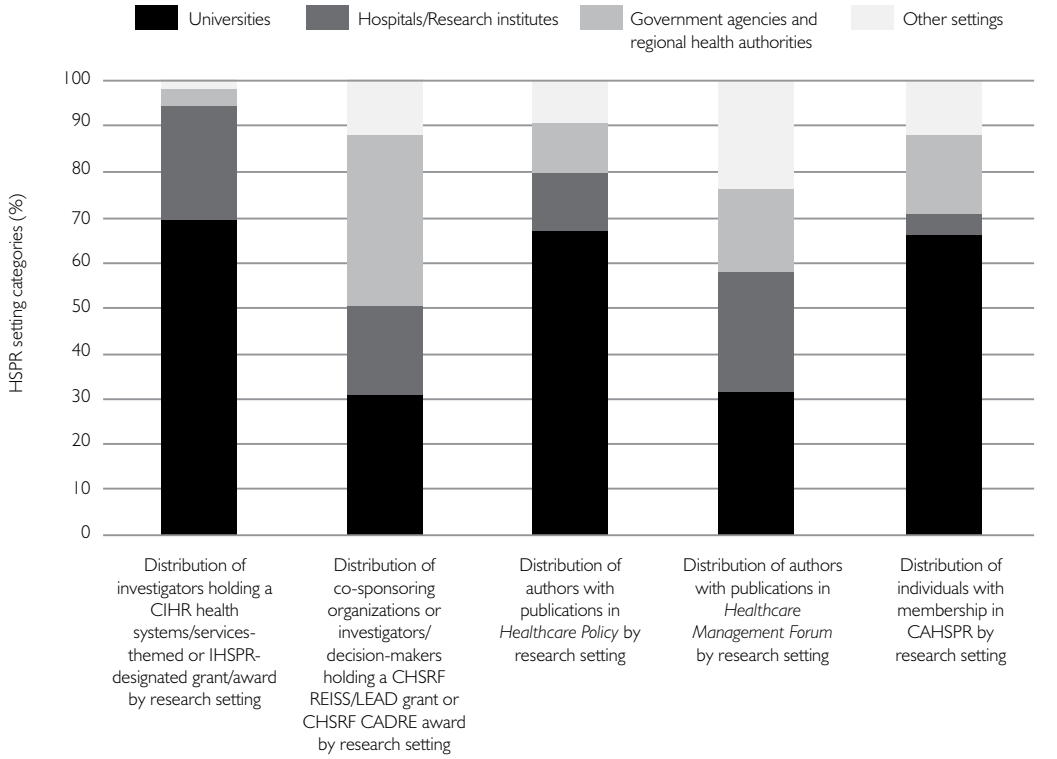


[a] Canadian Institutes of Health Research (CIHR) Funded Research Database results for 2006–2009 (searched May 16, 2010)
[b] Canadian Health Services Research Foundation (CHSRF) (REISS, LEAD and CADRE) competition results for period 2006–2009 (searched June 18, 2010)
[c] *Healthcare Policy* hand searched for issues published from 2006 to 2009 (searched July 6, 2010)
[d] *Healthcare Management Forum* hand searched for issues published from 2006 to 2009 (searched July 2, 2010)
[e] Canadian Association of Health Services and Policy Research (CAHSPR) Membership Directory (searched June 9, 2008)

Publicly available data on CHSRF funding of HSPR portrays a different picture. While CHSRF funds significantly less research than CIHR (Hutchison 2007), its focus is more clearly on HSPR (CHSRF 2009). CHSRF's main operating grant programs over the period 2006 to 2009 were the Research Exchange and Impact for System Support (REISS) and the Linking Evidence to Action on Decisions (LEAD) programs. Both programs required applicants to develop researcher/decision-maker partnerships, with a lead researcher and decision-maker applicant along with co-sponsoring organizations identified for each grant. CHSRF's main personnel awards program over the same period was the Capacity for Applied and Developmental Research and Evaluation (CADRE) program, which included postdoctoral fellowships (requiring both an academic and decision-maker mentor/organization) and chair awards for

senior investigators. Drawing on funding competition results posted on CHSRF's website, we examined the affiliations of awardees and documented the identified co-sponsoring organizations for both the REISS/LEAD (http://www.chsrf.ca/funding_opportunities/index_e.php) and CADRE (http://www.chsrf.ca/cadre/index_e.php) programs over the period 2006 to 2009.

FIGURE 2. Intensity by HSPR setting: Distribution of (1) investigators holding a CIHR health systems/services-themed or IHSPR-designated grant/award[a], (2) co-sponsoring organizations or investigators/decision-makers holding a CHSRF REISS/LEAD grant or CHSRF CADRE award[b], (3) authors with publications in *Healthcare Policy*[c], (4) authors with publications in *Healthcare Management Forum*[d] and (5) individuals with membership in CAHSPR[e].



[a] Canadian Institutes of Health Research (CIHR) Funded Research Database results for 2006–2009 (searched May 16, 2010)
[b] Canadian Health Services Research Foundation (CHSRF) (REISS, LEAD and CADRE) competition results for period 2006–2009 (searched June 18, 2010)
[c] *Healthcare Policy* hand searched for issues published from 2006 to 2009 (searched July 6, 2010)
[d] *Healthcare Management Forum* hand searched for issues published from 2006 to 2009 (searched July 2, 2010)
[e] Canadian Association of Health Services and Policy Research (CAHSPR) Membership Directory (searched June 9, 2008)

There were 54 CHSRF grants/awards over this period, with 88 unique organizations represented (i.e., exposure). Forty per cent were government agencies or regional health authorities, 25% were hospitals or research institutes, 16% were universities and 19% were other organizations (Figure 1). When we examined these data by the total

number of awardees and/or co-sponsoring organizations holding a CHSRF grant/award (i.e., intensity), the distribution shifted towards traditional research settings (from 41% to 51%) (Figure 2).

TABLE 1. CIHR health systems/services-themed or IHSPR-designated grants/awards for top 5 paid institutions (by department): 2006–2009[1]

	Top 5 paid institutions (by department) (number of grants/awards in parentheses) [department's percentage of university's grants/awards in square brackets]				
Department category	**University of Toronto (104) [100%]**	**University of British Columbia (90) [100%]**	**University of Alberta (67) [100%]**	**McMaster University (66) [100%]**	**McGill University (58) [100%]**
Healthcare policy, management and/or clinical epidemiology/ biostatistics	• Health Policy, Management and Evaluation (31) [30%]	• Healthcare and Epidemiology (21) • Centre for Health Services and Policy Research (6) • Clinical Epidemiology (1) • Healthcare Research (1) [32%]	[0%]	• Clinical Epidemiology and Biostatistics (26) [39%]	• Epidemiology and Biostatistics (9) • Clinical Epidemiology (1) • Epidemiology (1) • Epidemiology and Community Medicine (1) [21%]
Medicine	• Institute of Medical Sciences (7) • Medicine (4) • Surgery (3) • Medicine/ Cardiology (2) • Community Dentistry (1) • Community Medicine (1) • Internal Medicine (1) • Laboratory Medicine & Pathology (1) • Medical Sciences (1) • Medicine/ Endocrinology/ Metabolism (1) • Medicine/ Epidemiology and Biostatistics (1) • Psychiatry (1) [23%]	• Family Practice (3) • Continuing Medical Education (2) • Medicine (2) • Anaesthesia (1) • Internal Medicine (1) • Medicine/ Nephrology (1) • Oral Health Sciences (1) • Paediatrics (1) • Pathology (1) • Psychiatry (1) • Surgery (1) [17%]	• Medicine (10) • Paediatrics (9) • Emergency Medicine (2) • Clinical Neurosciences (1) • Internal Medicine (1) • Medicine/ Nephrology (1) • Oncology (1) [37%]	• Psychiatry (4) • Paediatrics (2) • Pathology and Microbiology (2) • Gerontology (1) [14%]	• Medicine (6) • Family Medicine (5) • Oncology (4) • Psychiatry (2) • Medicine/ Epidemiology and Biostatistics (1) • Neurology and Neurosurgery (1) [33%]
Nursing	• Nursing (3) • Nursing Research (2) • Nursing Administration (1) [6%]	• School of Nursing (5) • Nursing (3) [9%]	• Nursing (4) [6%]	• School of Nursing (5) • Nursing (4) [14%]	• School of Nursing (1) [2%]

TABLE 1. Continued

	Top 5 paid institutions (by department) (number of grants/awards in parentheses) [department's percentage of university's grants/awards in square brackets]				
Department category	**University of Toronto (104) [100%]**	**University of British Columbia (90) [100%]**	**University of Alberta (67) [100%]**	**McMaster University (66) [100%]**	**McGill University (58) [100%]**
Pharmacy/ allied health	• Physical Therapy (3) • Pharmacy (2) • Pharmaceutical Sciences (1) • Rehabilitation Sciences (1) [7%]	• Pharmacology and Therapeutics (4) • Human Nutrition (1) • Pharmaceutical Sciences (1) • Pharmacy Practice (1) • Physical Therapy (1) • Rehabilitation Sciences (1) [10%]	• Rehabilitation Sciences (1) [1%]	• Rehabilitation Sciences (5) [8%]	• Occupational and Physical Therapy (2) [3%]
Public health	• Public Health Sciences (5) [5%]	• Health Studies (2) • Health Promotion Research (1) • School of Public Health (1) [4%]	• Public Health Sciences (3) • Centre for Health Promotion (1) [6%]	• Health Sciences (1) • Health Studies (1) [3%]	• Dental Public Health Sciences (3) [5%]
Other	• Bioethics (1) • Centre for Bioethics (1) • Counselling Psychology (1) • Exercise Science (1) • History (1) • Industrial Engineering (1) • Institute of Biomedical Engineering (1) • Law (1) • Political Science (1) • Sociology (1) [10%]	• Applied Sciences (4) • Applied Ethics (2) • Interdisciplinary Studies (1) • Liu Institute for Global Issues (1) • School of Occupational and Environmental Hygiene (1) [10%]	• Educational Psychology (3) • Human Ecology (1) [6%]	• Geography and Geology (4) • Economics (3) • English (1) • Graduate Studies (1) [14%]	• Biochemistry (5) • Biomedical Ethics (4) • Anatomy and Cellular Biology (1) • Architecture (1) • Law (1) • Meakins-Christie Laboratories (1) • Psychology (1) • Social Studies & Medicine(1) [26%]
Unspecified	• Not specified/ applicable (21) [20%]	• Not specified/ applicable (16) [18%]	• Not specified/ applicable (29) [43%]	• Not specified/ applicable (6) [9%]	• Not specified/ applicable (6) [10%]

[1] CIHR Funded Research Database results for 2006–2009 (searched May 16, 2010)

There are clear differences between the two HSPR funding data sources. For both the exposure and intensity measures, a considerably higher proportion of CIHR's grants/awards went to applicants based in traditional research settings, compared to CHSRF. As all CHSRF operating grant programs require partnerships between researchers and decision-makers, we conducted sub-analyses of comparable CIHR

TABLE 2. CIHR health systems/services-themed or IHSPR-designated grants/awards (by province and institution paid): 2006–2009[1]

Province	Number of grants/awards (%)				Total grants/ awards funded
	University	Hospital and/ or research institute	Government agency and/ or regional health authority	Other organization	
Ontario	289 (56%)	215 (42%)	3 (1%)	7 (1%)	514 (100%)
Quebec	157 (65%)	81 (33%)	2 (1%)	2 (1%)	242 (100%)
British Columbia	117 (79%)	25 (17%)	2 (1%)	4 (3%)	148 (100%)
Alberta	119 (93%)	3 (2%)	4 (3%)	2 (2%)	128 (100%)
Nova Scotia	30 (88%)	3 (9%)	0 (0%)	1 (3%)	34 (100%)
Manitoba	27 (90%)	0 (0%)	1 (3%)	2 (7%)	30 (100%)
Saskatchewan	16 (84%)	0 (0%)	3 (16%)	0 (0%)	19 (100%)
Newfoundland and Labrador	10 (100%)	0 (0%)	0 (0%)	0 (0%)	10 (100%)
New Brunswick	7 (88%)	1 (13%)	0 (0%)	0 (0%)	8 (100%)
Prince Edward Island	1 (100%)	0 (0%)	0 (0%)	0 (0%)	1 (100%)
Total grants/awards funded (% of total grants/ awards funded)	**773 (68%)**	**328 (29%)**	**15 (1%)**	**18 (2%)**	**1,134 (100%)**

[1] CIHR Funded Research Database results for 2006–2009 (searched May 16, 2010)

partnership programs (e.g., PHSI and K2A) and found that these programs had similar distributions across research settings as other CIHR grants/awards, thus not explaining the differences between CIHR and CHSRF. We also compared CIHR and CHSRF's distributions of research settings for operating grants and personnel awards separately. For CIHR, the distribution of operating grants and personnel awards across research settings was consistent for both the exposure and intensity measures. However, for CHSRF, the distribution of operating grants and personnel awards across research settings differed. For both the exposure and intensity measures, a larger proportion of CHSRF operating grants was distributed to regional health authorities, other government agencies, hospitals and research institutes, while a smaller proportion of operating grants was distributed to universities, compared to the agency's personnel awards. These sub-analyses suggest that CHSRF's operating grant programs did result in both greater exposure and greater intensity of operating grants in non-traditional research settings compared to CHSRF's personnel award programs or any of CIHR's grant/award programs.

Following the publications: Authorship in HSPR-focused journals

To supplement the examination of the funding data sources, we extended our focus to a key source of HSPR output – publications in two Canadian peer-reviewed journals that primarily publish HSPR: *Healthcare Policy* and *Healthcare Management Forum*. While focusing on publications in just two journals clearly underestimates HSPR output in Canada, these journals both target academic and decision-making audiences and represent important dissemination vehicles for HSPR in Canada. There are inconsistencies in the number and type of institutional affiliations that authors identify or that these journals ultimately publish; however, we believe these data provide another reasonable proxy for mapping HSPR settings in Canada.

As we did with our analysis of research funding, we analyzed authorship in both journals in terms of organizational exposure and the intensity of organizational activity. To do this, we documented institutional affiliations of all authors contributing to papers in all issues of these two journals published from 2006 to 2009, excluding those authors for whom a Canadian affiliation was not provided. The data were obtained through hand searches of all *Healthcare Policy* and *Healthcare Management Forum* issues published over this time period.

For *Healthcare Policy*, we identified 116 organizations with at least one affiliated author having a publication in the issues examined (i.e., exposure measure). Traditional and non-traditional research settings were fairly evenly represented, with 41% of these organizations representing traditional research settings (18% with universities, 23% with hospitals/research institutes) and 58% representing non-traditional organizations (28% with government agencies or regional health authorities, 30% with other organizations) (Figure 2). However, when we consider the total number of author affiliations per organization (i.e., intensity measure), the picture shifts dramatically, with 80% of author affiliations linked to traditional research settings (67% in universities, 13% in hospitals/research institutes) and only 20% representing non-traditional research settings (11% with government agencies or regional health authorities, 9% with other organizations) (Figure 2). Thus, while a wide range of research settings contribute to publications in this journal, the clear majority of papers are authored by individuals based in traditional research settings.

For *Healthcare Management Forum*, we identified 107 organizations with at least one affiliated author having a publication in the journal over the period studied (i.e., exposure measure). Similar to the *Healthcare Policy* data, 57% of these organizations represent non-traditional research settings (24% with government agencies or regional health authorities, 33% with other organizations), while 43% represent traditional research settings (14% with universities, 29% with hospitals/research institutes) (Figure 2). However, in contrast to the *Healthcare Policy* data, when we consider the total number of author affiliations per organization (i.e., intensity measure), the picture reverses, with traditional research settings representing 57% and non-traditional

research settings representing 43% (Figure 2).

While data from both journals suggest that authors contributing to papers are affiliated with a wide range of research settings, the journals differ in terms of the depth of the contributions from specific types of research settings. Authors affiliated with traditional research settings contribute a much larger proportion of papers published in *Healthcare Policy* than in *Healthcare Management Forum*, a finding that likely reflects differences in each journal's mandate and target audiences.

Following the interest: Membership in a professional HSPR association

Explicit expression of interest in HSPR represents another proxy measure for mapping HSPR settings. The Canadian Association for Health Services and Policy Research is a national association of researchers and decision-makers that have expressed an interest in HSPR (CAHSPR 2007). Since 2004, CAHSPR has been hosting annual conferences that showcase contemporary Canadian and international HSPR and provide a key forum for researchers (including students) and decision-makers to network and discuss HSPR. The CAHSPR membership directory, accessible to members, provides basic information on each member's self-identified position and affiliated organization. Although 10% of members did not specify an organizational affiliation and membership may be influenced by proximity to the conference location (all attendees are provided a one-year membership in CAHSPR as part of their conference registration fees), the membership directory still provides insights on research settings that represent interest in HSPR.

Excluding members who did not provide an affiliation to a Canadian organization, there were 432 members registered on the CAHSPR directory as of July 2008. There were 134 organizations with at least one affiliated individual with membership in CAHSPR (i.e., exposure measure), distributed fairly evenly across the four research setting categories, with 31% of members based in government agencies or regional health authorities, 27% based in universities, 13% based in hospitals or research institutes and 29% based in other organizations (Figure 1). However, when we consider the total number of CAHSPR members across the four research setting categories (i.e., intensity measure), traditional research settings accounted for the majority (71%) of members (Figure 2).

Diverse Maps of HSPR Settings in Canada: Factors and Implications

The three measures (funding, publications and interest) derived from five separate data sources (CIHR, CHSRF, *Healthcare Policy*, *Healthcare Management Forum* and

CAHSPR) represent a subset of HSPR in Canada and inevitably miss important contributions. For example, some Canadian contributors to HSPR may not seek CIHR or CHSRF funding to support their research, or look to publish HSPR in either *Healthcare Policy* or *Healthcare Management Forum*, or view CAHSPR as a relevant professional association or network for their work. Similarly, the extent to which these measures should be aligned is unclear. For example, HSPR funding and HSPR publications data sources represent a bias towards HSPR settings of successful grant/award applicants and authors, thereby underestimating active (but potentially less successful, at least by these measures) HSPR contributors across Canada.

While we lack both a precise definition of HSPR and clear measures of HSPR settings, we believe the data sources analyzed permit an initial map of HSPR settings in Canada to be produced. However, in addition to efforts to improve definitions of HSPR, including core competencies for training the next cadre of researchers in the field, the data sources analyzed would provide more useful insights on HSPR if some of the following recommendations were addressed.

For example, while CIHR (through its PHSI and K2A programs) and CHSRF actively promote partnerships between researchers and decision-makers, it would be useful if more detailed information on the nature of these partnerships was provided. Currently, CHSRF identifies "co-sponsoring organizations" but does not link them to any specific individuals, making interpretation of the contributions of these organizations challenging. Greater transparency regarding how decision-making organizations contribute to HSPR may help decision-makers in non-traditional research settings better position their organizations to participate more effectively in, or draw benefits from, HSPR. It would also be helpful if HSPR-focused journals such as *Healthcare Policy* and *Healthcare Management Forum* considered more consistent policies regarding the publication of authors' affiliations (including both position and organization). Affiliations to traditional or non-traditional research settings reveal important insights and potential biases that should be made explicit to readers. Similarly, the CAHSPR membership directory would be a more useful source of information on HSPR settings if members were required to identify both a primary position and primary organization affiliation (with options to select "other" and provide multiple affiliations) as part of the process of confirming registration to the annual conference. Data on the number of years of membership status for each member would also help to assess the effects of proximity to the conference location on CAHSPR membership.

While we acknowledge the above limitations, our analyses still revealed important insights for health system planning and policy development. While the data sources produced varying pictures of HSPR settings in Canada, they consistently suggested that HSPR is not limited to traditional research settings.

Considering the 10 distributions of traditional and non-traditional research settings observed – that is, both exposure (was there any HSPR?) and intensity (how

much HSPR?) measures for each data source – only one distribution (CIHR intensity measure) exhibited less than 20% of HSPR in non-traditional settings (Figures 1 and 2). In fact, for the exposure measure, four of the five data sources indicated that non-traditional research settings accounted for more than half of all HSPR settings. However, for each data source, we observed an increase in the distribution of HSPR to traditional research settings when we shifted from exposure (Figure 1) to intensity (Figure 2) measures, with the shifts greatest for the CIHR, *Healthcare Policy* and CAHSPR data sources. The consistent discrepancy between exposure and intensity measures suggests that while non-traditional research settings are well represented, the majority of HSPR activity still resides in traditional research settings. This finding raises important questions regarding the nature of and expectations for HSPR contributions in non-traditional research settings, an issue that has received only limited attention to date (Ross et al. 2003). Even within traditional research settings, we found HSPR linked to university departments not typically associated with the field. While this finding reflects the multidisciplinary nature of the field, it does not provide insights on the extent to which these less typical university settings for HSPR are involved in truly interdisciplinary research.

Conclusions

Lomas concluded his provocative policy commentary by noting: "Achieving improved dissemination and uptake of health research will depend upon interested applied researchers, committed decision-makers, and both research sponsors and universities willing to consider new ways of doing business" (Lomas 1997: 42). While the Canadian landscape for HSPR has evolved with new research funding organizations, new journals and new professional associations dedicated to HSPR, our findings raise questions regarding the extent to which the Lomas-inspired vision of HSPR has truly emerged. While none of the data sources analyzed gave us a full and comprehensive picture of HSPR settings, considering these different data sources together has produced a more robust understanding of HSPR activity. The data clearly suggest that non-traditional research settings play a role in HSPR in Canada. However, the data provide only limited insight into the nature of their contributions, either to the development of the research or to its uptake. While more opportunity for researchers and decision-makers to work together is likely a good thing, we need to understand more about how researchers and decision-makers collaborate and contribute to the development and use of HSPR to guide policy and planning. Ultimately, this initial map of HSPR settings emphasizes important gaps in our knowledge, gaps that we hope will lead to further examination of the field and thereby facilitate its continued development.

ACKNOWLEDGEMENTS

The authors acknowledge and appreciate insightful comments from three peer-reviewers on the originally submitted manuscript.

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RESEARCH PAPER

Moral Distress among Healthcare Managers: Conditions, Consequences and Potential Responses

Souffrance morale chez les gestionnaires de la santé : conditions, conséquences et solutions potentielles

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Abstract

Moral distress – the physical and emotional response to feeling prevented from carrying out ethically proper action – can have serious consequences for health professionals and healthcare organizations. We investigated perceived moral distress qualitatively with managers in two BC health authorities.

Respondents described conditions under which they experienced distress: when they set priorities within highly resource-constrained environments, when they observed inequities between budget allocations and management responsibilities, and when organizational priorities did not align with their personal values. When coping proved insufficient, managers would respond by leaving positions, organizations or the healthcare field altogether.

Respondents asked for leadership development and the creation of spaces in which moral distress could be openly discussed. However, formal training in priority setting did not appear to be helpful on its own. Rather, it increased managers' awareness of the ethical dimensions of resource allocation without (in this instance) entrenching supports that would help them resolve these concerns.

Résumé

La souffrance morale – réaction physique et émotionnelle liée au fait de se sentir incapable d'accomplir éthiquement une action – peut avoir de sérieuses conséquences pour les professionnels de la santé et les organismes de soins de santé. Nous avons étudié la perception qualitative de la souffrance morale chez les gestionnaires de deux autorités sanitaires en Colombie-Britannique.

Les répondants ont décrit les conditions dans lesquelles ils éprouvent de la souffrance : quand ils établissent des priorités dans un contexte où les ressources sont très restreintes, quand ils observent des iniquités entre l'engagement des dépenses et les responsabilités de gestion et quand les priorités organisationnelles ne concordent pas avec leurs valeurs personnelles. S'ils se sentent incapables de faire face à la situation, les

gestionnaires peuvent envisager de laisser leur poste, l'organisme ou même le secteur de la santé. Les répondants demandent plus de formation en leadership et la création de lieux où ils peuvent discuter ouvertement de la souffrance morale. Cependant, la formation officielle portant sur l'établissement des priorités ne semble pas aider en soi. Elle semble plutôt augmenter la prise de conscience, chez les gestionnaires, des aspects éthiques de l'engagement des dépenses sans pour autant (dans ce cas) offrir le soutien qui les aiderait à résoudre leurs préoccupations.

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Healthcare managers face difficult challenges and distress in determining how best to allocate limited public resources. There is little likelihood that public sector spending in industrialized countries will grow by much over the next few years. Any recovery from the 2008 global recession is likely to be long and shallow, and the deficit spending incurred in the name of economic stimulus may be replaced, as it was in the 1990s, by significant public sector cuts. Managing and setting priorities in straitened times will be the norm.

In this study we sought to determine whether the concept of moral distress, previously identified and studied primarily in the clinical literature, is also relevant to mid- and senior-level managers. Building on previous work (Jameton 1984; Nathaniel 2002; Rushton 2006; Rodney et al. 2004), we defined moral distress as *the suffering experienced as a result of situations in which individuals feel morally responsible and have determined the ethically right action to take, yet owing to constraints (real or perceived) cannot carry out this action, thus believing that they are committing a moral offence*. Moral distress is rooted in one's sense that his or her value commitments are compromised (Webster and Baylis 2000). The suffering or personal anguish this perception entails presents as feelings of anger, frustration, guilt and/or powerlessness associated with a decreased sense of well-being. We are interested, in this study, in what these managers felt to cause them distress and how they were affected by it. We make no judgments regarding whether their views on ethically proper action are, or should be, shared by others.

Studies in clinical settings have related moral distress to low morale (Rodney and Starzomski 1993; Gaudine and Thorne 2000; Gaudine and Beaton 2002) and challenges with turnover and retention (Gaudine and Thorne 2000; Decker 1997; Corley et al. 2001). For example, Corley and colleagues (2001), in developing a quantitative scale to measure moral distress among nurses, found that 15% of their sample had left a previous nursing position for this reason. Other studies have found that up to half of nurses reported leaving a job, or the profession altogether, as a result of moral distress (Millette 1994). Pauly and colleagues (2009), using instruments developed by Corley and her team (2005) and Olson (1998), also found nurses reporting their intent to leave current positions, or nursing itself, because of moral distress. They found moral

distress to be a complex phenomenon; ethical climates were significantly correlated with individual moral distress. This may mean that "moral distress should not be framed or located as an individual concern … rather, further investigation of the ways in which organizational factors contribute to moral distress is needed" (Pauly et al. 2009: 569).

Based on findings reported elsewhere, we believe that moral distress does exist among managers in the context of priority setting and resource allocation (Mitton et al. 2010). Two key examples of moral distress were identified in this work: (1) managers having to "sell" a direction or decision that they themselves do not believe in and (2) managers breaking obligations to staff or colleagues. That is, on the basis of the evidence we collected, we were able to identify for these cases strongly held ethical/moral principles that the respondents felt they were being forced to violate. It is the presence of such a clear ethical dimension that distinguishes moral distress from the other demands of fast-paced and highly contentious healthcare workplace decision-making. These arguments are made in greater detail elsewhere (Mitton et al. 2010).

The current paper describes some of the organizational conditions under which moral distress occurs, or which might be thought to accentuate the experience. We show that the presence of moral distress, and how managers respond to it, has negative consequences for healthcare organizations. Finally, we consider possible organizational responses to the problem, including whether formal training in priority setting methods – such as the widely implemented program budgeting and marginal analysis (PBMA) framework (Mitton and Donaldson 2001; Peacock et al. 2006; Mitton et al. 2003) – might have beneficial impacts in terms of preventing or mitigating moral distress.

Methods

Given that this research was an early attempt to investigate a new topic, and in order to consider whether a particular concept could be usefully employed, thematic content analysis, guided by constructivist principles – the qualitative approach that we used – was appropriate (Green and Thorogood 2004). We conducted three focus groups (n=12 participants) and individual interviews (n=6) with mid-level managers and senior executives in two health authorities in British Columbia between June and December 2008. Participants' descriptive data were not systematically collected; however, their recorded comments and researchers' observations allowed us to assess certain key characteristics. Fourteen of 18 were female. Most had substantial years of administrative experience, either with their current employer or elsewhere in the public sector, and could best be described as in their middle to late careers.

Interviews and focus groups enable participants to give answers in their own words to researchers' questions; they allow respondents to describe situations and experiences in rich detail. When not enough is known about a topic to pose questions that can be addressed quantitatively using validated response options, qualitative

methods are better suited to addressing research objectives. While individual interviews were our preferred method, we employed focus groups pragmatically owing to time and resource constraints. That is, we were prepared to attach our data collection sessions to previously scheduled meetings when participants – very busy managers – would be available in the same location. The same interview guide was used with both one-on-one and group sessions. More detailed discussion of the methodological questions this approach might raise is available elsewhere (Mitton et al. 2010).

We purposively sought informants who had previous exposure to formal priority setting processes – in this case, with the PBMA framework, which has been used widely by decision-makers in British Columbia and elsewhere (Dionne et al. 2008; Teng et al. 2007; Urquhart et al. 2008; Patten et al. 2006; Halma et al. 2004) – and those who had not had such exposure. Decision-maker partners in the two health authorities helped us identify and approach potential participants. In one case, a senior member of the executive team recruited colleagues in comparable decision-making positions on our behalf. In the other authority, a senior executive member e-mailed all mid-level managers within the region, described the research, noting that it had endorsement by the health region, and invited any interested managers to contact the research team directly.

All the focus group discussions and the interviews were audio-recorded with permission and subsequently transcribed. Respondents were asked to think of situations in which they had experienced moral distress (according to the definition provided, in general and in relation to priority setting specifically), to describe what (if any) personal consequences resulted from these experiences and to identify personal or organizational characteristics that they thought might be related to moral distress in management. Respondents were also asked if there were steps that they thought their organization could take to alleviate or prevent the kinds of experiences that they considered to be morally distressing. The complete interview schedule is available elsewhere (Mitton et al. 2010).

Two of the authors independently analyzed subsets of the transcripts. We began with a template based on our research questions and interview guide. For example, we compared respondents' descriptions of their experiences to our given definition of moral distress, to see if they were consistent with that construct. As a second example, we isolated all mentions of PBMA to determine if they did or did not include mention of the alleviation of distress. Other themes were developed inductively. Analysis proceeded through constant comparison (Parry 2004). Conceptual labels developed through reading of the earliest transcripts were assigned to emerging thematic categories (open coding). Respondents' comments in subsequent transcripts were assigned to existing or new categories. Disagreements among authors were resolved by discussion. Categories were compared against one another and refined until the data were internally coherent and each category was distinct from the others. The study was approved

by the Behavioural Research Ethics Board at the University of British Columbia and the Human Research Ethics Board at the University of Victoria; it was also reviewed and approved by an internal ethics board as required at one of the health authorities.

Results

The first set of results reported here pertains to *organizational conditions* within which moral distress is likely to occur. We then turn to identified *negative consequences* of moral distress for respondents' personal well-being. Finally, *potential individual and organizational responses* are reported, including whether experience with a formal approach to priority setting and resource allocation was mentioned in regard to individual managers' experience of moral distress. The number of transcripts within which each theme is identified is noted; we do believe, however, that with qualitative research the frequency of a theme does not necessarily indicate its importance.

Organizational conditions

Respondents spoke of different aspects of priority setting situations that they found most difficult. Three interrelated themes arose: resource-constrained environments, inequities in budgets and misalignment of values. We do not suggest that these are exhaustive of the situations in which distress might arise.

Managers felt distressed when they had to make choices about what to do with limited funding (five of nine transcripts), including how to organize required care in circumstances when they were well aware of both human resource limitations and time constraints.

> I think that is one of the things that as managers we sometimes struggle with – actually having enough time to actually do a full analysis of the decisions that we are making. … sometimes when you are pushed to make some decisions where you don't feel that you have had enough time to actually walk it through properly, sometimes you end up with a decision that could have been a little bit better, which is a hard thing to swallow. (Int-1, p. 11)

The challenges of making decisions in these environments were compounded when managers felt that resources or opportunities were unfairly or inequitably distributed within their organizations. Respondents in five of nine transcripts explicitly described cases in which their clinical areas had, over time, become responsible for performing functions that other sectors of the organization had divested (e.g., purchasing, maintenance, housekeeping). These new responsibilities were not accompanied by any redistribution of budgets. Nor were they necessarily within the skill set of

these managers. In short, some departments achieved savings by leaving others to pick up, uncompensated, the performance of tasks that – from an organization-wide or system perspective – could not be abandoned.

Respondents also experienced distress in attempting to carry out management roles when they felt that the organization's overall or main priorities differed from those they personally held (seven of nine transcripts). They felt that they would be unable to follow through if they tried to pursue what they felt to be the best, most ethical, policy. They also felt that they had to position or frame their choices in a way that accorded with the organization's established directions. Among several examples, one that clearly stood out was a tension between patient care and risk management:

> We carry that moral distress of "Are we using our resources to mitigate those situations where we've actually got the highest need?" No, we use our resources to situations where we have the highest risk organizationally, which is a different template in a different sort of construction than the actual client risk. (Nov. FG, p. 7)

> When it becomes a risk management or when someone gets hurt, then that seems to be a trigger. Basically, anything I have sort of gone ahead with, I have had to appeal to the "risk" perspective. Like "politically this would not be popular," or "you're at risk," or "liability" … that seems to get the administrators' attention as compared to "hey, let's do this so we actually are looking after the health of our staff and of our patients." (Int-2, p. 3)

Negative consequences experienced by these managers

A number of potentially serious personal health consequences that respondents attributed, at least in part, to moral distress were described. These included high blood pressure, ulcers, loss of sleep, exhaustion/fatigue, poor diet and lack of energy. Of course, there are no data in this qualitative study to assess whether such claims are objectively justified. One key difference from the clinical literature on moral distress was the repeated claim (appearing in four of nine transcripts) that distress did not manifest in increased sick time claims, because managers "don't take time off." Decreased productivity (i.e., "presenteeism"), however, was noted.

In terms of emotional well-being, at various points in the interviews our respondents used the following words or phrases to describe their experiences of moral distress: discouragement, annoyance, sense of failure, sadness, anger, frustration, hopelessness, disappointment, angst, guilt, powerlessness, burnout, loss of idealism, loss of self-esteem, cynicism, apathy, bitterness and aloneness. Further consequences of moral distress identified by the respondents included impaired workplace relationships,

diminished staff morale and impaired family and interpersonal relationships (e.g., "I take it out on my family"). These managers noted that the moral distress of their workplace responsibilities could not be left behind at quitting time; one described how, during personal time, s/he was "always thinking about it."

Personal responses

Respondents mentioned a number of means by which they coped with or managed their experience of moral distress. The one to which we draw attention here, because of its implication for organizational as well as personal health, is what we may call the "exit option." That is, some managers may cope with distress by contemplating or planning to leave positions, organizations or the healthcare sector itself.

> I know for me personally, one of the things that I have been thinking of because I am one of the "future leaders" in healthcare, is "do I want to stay in healthcare?" I look at what is potentially happening for 15 years down the road and I don't know if I want to be [a] senior leader in healthcare at that point. (Dec. FG, p. 20)

> I am out in a position where I need to move something faster than I am ready with my teams and then I get into that huge piece of suffering. That is where I almost have a real problem personally and at that point wonder if I can stay in the system, because I don't believe in it and so then that gets me to the point where I question "am I really in the place where I need to be?" (June FG, p. 5)

Exiting might also take the form of detaching one's self, as much as possible, from organizational commitment and routine. That appears to have both an organizational behavioural component (e.g., ceasing to attend meetings) as well as an affective one (trying not to take things too much to heart).

> Sometimes you actually do some self-preservation by disengaging from some of the regional work, the committee meetings where you get frustrated, it doesn't really matter what you say. So therefore I will just put my head down and disengage from the system and just try to look after my own circle of influence. (Int-1, p. 14)

> I can only go so far and push so far and then I have to say, "I am not personally responsible for this, it is an organizational and institutional decision-making process and I can't fix it all." (Int-2, p. 7)

This theme was present in seven of nine transcripts.

Organizational responses

In addition to their personal choices, our respondents described ways in which the employer might usefully react. They felt that an important aspect of the problem was the failure of the organization to acknowledge the existence of moral distress as an issue in management (explicitly claimed in four of nine transcripts).

> It is validation – that is, the name of what you are trying to achieve – is to validate that this is a real experience and that it is not abnormal human beings that are having these reactions. (Nov. FG, p. 38)

> Being upfront about acknowledging the problem. Saying "Hey, we can understand that we have brought some issues here that are causing moral distress. Everything is not perfect, so let's start to look at creative ways to work on this." I am not going to tell you I have the answer. I wish I did. But at least acknowledging that the whole world isn't wonderful and special. (Int-3, p. 17)

Conversely, managers (in three of nine transcripts) described situations in which they clearly felt that the experience of moral distress was being dismissed, and that they were expected to slough it off or otherwise keep quiet about their feelings or concerns.

> We do get messages coming down the hierarchy that are quite distressing – including messages about "Don't let that distress you – that's your job." … And if you are contaminating the performance of your job with all of these feelings that you really shouldn't have, that is actually a performance issue. (Nov. FG, p. 14)

Finally, we looked in our data to see whether those managers with experience of PBMA – which included only the participants in the November and December focus groups – suggested that in any way this formal training with a systematic approach to priority setting and resource allocation had an effect on their experience of moral distress. We must note that PBMA had not been implemented, in either health authority, with an explicit intention to mitigate moral distress. There appears to be no strong evidence in these cases that respondents associated PBMA with reductions in their experience of moral distress. However, there did seem to be some possibility that it may have made things more difficult for managers by drawing their attention to differences between their values and desires for how organizations should set priorities and what actually occurs. In particular, they are made aware of how little evidence for good decision-making exists, or is used, and how often choices

made through an agreed-upon, transparent and formal process might be trumped by politics or other external influences.

The use of PBMA appeared to highlight, for some respondents, the lack of evidence-based decision-making within their organizations:

> That is the greatest moral distress for me, are we making decisions based on evidence, and the answer is a resounding "no" for the most part. (Dec. FG, p. 10)

> I had some unallocated dollars in my budget, so it got reallocated and I did my own PBMA, but I tell you the guilt I felt about giving this program more than this program … it was "I really shouldn't be giving these guys more." … I don't know. (Nov. FG, p. 10)

Respondents also found it distressing that priorities developed through formal resource allocation protocols were subsequently challenged and often superseded by choices based on other factors, such as politics or interest group pressures. Yet, as loyal members of the organization, they were expected to adopt and implement these new priorities.

> We did a resource allocation process three or four years ago, if you recall. … [Program A] was supposed to get the funding and then we ended up cancelling that out and funding [Program B] even though that showed less evidence in terms of its success and effectiveness. … That is a good case of moral distress, [when] you try to make program decisions based on what is most effective and then that gets cancelled. (Dec. FG, p. 10)

> [Consider] last year's PBMA process, which we went through and tried to honour all of the process. … In the end when the agreement was that the allocation should go to [Programs A and B], that those were the top two priorities, the response was, "Well, there must be something wrong with the tools," or "People didn't really understand what they were making a decision about." (Nov. FG, pp. 18–19)

Based on the data collected, we found no evidence that moral distress might be mitigated by experience with a formal priority setting framework (that is, no one spontaneously mentioned any beneficial effects), while conversely, we identified several examples of how a formal framework could result in increased moral distress. Given our qualitative design, these findings are suggestive but not conclusive and not necessarily generalizable to other settings.

Discussion

Prior to this study, we are not aware of research that has attempted to delineate the concept of moral distress in a broad range of mid- and senior-level healthcare managers. Our results suggest that moral distress is a relevant managerial concept not unique to clinical staff (Mitton et al. 2010). As reported here, we were able to identify conditions or circumstances in which moral distress occurs, examples of negative consequences of moral distress and some potential individual and organizational responses to the problem. We also had thought *a priori* that having experience with a formal priority setting framework might have some unintended benefit in mitigating instances of moral distress, but none of our respondents voluntarily offered any comments that supported this idea.

Respondents reported that moral distress plays a role in both personal and organizational consequences, including negative physical and emotional impacts upon employees. In this sense, our data confirm what has previously been reported in the clinical literature (Rodney and Starzomski 1993; Gaudine and Thorne 2000; Gaudine and Beaton 2002; Decker 1997; Corley et al. 2001; Millette 1994; Pauly et al. 2009). We must note, of course, that any links between moral distress and what was described as ill health or burnout are not causally proven here; we are reporting the managers' perceptions that there is such a relationship in their own cases.

Respondents felt that a key organizational response to moral distress should be to honour and validate the issue (i.e., name it). This response, too, has been found in the clinical literature, where recommendations to address the problem often revolve around creating opportunities for reflective dialogue and sharing of stories (Sporrong et al. 2006; Storch et al. 2009; Pauly et al. 2009; Austin et al. 2005). We note that in each focus group we conducted, the members expressed thanks for the opportunity to discuss issues of moral distress with colleagues, describing the research process itself as having almost therapeutic value. This finding occurs in other studies of moral distress as well (MacRae 2008; Storch et al. 2009). Clearly, many healthcare workers desire a forum in which they can build trust in one another and identify and discuss ethical concerns, including moral distress. Differences among perceptions, and questions as to whether individual judgments in fact ought to be shared by the organization as a whole, can also be considered, though not necessarily resolved, in such spaces.

Use of the formal priority setting approach known as PBMA has been shown in other contexts to make decision-makers more aware of the ethical issues involved in allocating scarce resources (e.g., see Gibson et al. 2006). In some cases, as shown in our findings, this awareness may lead to moral distress. It should be incumbent upon proponents of resource allocation methods and tools to consider such potential impacts. Such consideration has not always been explicitly applied, as these frameworks have tended to be seen in the past as primarily economic rather than ethical devices. That said, many of the things that respondents suggested would help them

cope, or would ease situations of distress, are among the principles and techniques contained by PBMA, such as a consensual approach, open and transparent decision-making, increased use of evidence and mitigation of political interference. Others have also speculated that for healthcare professionals to experience moral distress (as long as they are self-aware and reflective about it) may not be entirely bad, as it demonstrates that they are ethically sensitive to the moral and value conflicts inherent in the provision of care (Austin et al. 2005). Further research on these impacts is warranted.

Limitations

Some limitations exist with the current study. First, the study is restricted to two health authorities and 18 mid- and senior-level managers with participants purposively selected. Although people in a range of managerial roles were in fact included in the invitation, it may be that only those who had experienced moral distress agreed to participate. While this factor does not negate their own unique experiences, we cannot suggest how widespread the reported experiences are, nor can we suggest that they are necessarily representative. We did not set out to identify causal links between moral distress and any negative impacts on well-being.

Second, there may be some potential bias from the fact that many (though not all) of the participating managers knew members of the research team through working with them on previous projects.

Third, in our consideration of whether experience of moral distress was affected by the use of a formal priority setting framework, it should be noted that we did not directly ask respondents during the course of the focus groups about their experience with PBMA. Rather, we knew which respondents had used the PBMA framework and we specifically looked in their comment for any spontaneous, voluntary reference to it. These participants were nonetheless fully informed prior to the focus groups that the role of formal priority setting was a subject of the research and we would be interested in their comments on it. This design avoided leading the respondents to a spot where they may have sought to identify benefits of PBMA in order to please the researchers. It may, however, have failed to elicit positive instances. In other words, these findings can only be suggestive pending future, more focused, qualitative or quantitative study.

Conclusion

In the research reported here and elsewhere, we found that the concept of moral distress is relevant to healthcare managers as well as practitioners. We observed that, in this sample of mid- and senior-level managers, many of the perceived negative consequences and individual or organizational responses that were expected potentially to alleviate the problem seem to be similar to those reported in the clinical literature (e.g.,

Pauly et al. 2009; Storch et al. 2009). The added value of this study is the implication in identifying key conditions and potential consequences so that organizations can work towards developing appropriate responses. Future research should focus on outlining the relative importance of moral distress on the negative consequences identified vis-à-vis other potential contributing factors, as well as examining the merits of various organizational responses.

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ONLINE EXCLUSIVE

A Comparison of Drug Coverage in Alberta Before and After the Introduction of the National Common Drug Review Process

Comparaison de la couverture pour les médicaments en Alberta avant et après la mise en place du Programme commun d'évaluation des médicaments

JOHN-MICHAEL GAMBLE, DEAN T. EURICH AND JEFFREY A. JOHNSON

Abstract

Objective: The integration of the Common Drug Review (CDR) was a substantial change for Canada's public drug plans. Detailed comparisons of time-to-listing and proportion of medications covered by the province of Alberta's drug plans within the context of the CDR process have not been rigorously conducted.
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Conclusion: Following the implementation of the CDR, the proportion of drugs covered has decreased and overall median time-to-listing of new drugs has increased in the province of Alberta. For drugs listed on the AHWDBL, the proportion of time attributable to the CDR process (NOC to CDR recommendation) was 63% of the overall time-to-listing.

Résumé

Objectif : La mise en place du Programme commun d'évaluation des médicaments (PCEM) a constitué un changement important dans les régimes publics d'assurance-médicaments au Canada. Il n'y a pas encore eu de comparaisons rigoureuses, dans le contexte du PCEM, entre les délais d'inscription à la liste et la proportion de médicaments couverts par le régime d'assurance-médicaments de l'Alberta.
Méthodologie : Cette comparaison tient compte des nouveaux médicaments approu-

vés par Santé Canada cinq ans avant et cinq ans après la mise en place du PCEM (mai 2004). Les délais d'inscription et la proportion de nouveaux médicaments couverts par le régime d'assurance-médicaments de l'Alberta (*Alberta Health and Wellness Drug Benefit List, AHWDBL*) ont été comparés pour ces périodes. Le degré de concordance entre les recommandations du PCEM et la couverture en Alberta a été calculé au moyen du coefficient kappa.

Résultats : Deux cent vingt nouveaux médicaments qui réunissaient les critères de l'étude ont été répertoriés (118 avant la mise en place du PCEM et 102 après). Les délais médians d'inscription à la liste étaient de 312 jours pour les médicaments pré-PCEM et de 524 jours pour les médicaments post-PCEM, la différence étant grandement attribuable au temps entre l'avis de conformité et la recommandation du PCEM. Pour 73 médicaments, le taux de concordance entre les recommandations du PCEM et la couverture en Alberta était modéré (kappa 0.55).

Conclusion : Suite à la mise en place du PCEM, la proportion de médicaments couverts a diminué et le temps médian global d'inscription des nouveaux médicaments à la liste a augmenté dans la province de l'Alberta. Pour les médicaments inscrits sur la liste de l'AHWDBL, la proportion de temps attribuable au processus du PCEM (soit de l'avis de conformité à la recommandation du PCEM) équivaut à 63 % du temps global pour l'inscription à la liste.

Revue Pratiques et Organisation des Soins

Volume 41 Issue 4 /October-December 2010

Healthcare Policy / Politiques de Santé and the French publication *Pratiques et Organisation des Soins*, publish each other's Table of Contents and relevant articles – subject to editorial review.
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Original Research

Knowledge synthesis

Pratiques et Organisation des Soins

Volume 41 Numéro 4 /Octobre-Décembre 2010

Politiques de Santé / Healthcare Policy et la revue française *Pratiques et Organisation des Soins* publient réciproquement leurs tables des matières ainsi que des articles pertinents, sous réserve de révision.
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Recherches originales

Synthèses

Does Receiving Clinical Preventive Services Vary across Different Types of Primary Healthcare Organizations? Evidence from a Population-Based Survey

La prestation des services préventifs en milieu clinique varie-t-elle selon le type d'organismes offrant des soins de santé primaires? Données provenant d'une enquête auprès de la population

by SYLVIE PROVOST, RAYNALD PINEAULT, JEAN-FRÉDÉRIC LEVESQUE, STÉPHANE GROULX, GENEVIÈVE BARON, DANIÈLE ROBERGE AND MARJOLAINE HAMEL

TABLE 4. Factors associated with patient-reported CPS delivery. Patients with a regular source of PHC: Monteregie, Quebec, Canada, 2005

		Overall CPS score ≥ 75% (all)	Healthy diet counselling (all)	Tobacco use screening (all)	Tobacco cessation counselling (smokers)	HBP screening (all)	Pap test (W 18–69)	Mammography (W 50–69)	Colorectal cancer screening (50 +)
		N=3,161	N=3,161	N=3,161	N=923	N=3,161	N=1,463	N=695	N=1,441
Independent variables		OR†	OR†	OR†	OR†	OR†	OR†	OR†	OR†
Regular source of PHC (ref.: Private/ Group)	Private/Solo	1.23**	1.08	1.28**	1.53	3.18*	1.28	0.86	1.55*
	Mixed/FMG	1.22*	1.12	1.24*	1.23	1.31	1.34	0.85	1.39*
	Public/ CLSC–FMU	1.79*	1.22	1.50*	1.23	0.91	1.85**	1.38	3.27*
Has been going to regular source of PHC (ref.: <2 years)	2 years or +	1.09	1.00	0.83	1.04	1.10	0.66	2.73*	0.91
Visits to regular source of PHC, past 2 years (ref.: 1 visit)	2 to 5	1.36*	1.25**	1.14	1.69*	2.76*	1.92*	1.43	1.70*
	6 or more	1.83*	1.69*	1.33*	2.45*	6.42*	1.30	1.22	1.67*

† OR adjusted for age–sex group, smoking status, level of education, income, risk factors (having HBP, diabetes or hypercholesterolemia), health problems (having heart problems, respiratory problems, stroke or cancer).

HBP = high blood pressure

* $p<0.05$

** $p<0.10$

ONLINE EXCLUSIVE

A Comparison of Drug Coverage in Alberta Before and After the Introduction of the National Common Drug Review Process

Comparaison de la couverture pour les médicaments en Alberta avant et après la mise en place du Programme commun d'évaluation des médicaments

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Abstract

Objective: The integration of the Common Drug Review (CDR) was a substantial change for Canada's public drug plans. Detailed comparisons of time-to-listing and proportion of medications covered by the province of Alberta's drug plans within the context of the CDR process have not been rigorously conducted.
Methods: New drugs approved by Health Canada were identified five years prior to the CDR's first recommendation (May 2004) and five years after. The time-to-listing and proportion of new drugs covered on the Alberta Health and Wellness Drug Benefit List (AHWDBL) was compared between these periods. The level of agreement between CDR recommendations and coverage in Alberta was calculated using a kappa score.
Results: Two hundred and twenty new drugs were identified and met the study eligibility criteria (118 pre-CDR, 102 post-CDR). The median time-to-listing was 312 vs. 524 days in the pre-CDR and post-CDR periods, respectively, with the difference largely driven by time from notice of compliance (NOC) to the CDR recommendation. The level of agreement between 73 drugs with CDR recommendations and coverage in Alberta was fair (kappa 0.55).
Conclusion: Following the implementation of the CDR, the proportion of drugs covered has decreased and overall median time-to-listing of new drugs has increased in the province of Alberta. For drugs listed on the AHWDBL, the proportion of time attributable to the CDR process (NOC to CDR recommendation) was 63% of the overall time-to-listing.

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Méthodologie : Cette comparaison tient compte des nouveaux médicaments approuvés par Santé Canada cinq ans avant et cinq ans après la mise en place du PCEM (mai 2004). Les délais d'inscription et la proportion de nouveaux médicaments couverts par le régime d'assurance-médicaments de l'Alberta (*Alberta Health and Wellness Drug Benefit List, AHWDBL*) ont été comparés pour ces périodes. Le degré de concordance entre les recommandations du PCEM et la couverture en Alberta a été calculé au moyen du coefficient kappa.
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pré-PCEM et de 524 jours pour les médicaments post-PCEM, la différence étant grandement attribuable au temps entre l'avis de conformité et la recommandation du PCEM. Pour 73 médicaments, le taux de concordance entre les recommandations du PCEM et la couverture en Alberta était modéré (kappa 0.55).
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Pharmaceutical coverage in Canada is an important topic to many Canadians and has increasingly received significant media coverage as healthcare budgets are expanding while allocations are being squeezed. The pharmaceutical reimbursement system in Canada comprises a mixture of public and private drug plans. Currently, 19 publicly funded drug plans exist across the country, all of which vary in their scope and coverage (Gregoire et al. 2001). Some plans are universal, meaning they cover the entire population they serve; other plans are specific to a cohort, such as seniors. Federal public plans cover specific groups, including First Nations and Inuit individuals, federal inmates, members of the Canadian Armed Forces, immigrants and refugees, members of the Royal Canadian Mounted Police and veterans. Each province has its own public drug plan, and the variation in drug coverage in these plans has been studied extensively (Anis et al. 2001; Gregoire et al. 2001; MacDonald and Potvin 2004; Morgan et al. 2009). Each drug plan is responsible for deciding which drugs will be covered for their respective beneficiaries.

The Common Drug Review (CDR), which is administered by the Canadian Agency for Drugs and Technologies in Health (CADTH 2009b), was introduced in Canada to establish a centralized drug review process that would reduce duplication of drug reviews within government-sponsored drug plans (CADTH 2009a,d; McMahon et al. 2006; Tierney and Manns 2008). The CDR process is intended to be transparent and rigorous, and to provide evidence-based recommendations to participating publicly funded drug plans in Canada. Provinces were free to participate, or not, in the CDR process. The province of Quebec opted not to participate, while all other provinces opted in. The CDR uses a reproducible framework whereby a review team consisting of internal and external experts across various disciplines (e.g., epidemiology, pharmacy, medicine, health economics and information science) conducts a systematic review to critically appraise the clinical and economic importance of each drug

reviewed. Following this extensive review, a report is provided to the Canadian Drug Expert Advisory Committee (CEDAC), which is responsible for assessing the drug's clinical and cost effectiveness compared to existing treatment options and providing a recommendation for formulary listing to the provinces.

Although the CDR was established in 2002, it made its first recommendation on May 27, 2004. CDR recommendations may include listing the drug without any restriction, not listing the drug, listing the drug in a similar manner to other drugs in the same class, or listing the drug with criteria or conditions. Although a clear formulary recommendation is made for each drug reviewed, each of the participating drug plans is still required to make a final decision for its respective formulary. Participating drug plans are reported to agree with CEDAC recommendations approximately 90% of the time (CADTH 2009d).

As previously noted, significant differences in drug coverage exist across plans (Anis et al. 2001; Gregoire et al. 2001; MacDonald and Potvin 2004; Morgan et al. 2009), and although these differences may result in vastly different costs to patients (Demers et al. 2008), the majority of top-selling drugs are covered under all provincial plans (Morgan et al. 2009). Prior to the implementation of the CDR, each provincial and territorial jurisdiction was entirely responsible for its own drug reviews based on its own criteria. Each jurisdiction would perform its own evaluation of a drug submitted by the manufacturer for its respective government-sponsored drug plan. Thus, it is important to describe and analyze the differences among these time periods.

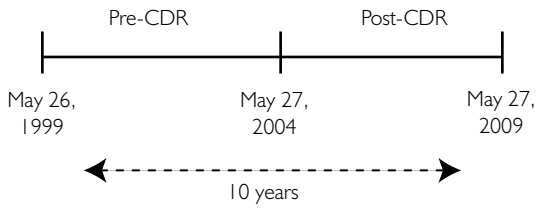
To our knowledge, a comparison of the time to drug reimbursement before and after the introduction of the CDR has not been rigorously conducted. Tierney and Manns (2008) concluded that the time from Health Canada's approval of a new drug to its listing on drug plan formularies has not changed with the implementation of the CDR process, based on a study by Kallah (2006). Skinner and Rovere (2009) have described federal and provincial delays in accessing new drugs approved by Health Canada, and Wyatt and colleagues (2008) have compared drug reimbursement decisions of drugs reviewed by the CDR within a national and international context.

We aimed to compare the time-to-listing and the proportion of new drug entities, both new chemical entities and new combination products, covered by Alberta's government-sponsored drug plans that received a notice of compliance (NOC) by Health Canada's Therapeutic Product Directorate five years prior to and five years following the CDR's first recommendation. We believe that describing Alberta's experience provides a useful case study for other researchers and policy makers interested in Canada's CDR process, especially those involved in Alberta's process. Furthermore, this topic is relevant given that several provinces, including Alberta, are currently undergoing various pharmaceutical policy reforms, one of which is the drug review process.

Methods

New drug entities that received an NOC between May 26, 1999, and May 27, 2009, were identified using Health Canada's Drug Products Database (DPD) available on its website (Health Canada 2009). Figure 1 illustrates the study timeline. Data extracts of the active and inactive DPD were imported, merged and analyzed using Stata/IC 10.1 (StataCorp LP, College Station, TX, USA). Exclusions included generic drugs, over-the-counter drugs, drugs scheduled for ethical use (i.e., do not require a prescription but are usually prescribed by a medical practitioner, e.g., nitroglycerine), homeopathic products, veterinary use products, neoplastic agents, vitamins, blood products and drugs withdrawn from the Canadian market. The date of the first NOC issued was used, or date of marketing notification if an NOC date was missing; thus, an NOC due to change in manufacturer, approved indications, route of administration or manufacturing processes was excluded. New drug entities were identified using the second portion (five digits) of the unique 10-digit active ingredient group number, which identifies the unique products with unique groups of active ingredients. These groups may have various strengths and will therefore be captured only once. These new drug entities were categorized into two mutually exclusive categories: five years prior to (May 26, 1999, to May 26, 2004) and five years after (May 27, 2004, to May 27, 2009) the CDR's first recommendation.

FIGURE 1. Timeline of study



Alberta has several government-sponsored drug plans, including coverage for seniors, social services, child health benefits and others. For this analysis, only drugs listed on the Alberta Health and Wellness Drug Benefit List (AHWDBL) were included. Drug benefit lists were collected from April 1999 to April 2010 and combined into a single PDF document. The date of coverage for the new drug entities receiving an NOC in the pre-specified pre-CDR and post-CDR time periods was determined using the advanced search function in Adobe Acrobat 8 Professional Version 8.1.2 (Adobe Systems Inc., San Jose, California). We considered drug-listing decisions up until April 2010 to allow a reasonable lag time between the last CDR recommendation and formulary coverage. Drugs were further categorized into three mutually exclusive groups: drugs that were listed as a full benefit, drugs that were listed with a set of

pre-specified criteria (restricted or special authorization products) and drugs that were not listed.

CDR recommendations completed as of May 27, 2009, were identified using the CDR drug database available on the CADTH website (2009c). If a drug had more than one recommendation (i.e., initial submission and repeat submission) for the same indication, only the latest recommendation was used in the analysis. For drug products that contained the identical active ingredient but were reviewed by CDR more than once because of a new indication or different manufacturer, only the first submission was included (e.g., tramadol).

Analysis

New drugs approved in the pre-CDR and post-CDR were classified according to their World Health Organization Anatomical Therapeutic and Chemical Classification (WHO 2009) and their AHWDBL status. Drugs with a completed CDR recommendation before May 27, 2009, were tabulated in order of calendar date of CEDAC recommendation. The proportions of new drugs according to coverage status (full benefit, restricted/special authorization and not listed) were stratified by study period and compared using chi-squared tests.

The median time from the date of Health Canada's NOC to listing on the AHWDBL was calculated for all drugs in the pre-CDR period and the post-CDR period. Median time-to-listing was the most appropriate measure of the central tendency, as opposed to the mean, owing to the skewed distribution of this variable. To further explore the notion of time-to-listing, we divided the time frames into two periods: time from NOC to CDR recommendation (i.e., federal time) and time from CDR recommendation to listing on the AHWDBL (i.e., provincial time). A Kaplan–Meier plot was used to describe the time-to-listing data, and a log-rank test was used to compare the time-to-event curves between the two study periods. Only drugs that were ultimately listed on the AHWDBL were included in the survival analysis. Kappa scores were used to measure the proportion of non-random agreement between CDR recommendations and AHWDBL status. In addition, a subgroup analysis of the change in time-to-listing between study periods was evaluated separately for drugs with full benefit status and those drugs with a restricted/special authorization status.

All analyses used two-sided hypothesis tests with an alpha level of 0.05, considered statistically significant. Analyses were performed using Stata/IC 10.1.

Results

There were 220 new drug entities identified that received an NOC between May 26, 1999, and May 27, 2009, and met the study eligibility criteria. The drug names

according to therapeutic class and study period are listed in Table 1. One hundred and eighteen (54%) drugs were identified pre-CDR's first recommendation and 102 (46%) were identified post-CDR. Alberta listed 52% (61/118) of new drug entities in the period five years pre-CDR compared to 25% (25/102) in the five years post-CDR. Table 2 shows the number of drugs that were listed, listed with a restriction and not listed in Alberta according to the study period.

TABLE 1. New drug entities according to ATC code, stratified by study period (bolded medications are listed on Alberta's government-sponsored drug plans)

	Pre-CDR (n=118)		Post-CDR (n=102)	
Therapeutic class (ATC)	**Drug**	**Date of NOC**	**Drug**	**Date of NOC**
Alimentary tract and metabolism	orlistat	03-Jun-99	laronidase	31-May-04
	rosiglitazone	21-Mar-00	rosiglitazone / glimepiride	21-Oct-04
	pioglitazone	17-Aug-00	insulin aspart / insulin aspart protamine	25-Feb-05
	sibutramine	28-Dec-00	insulin detemir	29-Sep-05
	rabeprazole	07-May-01	**insulin glulisine**	12-Apr-06
	insulin aspart	18-Jul-01	alglucosidase	14-Aug-06
	esomeprazole	17-Aug-01	idursulfase	13-Jun-07
	glimepiride	25-Jan-02	**aprepitant**	24-Aug-07
	nateglinide	13-Feb-02	sitagliptin	14-Dec-07
	insulin glargine	03-Apr-02	methylnaltrexone	28-Mar-08
	rosiglitazone / metformin	13-Feb-03		
	agalsidase beta	23-Jan-04		
	agalsidase alfa	06-Feb-04		
	miglustat	31-Mar-04		
Blood and blood-forming organs	eptifibatide	11-Jun-99	dabigatran	10-Jun-08
	tirofiban	19-Aug-99	**rivaroxaban**	15-Sep-08
	lepirudin	01-Oct-99	romiplostim	19-Feb-09
	argatroban	04-Jun-01		
	tenecteplase	17-Oct-01		
	fondaparinux	13-Jun-02		

TABLE 1. Continued

	hydroxyethylstarch	08-Jul-02		
	darbepoetin alfa	02-Aug-02		
	treprostinil	04-Oct-02		
	bivalirudin	09-Oct-02		
	drotrecogin alfa	31-Jan-03		
Cardiovascular system	**eprosartan**	07-Jul-99	**eprosartan / hydrochlorothiazide**	08-Jun-04
	telmisartan	26-Aug-99	niacin / lovastatin	31-Aug-05
	bisoprolol	08-Nov-99	amlodipine / atorvastatin	17-Nov-05
	erbesartan / hydrochlorothiazide	29-Feb-00	pravastatin / acetylsalicylic acid	07-Dec-05
	valsartan / hydrochlorothiazide	15-Mar-00	**ramipril / hydrochlorothiazide**	13-Jul-06
	ibutilide	14-Jul-00	sitaxsentan	30-May-07
	candesartan / hydrochlorothiazide	18-Jun-01	nesiritide	08-Nov-07
	telmisartan / hydrochlorothiazide	15-Aug-01	aliskiren	14-Nov-07
	bosentan	30-Nov-01	ambrisentan	20-Mar-08
	perindopril / hydrochlorothiazide	18-Oct-02	nifedipine / acetylsalicylic acid	11-Jul-08
	rosuvastatin	18-Feb-03	**olmesartan**	28-Oct-08
	ezetimibe	12-May-03	**olmesartan / hydrochlorothiazide**	21-Nov-08
			eplerenone	26-Feb-09
Dermatologicals	**clindamycin / benzoyl peroxide**	11-Dec-00		
	mequinol / tretinoin	17-Jan-01		
	eflornithine	10-May-01		
	calcipotriol / betamethasone	11-Jul-01		
	pimecrolimus	19-Mar-03		
	ciclopirox	19-Apr-04		

TABLE 1. Continued

Genito-urinary system and sex hormones	**norethisterone / estrogen**	13-Mar-00	oxybutynin	22-Jun-04
	follitropin beta	13-Jun-00	**desogestrel / ethinyl estradiol**	19-Aug-04
	cabergoline	30-Jun-00	**drospirenone / ethinyl estradiol**	10-Dec-04
	medroxyprogesterone / estrogen	16-Oct-00	choriogonadotropin alfa	16-Dec-04
	alfuzosin	21-Feb-02	lutropin alfa	24-Jun-05
	norelgestromin / ethinyl estradiol	20-Aug-02	drospirenone / ethinyl estradiol	08-Jul-05
	human menopausal gonadotrophin	02-Jul-03	**darifenacin**	14-Nov-05
	dutasteride	22-Jul-03	**trospium**	10-Jan-06
	tadalafil	17-Sep-03	solifenacin	20-Feb-06
	butoconazole	23-Dec-03		
	vardenafil	17-Mar-04		
	levonorgestrel / ethinyl estradiol	08-Apr-04		
	etonogestrel / ethinyl estradiol	11-May-04		
Systemic hormonal preparations excluding sex hormones	**glucagon**	11-Jan-01	teriparatide	03-Jun-04
	doxercalciferol	30-Apr-01	cinacalcet	09-Aug-04
	ganirelix	01-May-02	paricalcitol	31-Mar-05
	cetrorelix	13-Aug-03	pegvisomant	17-Oct-05
			lanreotide	17-Jul-06
			desmopressin	08-Sep-06
General anti-infectives for systemic use	abacavir	04-Jun-99	**voriconazole**	20-Aug-04
	fosfomycin	09-Jun-99	fosamprenavir	10-Dec-04
	zanamivir	02-Nov-99	abacavir / lamivudine	25-Jul-05
	quinopristin / dalfopristin	10-Dec-99	emtricitabine	21-Nov-05
	oseltamivir	23-Dec-99	tipranavir	21-Nov-05
	moxifloxacin	19-Oct-00	emtricitabine / tenofovir	06-Jan-06
	lopinavir	09-Mar-01	**entecavir**	16-Jun-06

TABLE 1. Continued

	linezolid	02-Apr-01	darunavir	28-Jul-06
	caspofungin	19-Jul-01	tigecycline	14-Sep-06
	zidovudine / lamivudine / abacavir	17-Oct-01	telbivudine	28-Nov-06
	valganciclovir	03-May-02	posaconazole	26-Mar-07
	palivizumab	15-May-02	micafungin	22-May-07
	tenofovir	18-Mar-03	maraviroc	21-Sep-07
	ertapenem	12-May-03	daptomycin	24-Sep-07
	telithromycin	28-May-03	efavirenz / emtricitabine / tenofovir	15-Oct-07
	enfuvirtide	14-Jul-03	anidulafungin	14-Nov-07
	adefovir	27-Aug-03	raltegravir	27-Nov-07
	atazanavir	05-Dec-03	etravirine	27-Mar-08
			ceftobiprole	26-Jun-08
Immunomodulating agents	daclizumab	04-Jan-00	**adalimumab**	24-Sep-04
	leflunomide	16-Mar-00	alefacept	06-Oct-04
	basiliximab	01-Sep-00	mycophenolate	04-Feb-05
	peginterferon alfa-2b	20-Oct-00	**efalizumab**	24-Oct-05
	etanercept	01-Dec-00	**abatacept**	29-Jun-06
	sirolimus	05-Jan-01	**natalizumab**	28-Sep-06
	infliximab	06-Jun-01	temsirolimus	21-Dec-07
	aminolevulinic acid	20-Jun-01	lenalidomide	17-Jan-08
	imatinib	19-Sep-01	ustekinumab	12-Dec-08
	anakinra	24-May-02		
	peginterferon alfa-2b / ribavirin	31-May-02		
	peginterferon alfa-2a	13-Aug-03		
	pegfilgrastim	12-Mar-04		
	peginterferon alfa-2a / ribavirin	10-May-04		
Musculo-skeletal system	**zoledronic acid**	21-Aug-00	alendronate / cholecalciferol	03-Feb-06
	meloxicam	31-Aug-00	risedronate / calcium	17-May-06
Nervous system	**rizatriptan**	16-Jul-99	eletriptan	05-Aug-04

TABLE 1. Continued

	oxcarbazepine	13-Apr-00	frovatriptan	03-Sep-04
	rivastigmine	13-Apr-00	memantine	08-Dec-04
	riluzole	30-Aug-00	atomoxetine	24-Dec-04
	entacapone	08-May-01	escitalopram	24-Dec-04
	mirtazapine	18-May-01	delta-9-tetrahydrocannabinol / cannabidiol	15-Apr-05
	methadone	30-Jul-01	pregabalin	03-Jun-05
	galantamine	31-Jul-01	tramadol / acetaminophen	20-Jul-05
	levetiracetam	06-Mar-03	sodium oxybate	05-Aug-05
	almotriptan	29-Sep-03	rasagiline	17-Aug-06
	mixed amphetamine salts	23-Jan-04	tramadol	28-Sep-06
			varenicline	24-Jan-07
			acamprosate	16-Mar-07
			buprenorphine / naloxone	18-May-07
			ziprasidone	27-Aug-07
			paliperidone	26-Sep-07
			duloxetine	01-Nov-07
			carbidopa / levodopa / entacapone	18-Feb-08
			idebenone	23-Jul-08
			desvenlafaxine	04-Feb-09
Respiratory system	**salmeterol / fluticasone**	03-Sep-99	omalizumab	18-Nov-04
	formoterol / budesonide	08-Feb-02	nitric oxide	23-Sep-05
	tiotropium bromide	20-Nov-02	**ciclesonide**	11-Sep-06
			fluticasone	14-Aug-07
Sensory organs	verteporfin	31-May-00	pegaptanib	02-May-05
	travoprost	09-Nov-01	**travoprost / timolol**	17-Mar-06
	bimatoprost	24-May-02	ranibizumab	26-Jun-07
	latanoprost / timolol	15-Oct-02	nepafenac	17-Apr-08
	brimonidine / timolol	09-Dec-03		
	ciprofloxacin / dexamethasone	10-May-04		

TABLE 1. Continued

Various	sevelamer	24-Feb-00	palifermin	09-Dec-05
	fomepizole	30-Nov-00	lanthanum	17-Oct-06
	thyrotrophin	31-May-02	**deferasirox**	18-Oct-06
	rasburicase	29-Oct-03		

TABLE 2. Summary of new drug entity coverage in Alberta, stratified by 5 years pre-CDR and 5 years post-CDR

Variable	Pre-CDR n (%)	Post-CDR n (%)
Number of drugs listed or not listed		
Listed	61 (51%)	25 (25%)
Full benefit	24 (20%)	14 (14%)
Restricted	37 (31%)	11 (11%)
Not listed	57 (48%)	77 (75%)
Time from NOC to listing (n=86)		
Median (days)	312	524
Range (days)	106–2,821	198–1,450
Average (days)	551	581
Full benefit (n=38)		
Median (days)	296	544
Range (days)	133–2,821	202–1,450
Average (days)	527	607
Restricted (n=48)		
Median (days)	353	440
Range (days)	106–2,297	198–1,007
Average (days)	567	548
Time from NOC to listing for drugs listed with a CDR recommendation (n=24)		
Median (days)	n/a	482
Range (days)	n/a	198–1,450
Average (days)	n/a	569

TABLE 2. Continued

Time from NOC decision to CDR recommendation for listed drugs (n=24)		
Median (days)	n/a	239
Range (days)	n/a	93–1,249
Average (days)	n/a	356
Time from NOC decision to CDR recommendation for non-listed drugs (n=49)		
Median (days)	n/a	278
Range (days)	n/a	135–1,272
Average (days)	n/a	356
Time from CDR decision to listing (n=24)		
Median (days)	n/a	167
Range (days)	n/a	15–677
Average (days)	n/a	213

The CDR provided 133 drug coverage recommendations as of May 27, 2009; 73 of these reviews met our eligibility criteria (Table 3). We excluded 39 of the 133 drugs for the following reasons: duplicate generics (n=26); neoplastic agents (n=7); market withdrawal (n=1); manufacturer change or formulation change (n=5). A further 21 drugs were excluded because they were issued an NOC prior to CDR's first recommendation (May 27, 2004); thus, the manufacturers may have submitted an application to be listed directly to Alberta Health and Wellness. Of the 73 drugs that received an NOC in the post-CDR period and were used in the analysis, CEDAC recommend 41 of these to be listed on the participating public drug plans: four recommended to "list," nine recommended to "list in a similar manner to other drugs in class" and 28 recommended to "list with criteria/condition." Table 4 shows the frequency of drugs in each coverage classification for the province of Alberta by CDR recommendation.

There were 41 drugs recommended to be listed in some manner by the CDR, of which 24 (59%) were approved for listing on the AHWDBL. All drugs that received a "do not list" recommendation from the CDR were not listed on the AHWDBL (32/32). The kappa score was 0.55 when CDR recommendations were classified as "to list" (regardless of criteria) or "not to list," and drugs on the AHWDBL were classified as "listed" (with or without criteria) or "not listed." This level of agreement between CDR recommendations and AHWDBL would be considered fair to good (Fleiss 1981).

The median time-to-listing from NOC issue was 312 days (n=61; interquartile range [IQR] = 219 to 588 days) in the pre-CDR period (average 551 days; min. 106

TABLE 3. CDR recommendations of study drugs in order of calendar date of recommendation until May 27, 2009 (n=73)

Drugs reviewed		Date of NOC	Date of recommendation	CDR recommendation
Generic name	**Brand name**			
eprosartan / hydrochlorothiazide	Teveten Plus	08-Jun-04	15-Dec-04	List in a similar manner to other drugs in class
teriparatide	Forteo	03-Jun-04	22-Dec-04	Do not list
adalimumab	Humira	24-Sep-04	11-Feb-05	List with criteria/condition
cinacalcet	Sensipar	09-Aug-04	23-Mar-05	Do not list
eletriptan	Relpax	05-Aug-04	23-Mar-05	Do not list
voriconazole	Vfend	20-Aug-04	14-Apr-05	List with criteria/condition
fosamprenavir	Telzir	10-Dec-04	16-Jun-05	List in a similar manner to other drugs in class
drospirenone / ethinyl estradiol	Yasmin	10-Dec-04	16-Jun-05	List
mycophenolate	Myfortic	04-Feb-05	08-Jul-05	List in a similar manner to other drugs in class
laronidase	Aldurazyme	31-May-04	14-Jul-05	Do not list
atomoxetine	Strattera	24-Dec-04	28-Sep-05	Do not list
memantine	Ebixa	08-Dec-04	23-Nov-05	Do not list
abacavir / lamivudine	Kivexa	25-Jul-05	07-Dec-05	List in a similar manner to other drugs in class
pregabalin	Lyrica	03-Jun-05	25-Jan-06	Do not list
omalizumab	Xolair	18-Nov-04	07-Mar-06	Do not list
niacin / lovastatin	Advicor	31-Aug-05	26-Apr-06	List
insulin aspart / insulin aspart protamine	Novomix	25-Feb-05	26-Apr-06	Do not list
tipranavir	Aptivus	21-Nov-05	17-May-06	List with criteria/condition
amlodipine / atorvastatin	Caduet	17-Nov-05	17-May-06	List with criteria/condition
pegaptanib	Macugen	02-May-05	25-May-06	Do not list
insulin detemir	Levemir	29-Sep-05	02-Aug-06	Do not list
pegvisomant	Somavert	17-Oct-05	02-Aug-06	Do not list
travoprost / timolol	Duotrav	17-Mar-06	24-Aug-06	List with criteria/condition
efalizumab	Raptiva	24-Oct-05	24-Aug-06	List with criteria/condition
trospium	Trosec	10-Jan-06	24-Aug-06	List with criteria/condition

TABLE 3. Continued

alefacept	Amevive	06-Oct-04	27-Sep-06	Do not list
alendronate / cholecalciferol	Fosavance	03-Feb-06	27-Sep-06	Do not list
ciclesonide	Alvesco	11-Sep-06	20-Dec-06	List
escitalopram	Cipralex	24-Dec-04	24-Jan-07	Do not list
solifenacin	Vesicare	20-Feb-06	24-Jan-07	Do not list
darunavir	Prezista	28-Jul-06	14-Feb-07	List with criteria/condition
rasagiline	Azilect	17-Aug-06	28-Mar-07	Do not list
deferasirox	Exjade	18-Oct-06	19-Apr-07	List with criteria/condition
tramadol / acetaminophen	Tramacet	20-Jul-05	17-May-07	Do not list
ramipril / hydrochlorothiazide	Altace	13-Jul-06	14-Jun-07	List
alglucosidase	Myozyme	14-Aug-06	14-Jun-07	List with criteria/condition
abatacept	Orencia	29-Jun-06	27-Jun-07	List with criteria/condition
lanreotide	Somatuline	17-Jul-06	19-Jul-07	List in a similar manner to other drugs in class
varenicline	Champix	24-Jan-07	16-Aug-07	List with criteria/condition
tramadol	Zytram	28-Sep-06	26-Sep-07	Do not list
delta-9-tetrahydrocannabinol / cannabidiol	Sativex	15-Apr-05	26-Sep-07	Do not list
telbivudine	Sebivo	28-Nov-06	26-Sep-07	Do not list
entecavir	Baraclude	16-Jun-06	28-Nov-07	List with criteria/condition
idursulfase	Elaprase	13-Jun-07	19-Dec-07	Do not list
posaconazole	Posanol	26-Mar-07	30-Jan-08	Do not list
lanthanum	Fosrenol	17-Oct-06	30-Jan-08	Do not list
aprepitant	Emend	24-Aug-07	20-Feb-08	List with criteria/condition
ranibizumab	Lucentis	26-Jun-07	27-Mar-08	List with criteria/condition
acamprosate	Campral	16-Mar-07	27-Mar-08	List with criteria/condition
efavirenz / emtricitabine / tenofovir	Atripla	15-Oct-07	17-Apr-08	List with criteria/condition
raltegravir	Isentress	27-Nov-07	14-May-08	List with criteria/condition
paliperidone	Invega	26-Sep-07	28-May-08	Do not list
sitagliptin	Januvia	14-Dec-07	18-Jun-08	Do not list

TABLE 3. Continued

aliskiren	Rasilez	14-Nov-07	25-Jun-08	Do not list
etravirine	Intelence	27-Mar-08	14-Aug-08	List with criteria/condition
duloxetine	Cymbalta	01-Nov-07	14-Aug-08	List with criteria/condition
ziprasidone	Zeldox	27-Aug-07	14-Aug-08	List with criteria/condition
buprenorphine / naloxone	Suboxone	18-May-07	24-Sep-08	List with criteria/condition
daptomycin	Cubicin	24-Sep-07	24-Sep-08	Do not list
carbidopa / levodopa / entacapone	Stalevo	18-Feb-08	16-Oct-08	List in a similar manner to other drugs in class
maraviroc	Celsentri	21-Sep-07	12-Nov-08	List with criteria/condition
ambrisentan	Volibris	20-Mar-08	17-Dec-08	List with criteria/condition
emtricitabine / tenofovir	Truvada	06-Jan-06	17-Dec-08	List with criteria/condition
rivaroxaban	Xarelto	15-Sep-08	17-Dec-08	List with criteria/condition
methylnaltrexone	Relistor	28-Mar-08	28-Jan-09	Do not list
dabigatran	Pradax	10-Jun-08	28-Jan-09	Do not list
sodium oxybate	Xyrem	05-Aug-05	28-Jan-09	Do not list
sitaxsentan	Thelin	30-May-07	28-Jan-09	Do not list
insulin glulisine	Apidra	12-Apr-06	19-Feb-09	List in a similar manner to other drugs in class
natalizumab	Tysabri	28-Sep-06	25-Feb-09	List with criteria/condition
darifenacin	Enablex	14-Nov-05	16-Apr-09	List with criteria/condition
olmesartan / hydrochlorothiazide	Olmetec Plus	21-Nov-08	27-May-09	List in a similar manner to other drugs in class
olmesartan	Olmetec	28-Oct-08	27-May-09	List in a similar manner to other drugs in class

days; max. 2,821 days) and 524 days (n=25; IQR=315 to 700 days) in the post-CDR period (average 581 days; min. 198 days; max. 1,450 days) (Table 2 and Figure 2). Figure 2 illustrates the increase in time-to-listing for drugs issued an NOC post-CDR implementation. There are noticeably fewer outliers in the post-CDR period. The Kaplan–Meier plot provides a comparison between the pre-CDR and post-CDR periods, and a log-rank test failed to demonstrate a statistically significant difference between the two periods (p value = 0.53) (Figure 3). Among drugs that received full

benefit status, the median time-to-listing was 248 days longer following the implementation of the CDR process (period 1: n=24; median=296; IQR=206 to 580 and period 2: n=14; median = 544; IQR=314 to 700). The median time-to-listing for drugs that were listed as restricted or available via special authorization was 87 days longer (period 1: n=37; median=353; IQR=236 to 588 and period 2: n=11; median=440; IQR=315 to 825).

TABLE 4. Alberta Health and Wellness coverage, stratified by CDR recommendation

	Alberta drug benefit status			
CDR recommendation	**Full benefit**	**Restricted/Special authorization**	**Not listed**	**Total**
List	3 (75%)	0	1 (25%)	4
List in a similar manner	5 (56%)	1 (11%)	3 (33%)	9
List with criteria/condition	5 (18%)	10 (36%)	13 (46%)	28
Do not list	0	0	32 (100%)	32
Total	13	11	49	73

* Chi-squared test, p value < 0.001

FIGURE 2. Distribution of time-to-listing for drugs covered in Alberta, 1999–2009

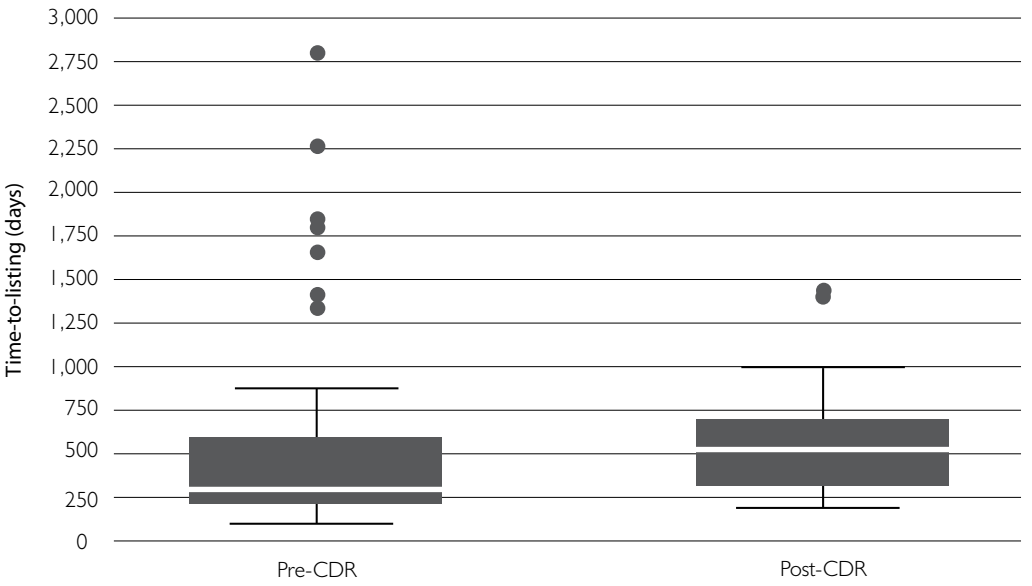


FIGURE 3. Kaplan–Meier plot of time-to-listing for new drug entities between pre-CDR and post-CDR periods

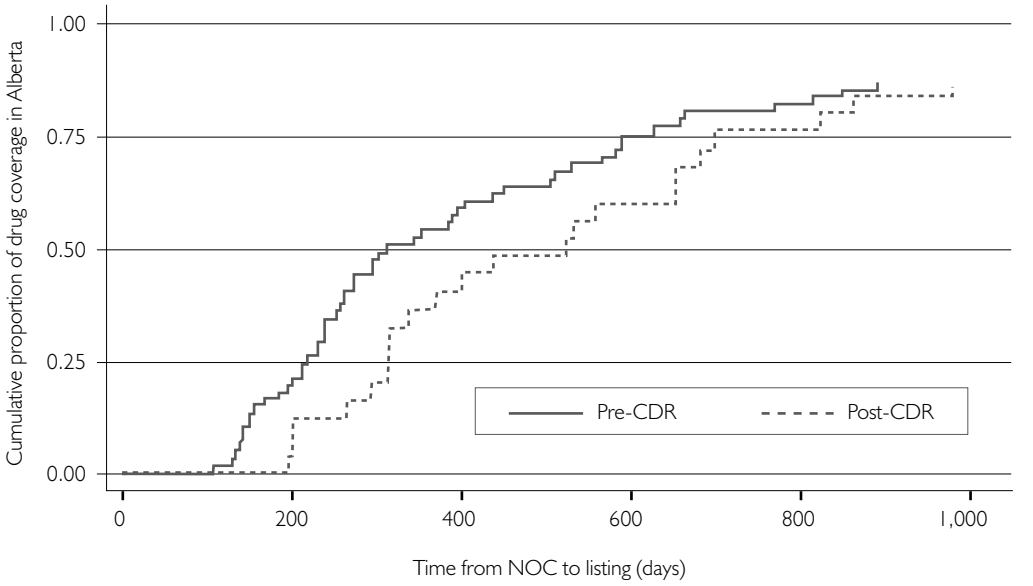


Table 2 provides the median, mean and ranges for time-to-listing for drugs with a CDR recommendation broken into two time frames: time from NOC to CDR recommendation, and time from CDR recommendation to listing on the AHWDBL. The median time from NOC to CDR recommendation was 275 days (mean: 356 days) for all 73 drugs with a CDR recommendation. To explore the potential time delay responsible for the increase in time-to-listing post-CDR, we compared the median time-to-listing for the 24 drugs listed with a CDR recommendation. The median time from NOC to CDR recommendation was 72 days longer than the median time from CDR recommendation to listing. On average, for drugs listed on the AHWDBL, the proportion of time attributable to the CDR process (NOC to CDR recommendation) was 63% (356 days of 569) of the overall time-to-listing.

Discussion

Main findings

The implementation of the CDR, intended to streamline the process of drug reimbursement by public drug plans, was associated with an increased median time-to-listing in the province of Alberta. In the five years following the CDR's first recommendation, the median time from Health Canada's issuing an NOC to drug approval in Alberta was 212 days longer compared to the five-year period prior to the CDR's first recommendation. Notably, however, the majority of the time between NOC and listing was spent between the NOC's being issued and the CDR recommendation.

This finding suggests that the CDR may provide a more efficient system for province-level decision-making, as opposed to the overall timeline of listing of drugs. In fact, the median and average time-to-listing prior to CDR (from NOC to listing) was 312 and 551 days, respectively, whereas post-CDR the median and mean time-to-listing from CDR recommendation to listing was 167 and 213 days, respectively.

The implications of this finding on the health of the population and individuals are context-specific and dependent on the risks and benefits of each drug and, subsequently, the use (whether appropriate or inappropriate) of each drug. This difference represents more than a six-month time frame, which may represent a substantial amount of time from the drug manufacturer's perspective; however, efficiencies for the payer, in this case Alberta Health and Wellness, may have been gained.

Alberta's drug review process

Currently, there are five separate government ministries that administer government-sponsored drug plans in Alberta: Health and Wellness, Children and Youth Services, Employment and Immigration, Seniors and Community Supports, and Solicitor General and Public Security. Each of these ministries administers its own drug programs for which different rules and eligibility apply; however, the AHWDBL serves as a common core list for each of the programs. Many of the programs cover drugs that are not listed on the AHWDBL, for example, hospitalized patients, cancer patients and transplant patients.

The drug review process in Alberta is outlined within the publicly available Alberta Health and Wellness Drug Benefit List (Government of Alberta 2010b). The AHWDBL was implemented in 1991, lists over 3,600 drugs and is currently updated on a quarterly basis. The Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics (ECDET), comprising physicians and pharmacists, recommends listing decisions for drugs to Alberta Health and Wellness through the Executive Director of the Pharmaceutical Funding and Guidance Branch. The Minister of Health and Wellness is responsible for the final listing decision. The ECDET considers both clinical and economic evidence for its recommendations. The AHWDBL lists general criteria that the ECDET and the minister are to consider prior to making a recommendation or listing decision; however, the criteria are not rigid and permit flexibility depending on the situation. Hospital-based drugs, childhood vaccinations, cancer agents, tuberculosis agents and drugs used to treat erectile dysfunction are not considered for coverage under the AHWDBL. The AHWDBL lists a drug as a regular benefit, special authorization benefit, optional special authorization, step therapy, restricted benefit or limited restricted benefit. Special authorization guidelines are available for each drug product that assist in determining coverage eligibility. These requests can be made by prescribers and are reviewed by clinical pharmacists, analysts or both.

Restricted benefits refer to drugs that have restricted coverage criteria that are automatically adjudicated (i.e., a person is not required to be screened).

In the July 1, 2004 AHWDBL, the CDR process was integrated into Alberta's drug review procedure. Introduction of the CDR affected several components of Alberta's drug review process. Firstly, for both new chemical entities and new combination products, drug manufacturers no longer initiated the drug review process at the provincial level. Instead, they were required to submit drugs that fell under the CDR mandate directly to the CDR. Second, the ECDET is provided with recommendations regarding listing status from CEDAC. If the recommendation is not to list, the drug is not reviewed by the ECDET; the ECDET is simply informed of the decision. Our study supports this notion, as 32 drugs with a "do not list" recommendation from CDR were not listed on the AHWDBL. If the CDR recommends a product to be listed, listed in a similar manner to other drugs in class, or listed with criteria/condition, the ECDET is usually (a small number of products with a "yes" recommendation with no criteria/conditions have not been additionally reviewed by the ECDET) provided with a summary and complete clinical and pharmaco-economic review report from the CDR. In addition, the ECDET considers a review of provincial economic considerations (pricing, utilization and budget impact) for drugs for which CDR makes recommendations.

Notwithstanding changes due to the CDR process, normal changes in the policy environment (elected and unelected AHW personnel) and changes to the ECDET's committee membership, the drug review process in Alberta remained similar before and after the CDR was introduced. Major reforms to the drug review process are currently being implemented through the Alberta Pharmaceutical Strategy, although these changes did not occur during this study period (Government of Alberta 2010a).

Comparison to previous reports on time-to-listing

We are aware of three previous reports that have commented on provincial drug reimbursement decisions, time-to-listing post-CDR implementation or both (Kallah 2006; Skinner and Rovere 2009; Wyatt et al. 2008).

An IMS Health report, *Provincial Reimbursement Advisor* (Kallah 2006) calculated the average time-to-listing of all drugs that had completed a CDR review as of October 20, 2006. Alberta had listed 10 of 22 drugs reviewed, with an average time-to-listing of 413 days. Because the IMS report used single-source products only and included alternative formulations of similar products, the number of listings is not directly comparable to our analysis. The report also showed an average historical time-to-listing of 406 days for Alberta, which was defined as the average time-to-listing for drugs approved between September 1, 2000, and August 31, 2003 (i.e., a two-year period prior to the CDR). Based on this report, Tierney and Manns (2008) found that the time-to-listing of drugs had not changed from before the CDR compared to after

its implementation (471 vs. 479 days). This finding is misleading because there was substantial variability among average times-to-listing across provinces (Kallah 2006). Among participating drug plans in the CDR process, the minimum time-to-listing was 372 days (Nova Scotia) and the maximum was 753 days (PEI) post-CDR (Kallah 2006). There was also a wide range in the time-to-listing changes among different drug plans, with Ontario's time-to-listing decreasing by 85 days but non-insured health benefits (NIHB) time-to-listing increasing by 173 days (Kallah 2006). Although the data presented in the IMS *Provincial Reimbursement Advisor* (Kallah 2006) describe time-to-listing for public drug plans participating in the CDR and compare the time-to-listing before and after CDR's implementation, there were no formal statistical comparisons. Our study demonstrates a six-month difference and one-month difference in median and mean time-to-listing for one participating drug plan – Alberta's.

A report published by Wyatt Health (Wyatt et al. 2008) compared provincial drug reimbursement decisions and those of other countries for drugs issued a CEDAC recommendation as of December 31, 2007. Of 78 different drugs with a recommendation, 36 drugs were included in Wyatt's comparisons because they were common among all countries. These authors reported that provincial drug plans made positive decisions 49% of the time and contrasted this with CEDAC's recommending reimbursement for 61% of the 36 drugs and 14 EU countries' averaging a 91% reimbursement. We found that Alberta listed 24 (58%) drugs for which CEDAC recommended reimbursement.

The third annual report by the Fraser Institute (Skinner and Rovere 2009) examining wait times for access to medications at both the federal and provincial levels provides information regarding the proportion of drugs reimbursed in Alberta from 2004–2007 that received an NDS-class NOC from Health Canada. The report found that out of 174 NOCs issued for NDS-class drugs, 20 (11.5%) were approved in Alberta. Within this time period (2004–2007), we identified 24 drugs approved of 96 (25% approval rate) deemed eligible for our study. Our approval rate is expected to be somewhat higher, as we did not limit our comparison to NDS-class drugs. Skinner and Rovere (2009) also report time-to-listing for new drugs approved by Health Canada separately for 2004 through 2007. There appears to be a wide variation between the years for Alberta, ranging from approximately 250 days in 2007 to over 600 days in 2005. Our average time-to-listing for drugs receiving an NOC between 2004 and 2007 followed a similar pattern, with 2005 having the longest time-to-listing.

Clinical and policy implications

In order to define what constitutes a meaningful difference in terms of time-to-listing, one must consider the clinical perspective as well as the population health perspective. A meaningful difference from a clinical perspective depends on individuals having access to new drug products that may be of benefit or harm to their health. For certain

individuals who have tried the currently available therapies and cannot afford more expensive innovative therapies, any amount of time may be important, especially for symptomatic treatment. Conversely, a rapid increase in the use of a drug (potentially as a consequence from a listing decision) may be associated with harm, as was the case in Ontario, which had a more liberal drug policy compared to British Columbia when COX-2 inhibitors were introduced to the market. Consequently, Ontario experienced a larger increase in the hospitalization rate for upper gastrointestinal haemorrhage compared to British Columbia (Mamdani et al. 2006).

From a population health perspective, one must consider the nature of the drug and prevalence of its indicated use within the population. For example, a drug that is expected to be used by <1% of the population will not have as large an impact on health outcomes compared to a drug of equal effectiveness for conditions with a higher prevalence (i.e., >10%). Further, the degree to which newly marketed drugs are truly considered to be "innovative" should also be considered. New products that are "me-toos" or fixed-dose combinations or previously listed products may have less of an impact than new products that truly represent therapeutic breakthroughs.

For each drug that the CDR recommends, there is often a specific indication associated with the recommendation. This practice has policy implications for the province of Alberta, because when a drug is given full-benefit status no specific indication is attached. The drug may be listed under special authority to address an indication's specific requirements, although this depends on the nature of the drug, particularly if it is indicated for both acute and chronic requirements; a special authority policy may have a negative impact on the population's health (Jackevicius et al. 2008).

Under current pharmaceutical policy reforms, Alberta is Canada's first province with a government-sponsored drug plan for rare diseases, which came into effect on April 1, 2009. Diseases for which treatment coverage will be considered include Gaucher's disease, Fabry's disease, MPS I (Hurler's/Hurler Scheie syndrome), Hunter's syndrome and Pompe's disease. The CDR has made recommendations for listing regarding drugs used to treat some of these diseases, such as alglusidase (Pompe), agalsidase beta (Fabry) and idursulfase (Hunter). For this class of medications, it is especially difficult to make listing decisions using the same framework and standards regarding clinical and economic evidence as drugs used for more prevalent conditions.

Limitations

Several limitations of our study must be addressed. First, our measurement of time-to-listing started when a drug was issued an NOC, which may not accurately reflect time-to-listing because a time lag occurs between time of NOC and submission for reimbursement. Second, it was not possible to discern which drugs Alberta Health and Wellness reviewed and subsequently declined. Thus, drugs that were not listed

include both those that were reviewed as well as those not reviewed. Third, drugs may not be reviewed because a manufacturer may decide not to submit its product for coverage, especially for medications that belong to a class of drugs that is pre-specified not to be covered (e.g., hospital-based drugs or drugs used for erectile dysfunction). Fourth, the difference between median time-to-listing in the pre-CDR and post-CDR periods may be exaggerated owing to delays for drugs with an NOC issued around the time of CDR implementation, most likely because of institutional procedural adjustments and adaptations. When drugs issued an NOC in 2005 are excluded, our results are consistent (pre-CDR median 312 days vs. post-CDR median 440 days). Lastly, unknown changes in the drug review process, government personnel changeover and secular changes, such as the types of drugs receiving marketing approval, may have influenced the results of our study.

Conclusions

The CDR has been completing drug reviews and recommendations for Canada's publicly funded drug plans for over five years now. Although Alberta's government-funded drug plan is a participating drug plan, it does not always follow the CDR's recommendations. The overall agreement in the first five years of CDR recommendation was fair to good (kappa= 0.55); the time to drug coverage slowed significantly (median time is 212 days longer), although it is more consistent. Moreover, the CDR may act as a catalyst and speed up the decisions for reimbursement at the provincial level. Whether similar results would be observed in other provinces and territories, or only in select parts of the country, remains to be demonstrated in the peer-reviewed literature.

ACKNOWLEDGEMENTS

Mr. Gamble receives salary support through a full-time Health Research Studentship from the Alberta Heritage Foundation for Medical Research Endowment fund and a Canada Graduate Scholarship from the Canadian Institutes of Health Research (CIHR); Dr. Eurich is a population health investigator with Alberta Innovates – Health Solutions and a New Investigator with the CIHR. Dr. Johnson is a senior health scholar with Alberta Innovates – Health Solutions and Canada Research Chair in Diabetes Health Outcomes.

The authors would like to thank Mr. Steve Long, Ms. Mary Jo Macleay and Dr. Carlyn Volume-Smith for their assistance in gathering background information for this manuscript.

Dr. Johnson is a member of the Expert Committee for Drug Evaluation and Therapeutics for Alberta Health and Wellness. The opinions expressed in this manuscript are his and not those of AHW or the ECDET.

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Appendices

Legend

CDR recommendations:
Y=List
S=List in a similar manner to other drugs in class
R=List with criteria/condition
N=Not list

Alberta Coverage Status:

Y=Listed as a full benefit
R=Listed with restriction/special authorization
N=Not listed

APPENDIX 1. Drugs that were not listed in Alberta and were recommended to be listed by the CDR (n=17)

Generic name	Brand name	AB coverage status	CDR recommendation
abacavir / lamivudine	Kivexa	N	S
acamprosate	Campral	N	R
alglucosidase alfa	Myozyme	N	R
ambrisentan	Volibris	N	R
atorvastatin / amlodipine	Caduet	N	R
darunavir	Prezista	N	R
emtricitabine / tenofovir / efavirenz	Atripla	N	R
emtricitabine / tenofovir	Truvada	N	R
etravirine	Intelence	N	R
fosamprenavir	Telzir	N	S
maraviroc	Celsentri	N	R
mycophenolic acid	Myfortic	N	S
niacin / lovastatin	Advicor	N	Y
raltegravir	Isentress	N	R
ranibizumab	Lucentis	N	R
tipranavir	Aptivus	N	R
varenicline*	Champix	N	R

* Under review as of April 2010

APPENDIX 2. Drugs that were listed in Alberta and recommended to be listed by the CDR (n=24)

Generic name	Brand name	AB coverage status	CDR recommendation
abatacept	Orencia	R	R
adalimumab	Humira	R	R
aprepitant	Emend	R	R
buprenorphine / naloxone	Suboxone	Y	R
carbidopa / levodopa / entacapone	Stalevo	Y	S
ciclesonide	Alvesco	Y	Y
darifenacin	Enablex	R	R

APPENDIX 2. Continued

deferasirox	Exjade	R	R
drospirenone / esthinyl estradiol	Yasmin	Y	Y
duloxetine	Cymbalta	R	R
efalizumab	Raptiva	R	R
entecavir	Baraclude	R	R
eprosartan / hydrochlorothiazide	Teveten Plus	Y	S
insulin glulisine	Apidra	Y	S
lanreotide	Somatuline	R	S
natalizumab	Tysabri	R	R
olmesartan	Olmetec	Y	S
olmesartan / hydrochlorothiazide	Olmetec Plus	Y	S
ramipril / hydrochlorothiazide	Altace-HCT	Y	Y
rivaroxaban	Xarelto	R	R
travoprost / timolol	Duo Trav	Y	R
trospium	Trosec	R	R
voriconazole	Vfend	R	R
ziprasidone	Zeldox	Y	R

APPENDIX 3. Drugs that were not listed in Alberta and were not recommended to be listed by the CDR (n=32)

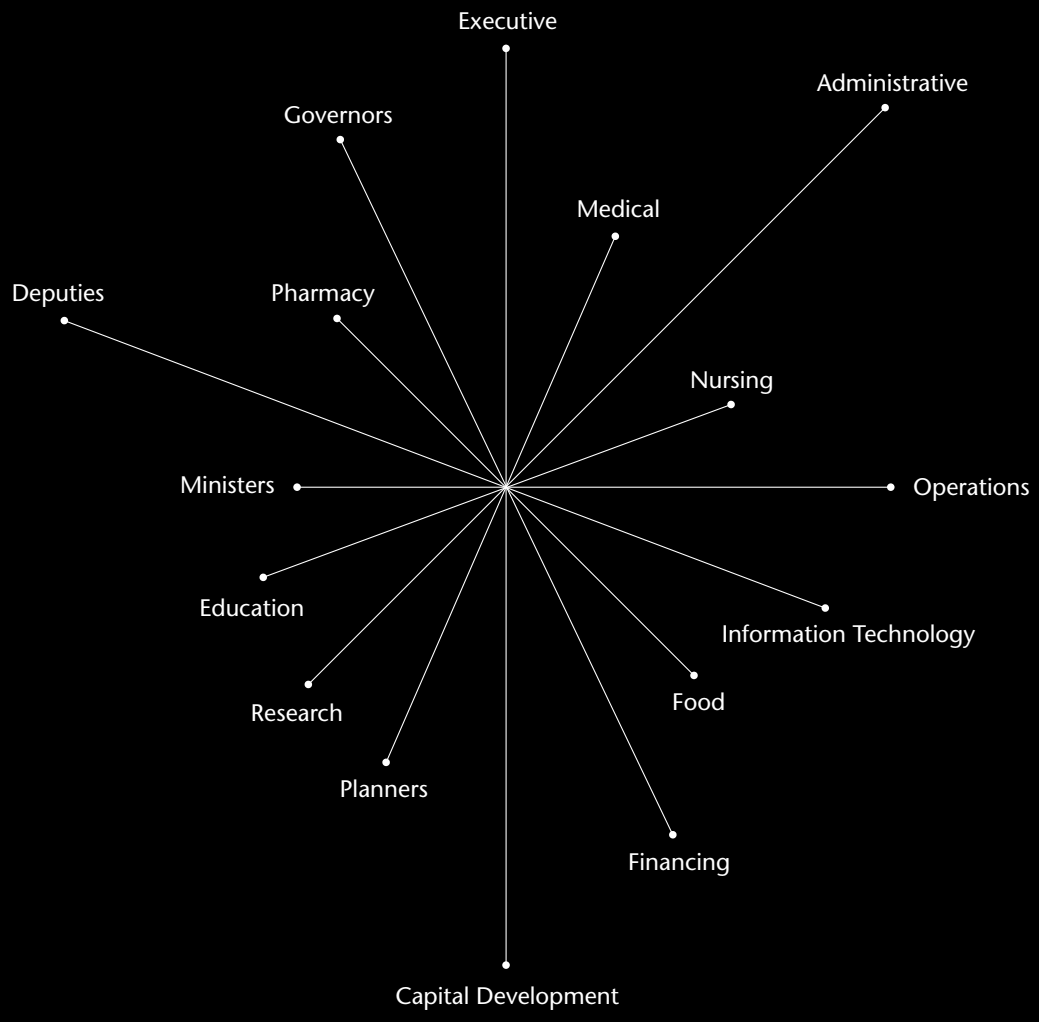
Generic name	Brand name	AB coverage status	CDR recommendation
alefacept	Amevive	N	N
alendronate / cholecalciferol	Fosavance	N	N
aliskiren	Rasilez	N	N
atomoxetine	Strattera	N	N
cinacalcet	Sensipar	N	N
dabigatran	Pradax	N	N
daptomycin	Cubicin	N	N
delta-9-tetrahydrocannabinol / cannabidiol	Sativex	N	N
eletriptan	Relpax	N	N
escitalopram	Cipralex	N	N

APPENDIX 3. Continued

idursulfase	Elaprase	N	N
insulin aspart / protamine	Novomix	N	N
insulin detemir	Levemir	N	N
lanthanum carbonate	Fosrenol	N	N
laronidase	Aldurazyme	N	N
memantine	Ebixa	N	N
methylnaltrexone	Relistor	N	N
omalizumab	Xolair	N	N
paliperidone	Invega	N	N
pegaptanib	Macugen	N	N
pegvisomant	Somavert	N	N
posaconazole	Posanol	N	N
pregabalin	Lyrica	N	N
rasagiline	Azilect	N	N
sitagliptin	Januvia	N	N
sitaxsentan	Thelin	N	N
sodium oxybate	Xyrem	N	N
solifenacin	Vesicare	N	N
telbivudine	Sebivo	N	N
teriparatide	Forteo	N	N
tramadol	Zytram	N	N
tramadol / acetaminophen	Tramacet	N	N

Networking*

One on One



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