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Services de santé, gestion et recherche de politique

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HEALTHCARE
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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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Politiques de Santé/Healthcare Policy 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 *Politiques de Santé/Healthcare Policy* 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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EDITORIAL

The Rewards of Volunteering

Whichever perspective you take on the "if a tree falls in the forest" question, it is certainly true that the easier a journal is to search and access, the more its content is likely to influence thinking, research and policy. With this in mind, I am happy to announce that the National Library of Medicine (NLM) recently decided to index *Healthcare Policy/Politiques de Santé* in its Medline database.

While the journal has been indexed in the Library's PubMed Central – and CINAHL, CSA (Cambridge), Ulrich's, Embase, IndexCopernicus and Scopus, and is a partner of HINARI – for some time, this decision marks a step change in the ability to search for and access key information from the journal's articles. Citations from indexed articles, the Medical Subject Heading terms used by NLM staff to index the articles and the articles' abstracts will now be searchable in Medline. This will be true of past papers as well as future ones, as the NLM retrospectively adds previous issues of the journal to its database.

Our ability to achieve this milestone is due, in large part, to the work of our strong team of volunteer editors and peer reviewers. Central to the process are the journal's editors (see page 6) who guide the path of papers through all stages of the review and publication process. I would particularly like to thank Dr. Pat Martens, who has recently concluded her role as the journal's Data Matters editor. Throughout her tenure, her insightful and helpful contributions have been much appreciated by authors, reviewers and colleagues on the editorial panel alike.

Thanks are also due to our peer reviewers. We depend on their breadth of expertise, thoughtful comments and guidance, and generous contributions to improving research and policy debate to ensure the quality and relevance of the papers that we publish in the journal's pages. This year's issues had a broader range of reviewers than ever before, including experts from around the world (see page 100). I would like to take this opportunity to thank them all for their essential assistance.

Would you consider becoming a reviewer to help advance scholarship and evidence-informed discussion in health policy? If so, please register for our database of potential reviewers at http://www.longwoods.com/reviewer-registration/healthcare-policy. This tool helps our editors to match papers that we send out for comment with the expertise and interests of reviewers.

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

ÉDITORIAL

Les bienfaits du bénévolat

Peu importe l'angle que l'on prend pour étudier la question « si un arbre tombe au milieu d'une forêt », il ne fait pas de doute que plus on facilite l'accès à une revue, plus son contenu est susceptible d'influencer la réflexion, la recherche ou les politiques. C'est pourquoi je suis ravie d'annoncer que la National Library of Medicine (NLM) a récemment indexé *Politiques de Santé/Healthcare Policy* dans sa base de données Medline.

Bien que la revue soit indexée au PubMed Central de la NLM depuis quelque temps – ainsi qu'aux bases de données CINAHL, CSA (Cambridge), Ulrich's, Embase, IndexCopernicus et Scopus, tout en étant partenaire de HINARI –, cette décision marque une étape décisive dans les possibilités de recherche et d'accès aux informations des articles de la revue. Les citations des articles indexés, les descripteurs médicaux employés par le personnel de la NLM pour indexer les articles et les résumés seront tous accessibles sur Medline. Et cela pour les anciens articles comme pour ceux à venir, puisque la NLM inclura aussi à sa base de données les anciens numéros de la revue.

Cette étape a été franchie grâce, en grande partie, au travail de notre excellente équipe d'éditeurs et de pairs réviseurs. Les éditeurs de la revue (voir page 6) sont essentiels à ce processus, en menant les articles à travers toutes les étapes de révision et de publication. J'aimerais remercier particulièrement Pat Martens qui vient de terminer son mandat à titre d'éditrice de la section Questions de données. Au cours de son mandat, son précieux apport a été très apprécié des auteurs, des réviseurs et des collègues de l'équipe de rédaction.

Nous tenons également à remercier les pairs réviseurs. La qualité et la pertinence des articles de la revue dépendent de l'étendue de leur expertise, de leurs commentaires éclairés et de leurs généreuses contributions à l'avancement des débats de recherche et de politiques. Nous avons, cette année, plus de réviseurs que jamais, y compris des réviseurs provenant de l'étranger (voir page 100). J'aimerais profiter de cette occasion pour les remercier tous et toutes.

Êtes-vous intéressé à devenir réviseur et à faire progresser la science et les débats éclairés par les données probantes? Si c'est le cas, je vous prie de bien vouloir vous inscrire à la base de données des réviseurs potentiels à http://www.longwoods.com/reviewer-registration/healthcare-policy. Cet outil aide nos éditeurs à jumeler les articles à l'expertise et aux intérêts des réviseurs.

JENNIFER ZELMER, BSC, MA, PHD
Rédactrice en chef

"It Doesn't Have to Be This Way"

« Ça ne doit pas être nécessairement de cette façon »

ROBERT G. EVANS

Abstract

Clyde Hertzman's sudden and untimely death was a terrible blow to those who knew him. It was also a major loss to health research and policy in Canada and well beyond. He was an outstanding public academic, at the top of his intellectual game. Here I attempt a highly selective and personal account of how he developed the conceptual framework that he called "the whole enchilada," of the social context influencing both biological and behavioural development from earliest infancy. From these roots spring our life trajectories, evolving social gradients of more – or less – successful experience at each life stage. The international performance of a society reflects the sum of these trajectories. Canada could do much better, but not in Harperland.

Résumé

Le décès soudain et prématuré de Clyde Hertzman a été un grand choc pour ceux qui l'ont connu. C'est aussi une grande perte pour les politiques et la recherche en santé au Canada et ailleurs. C'était un remarquable érudit de la scène publique, au sommet de ses facultés intellectuelles. Je tente ici de brosser un portrait personnel de la façon dont il a créé ce cadre conceptuel qu'il nommait « l'enchilada complète » du contexte social, lequel influence le développement biologique et comportemental dès la petite enfance. De ces racines naissent nos trajectoires de vie, des gradients sociaux d'expériences plus ou moins réussies. Le rendement international d'une société est le reflet de la somme de ces trajectoires. Le Canada pourrait faire beaucoup mieux, mais pas dans le Harperland.

"Great-Heart Is Gone"

Clyde Hertzman is dead. The news was shattering for many across Canada and well beyond. Some, not a few, wept. Myself, I swore. He leaves a huge hole in the hearts of those who knew him.

But Clyde's death, just short of his sixtieth birthday and at the height of his powers as a public academic, is also a major blow to Canadian health research and policy.

In December 2012, Clyde was made an Officer of the Order of Canada. The appointment recognizes "the highest degree of merit, an outstanding level of talent and service, or an exceptional contribution to Canada and humanity."

That sounds about right for Clyde. The motto of the Order is "*Desiderantes meliorem patriam*" or "They desire a better country," which must be read as seeking to improve the lives of Canadians.

Clyde's work was consistently focused on the evidence that "a better country" is possible, and on how to get there. But he was also an activist; he devoted enormous effort and energy to trying to move us towards that better country. He would, I know, have strongly approved the title of this essay. (I know because I lifted it from some of his writings; see below.)

"In My Beginning Is My End"

Clyde is best known, nationally and internationally, for his work on and advocacy for early childhood development. The dominant theme might be summarized as "The child is father to the man" (suitably de-gendered) applied to a very broad concept of public health or, perhaps better, of well-being. Such public health writ large encompasses a wide range of interrelated dimensions of social functioning over the life course. The health of a population is expressed through levels of morbidity and mortality, and particularly the distribution of these across different subgroups. But these are also causally linked with such factors as education, income, employment and contacts with the criminal justice system. Each of these has a highly autocorrelated trajectory over the life course, with roots deep in the circumstances of early life.

These trajectories are quite sensitive to those early circumstances; there is much more going on than simply the prudent selection of grandparents. Since the performance of a society is the aggregate of the trajectories of its members, it follows that successful societies are those that take pains to nurture the early development of their members. Others, not so much.

So how did Clyde work his way to this concept of "the whole enchilada," as he came to call it? In this column I want to offer a highly selective and personal interpretation of the sequence of ideas. Does such an account, which is not primarily about healthcare, belong in *Healthcare Policy*? I think so, for two reasons.

First, the emerging understanding of early childhood development, to which Clyde has contributed so much, has powerful implications for the determinants of health more narrowly defined. Can one then seriously argue that these have no implications for health

policy? (Sadly, the empirical answer is too often "yes." But it ought not to be.) But second, much of Clyde's earlier work, prior to the child development studies for which he is now most widely known, was "mainstream" health services research.

Aging and Healthcare: Inconvenient Truths and Convenient Falsehoods

Clyde came to the University of British Columbia in 1985 as a specialist in occupational health – an "occ doc." But he quickly became involved with researchers at the Centre for Health Services and Policy Research (CHSPR), in what one might call conventional health services research. He spent many hours hunched over a hot word-processor with Morris Barer and myself, analyzing patterns of hospital and healthcare use by the elderly. He had a genius for titles; such papers as "Flat on Your Back or Back to Your Flat?" and "The Long Good-Bye" came from that period. So did the "Barer Causogram," explicating the eight different causal pathways through which healthcare could be linked with health (Barer et al. 1987).

We were among those who were then demonstrating, even 25 years ago, that demographic changes, and in particular the oncoming "boomers," would not and could not in themselves render the Canadian healthcare system "unsustainable." This finding, subsequently confirmed a number of times with other data, by ourselves and other research groups, has had remarkably little success in penetrating either the media or the world of political commentary. A convenient falsehood – in this case the "grey tsunami" – trumps the evidence. This is a theme that emerges in Clyde's more recent work as well.

"Tell Me How a People Live": The CIAR Population Health Program

In 1987 the Canadian Institute for Advanced Research (CIAR) established a program in population health, and Clyde was one of the first people invited to join. He later became its director.

The research focus of this program was summarized by another member, Jonathan Lomas, as "Why are some people healthy and others not?" The answers, in modern high-income societies, clearly do not lie in differential exposure to material deprivation, or access to medical care. Rather, they reflect the powerful impact of the social environments in which people live and work.

What calls for explanation is not so much that individuals have different health experiences, but that these differences are so obviously patterned. Health is heterogenous: there are systematic, and large, variations in average mortality and morbidity among social groups. Of these, the most prominent is the social gradient, the fact that health is highly correlated with social position whether measured by income, or education, or other indicators of status. These gradients are found in all societies, but they are much more pronounced in some than in others. So what are the processes by which social position influences health, and what are the characteristics of different societies that enhance or mitigate the effects of those processes?

Dr. Hertzman's Eastern Tour: Post-Soviet Europe

Clyde was a particularly active and stimulating participant in the collective work of the Population Health Program. But he also took on an international program of his own, when he was commissioned to survey the health status of the Eastern European countries that had just been liberated from Soviet control at the beginning of the 1990s. It was well known that the health status of those societies had been falling behind that in "the West" for at least 20 years – why?

The conventional answer was the physical environment – pollution. Industrialization in the Soviet era had proceeded with minimal concern for environmental contamination. The result was some appalling, and very unhealthy, regional messes.

Clyde's reports showed that, while this was indeed true, the unhealthy effects of localized pollution could not possibly account for the relatively poor health experience of entire nations. Something else, much more fundamental, was going on, perhaps linked to the crushing of public aspirations during and after the "Prague Spring."

Whatever the processes, the studies of Eastern Europe were very powerful evidence for the major impact of social context on health. People in those countries were not suffering from significant deprivation – there was food, shelter, medical care. These might not meet the quality standards of the West, but they were more than adequate for a healthy life. Moreover, the East–West mortality gap that had emerged after 1970 was not among those typically most vulnerable to deprivation or disease – the elderly, children – but among males above the age of fifteen. It was associated not with physical deprivation but with social disruption.

Clyde's Eastern European studies thus powerfully reinforced, from a completely different direction, the message of social gradients. Ill health is associated with social context. Social experiences become "biologically embedded" in the way in which the organism responds, whether physiologically or behaviourally, to stress, and these responses may be healthy or unhealthy. Clearly the social environment, social experience, "gets under the skin." But how?

…[T]he Very Beginning / A Very Good Place to Start

This question led Clyde to a particular focus on children, to becoming a leader of the "kiddies' group" within the Population Health Program. The logic was sound; there was increasing evidence of the much greater malleability, for good or ill, of the organism in the early years of life. Neurological research, in particular, was showing how the brain responds to experience by creating a more or less dense network of connections among some of the neurons (more is better) and de-activating others. These growing insights underlay the later creation of the Program in Experience-Based Brain and Biological Development (E triple-B D) within CIFAR, of which Clyde was also a member. The science behind a focus on early childhood development was strong when his interests moved in this direction; it grows ever stronger today.

But I think Clyde's focus on children, and on early childhood development, had other roots as well. He was always as interested in changing the world as in understanding it. But he

knew very well that all such efforts to make "a better country" would inevitably be opposed by powerful ideological and economic interests, suppressing inconvenient truths while maintaining a cover of convenient falsehoods. Clyde might well have considered that it would be politically and perhaps even emotionally more difficult to dismiss the health gradient in children. The various convenient falsehoods that support victim-blaming in the adult population are not as readily available. If kids lower in the social gradient are less healthy, it is not their fault. There is a strong moral case for measures to improve their lot and to try to smooth out some of the more egregious biases on the social playing-field.

Moreover, on a personal level Clyde genuinely cared about children – he liked kids. It is not a sentiment universal among male academics.

Multiple Gradients, Unfolding Over Time

Once one begins to think seriously about the health gradient in children, however, it is hard to miss the fact that such gradients are strongly correlated with – one might say embedded in – a whole set of other social gradients. School performance is perhaps the most obvious and readily documented, but this is associated with drop-out rates and a cascade of subsequent advantage or disadvantage throughout adult life.

From these observations, Clyde worked out a broader conceptualization of a general social gradient that is expressed in different ways over the life course. There is a coherent trajectory through which advantage or disadvantage builds on the previous stage and projects into the next, although these might be observed in different ways at different stages of the life cycle.

Development in very early life may be biologically embedded in coping styles and stress responses. At school entry, the gradient shows up as differential readiness to learn that persists as better or worse school performance, and associated psychological effects – self-esteem or the lack of it, as an example. Moving into the teenage years, the gradient is found in rates of delinquency (boys) or teen pregnancy (girls). These factors then feed forward into unemployment and low-productivity employment, and welfare dependency. Finally, in later life the gradient emerges strongly in mortality differentials. But the story begins long before – very shortly after, or even before, birth.

This conceptual framework, "the whole enchilada" referred to above, was not simply developed in the ivory tower. In the process of gathering the underlying data, and developing some of the instruments that would track performance over time, Clyde was constantly talking with and listening to those who have close contact with children and youths, and with their problems. He was a principal organizer of the Human Early Learning Project (HELP) at UBC, which reaches out into the community. He found that these ideas resonated with school teachers, social workers – and the police. The concepts tested on aggregate data were thus also "ground-truthed" with those who had to deal, day-to-day, with the consequences of the social gradient trajectory.

Winners and Losers: International Comparisons

But can these individual trajectories be modified? The international evidence says clearly: "yes." Comparing data from a number of countries, Clyde observed that while all showed a social gradient in school performance, these gradients were much steeper in some than in others.

There was a fan-like pattern. Average performance levels at the top end of the social scale were quite similar across countries. But they fell away, with declining social position, much more rapidly in some countries than in others.

There are always going to be winners and losers; some life trajectories will soar and others crawl. But the proportion of losers varies markedly from one society to another, indicating that some societies provide environments more conducive to individual success. Others, as noted above, less so.

No Bronze Medal for Canada

On this measure, Canada showed a rather mediocre performance compared to a number of other industrialized countries. And the differences matter. The performance gradient indicated that

> over 25% of Canadians reach adulthood without the competences they need to cope in the modern economy. …It does not have to be this way; international experience indicates that our 25% rate could be reduced to under 10%. (Evans et al. 2007; see also Maggi et al. 2010)

Canadians are thus carrying a large and unnecessary burden of "social overhead costs" from failure to invest adequately in our children, and particularly in their earliest development. Most of this burden is, of course, borne by the individuals themselves who are left behind, but much is also borne by the rest of us through welfare budgets, the criminal justice system (and crime itself) and, more generally, through the relatively low rates of growth in economic productivity, of which our economic elites constantly remind us.

The persistence of relatively high rates of unemployment alongside employers' frequent complaints of shortages of skilled personnel may point to a need for more (and more appropriate) training programs. But they may also have their roots much farther back, in the early childhood development trajectory, where the "loser" first begins to fall, and be left, behind.

Nor are these 25% concentrated only at the bottom end of the social scale, a problem of "them." While more concentrated lower down, those ill equipped to cope with a modern economy can be found across the social spectrum. Any programmatic response would therefore have to be universal as, indeed, such programs are in more successful countries.

A Whole Lot of Science Since Lalonde: Biology Is Not Destiny

While extending his interests in child development well beyond health, and beyond Canada, Clyde was also following and interpreting developments in the biological sciences, and in

particular in neurobiology and genetics. Here the news is very interesting – science has moved a long way in the 40 years since *A New Perspective on the Health of Canadians* (Lalonde 1974) laid out its Four Fields framework for thinking about the determinants of health.

That document was a major step forward for its time, refocusing understanding of health – and therefore the proper concerns of health policy – much more broadly than just the provision of traditional healthcare ("sick care"). Not that the latter was or is unimportant, but the New Perspective emphasizes the significance of three additional "fields" – human biology, the physical environment and "lifestyle."

At that time, however, human biology – and particularly the genetic endowment of each individual – was understood as a given background against which other factors and policies might play out. Today, advances in epigenetics have shown that while the genetic endowment itself is fixed at conception, the way in which these genes are expressed is not. That expression is influenced by the early experiences of the individual, and particularly the social context in which the child – or indeed any animal – is reared. Similarly, advances in neurobiology have demonstrated the importance of "neuroplasticity" and the ways in which the organization and function of brains and other neural structures develop in response to experience. This plasticity appears to persist throughout life, but is particularly marked in the earliest years. So biology is definitely not destiny. You may not be able to put in what God left out, but the early environment in particular can have a significant influence on whether what was put in is used well – or bungled.

So our understanding of the role of the social environment, and its interaction with the biological endowment, has greatly expanded since the New Perspective. Unfortunately, these advances in science have not wholly penetrated the general public and political discourse, much of which remains stuck in the frameworks of 40 years ago. Worse, the rather loose term "lifestyle" is all too frequently misinterpreted as referring to individual behavioural choices, rather than the original meaning as the conditions in which people live and work. The trivialization of lifestyle as individual choice is a convenient falsehood that completely ignores the fundamental significance of social context, biological embedding and the life course trajectory.

But no such sins, whether of commission or of omission, can be charged to Clyde Hertzman. No one was more dedicated, or energetic, in identifying, interpreting and communicating the emerging framework of understanding, and the supporting evidence. There was a very good reason why the Canadian Institutes of Health Research in 2010 named him Canada's Health Researcher of the Year. So where do we go from here?

The Power of Ideas – Right and Wrong

Clyde's primary legacy is a well-thought-out set of connected ideas, and ideas can be powerful things. John Maynard Keynes wrote a classic "idealist" statement of their significance, in a passage well known to most economists:

> The ideas of economists and political philosophers, both when they are right and when they are wrong, are more powerful than is commonly understood. Indeed the world is ruled by little else. Practical men, who believe themselves to be quite exempt from any intellectual influences, are usually the slaves of some defunct economist. (Keynes 1961: 383)

But this ringing endorsement of the power of ideas is very much a two-edged sword. While on the one hand he emphasizes the power of ideas, on the other Keynes adds "both when they are right, and when they are wrong." (He was writing in 1936.)

Worse, Keynes refers specifically to the ideas of "economists and political philosophers." Clyde was neither. In a survey some years ago of Canadian federal and provincial civil servants, Lavis and colleagues (2003) found that the concepts of population health had penetrated quite broadly into the thinking of the line departments. Like Clyde's studies of early childhood development, they resonated well with the experience of those on the "front lines" of public policy.

Convenient Falsehoods Again: The Ideology of Economics

The great exceptions were those, principally economists, in ministries of finance and treasuries. Mainstream economists in government appear to be strongly armoured against new ideas in the professional ideology (which some are pleased to call "science").

They have other strong ideas, painstakingly learned and deeply embedded, based on complex theories about the behaviour of autonomous individuals making optimizing choices. These leave little room for social context, and none for human development or the life cycle. Government economists, like their business sector counterparts, are largely unaware, if not actually dismissive, of the evidence that researchers such as Clyde have assembled. Yet, they predominate in the most powerful ministries.

Indeed, the present Prime Minister of Canada, Stephen Harper, seems to go even further. In his first year in power he declared forthrightly that "we don't need the experts"; he was then referring specifically to those working on early childhood development and advocating for a national children's agenda. (He may even have had Clyde in mind, which would be a back-handed compliment to the significance of Clyde's work.) Immediately on taking power, Harper crushed hopes for a national daycare program that might have been the vehicle for mitigating our costly social gradients and advancing a national children's agenda. He has followed through by gagging government scientists – and even archivists – and with the deliberate destruction of long-term public research programs and data sources. Last year, there were public demonstrations in Ottawa by scientists protesting "the death of evidence" (Fitzpatrick 2012).

Our current prime minister is clearly determined not merely to ignore inconvenient evidence, but to suppress and, where possible, destroy it. Perhaps he fears it. Perhaps he has reason. He may be aware that whatever ideas he does find congenial would not withstand confrontation with evidence, at least in anyone else's mind but his.

We are clearly observing, in Harperland, a demonstration of the power of ideas, although it is unclear what those ideas are, or where they came from. Perhaps, to go back to Keynes, he is "the [slave] of some defunct economist." From the University of Chicago?

So Clyde was not wrong, or naïve, to desire a better country. He, and others, have shown conclusively that "it does not have to be this way." But first, we may need a better federal government.

References

Barer, M.L., R.G. Evans, C. Hertzman and J. Lomas. 1987. "Aging and Health Care Utilization: New Evidence on Old Fallacies." *Social Science and Medicine* 24(10): 851–62.

Evans, R.G., C. Hertzman and S. Morgan. 2007. "Improving Health Outcomes in Canada." In J. Leonard, C. Ragan and F. St. Hilaire, eds., *A Canadian Priorities Agenda: Policy Choices to Improve Economic and Social Well-Being* (pp. 291–325). Montreal: Institute for Research on Public Policy.

Fitzpatrick, M. 2012 (July 10). "Death of Scientific Evidence Mourned on Parliament Hill." CBCnewsCanada. Retrieved April 15, 2013. <http://www.cbc.ca/news/canada/story/2012/07/10/pol-death-evidence-protest-parliament-hill.html>.

Keynes, J.M. 1961. *The General Theory of Employment, Interest and Money*. London, UK: Macmillan.

Lalonde, M. 1974. *A New Perspective on the Health of Canadians*. Ottawa: Government of Canada.

Lavis, J.N., S.E. Ross, G.L. Stoddart, J.M. Hohenadel, C.B. McLeod and R.G Evans. 2003. "Do Canadian Civil Servants Care About the Health of Populations?" *American Journal of Public Health* 93(4): 371–79.

Maggi, S., L.J. Irwin, A. Siddiqi and C. Hertzman. 2010. "The Social Determinants of Early Child Health: An Overview." *Journal of Paediatrics and Child Health* 46(11): 627–35.

How to Summarize a 6,000-Word Paper in a Six-Minute Video Clip

Comment résumer un texte de 6 000 mots en une vidéo de six minutes

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Abstract

As part of our research team's knowledge transfer and exchange (KTE) efforts, we created a six-minute video clip that summarizes, in plain language, a scientific paper that describes why and how three teams of academic entrepreneurs developed new health technologies. Recognizing that video-based KTE strategies can be a valuable tool for health services and policy researchers, this paper explains the constraints and sources of inspiration that shaped our video production process. Aiming to provide practical guidance, we describe the steps and tools that we used to identify, refine and package the key content of the scientific paper into an original video format.

Résumé

Dans le cadre des initiatives de transfert et d'échange de connaissances (TEC) de notre équipe de recherche, nous avons produit une vidéo de six minutes qui résume, en langage simple, un article scientifique décrivant pourquoi et comment trois équipes d'entrepreneurs universitaires ont développé de nouvelles technologies de la santé. Tout en reconnaissant que la vidéo constitue une stratégie de TEC valable pour les chercheurs en services et politiques de santé, cet article décrit les contraintes et les sources d'inspiration qui ont entouré la production de notre vidéo. En guise de guide pratique, nous décrivons les étapes et outils que nous avons employés pour déterminer, affiner et formuler le contenu clé de l'article scientifique en un format vidéo original.

Health services and policy researchers seek to influence diverse professional, policy and non-expert communities that may never have access to research findings in the form of scientific papers. Because audio-visual material can convey complex arguments and trigger new reflections (Harrison 2002), we developed a six-minute video clip as part of our integrated knowledge transfer and exchange (KTE) efforts. Within the context of a workshop, our goal was to foster productive deliberations by health technology developers, clinicians and patient representatives. Our video clip summarizes, in plain language, the key findings of a qualitative study that describes the process by which three teams of academic entrepreneurs each developed a new technology: a cardiac ablation catheter, a labour decision support software application and a home monitoring system (Lehoux et al. 2011). While technology developers, clinicians and patient representatives influence, and are influenced by, the development of new medical technologies, they may not share a common understanding of the issues at hand and may also lose sight of the "bigger picture" when it comes to technological development in healthcare. For an audience that may not be reached by scientific communication channels (e.g., healthcare providers, patients), our video clip provides an opportunity to ponder the broader implications of three different approaches to the design of medical technologies: "Building, Assembling, Adapting" (see video, in French): http://vimeo.com/48372194.

Since health services and policy researchers are increasingly involved in KTE and interested in novel communication strategies (Straus et al. 2009), this paper explains the key constraints and sources of inspiration that nourished our video production process. Our goal being to provide practical guidance, we describe the KTE approach that we adopted, along with the steps and tools that we used to iteratively identify, refine and package our key messages into an original video clip.

Overall KTE Approach and Sources of Inspiration

While those who develop medical devices make several assumptions on behalf of clinicians,

patients and society as a whole (about their feasibility as well as their relevance), they rarely question why and how such technologies are being developed, and whether these technologies are synergistic with healthcare systems' goals. We produced this KTE-oriented video clip in order to explore such complex issues with a mixed audience at an invitational workshop, which we hosted in Montreal on June 15, 2012. Combining multimedia tools and small-group discussions, this workshop was a rare opportunity for clinicians, technology designers and patient representatives to debate policy issues pivotal to the sustainability of healthcare systems (see the program: http://www.medsp.umontreal.ca/crcinnovations/TechMed2012/TechMed2012.html).

In discussions within heterogeneous groups, audio-visual material can be a particularly effective medium for increasing the reactivity of participants because it puts "images to work" while sharing knowledge on matters with which some participants may be less familiar (Harrison 2002). Such audio-visual elicitation-based KTE material can help participants articulate their views and acknowledge differences between individual perspectives. We adopted the perspective of Golden-Biddle and colleagues (2003: 21), which emphasizes the "communicative elements called upon in knowledge making and using efforts." Because specialization and disciplinary frameworks often limit the quality and depth of discussions within mixed audiences (Denis et al. 2004), our team sought to facilitate the ability of "each party to translate between, and at least partially integrate, their own and the others' frameworks" (Bartunek et al. 2003: 66).

To create a lively and informal video, our team tapped into various sources of inspiration and input (see Acknowledgements). While a few scientific journals and research institutes have begun to integrate videos as web-based supplemental information, most of these initiatives replicate conventional scientific communication practices (e.g., videos of conferences, expert interviews or panels). Equally misaligned with our KTE aim are the tone and structure of science popularization documentaries, which are explicitly geared to "educating" a non-expert audience and tend to put scientists centre stage.

We therefore turned our attention to other types of video. Of particular interest were those produced by RSA, a charity based in the United Kingdom, whose "purpose is to develop and promote new ways of thinking about human fulfilment and social progress" (http://www.thersa.org). In our opinion, the RSA Animate videos are truly exceptional in their ability to convey complex arguments while being visually captivating. Some of their videos have been seen 10 million times on YouTube. They use animated hand drawings that schematize key arguments made by a speaker who never appears on screen (voice-over). Our creative process was also informed by academic initiatives that seek to involve members of the public in deliberations about technological developments (Boenink et al. 2010). A consortium led by the Norwegian Centre for the Study of the Sciences and the Humanities at the University of Bergen recently completed the Technolife project (http://www.technolife.no), which combined audio-visual and online tools. These videos rely on both static and dynamic images, including interventions by actors who personify, for instance, the chief executive officer of a company or a scientist.

These are only a few of the examples that inspired our team and shaped our decisions regarding what techniques to use. While we were seduced by the RSA Animate videos, using this technique would have required too great an investment in human and financial resources. Overall, we felt that our message did not require complex visual support, but that our qualitative study findings (i.e., three stories of technological development) would lend themselves to a personal engagement with the audience. We thus decided to combine animation with actors to personify three academic entrepreneurs and a "researcher-narrator" (the first author).

Tools to Support the Production Process

Producing a video requires tight control of (a) what is said, (b) what is shown visually and (c) how the combination of what is said/shown visually unfolds. Accordingly, three tools were pivotal in moving our creative process forward. The first was a script organizing the information and key messages contained in the scientific paper into a continuous flow (i.e., a narrative). While this script was repeatedly condensed, revised and modified, it offered a template with clear boundaries. The amount of information that could be effectively conveyed in a six-minute video clip is limited. Table 1 summarizes our distillation process and the lessons learned. Established principles in KTE, such as identifying the messages that should be transferred, those to whom it should be directed and how, and the potential effects (Lavis et al. 2003), were an indispensable starting point. However, writing the script involved considerable trade-offs. In order to tell the three technological stories that are described in the paper, we had to choose carefully which empirical observations to include. While trying not to oversimplify our scholarly endeavour, we used concepts that are, from a communication standpoint, easily graspable (e.g., worlds, lenses) and abandoned those requiring a fuller explanation (i.e., modalities of engagement). The script enabled us to swiftly record audio tests (using the Microsoft Word "memo" function), which enhanced the clarity and readability of the script, forcing our team to focus on what would be said rather than being distracted by what would be shown.

The second tool was a storyboard showing the visuals that would accompany the script. We used PowerPoint because it enabled us to play with the images and text that might illustrate each sequence of the script. Discussing this storyboard with the team not only generated many new ideas, but also allowed us to troubleshoot parts of the script that were not working properly. The ability to test different visuals rapidly was pivotal. Both animation and video editing are time-consuming. Hence, the sooner one can estimate, even roughly, the number of hours that will be required to create a given number of seconds of video, the better. The storyboard also enabled our team to explore how varying spatial arrangements on the screen and text colour schemes could facilitate comprehension of our key points. This simple visual communication tool provided a structure for organizing the three empirical stories and the points being made by the researcher-narrator. The actors were shown both the final script and the storyboard (available upon request), and they were also given general cues about the characters they were personifying.

TABLE 1. Lessons learned during the process of identifying and distilling the paper's key messages

Steps in Writing the Script	Lessons Learned
1. Three co-authors independently extracted all the messages contained in the paper with respect to: • Background to the study • Purpose of the study • Findings (the three cases of technology development) • Implications of the study	• Many team discussions regarding the key messages and implications of our case study were necessary • Our team needed external input and communication expertise because we were "too close" to our research findings
2. Gathered external input and feedback regarding how the "story should be told" to a non-specialized audience (see Acknowledgements)	• While we did not follow all the advice we gathered, seeking external input helped us clarify the trade-offs that would be necessary • Pondering which concepts were useful from a communication standpoint was pivotal • Realizing that the scientific structure of the paper should be abandoned was an eye-opener; it enabled us to envision a different way of telling the "story"
3. Developed a "one-pager" with the key messages	• Establishing a hierarchy between primary and secondary messages helped us identify the most salient messages
4. Drafted and refined iteratively the script (tool #1)	• Realizing that some empirical details and nuances were not essential to illustrating the key dynamics of the three empirical cases helped us to streamline the script

The third tool was a sequence-by-sequence shooting plan. This was created after repeated adjustments were made to the storyboard and the script in order to better articulate the key messages. The shooting plan was created by our multimedia expert (PV) and contained very detailed information regarding the positioning of the camera and the movements of the visuals (animation and text). It not only provided precise information about what should precede and follow each scene (for instance, how many seconds the comedian should remain still), but also served as a "roadmap" for coordinating all of the tasks of team members on the day of shooting (e.g., positioning and testing of microphones, holding prompts and moving the lighting system). That being said, some room was left to allow for deviating from this plan. Continuous feedback from team members and the actors led us to modify some passages in the script during the shooting. Not surprisingly, several takes were needed to obtain high-quality audio-visual material; it took almost seven hours of shooting to create our six-minute video.

Constraints that Fuelled the Creative Process

Table 2 summarizes the key steps that helped coordinate our team efforts from the pre- to post-production stage. Although software and multimedia tools for making high-quality videos are becoming increasingly accessible to the non-expert, technical expertise is required. Researchers who wish to create videos should involve a multimedia expert throughout the process because both format and content influence each other. In our experience, engaging in the process as a team – valuing one another's contributions and appraising together the strengths and weaknesses of diverse solutions – is of paramount importance.

TABLE 2. The steps and tools that helped coordinate our team efforts from the pre- to post-production stage

Pre-Production	
Content:	**Format:**
1. Following the steps described in Table 1, write and revise the **script: Tool #1** "the story to tell"	• Define the constraints: length, resources available, technical requirements and capacity, etc.
2. Obtain feedback from various perspectives (see Acknowledgements)	• Define artistic direction (what should the video look like?)
3. Test the vocal delivery of the script through audio recordings (How well does it flow? At what pace should the delivery unfold?)	• Sketch and revise the **storyboard: Tool #2** – the script is broken down into separate sequences with visual cues for what will be shown as the story unfolds
4. Recruit and provide guidance to the actors and researcher-narrator	• Test technical solutions (lighting and shooting methods, special effects, transitions, rough animations, feasibility) • Create the **sequence-by-sequence shooting plan: Tool #3** – a production master plan for turning the storyboard into reality • Review with team members the shooting order, camera placement and movements, transitions, etc., making sure that all sound/images needed will be recorded • Secure equipment, set up the shooting space and lighting, find accessories, prepare cue cards
Production (Shooting)	
Coordination of each team member's roles and tasks by the director (camera, audio, assistant director, prompter, production assistant)	
Provide delivery instructions and guidance to the actors and researcher-narrator	
For each scene, do several takes in order to obtain the best one in terms of video/audio quality and delivery	
Post-Production	
Editing:	**Dissemination:**
1. Review and select the best shots	• Prepare and host a first public viewing
2. Create animation sequences	• Prepare the web delivery of the video clip
3. Create music and audio mix	• Develop a "two-liner" to introduce the video clip
4. Add special effects, titles and end credits	• Identify relevant electronic distribution lists and send the announcement
5. Final review with team members	• Identify relevant venues for small-group discussions (workshop, brown bag session) or interactive web postings

We found that constraints related to content, video format or both often acted as a stepping stone, pushing us to find creative solutions. When we were writing the script, the key challenge was concision. We succeeded in overcoming this challenge only when, with the help of communication experts, we realized that the structure of the paper (i.e., background, conceptual framework, methods, results, discussion and conclusion) could and should be dropped. It was also a challenge having actors personify actual study participants. We found this approach appealing because it reinforces the fact that medical technology is designed by people who make decisions on behalf of clinicians and patients. However, it also introduced

an ethical issue: viewers might believe that the actors appearing on screen were the individuals that we interviewed anonymously for the study. This constraint led to a creative solution: the silhouette technique. This concealed the identity of the actors while invoking real persons whose anonymity was preserved (a strategy akin to the use of pseudonyms in qualitative research).

What Was Left Out, and What Lies Ahead

Creating a six-minute video clip that summarizes a 6,000-word scientific paper implies putting aside a researcher's conceptual and methodological armamentarium and some of the empirical subtleties and contextual nuances of a qualitative study. While addressing the likely impact of video-based KTE falls beyond the scope of this paper, according to data collected at the end of our workshop, on a five-level Likert-type scale, the majority of the participants who completed the survey (n=17; 90% response rate) gave a score of 4 or 5 to the following items: the videos "generated interest" (82%); "contributed to their knowledge" (71%); "contained clear messages" (77%); and "addressed important issues" (88%). Records from Vimeo and Google Analytics indicate around 220 views since September 2012. While dissemination strategies that tap into small-group discussions (e.g., "brown bag lunch" sessions) or interactive web platforms (e.g., blogs) seem logically adapted to the kind of video we created, there is a need for comparative studies. For instance, would there be types of study design (or research findings) that should instead be summarized in shorter clips, with clear "actionable" messages, and aiming at swift, "viral-like" dissemination? Alternatively, would there be studies that would mainly require a one-page summary for their findings to be put into action?

Many challenges thus lie ahead, as the knowledge base remains limited. Continuing experimentation with video-based KTE activities by researchers, including the application of the process and tools described in this paper, could eventually fill some important gaps in communication and knowledge transfer. In many areas, there is a need for communication tools that can help multiple stakeholder groups understand one another's role in the "bigger picture" of healthcare management and policy. Furthermore, one is forced to recognize that most scientific papers will never be read by the professional, policy and non-expert communities that health services and policy researchers are trying to inform or influence through their research. Ultimately, engaging in non-traditional KTE exercises can help consolidate researchers' ability to communicate complex research-based arguments.

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References

Bartunek, J., J. Trullen, E. Bonet and A. Sauquet. 2003. "Sharing and Expanding Academic and Practitioner Knowledge in Health Care." *Journal of Health Service Research and Policy* 8(Suppl. 2): 62–68.

Boenink, M., T. Swierstra and D. Stemerding. 2010. "Anticipating the Interaction between Technology and Morality: A Scenario Study of Experimenting with Humans in Bionanotechnology." *Studies in Ethics, Law and Technology* 4(2). doi: 10.2202/1941-6008.1098.

Denis, J.-L., P. Lehoux and F. Champagne. 2004. "Knowledge Utilization in Health Care: From Fine-Tuning Dissemination to Contextualizing Knowledge." In L. Lemieux-Charles and F. Champagne, eds., *Using Knowledge and Evidence in Health Care: Multidisciplinary Perspectives*. Toronto: University of Toronto Press.

Golden-Biddle, K., T. Reay, S. Petz, C. Witt, A. Casebeer, A. Pablo and B. Hinings. 2003. "Towards a Communicative Perspective of Collaborating in Research: The Case of the Researcher–Decision-Maker Partnership." *Journal of Health Service Research and Policy* 8(Suppl. 2): 20–25.

Harrison, B. 2002. "Seeing Health and Illness Worlds: Using Visual Methodologies in a Sociology of Health and Illness: A Methodological Review." *Sociology of Health & Illness* 24: 856–72.

Lavis, J., D. Robertson, J. Woodside, B. McLeod, J. Abelson and the Knowledge Transfer Study Group. 2003. "How Can Research Organizations More Effectively Transfer Research Knowledge to Decision-Makers?" *Milbank Quarterly* 81(2): 221–48.

Lehoux, P., M. Hivon, B. Williams-Jones and D. Urbach. 2011. "The Worlds and Modalities of Engagement of Design Participants: A Qualitative Case Study of Three Medical Innovations." *Design Studies* 32(4): 313–32.

Straus, S., J. Tetroe and I. Graham. 2009. *Knowledge Translation in Health Care: Moving from Evidence to Practice*. Singapore: Wiley–Blackwell Publishing.

DATA MATTERS

The Rising Prevalence of Asthma: True Increase, Diagnostic Exchange or Diagnostic Accuracy?

Prévalence à la hausse de l'asthme : hausse réelle, substitution de diagnostic ou exactitude diagnostique?

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Abstract

In the midst of frequent reports about "the asthma epidemic," results from a number of studies by the Manitoba Centre for Health Policy have shown stable or decreasing prevalence of an overall indicator of respiratory diseases which includes asthma. To resolve these apparently contrary findings, we conducted a time trend analysis using administrative data. Results revealed significant potential for diagnostic exchange: asthma prevalence increased, but that of bronchitis decreased.

Résumé

Dans le contexte des fréquents rapports indiquant une « épidémie d'asthme », les résultats de plusieurs études effectuées par le Centre des politiques de santé du Manitoba montrent une prévalence stable ou en déclin d'un indicateur global des maladies respiratoires, y compris l'asthme. Afin de résoudre la contradiction apparente de ces résultats, nous avons effectué une analyse évolutive des tendances au moyen de données administratives. Les résultats révèlent une forte possibilité de substitution de diagnostic : la prévalence de l'asthme a augmenté, mais celle de la bronchite a diminué.

In Manitoba, as in Canada and elsewhere, many studies have reported increasing rates of asthma prevalence over time, especially among children (Akinbami and Schoendorf 2002; Burney et al. 1990; Erzen et al. 1995; Garner and Kohen 2008; Kozyrskyj and Hildes-Ripstein 2002; Kozyrskyj et al. 2004; Lawson and Senthilselvan 2005; Lundback et al. 2001; Manfreda et al. 1993; Mannino et al. 2002; Millar and Hill 1998; Moorman et al. 2007; Senthilselvan et al. 2003; Senthilselvan 1998). This "asthma epidemic" has raised concern among clinicians, researchers, policy makers and the public, sparking new studies to understand the causes of this increase. There are also significant potential implications for population health and the management of health services.

Contrary to this increasing trend for asthma, the results in a series of "atlas-style" population health reports by the Manitoba Centre for Health Policy (MCHP) since the mid-1990s have shown stable, then slightly decreasing rates of a larger grouping of respiratory conditions, including asthma and other respiratory diseases (Martens et al. 2003; Fransoo et al. 2005, 2009). These two sets of findings – increasing rates of asthma amid stable or decreasing rates of the larger grouping – seemed contrary, prompting further investigation.

Key messages:

The prevalence of asthma increased over time, especially among children, but seems to have leveled off by 1997.

The noted increase may not accurately reflect underlying population health status, but rather, temporal shifts in diagnostic categories used.

The MCHP reports used a grouping called "total respiratory morbidity" (TRM), which combines several related diseases: asthma, bronchitis, emphysema and chronic obstructive pulmonary disease (COPD). The idea was developed by a team of respirologists doing research using clinical and administrative data (Erzen et al. 1995, 1997; Huzel et al. 2002; Manfreda et al. 1993). Their work revealed significant inconsistency in the diagnostic coding of respiratory diseases between generalists and specialists, and among individual physicians. That is, what one physician called "asthma" might be diagnosed as "chronic bronchitis" by another, depending on patient age and clinical characteristics, and the physician's background and training (Dodge et al. 1986; Erzen et al. 1997; Manfreda et al. 2004; Tinkelman et al. 2006). Similar observations have been reported by others, attributed to "diagnostic exchange" (Fletcher 1978; Dodge et al. 1986; Burney et al. 1990; Lundback et al. 2001; Tinkelman et al. 2006). The TRM grouping was created to overcome the limitations associated with inconsistent coding across these related diagnoses, and reflect the overall level of respiratory disease in a population served by a mix of providers.

The objective of this analysis was to describe long-term trends in the diagnosed prevalence of total respiratory morbidity, along with that of its constituent diagnoses. Rudimentary case definitions were used in order to provide a "big picture" view of changes in diagnostic codes assigned, knowing that diagnostic accuracy for each condition would be affected. The larger goal was to examine the possibility of diagnostic exchange among related disorders, versus true changes in the prevalence of disease in the population.

Methods

Using administrative data from 1984/85 through 2010/11, we calculated the prevalence of total respiratory morbidity and its six constituent diagnoses: asthma, acute bronchitis and bronchiolitis, chronic bronchitis, bronchitis NOS (not otherwise specified), emphysema and chronic obstructive pulmonary disease (ICD-9-CM codes 493, 466, 491, 490, 492 and 496, respectively; ICD-10-CA codes J20-J21, J40-J45). While Manitoba has introduced new physician tariffs over the study period, none affect claims for these diagnoses, which remain eligible for reimbursement using any tariff.

Within each fiscal year, people with at least one physician visit or one hospitalization coded with one of these disorders was defined as a "case" of that disease for that year. People could be assigned to only one disease each year. Those with diagnoses for more than one disease were assigned to the one for which they had the most diagnoses in that year. When two diagnoses were equally frequent, the person was assigned to the one for which the first diagnosis in that year was received. The population was separated into five age groups: 0–4, 5–19, 20–49, 50–74 and 75+ years. This approach was not intended to assess data quality nor to provide definitive diagnoses for each patient, as it has been shown to be imprecise when using administrative data (Aaron et al. 2008). Rather, our intent was to examine population-based rates of the "diagnosed prevalence" of the total and each of the conditions over time.

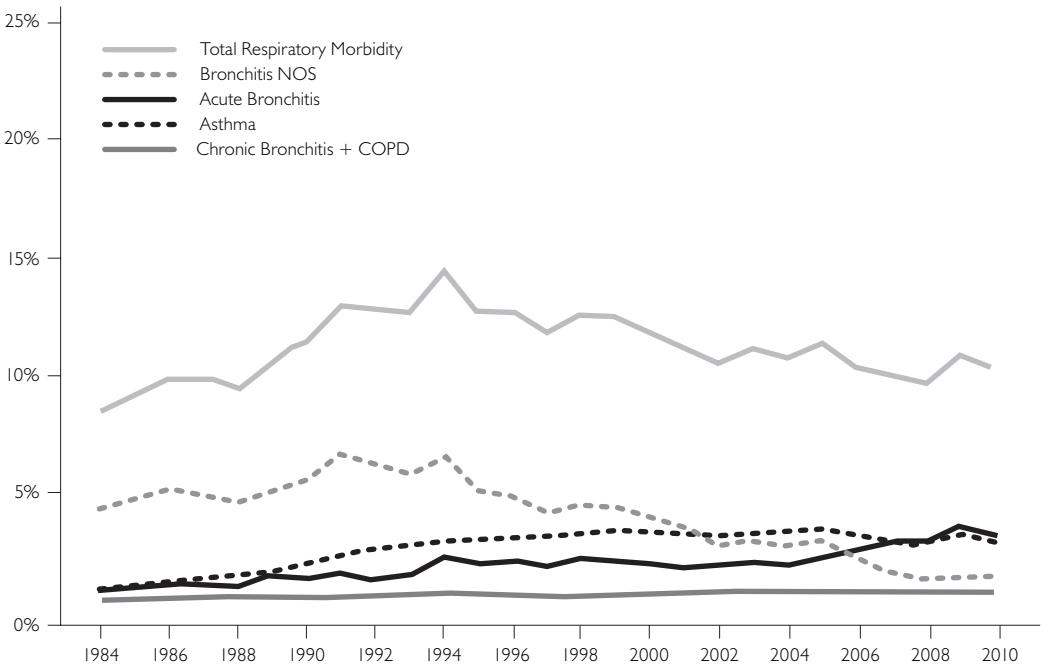
Virtually all Manitoba residents are included in the data system, which has been extensively studied and validated (Roos et al. 1993, 2005). Analyses were conducted on a secure server, using SAS version 9.2. This work was initiated as part of a larger report on population health in Manitoba (Fransoo et al. 2009).

Results

Preliminary analyses revealed that chronic bronchitis, emphysema and COPD were considerably less common than the other diagnoses, so these three were combined and are shown as "chronic bronchitis + COPD."

Figure 1 shows the overall time trends in the diagnostic prevalence of TRM and each of the diagnoses studied. The prevalence of TRM rose sharply from about 8.5% of the population in 1984/85 to almost 15% in 1994/95, then fell through 2001/02, at which time it seems to have stabilized around 11%.

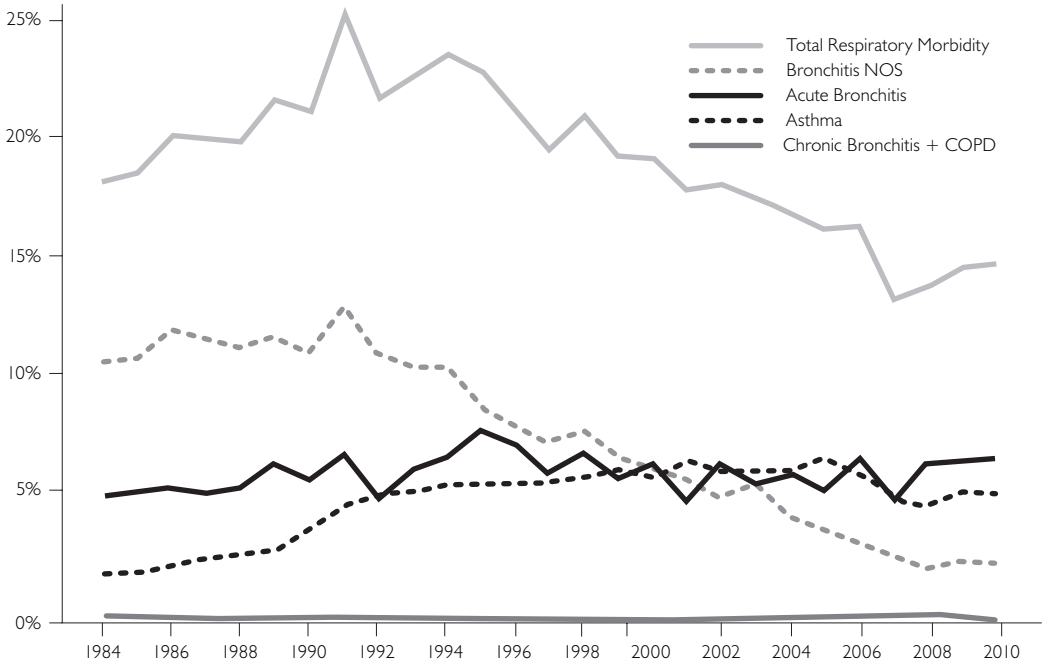
FIGURE 1. Prevalence of respiratory diseases over time, all ages



The prevalence of diagnosed asthma increased from about 1.5% in 1984/85 to just under 4% in 1999/2000, and remained relatively stable thereafter. Acute bronchitis also increased, from 1.4% to 4%. The prevalence of bronchitis NOS rose from 5% in 1984/85 to 7% in 1994/95, then fell steadily to 2% by 2008/09. The group including chronic bronchitis, emphysema and COPD increased slowly over the entire period, from 1% in 1984/85 to 1.4% in 2010/11.

The analyses by age group revealed interesting differences across the broad age groups used: the large 20- to 49-year-old group showed results largely similar to the population trends shown in Figure 1, except with slightly lower prevalence values. The younger age groups (0–4 and 5–19) revealed trends similar to each other, but different from the trends in the older age groups (50–74 and 75+). TRM prevalence values were highest and most dynamic among the 0- to 4-year-olds, shown in Figure 2. TRM prevalence rose from 18% in 1984/85 to 25% in 1992/93, then fell steadily through 2007/08, by which time it appears to have stabilized near 15%. The prevalence of asthma was 2.0% in 1984 and increased steadily to 6.7% in 2005/06 before decreasing to about 5% in 2010. Conversely, the prevalence of bronchitis NOS was stable at about 11.5% from 1984 to 1994, after which it fell sharply, to 2.5% in 2010/11. Because the drop in bronchitis NOS was later and much larger than the increase in asthma, the combined prevalence of TRM rose and then fell sharply. Similar but weaker trends were seen in the 5- to 19-year-old group, but with lower prevalence values for all conditions.

FIGURE 2. Prevalence of respiratory diseases over time, ages 0–4 years

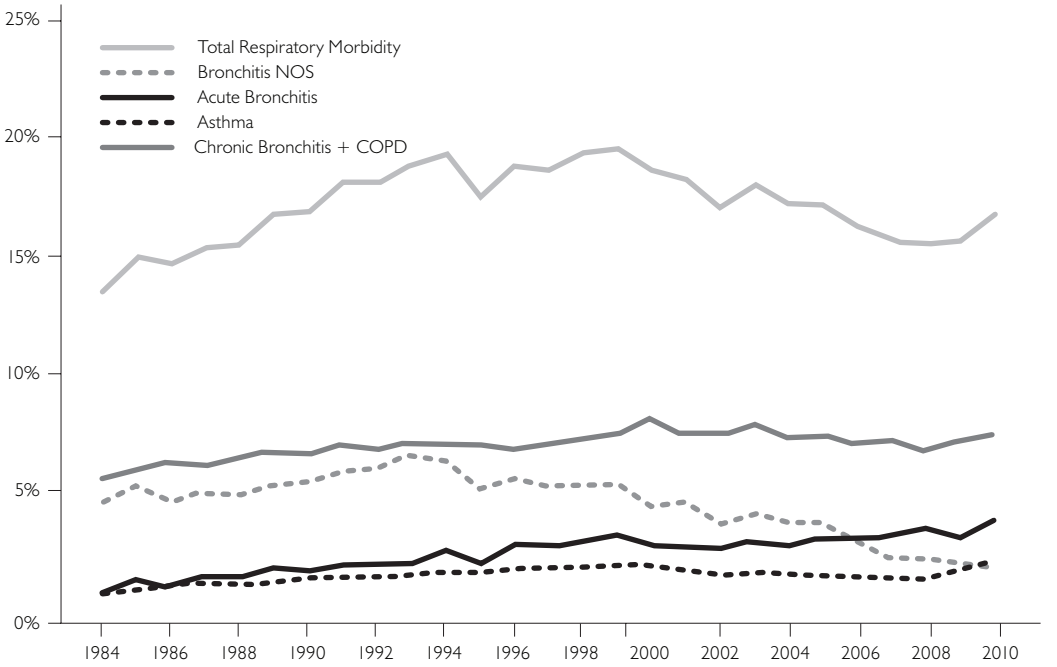


Among those aged 75+, the trends over time were much more stable, as shown in Figure 3. TRM prevalence rose from 13.5% in 1984/85 to 19.5% in 1999/2000, then fell to 15.5% in 2008/09. In this age group, asthma prevalence is much lower than in younger age groups, and that of COPD + emphysema is much higher. Asthma prevalence increased from 1.3% to 2.3%, while bronchitis NOS decreased from 5% to 2.6%, with a peak of 7% in 1993/94.

Discussion

This analysis was prompted by the desire to resolve what appeared to be contrary findings: the increasing prevalence of asthma reported by many studies, with MCHP data showing stable or decreasing prevalence of total respiratory morbidity. The results revealed that they are not contrary; both observations are true. The prevalence of asthma increased, and the prevalence of TRM decreased. The decrease in TRM was driven by the decrease in the diagnosed prevalence of bronchitis NOS, which was much larger than the increase in asthma prevalence. It is possible that diagnostic exchange may play a role in explaining these trends, with fewer people being diagnosed with bronchitis NOS and more with asthma. These results are in keeping with other reports of diagnostic exchange (Burney et al. 1990; Dodge et al. 1986; Fletcher 1978; Lundback et al. 2001; Tinkelman et al. 2006). Our finding of stabilized rates of asthma prevalence in more recent years has also been observed by others (Lawson and Senthilselvan 2005).

FIGURE 3. Prevalence of respiratory diseases over time, ages 75+



Comparing the actual prevalence values from this study to those of others is challenging, because of differences in measures used and analytic methods (Burney et al. 1990; Erzen et al. 1995; Garner and Kohen 2008; Lawson and Senthilselvan 2005; Lundback et al. 2001; Manfreda et al. 1993; Senthilselvan et al. 2003; Senthilselvan 1998). However, our primary interest was in monitoring the changes over time, using a consistent definition and data source. These data are clearly unable to resolve true changes in prevalence versus diagnostic exchange, though they do imply issues with data reliability within categories.

These trends may also indicate a positive change in clinical practice: patients may be getting "more accurate" or at least "more definitive" diagnoses, as suggested by the drop in the diagnoses for bronchitis NOS. This trend was seen in all age groups, though more clearly among younger patients. However, the available data cannot confirm that these changes are improvements – a critical distinction because misdiagnoses can result in mistreatment, which is potentially harmful.

Conclusion

Concerns about the increasing prevalence of asthma, especially in young children, need to be tempered by the decreasing prevalence of bronchitis NOS, as this shift may be an example of diagnostic exchange. Despite these changing indicators, there may be no "real" change in underlying population health status. The combined prevalence of total respiratory morbidity may be a better overall indicator of respiratory disease burden in the population than indicators of individual diseases.

These findings highlight the limitations of using administrative data alone for monitoring the prevalence of individual diseases, while simultaneously showing the insight they can provide using a broader perspective. Many studies have reported an increase in the prevalence of asthma, but none have documented concurrent decreases in the prevalence of related respiratory diseases.

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References

Aaron, S.D., K.L. Vandemheen, L.P. Boulet, R.A. McIvor, J.M. Fitzgerald, P. Hernandez et al. 2008. "Overdiagnosis of Asthma in Obese and Nonobese Adults." *Canadian Medical Association Journal* 179(11): 1121–31.

Akinbami, L.J. and K.C. Schoendorf. 2002. "Trends in Childhood Asthma: Prevalence, Health Care Utilization and Mortality." *Pediatrics* 110(2 Pt. 1): 315–22.

Burney, P.G., S. Chinn and R.J. Rona 1990. "Has the Prevalence of Asthma Increased in Children? Evidence from the National Study of Health and Growth 1973–86." *British Medical Journal* 300(6735): 1306–10.

Dodge, R., M.G. Cline and B. Burrows. 1986. "Comparisons of Asthma, Emphysema and Chronic Bronchitis Diagnoses in a General Population Sample." *American Review of Respiratory Disease* 133(6): 981–86.

Erzen, D., K.C. Carriere, N. Dik, C. Mustard, L.L. Roos, J. Manfreda et al. 1997. "Income Level and Asthma Prevalence and Care Patterns." *American Journal of Respiratory and Critical Care Medicine* 155(3): 1060–65.

Erzen, D., L.L. Roos, J. Manfreda and N.R. Anthonisen. 1995. "Changes in Asthma Severity in Manitoba." *Chest* 108(1): 16–23.

Fletcher, C.H. 1978. "Terminology in Chronic Obstructive Lung Diseases." *Journal of Epidemiology and Community Health* 32(4): 282–88.

Fransoo, R.R., P.J. Martens, E. Burland, The Need to Know Team, H. Prior and C. Burchill. 2009. *The Manitoba RHA Indicators Atlas 2009*. Winnipeg: Manitoba Centre for Health Policy.

Fransoo, R.R., P.J. Martens, The Need to Know Team, E. Burland, H. Prior, C. Burchill et al. 2005. *Sex Differences in Health Status, Health Care Use and Quality of Care*. Winnipeg: Manitoba Centre for Health Policy.

Garner, R. and D. Kohen. 2008. "Changes in the Prevalence of Asthma among Canadian Children." *Health Reports* 19(2): 45–50.

Huzel, L., L.L. Roos, N.R. Anthonisen and J. Manfreda. 2002. "Diagnosing Asthma: The Fit between Survey and Administrative Database." *Canadian Respiratory Journal* 9(6): 407–12.

Kozyrskyj, A.L. and G.E. Hildes-Ripstein. 2002. "Assessing Health Status in Manitoba Children: Acute and Chronic Conditions." *Canadian Journal of Public Health* 93(Suppl.): 2S44–S49.

Kozyrskyj, A.L., C.A. Mustard and A.B. Becker. 2004. "Identifying Children with Persistent Asthma from Health Care Administrative Records." *Canadian Respiratory Journal* 11(2): 141–45.

Lawson, J.A. and A. Senthilselvan. 2005. "Asthma Epidemiology: Has the Crisis Passed?" *Current Opinion in Pulmonary Medicine* 11(1): 79–84.

Lundback, B., E. Ronmark, E. Jonsson, K. Larsson and T. Sandstrom. 2001. "Incidence of Physician-Diagnosed Asthma in Adults – A Real Incidence or a Result of Increased Awareness? Report from The Obstructive Lung Disease in Northern Sweden Studies." *Respiratory Medicine* 95(8): 685–92.

Manfreda, J., A.B. Becker, P.Z. Wang, L.L. Roos and N.R. Anthonisen. 1993. "Trends in Physician-Diagnosed Asthma Prevalence in Manitoba between 1980 and 1990." *Chest* 103(1): 151–57.

Manfreda, J., M.R. Sears, M.R. Becklake, M. Chan-Yeung, H. Mich-Ward, H.C. Siersted et al. 2004. "Geographic and Gender Variability in the Prevalence of Bronchial Responsiveness in Canada." *Chest* 125(5): 1657–64.

Mannino, D.M., D.M. Homa, L.J. Akinbami, J.E. Moorman, C. Gwynn and S.C. Redd. 2002. "Surveillance for Asthma – United States, 1980–1999." *MMWR Surveillance Summaries* 51(1): 1–13.

Martens, P.J., R.R. Fransoo, The Need to Know Team, E. Burland, L. Jebamani, C. Burchill et al. 2003. *The Manitoba RHA Indicators Atlas 2003*. Winnipeg: Manitoba Centre for Health Policy.

Millar, W.J. and G.B. Hill. 1998. "Childhood Asthma." *Health Reports* 10(3): 9–21.

Moorman, J.E., R.A. Rudd, C.A. Johnson, M. King, P. Minor, C. Bailey et al. 2007. "National Surveillance for Asthma – United States, 1980–2004." *MMWR Surveillance Summaries* 56(8): 1–54.

Roos, L.L., S. Gupta, R.A. Soodeen and L. Jebamani. 2005. "Data Quality in an Information-Rich Environment: Canada as an Example." *Canadian Journal on Aging* 24(Suppl.): 1153–70.

Roos, L.L., C.A. Mustard and P.J. Nicol. 1993. "Registries and Administrative Data: Organization and Accuracy." *Medical Care* 3: 201–12.

Senthilselvan, A. 1998. "Prevalence of Physician-Diagnosed Asthma in Saskatchewan, 1981 to 1990." *Chest* 114(2): 388–92.

Senthilselvan, A., J. Lawson, D.C. Rennie and J.A. Dosman. 2003. "Stabilization of an Increasing Trend in Physician-Diagnosed Asthma Prevalence in Saskatchewan, 1991 to 1998." *Chest* 124(2): 438–48.

Tinkelman, D.G., D.B. Price, R.J. Nordyke and R.J. Halbert. 2006. "Misdiagnosis of COPD and Asthma in Primary Care Patients 40 Years of Age and Over." *Journal of Asthma* 43(1): 75–80.

DATA MATTERS

Wait Time from Primary to Specialty Care: A Trend Analysis from Edmonton, Canada

Temps d'attente entre les services de première ligne et les soins d'un spécialiste : analyse de la tendance à Edmonton, Canada

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Abstract

Medical wait time is a top health policy issue in Canada. Reliable data on the referral wait time from primary to specialty care are limited. Existing data on referral wait times are generally self-reported by specialists. In 2008, the Edmonton North Primary Care Network (PCN) developed a Centralized Referral Program, including a specialist database that contains information on specialists' referral requirements, forms and protocols, and has the capability of tracking referrals that the PCN makes on behalf of its family physicians to specialty care. We performed a trend analysis of the referral wait time (defined as the time from referral by a family physician to an appointment date with a specialist) from 2009 to 2011 using the program database (n=33,281 referrals). The study provided a unique and comprehensive picture of wait times for 22 specialties. We identified a decrease in the overall wait time year over year, and improvement in the number of referrals that are accepted the first time. Additionally, specific opportunities for further improvement in referral wait time were noted.

Résumé

Les temps d'attente pour les services médicaux constituent un des principaux enjeux de politique de santé au Canada. Il y a peu de données fiables sur le temps d'attente entre les services de première ligne et l'aiguillage vers les soins d'un spécialiste. Les données sur ces temps d'attente sont généralement signalées par les spécialistes eux-mêmes. En 2008, le réseau Edmonton North Primary Care Network (PCN) a mis au point un programme centralisé d'aiguillage, doté d'une base de données spécialisée qui contient des renseignements sur les conditions, les formulaires et les protocoles d'aiguillage vers les spécialistes. Cette base de données permet d'assurer le suivi des aiguillages que le PCN fait au nom des médecins de famille vers les soins de spécialistes. Nous avons effectué une analyse de la tendance des temps d'attente pour l'aiguillage (défini comme étant le temps entre la recommandation de la part du médecin de famille et la date de rendez-vous chez le spécialiste), de 2009 à 2011, à l'aide de la base de données du programme (n=33 281 aiguillages). L'étude brosse un portrait unique et complet des temps d'attente pour 22 spécialités. Nous avons observé un déclin, d'année en année, du temps général d'attente ainsi qu'une amélioration du nombre d'aiguillages qui sont acceptés dès la première fois. De plus, nous avons dégagé des occasions précises pour améliorer davantage le temps d'attente pour les aiguillages.

Referral wait time refers to the wait time from referral by a family physician (FP) to appointment/consultation with a specialist. According to Barua and colleagues (2010), the median referral wait time in Canada, across 12 specialties (plastic surgery, gynaecology, ophthalmology, otolaryngology, general surgery, neurosurgery, orthopaedic surgery, cardiovascular surgery, urology, internal medicine, radiation oncology and medical oncology) and 10 provinces surveyed was 8.9 weeks in 2010. The referral wait time varies greatly by province, with the shortest being reported in Saskatchewan (6.7 weeks) and the longest in New Brunswick (24.6 weeks). In Alberta, the median wait time was 9.9 weeks (or 69.3 days), and reducing wait times is one of the priorities identified in Alberta's Five-Year Health Action Plan (established by the Government of Alberta and Alberta Health Services in 2010).

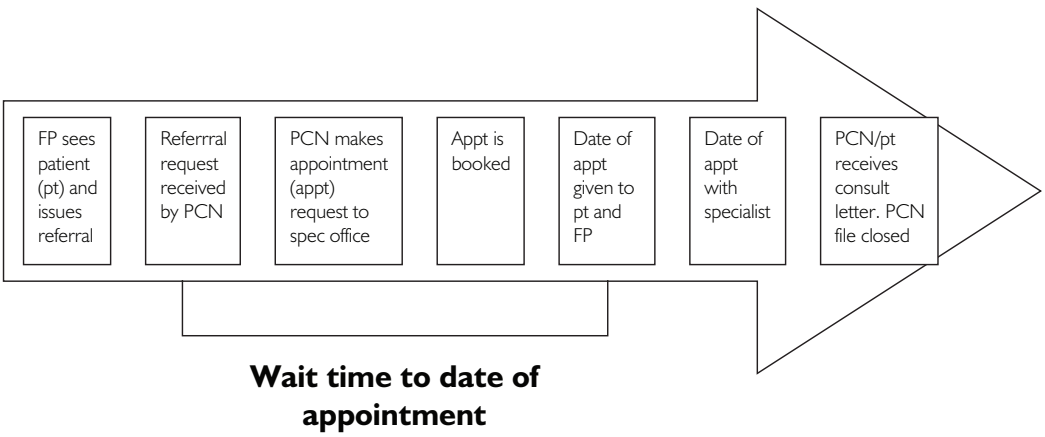
A primary care network (PCN) is an independent, stand-alone organization jointly owned by a group of FPs practising in a geographic area and Alberta Health Services. Formed by a trilateral agreement in 2003 among the Alberta Medical Association, Alberta Health and Alberta Health Services, Alberta's 40 PCNs are tasked with achieving five provincial objectives that include, among others, increasing the number of Albertans with access to primary care services and improving coordination of primary health services with other healthcare services including hospitals, long-term care and specialty care services (Primary Care Initiative 2012).

Edmonton North PCN, started in 2007, is one of the largest PCNs in the province both in terms of number of patients and number of member FPs. It is made up of 140 FPs working in over 45 clinics providing care to over 150,000 patients. The PCN employs over 90 staff to support the FPs in delivering primary care.

From its inception, improving links with specialists and reducing the referral wait time from family practice to specialty care has been a key priority for this PCN. The Centralized Referral Program, developed in 2008, maintains a customized specialist database with capacity for two data sets. The first involves a comprehensive list of over 800 specialists in and around Edmonton, including their referral requirements, forms and protocols. The second data set contains tracking information on the referrals the PCN makes on behalf of its participating FPs to specialists.

There are 6.8 full-time equivalent (FTE) coordinators who process referrals at the Edmonton North PCN. (Of note, PCN staff do not process urgent referrals as these are made directly by the FP.) The referral process involves seven milestones as shown in Figure 1. After receiving a referral request from the FP, PCN staff make an appointment request to the specialist office. If the referral is accepted by a specialist, the date of booking and date of appointment are noted. If a referral is declined, PCN staff continue to seek an appointment from subsequent specialists until an appointment is received. The advantages of the program are twofold in improving wait time. By tracking the wait time for each specialist, staff can refer patients to the one with the shortest wait list (unless the FP requests a certain specialist). Furthermore, PCN staff ensure that all forms and labs are completed and do relevant investigations to improve the quality and appropriateness of each referral, thus increasing the likelihood that the referral is accepted the first time.

FIGURE 1. Referral process at PCN



Anecdotal feedback on the program has been positive, and some other PCNs in the province are now using the Edmonton North PCN database; however, the impact of the Centralized Referral Program and its database has never been quantitatively reviewed. Partly to fill this gap, given the unavailability of both control data and baseline data, we performed a trend analysis of the referral wait time from 2009 to 2011 using data from the Edmonton North PCN database.

Methods

Because the referral wait time was calculated from the date of referral received by the PCN to the date of appointment with a specialist, referrals that had not yet received an appointment date were excluded from the study. We used both univariate and multivariate statistical techniques for describing and analyzing the referral wait time among referrals with an appointment date, in terms of mean, median, percentile 90% and percentage of referrals with a wait time of less than or equal to three months – a cut-off that was previously used by Carrière and Sanmartin (2010).

The univariate analysis was undertaken to describe the referral wait time by year (2009, 2010 and 2011) and by characteristics of patients (age and sex) and characteristics of referrals (seasons, referral modes, re-referrals and specialties). The multivariate analysis was used to compare the wait time in 2010 and 2011 to that of 2009, controlling for potential confounders, which were the characteristics of patients and the characteristics of referrals. We used a multiple linear regression for the mean, a multiple quantile regression for the median and for the percentile 90% (Hao and Naiman 2007), and a multiple logistic regression for the percentage of referrals with a wait time of less than or equal to three months.

In this study, male and female patients were categorized into three age groups representing children (0–18 years old), adults (19–64 years old) and seniors (65 years or older).

We grouped referrals with a referral date between February and April as spring, between May and July as summer, between August and October as fall, and between November and January as winter. Referral modes included telephone (where specialists accept referrals by telephone) or letter (where specialists do not make appointments over the telephone but first require a faxed letter). Re-referrals represented instances when a first referral is declined by the specialist, necessitating a subsequent referral to another specialist. Reasons for specialists' declining referrals included not accepting new patients, not assessing or treating the problem listed in the referral, failure to receive required laboratory findings, or the patient's having previously seen another doctor in the same specialty (and who thus should be referred back to that physician). Specialties refer to the medical specialties to which the patients were referred. We included 22 specialties and one "other" category, which comprised a number of specialties having a small number of referrals (this combination was for increasing the statistical power); all are listed in Table 3 (available online at longwoods.com/content/23375).

We used the 5% significance level and Stata MP 11.2 (StataCorp, College Station, Texas, USA) for data analyses.

This study and the Centralized Referral Program were approved by the North Edmonton PCN board of directors, which provides overall approval, oversight and accountability for all PCN programs, including their management, evaluation and research.

Results

In total, 33,281 referrals with an appointment date were included for analysis. Of these, 33% were received by the PCN in 2009, 38% in 2010 and 29% in 2011. The reduced number of referrals in 2011 may be explained by the exclusion of incomplete referrals (those still pending an appointment at year end). The number of referrals also varied greatly across the characteristics of patients and referrals, and across specialties. For example, the most frequent age group, sex, season and referral mode was "19–64," "female" (Table 1), "summer" and "letter" (Table 2), respectively. Re-referrals accounted for 10% of all referrals (Table 2). Regarding specialties, dermatology had the most (4,219 referrals, or 13%) and neurosurgery had the least (107 referrals, or 0.3%) number of referrals (Table 3 – available online at longwoods.com/content/23375).

TABLE 1. Referral wait time (days) by year and characteristics of patients

		Year			
	Measures	**2009**	**2010**	**2011**	**Total**
All referrals	N	10,919	12,742	9,620	33,281
	Mean	96	88	73	86
	Median	63	63	56	61
	p90	209	185	154	181
	% ≤3 months	66%	66%	71%	67%
Characteristics of patients					
Age groups					
0–18 years old	n	719	920	645	2,284
	Mean	93	95	74	89
	Median	65	71	55	63
	p90	181	202	168	187
	% ≤3 months	65%	60%	71%	64%
19–64 years old	n	7,834	9,097	6,864	23,795
	Mean	99	88	75	88
	Median	67	64	57	63
	p90	217	185	158	183
	% ≤3 months	65%	66%	70%	67%
65+ years old	n	2,366	2,725	2,111	7,202
	Mean	87	84	67	80
	Median	55	57	51	55
	p90	189	181	143	168
	% ≤3 months	71%	69%	75%	71%

TABLE 1. Continued

		Year			
	Measures	**2009**	**2010**	**2011**	**Total**
Characteristics of patients					
Sex					
Male	n	2,783	4,840	3,791	11,414
	Mean	94	88	72	84
	Median	63	63	55	60
	p90	202	187	153	174
	% ≤3 months	67%	64%	71%	67%
Female	n	4,953	7,498	5,444	17,895
	Mean	103	87	74	87
	Median	69	63	57	62
	p90	227	185	156	184
	% ≤3 months	63%	67%	71%	67%
Unknown sex	n	3,183	404	385	3,972
	Mean	88	86	69	86
	Median	57	65	51	57
	p90	185	169	144	180
	% ≤3 months	69%	69%	74%	70%

Tables 1, 2 and 3 show descriptive statistics of the wait time by year and by characteristics of patients, characteristics of referrals and specialties. For all referrals and years, the wait time mean, median and percentile 90% were 86 days, 61 days and 181 days, respectively. Referrals with a wait time of less than or equal to three months accounted for 67% of all referrals (Table 1).

The trend of wait times showed improvement over time. From 2009 to 2011, the mean decreased from 96 days to 73 days, median from 63 days to 56 days, percentile 90% from 209 days to 154 days and the percentage of referrals with a wait time of less than or equal to three months increased from 66% to 71% (Table 1). The trend of improvement seemed to be consistent among characteristics of patients and referrals, but varied greatly by specialties. For example, the generally positive trend was reversed in the specialties of allergy and clinical immunology, otolaryngology and rheumatology. Between 2009 and 2011 in allergy and clinical immunology, the mean increased from 79 days to 181 days, median from 48 days to 180 days, percentile 90% from 113 days to 276 days and the percentage of referrals with a wait time of less than or equal to three months decreased from 89% to 7%. The corresponding changes in otolaryngology were mean from 71 days to 94 days, median from 37 days to 84 days, percentile 90% from 155 days to 188 days and the percentage of referrals with a wait time of less than or equal to three months from 74% to 53%. In rheumatology, the trend was reversed for mean (from 78 days to 82 days), median (from 73 days to 78 days) and the percentage of referrals with a wait time of less than or equal to three months (from 72% to 57%), but percentile 90% dropped (from 148 days to 136 days) (Table 3 – available online at longwoods.com/content/23375).

TABLE 2. Referral wait time (days) by year and characteristics of referrals

Characteristics of referrals		Year			
	Measures	2009	2010	2011	Total
Season/months					
Spring (Feb–Apr)	n	2,572	3,196	2,835	8,603
	Mean	94	90	79	88
	Median	57	61	59	59
	p90	209	199	174	192
	% ≤3 months	68%	67%	68%	68%
Summer (May–Jul)	n	2,928	3,223	2,731	8,882
	Mean	104	92	80	92
	Median	68	69	63	67
	p91	229	192	162	189
	% ≤3 months	61%	63%	65%	63%
Fall (Aug–Oct)	n	2,818	3,185	2,215	8,218
	Mean	93	85	66	82
	Median	64.5	63	54	61
	p92	189	181	129	166
	% ≤3 months	68%	66%	76%	69%
Winter (Nov–Jan)	n	2,601	3,138	1,839	7,578
	Mean	93	83	63	82
	Median	63	62	45	57
	p93	205	165	141	168
	% ≤3 months	67%	68%	79%	70%
Modes of referrals					
Phone	n	3,561	3,446	2,964	9,971
	Mean	70	63	66	66
	Median	50	46	49	48
	p90	134	127	149	138
	% ≤3 months	77%	78%	74%	77%
Letter	n	7,114	8,991	6,583	22,688
	Mean	109	97	76	95
	Median	71	71	58	67
	p90	237	201	158	198
	% ≤3 months	61%	61%	70%	64%
Unknown mode	n	244	305	73	622
	Mean	105	80	74	89
	Median	77	48	68	62
	p90	217	204	143	200
	% ≤3 months	56%	68%	66%	63%
Re-referrals					
No	n	9,646	11,366	8,801	29,813
	Mean	82	80	70	78
	Median	58	58	54	56
	p90	170	165	148	161
	% ≤3 months	70%	69%	73%	71%
Yes	n	1,273	1,376	819	3,468
	Mean	203	150	106	159
	Median	145	118	90	118
	p90	468	309	204	332
	% ≤3 months	31%	38%	51%	38%

Table 4 (viewable online at longwoods.com/content/23375) shows results from multiple regressions on the wait time. Controlling for characteristics of patients, referrals and specialties, the regressions show an improvement in the wait time over time. Compared to 2009, the mean (median; percentile 90%) of wait time was reduced by 11 days (2 days; 18 days) in 2010 and by 21 days (7 days; 27 days) in 2011. All the differences were statistically significant. The odd ratios of the logistic regression indicated that compared to 2009, the percentage of referrals with a wait time of less than or equal to three months increased by 6% in 2010 and by 23% in 2011. However, only the difference between 2009 and 2011 was significant.

Regarding patient characteristics, there was a significant difference in wait time between men and women. However, the "unknown sex" group, which accounted for 12% of the sample, may bias this association. Compared to patients aged 19–64 years, patients aged 18 years or younger (referred to all specialties) had a significantly longer wait time, while patients aged 65 years or older had a significantly shorter wait time.

On average, referrals in summer had 4 days', 11 days' and 12 days' longer wait time than those in spring, fall and winter, respectively. This variance is likely explained by the summer vacation season.

Patients who needed to be re-referred waited 68 days longer than those whose initial referrals were accepted. Patients referred to specialists who required letters before an appointment could be made had to wait 23 days longer than those whose doctors accepted appointments over the telephone. These patterns held true for median and percentile 90% of the wait time and true for the percentage of referrals with a wait time of less than or equal to three months. All the differences were statistically significant.

The wait time varied substantially among specialties. Compared to paediatrics, the shortest wait time mean specialty (of note, only 54% of children aged 18 years or younger were referred to paediatricians), all other specialties had a significantly longer wait time and a significantly lower percentage of referrals with a wait time of less than or equal to three months. The exceptions were cardiology, dermatology and respirology for percentile 90%, and dermatology and respirology for the percentage.

Discussion

The main finding of this study is the trend of improvement in referral wait time from 2009 to 2011 at the Edmonton North PCN. It is possible that the Centralized Referral Program – by tracking and maintaining specialist data, striving to ensure referrals are accepted the first time and referring patients to specialists with shorter wait lists – has had a positive impact. However, this attribution is weakened by the absence of control data. During the study time period, some specialties in Edmonton implemented a number of strategies and activities to reduce their wait times (Alberta Health Services 2010, 2011), and it is possible these also had a positive impact on the wait time. In order to confirm whether the Centralized Referral Program has had a positive impact on wait times, control data are required.

In terms of related data, Alberta has a wait time registry where Albertans interested in treatment options can view wait time information (including trends over time) on medical procedures and diagnostic tests and then discuss their choices with their healthcare provider (Alberta Health and Wellness and Alberta Health Services 2012). However, the registry defines wait time as the interval between a patient's or specialist's decision that a procedure or test is required and the date the procedure or test is performed. Because this is different from the definition in the current study, outcomes cannot be directly compared. Another source of data showing the trend over time of referral wait times is the series of reports titled *Waiting Your Turn: Wait Times for Health Care in Canada* by the Fraser Institute (Barua et al. 2010, 2011). By surveying practitioners of 12 specialties, the reports show that the median referral wait times in Alberta in 2009, 2010 and 2011 were 10.0, 9.9 and 10.7 weeks, respectively. Compared to this self-reported trend, our results favour the Centralized Referral Program.

Several findings from this study have policy implications. First, the referral wait time and its trend over time vary substantially by specialty. More investigation is warranted to understand these differences and resolve any bottlenecks, especially for specialties with a long wait time and those with the reverse trend. Second, patients have to wait for more than two months longer if they need to be re-referred, suggesting that efforts to improve referral appropriateness, such as those attempted through the Centralized Referral Program, are warranted. Third, patients have to wait considerably longer if a specialist requires a letter of referral before a booking is made rather than making an appointment over the telephone (with a letter to follow). Simply eliminating this one step in the booking process could result in reducing wait times by over three weeks.

A limitation regarding the data that needs to be acknowledged is that, as the data were extracted in early January 2012, the referrals received by Edmonton North PCN in late 2011, or referrals in 2011 that needed a long time to receive an appointment date, were not included in the analysis (that is, only completed referrals were included). Such exclusions may bias the wait time results in 2011. However, the wait time improvement from 2009 to 2010 is unlikely to be biased. One may also argue that the wait time improvement between 2009 and 2011 is due to the reduction in the volume of referrals. However, this seems unlikely as there was also an improvement of the wait time between 2009 and 2010, when the volume increased. Finally, the wait time from the date on which a FP sees the patient and issues a referral to the date on which the PCN receives the referral was not available for this analysis.

In conclusion, this study demonstrates the potential value in tracking referral information from primary to specialty care. While there is not enough evidence to attribute the improvements directly to the Centralized Referral Program, the study findings are encouraging and further investigation, preferably through a controlled study, is recommended. Referral wait time from primary to specialty care is an immensely complex issue, and substantive improvement will likely require focused system-level attention. However, this study suggests that change is possible and that further improvements can be made.

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References

Alberta Health Services. 2011. 2011–2015 *Health Plan*. Retrieved April 13, 2013. <http://www.albertahealthservices.ca/Publications/ahs-pub-2011-2015-health-plan.pdf>.

Alberta Health and Wellness and Alberta Health Services. 2012. "Alberta Wait Times Reporting, Wait Time Trends." Retrieved April 13, 2013. <http://waittimes.alberta.ca/>.

Barua, B., M. Rovere and B.J. Skinner. 2010. *Waiting Your Turn: Wait Times for Health Care in Canada* (20th ed.). Retrieved April 13, 2013. <http://www.fraserinstitute.org/uploadedFiles/fraser-ca/Content/research-news/research/publications/waiting-your-turn-2010.pdf>.

Barua, B., M. Rovere and B.J. Skinner. 2011. *Waiting Your Turn: Wait Times for Health Care in Canada* (21st ed.). Retrieved April 13, 2013. <http://www.fraserinstitute.org/uploadedFiles/fraser-ca/Content/research-news/research/publications/waiting-your-turn-2011.pdf>.

Carrière, G. and C. Sanmartin. 2010. "Waiting Time for Medical Specialist Consultations in Canada, 2007." *Health Reports* 21(2): 1–8. Statistics Canada Catalogue no. 82-003-XPE.

Government of Alberta and Alberta Health Services. 2010. "Becoming the Best: Alberta's 5-Year Health Action Plan 2010–2015." Retrieved April 13, 2013. <http://www.health.alberta.ca/documents/Becoming-the-Best-2010.pdf>.

Hao, L. and D.Q. Naiman. 2007. *Quantile Regression.* Quantitative Applications in the Social Sciences Series 149. Thousand Oaks, CA: Sage Publications.

Primary Care Initiative. 2012. "About PCNs." Retrieved April 13, 2013. <http://www.albertapci.ca/AboutPCNs/Pages/default.aspx>.

RESEARCH PAPER

Use of Product Listing Agreements by Canadian Provincial Drug Benefit Plans

Recours aux ententes relatives à l'inscription des produits par les régimes provinciaux d'assurance médicaments au Canada

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Abstract

Background: Product listing agreements (PLAs) between drug manufacturers and drug plans are increasingly common worldwide. Use of PLAs by Canadian provinces has not previously been documented.

Methods: We collected data from all provinces on funding and PLA use for 25 drugs that were reviewed by the Common Drug Review (CDR) in 2010 or 2011 and funded by at least one province as of May 2012. We measured correlations between coverage and PLA use, and CDR recommendations and PLA use.

Results: The number of drugs from our sample funded by provinces ranged from three in Prince Edward Island to 21 in Ontario. PLA use ranged from zero in Quebec, Prince Edward Island, and Newfoundland and Labrador to 20 in Ontario. The correlation between drugs funded and PLAs used by each province was statistically significant (r=0.57, p=0.04); excluding Ontario, however, the correlation was not significant (r=0.10, p=0.40). There was a stronger correlation between the number of provinces funding a drug and the number using PLAs among the subset of drugs with negative CDR recommendations (r=0.87, p<0.01) versus those with positive recommendations (r=0.52, p=0.03). Of the 12 drugs sampled with a negative CDR recommendation, 10 were funded with a PLA in at least one province.

Interpretation: There is wide interprovincial variation in PLA use and evidence that PLAs may be used to fund drugs that are not otherwise cost-effective. If global pricing strategies are making PLAs necessary, Canadian governments should collaborate to improve the equity, transparency and effectiveness of PLAs across provinces.

Résumé

Contexte : Les ententes relatives à l'inscription des produits (EIP) entre fabricants de médicaments et régimes d'assurance médicaments sont de plus en plus communes dans le monde. Le recours aux EIP par les provinces canadiennes n'a pas été documenté jusqu'à maintenant.

Méthodes : Nous avons recueillis des données de toutes les provinces sur le financement et le recours aux EIP pour 25 médicaments qui ont été évalués dans le cadre du Programme commun d'évaluation des médicaments (PCEM), en 2010 et 2011, et qui ont été financés par au moins une province en mai 2012. Nous avons calculé la corrélation entre la couverture par le régime d'assurance et le recours aux EIP, ainsi qu'entre les recommandations du PCEM et le recours aux EIP.

Résultats : Dans notre échantillon, le nombre de médicaments financés par les provinces varie entre 3 à l'Île-du-Prince-Édouard et 21 en Ontario. Le recours aux EIP varie entre 0 au Québec, à l'Île-du-Prince-Édouard et à Terre-Neuve-et-Labrador et 20 en Ontario. La corrélation entre les médicaments financés et le recours aux EIP dans chaque province est statistiquement significative (r=.57, p=.04); à l'exception de l'Ontario, toutefois, où la corrélation n'est pas significative (r=.10, p=.40). Il y avait une plus forte corrélation entre le nombre de provinces qui financent un médicament et le nombre de provinces qui ont recours aux EIP, et ce, pour la sous-catégorie de médicaments qui ont reçu une recommandation défavorable de la part du PCEM (r=0.87, p<0.01), par rapport à ceux dont la recommandation était favorable

(r=0.52, p=0.03). Parmi les 12 médicaments de l'échantillon qui ont reçu une recommandation défavorable du PCEM, 10 étaient financés dans le cadre d'une EIP dans au moins une province.
Interprétation : Il y a une grande variation interprovinciale dans le recours aux EIP et il s'avère que le recours aux EIP est peut-être employé pour financer des médicaments qui ne seraient pas efficient par rapport au coût. Si les stratégies de prix mondiales rendent nécessaire le recours aux EIP, les gouvernements au Canada devraient collaborer pour améliorer l'équité, la transparence et l'efficacité des EIP dans les provinces.

Around the world, negotiated contracts between drug manufacturers and healthcare payers are becoming increasingly common (Adamski et al. 2010; Carlson et al. 2010). Known under a variety of names, a common element of these product listing agreements (PLAs) is the negotiation of confidential prices that are typically achieved through rebates that may or may not be tied to drug expenditures, utilization patterns or health outcomes. Though Canadian hospitals have long used confidential purchasing arrangements, provincial drug plans rarely negotiated confidential price rebates before 2006 (Gorecki 1992; Morgan et al. 2003; Paris and Docteur 2007). In recent years, however, some provinces have begun to use PLAs routinely, and in 2010, a Pan-Canadian Purchasing Alliance was established to coordinate PLA negotiations for some new medicines on behalf of participating provinces (Lynas 2010).

The use of PLAs may result in otherwise unattainable price discounts as manufacturers are said to be increasingly reluctant to provide transparent price reductions because other domestic or international payers will demand the same (Docteur et al. 2008; Seiter 2010). PLAs may also promote appropriate utilization, budgetary certainty or value-based remuneration if they include appropriate terms related to drug marketing, expenditure or outcomes (Carlson et al. 2010). These potential benefits do, however, come with drawbacks, including reduced decision-making transparency, additional administrative and legal costs, and potential for increased price disparities across payers (Adamski et al. 2010).

The levels of and variations in PLA use among Canadian provinces have potentially important implications for the consistency of drug prices and access across the country. At present, however, no province currently publishes information about PLA use for all funded medicines. This lack of public information about provincial use of PLAs to date makes it difficult to engage in informed debate about this policy tool in Canada. Several authors have gathered information about the types of negotiated agreements that have been tried in one or more provinces (Carlson et al. 2010; Nason and Sproule 2011; Stafinski et al. 2010). To our knowledge, however, no study has systematically documented the use of PLAs in Canada. We aimed to fill this evidence gap by collecting information from all provinces about PLA use for a sample of pharmaceuticals for which manufacturers recently sought coverage under provincial drug plans.

Methods

Lacking public sources of data, we requested information about PLA use directly from policy makers in each province. Owing to the sensitive nature of information concerning PLAs, we first consulted with policy makers to determine the information that could and could not be made publicly available. In May 2012, we asked policy makers whether they could disclose drug-specific information about coverage, PLA use and PLA type (for example, simple rebates, price-volume agreements or outcomes-based pricing). After gathering information and feedback from all 10 provinces, in July 2012 we requested drug-by-drug information for a sample of drugs that received an initial Common Drug Review (CDR) recommendation in 2010 or 2011 and that were funded in one or more of the provinces at the time. A total of 35 drugs had been first reviewed by the CDR in 2010–2011. We excluded nine of these drugs because they were not listed for coverage by any province as of May 2012 – and, hence, wouldn't generate data about PLAs. We also excluded one drug, Janumet, on advice that confidentiality clauses regarding related PLAs in some unnamed provinces would necessarily limit participation in our study.

Provinces were asked to indicate whether each of the selected drugs was funded by the drug plan as of the survey date, the conditions of funding (i.e., special authority or otherwise) and whether a PLA was in place. Although Quebec does not participate in the CDR process, we selected these drugs for study because, being relatively new medicines for which manufacturers have sought public coverage, they were likely candidates for PLAs in provinces that now regularly use such contracts.

For each province, we computed the total number of drugs in our sample that were funded and the total number for which a PLA was in place. For each drug in our sample, we computed the total number of provinces providing funding and the total number of provinces with a PLA in place. Across provinces, we tested for correlations between the number of drugs covered and the number of PLAs used. Between the subset of drugs receiving a positive CDR recommendation and the subset receiving a negative CDR recommendation, we compared the average number of provinces providing funding and the average number of provinces with a PLA in place. Within the subsets of drugs with positive and negative CDR recommendations, we tested for correlations between the number of provinces covering a drug and the number of provinces with a PLA in place. All correlations were tested using two-tailed Pearson's product-moment correlation coefficients (r).

Results

Policy makers advised that provinces are unable to provide details about the specific terms of each PLA in place because these are confidential. We were therefore limited to documenting only the presence of a PLA for each drug but not the type of PLA applied. Table 1 lists for each province the total number of drugs from our sample that were funded and the total number for which a PLA was in place (full results regarding drug-by-drug coverage and PLA use provided by each province are available in Appendix 1 [available online at longwoods.com/

content/23376). The number of drugs funded by each province ranged from three (Prince Edward Island) to 21 (Ontario). The number of drugs for which provinces had PLAs in place ranged from zero (Quebec, Prince Edward Island, and Newfoundland and Labrador) to 20 (Ontario).

TABLE 1. Province-specific totals for drugs funded and PLAs used

	Total Funded (n=25)	Total PLAs	% Funded with PLAs
Ontario	21	20	95
British Columbia	14	7	50
Manitoba	6	6	100
Saskatchewan	17	3	18
Alberta	11	3	27
Nova Scotia	10	1	10
New Brunswick	8	1	13
Quebec	17	0	0
Newfoundland and Labrador	11	0	0
Prince Edward Island	3	0	0

Policy makers in Quebec and Newfoundland and Labrador indicated that current legislative frameworks governing their public drug plans do not allow for PLA negotiation. Specifically in Quebec, PLAs are not used owing to legislation that requires equal pricing between the public drug plan and private insurers. In contrast, in Manitoba, a utilization management agreement (UMA; akin to a PLA) is a statutory requirement for all drugs funded by Manitoba Pharmacare. Thus, although Manitoba funded among the fewest drugs from our sample, PLAs were in use for all six of the drugs funded there. A further 13 drugs from our sample were under review for coverage in Manitoba at the time we requested information; if listed, those drugs would also have UMAs/PLAs in place. PLAs are also used for virtually all funded drugs in Ontario. Of the 21 drugs in our sample funded by Ontario, the only one funded without a PLA is a combination product (telmisartan and amlodipine) that costs less than the individual drugs would cost separately (Ontario 2012). Policy makers in British Columbia were able to disclose that they had PLAs in place for seven of the 14 drugs from our sample funded by BC PharmaCare; for our sample of drugs, this was the second highest number of PLAs in use by any province. However, BC policy makers were not able to identify which drugs were funded with PLAs in place except for the case of eculizumab, for which a PLA was negotiated by the Pan-Canadian Purchasing Alliance (Blackwell 2012). Eculizumab was also the only drug in our sample for which New Brunswick and Nova Scotia had PLAs in place.

TABLE 2. CDR recommendations and rates of drug coverage and PLA use by provinces

Drug	Most Recent CDR Recommendation	Number of Provinces Funding Drug	Number of Provinces with PLA for Drug
Azelaic acid	List	8	2[a]
Telmisartan / Amlodipine	List	7	0
Brinzolamide and timolol maleate suspension	List in manner similar to comparator(s)	10	2[a]
Golimumab	List in manner similar to comparator(s)	9	1[a]
Fingolimod	List with criteria/conditions	2	0
Aripiprazole	List with criteria/conditions	9	2[a]
Aztreonam for Inhalation Solution	List with criteria/conditions	4	0
Denosumab	List with criteria/conditions	8	2[a]
Febuxostat	List with criteria/conditions	7	1[a]
Lacosamide	List with criteria/conditions	8	1[a]
Tadalafil	List with criteria/conditions	4	1[a]
Tocilizumab	List with criteria/conditions	8	2[a]
Velaglucerase alfa	List with criteria/conditions	1	1
Eculizumab[b]	Do not list	5	6
Ticagrelor	Do not list	2	0
Calcitriol	Do not list	2	1
Canakinumab	Do not list	1	1
Certolizumab pegol	Do not list	3	1[a]
Eltrombopag olamine	Do not list	1	1
Mometasone furoate + formoterol	Do not list	3	1[a]
Paliperidone palmitate	Do not list	5	3[a]
Prasugrel hydrochloride	Do not list	4	1[a]
Romiplostim	Do not list	1	1
Sapropterin dihydrochloride	Do not list	1	0
Saxagliptin	Do not list	5	4

[a] Numbers may be higher as British Columbia was unable to disclose the specific drugs for which it had PLAs in place.

[b] The Pan-Canadian Purchasing Alliance negotiated a PLA for eculizumab; Nova Scotia has this PLA in place should the drug be funded on a case-by-case basis.

The correlation between the number of drugs funded by each province and the number of drugs with PLAs in use by each province was positive, moderate and statistically significant ($r=0.57$, $p=0.04$). At the time data were collected, however, Ontario funded significantly more

of the sample drugs than most other provinces and used PLAs far more frequently than all other provinces. When Ontario's data are excluded, the correlation between the number of drugs funded and the number of PLAs in place for each province was no longer significantly different from zero (r=0.10, p=0.40).

Table 2 summarizes the CDR recommendations and the extent of provincial coverage and PLA use for each of the 25 drugs in our sample. More provinces funded drugs that received positive CDR recommendations (mean = 6.5 provinces, CI: 5.0, 8.1) than those with negative CDR recommendations (mean = 2.8 provinces, CI: 1.8, 3.7). Excluding British Columbia because of incomplete PLA data at the product level, there weren't significant differences in the average number of provinces using PLAs for drugs with positive CDR recommendations (mean = 1.2, CI: 0.7, 1.6) versus drugs with negative CDR recommendations (mean = 1.6, CI: 0.7, 2.5). Within these categories, and excluding British Columbia, there was a stronger correlation between the number of provinces funding a drug and the number using PLAs for that drug among the subset with negative CDR recommendations (r=0.87, p<0.01) versus those with positive CDR recommendations (r=0.53, p=0.03).

Interpretation

We documented wide interprovincial variation in the coverage and use of PLAs for a sample of 25 drugs recently reviewed by the CDR. Such variations may result in disparities in drug prices, access to medicines, or both. We also found that the recommendations of the CDR were correlated with the number of provinces funding drugs but not with the number of provinces using PLAs. That is, among recently reviewed drugs, a CDR "yes" generally means "yes" in terms of coverage decisions by multiple provinces, but a CDR "no" does not necessarily mean "no" in terms of coverage in all provinces. It appears that some provinces are using PLAs to fund drugs that would otherwise not be fundable at list prices. For example, saxagliptin was issued a "no" recommendation by the CDR, but was listed in five provinces, with four of the provinces using a PLA.

The use of PLAs in Canadian provinces reflects a global trend. Manufacturers' pricing strategies are shifting in response to the widespread use of external reference pricing policies internationally. As of 2010, it is estimated that at least 24 European countries use external reference pricing policies to limit domestic pharmaceutical prices to levels determined by prices available in other countries (Leopold et al. 2012). Price tests of Canada's Patented Medicine Prices Review Board are also based on international comparisons (PMPRB 2012). Similarly, the Quebec government limits drug prices according to prices in other provinces (Quebec 2012). When such policies are in place, any transparent price concession offered to one payer must be passed on to other payers. The Organisation for Economic Co-operation and Development and the World Bank have both observed that the widespread use of such external reference pricing policies is resulting in the harmonization of official "list" prices for pharmaceuticals and the increased use of confidential negotiations as a means for manufacturers to price-discriminate across payers (Docteur et al. 2008; Seiter 2010).

The global trends in drug pricing strategies have important implications for Canada. PLA-based pricing strategy places each purchaser into independent negotiations wherein only the manufacturer knows the final prices paid in all markets. Smaller jurisdictions are at a disadvantage in such a marketplace for at least two reasons. First, significant technical, legal and administrative resources are required for PLA negotiation and enforcement that were not required in the era of transparent drug pricing. Second, the outcome of drug price negotiations is influenced primarily by the purchasing power of the drug plan, which in turn is a function of the size of the population the drug plan covers. Because of these factors, larger jurisdictions can better afford negotiations and will likely obtain better deals.

PLAs can also leave patients at a significant disadvantage if drug coverage is inadequate. When price rebates are confidential and paid directly from a manufacturer to an insurer (private or public), patients must still pay inflated list prices if they are uninsured or if their coverage involves deductibles or co-insurance. This is a particularly serious problem in Canada because many Canadians are uninsured and most provincial drug plans involve significant patient cost-sharing that is a function of list prices for drugs (Daw and Morgan 2012). Thus, Canadian patients are not currently protected against paying inflated list prices for pharmaceuticals – whether those inflated prices are a result of domestic PLA use by government, global pharmaceutical pricing strategies by firms, or both.

Finally, the secrecy of PLAs raises important concerns in terms of policy transparency and accountability. Robertson and colleagues (2009) have argued that the obfuscation of price information through PLAs used for Australia's national Pharmaceutical Benefit Scheme makes it difficult for physicians to consider cost-effectiveness and potentially undermines the evidence-based approach to formulary decision-making that has long been established there. In the Canadian context, Dhalla and Laupacis (2008) have argued that price secrecy is part of a wider problem of opacity concerning the evaluation of medicines that limits informed decision-making by funders, prescribers and even patients. Notwithstanding these concerns, some level of price secrecy may be justified if global market trends are inflating list prices to facilitate price discrimination by way of confidential negotiations across and within all markets. That is, provided safeguards are in place to protect small provinces and patients from bearing undue costs, there may be legitimate public value in price secrecy through PLAs.

Limitations

Our study has several limitations worthy of discussion. First, our analysis of PLA use was based on a small sample of recently reviewed medicines and therefore provides no information concerning trends in the use of PLAs or the extent of PLA use for older medicines. Secondly, our data collection process was deliberately consultative given the sensitive nature of information concerning PLAs. This is unlikely to have biased the results in terms of accuracy of reporting; however, it might have resulted in requesting less information than might have

been made available through freedom of information requests or legal appeals. Finally, it is important to note that we did not assess whether PLAs are effective at achieving desired goals. Owing to the confidentiality of PLAs, an analysis of their effectiveness would be possible only by governments themselves, perhaps by auditors-general across provinces.

Conclusion

The significant variation observed in PLA use across Canada establishes a tension that will need to be resolved. The largest funder of medicines in Canada, the Ontario government, uses PLAs routinely as part of its drug coverage process. Major healthcare funders worldwide are also doing so, including public and private insurers in the United States, United Kingdom, Australasia and Europe (Adamski et al. 2010; Carlson et al. 2010). Yet, many small-scale payers (in Canada and internationally) do not use PLAs and may therefore be paying more than their fair share for medicines.

In an effort to increase collective negotiation power and make the benefits of PLA negotiation available across Canada, provinces have taken important steps towards collaboration on PLA negotiation through the Pan-Canadian Purchasing Alliance. Collaboration is critical to equity of outcomes in Canada considering that the public drug budget for Ontario ($4.48 billion) is on the same order of magnitude as the entire gross domestic product for Prince Edward Island ($5.01 billion) (CIHI 2012 ; Statistics Canada 2011). Making collaboration a routine and sustainable practice will require new resources to coordinate actors and maintain commitment on joint decisions that often involve significant local political pressures. However, if a new global paradigm of confidential drug pricing has in fact undermined the value of price regulation by international price comparisons, some federal support for collaboration on PLA negotiations could come through a modernization of the PMPRB's roles and regulations or through a redeployment of some of its $11.8-million budget (PMPRB 2012).

Canadian policy makers at the federal and provincial levels also need to consider the out-of-pocket burden of under- and uninsured Canadians who would face "list prices" that do not reflect the discounts offered internationally under the new global paradigm of drug pricing through PLAs. The same problem has been identified in the United States, where private and public insurers have been negotiating rebates on inflated list prices for many years. Experts there suggest that the only viable means to protect patients from inflated prices is to provide adequate drug coverage for all (Danzon and Towse 2003). In the Canadian context, this would require that governments stitch gaps in pharmacare coverage. Doing so could increase the purchasing power of pharmacare programs while addressing this key drawback of the new global pricing paradigm.

Finally, if PLA negotiations are here to stay, provinces and the federal government must work together to define national standards for transparency of policy making in this arena. Such a standard should be based on a careful analysis of principles and purposes behind transparency so as not to take power away from governments when the use of confidential rebates can be legitimately defended. Following such a process, it is likely that disclosure of

information about when PLAs are used and their general structure would be among the minimum requirements for legitimate accountability and, therefore, legitimate authority in negotiation processes (Bovens 2007). Establishing such a standard of PLA disclosure to which all provinces are bound would set clear rules of engagement and thereby reduce negotiation costs, prevent manufacturers' using price secrecy to game the system and increase the legitimacy of PLA processes.

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References

Adamski, J., B. Godman, G. Ofierska-Sujkowska, B. Osińska, H. Herholz, K. Wendykowska et al. 2010. "Risk Sharing Arrangements for Pharmaceuticals: Potential Considerations and Recommendations for European Payers." *BMC Health Services Research* 10: 153.

Blackwell, T. 2012 (April 26). "Provinces' New Weapon Against Big Pharma: Each Other." *National Post*. Retrieved April 2, 2013. <http://news.nationalpost.com/2012/04/26/provinces-new-weapon-against-big-pharma-each-other/>.

Bovens, M. 2007. "Public Accountability." In E. Ferlie, L.E. Lynn and C. Pollitt, eds., *The Oxford Handbook of Public Management* (pp. 182–208). Oxford: Oxford University Press.

Canadian Institute for Health Information (CIHI). 2012. *Drug Expenditure in Canada*, 1985–2011. Ottawa: Author.

Carlson, J.J., S.D. Sullivan, L.P. Garrison, P.J. Neumann and D.L. Veenstra. 2010. "Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance-Based Reimbursement Schemes between Healthcare Payers and Manufacturers." *Health Policy* 96(3): 179–90.

Danzon, P.M. and A. Towse. 2003. "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents." *International Journal of Health Care Finance & Economics* 3(3): 183–205.

Daw, J.R. and S.G. Morgan. 2012. "Stitching the Gaps in the Canadian Public Drug Coverage Patchwork? A Review of Provincial Pharmacare Policy Changes from 2000 to 2010." *Health Policy* 104(1): 19–26.

Dhalla, I. and A. Laupacis. 2008. "Moving from Opacity to Transparency in Pharmaceutical Policy." *Canadian Medical Association Journal* 178(4): 428–31.

Docteur, E., V. Paris and P. Moise. 2008. *Pharmaceutical Pricing Policies in a Global Market*. Paris: Organisation for Economic Co-operation and Development.

Gorecki, P.K. 1992. *Controlling Drug Expenditures in Canada: The Ontario Experience*. Ottawa: Economic Council of Canada.

Leopold, C., S. Vogler, A.K. Mantel-Teeuwisse, K. de Joncheere, H.G.M. Leufkens and R. Laing. 2012. "Differences in External Price Referencing in Europe – A Descriptive Overview." *Health Policy* 104(1): 50–60.

Lynas, K. 2010. "New Momentum for a Pan-Canadian Purchasing Alliance for Prescription Drugs." *Canadian Pharmacists Journal* 143(6): 264–65.

Morgan, S., M. Barer and J. Agnew. 2003. "Whither Seniors' Pharmacare: Lessons from (and for) Canada." *Health Affairs* 22(3): 49–59.

Nason, E. and J. Sproule. 2011. *Industry–Payor Agreements for Pharmaceuticals: Backgrounder for Roundtable*. Edmonton: Institute of Health Economics.

Ontario. 2012. Ontario Drug Benefit Formulary/Comparative Drug Index, Effective from April 1, 2013. Retrieved April 2, 2013. <https://www.healthinfo.moh.gov.on.ca/formulary/index.jsp>.

Paris, V. and E. Docteur. 2007. *Pharmaceutical Pricing and Reimbursement Policies in Canada*. OECD Health Working Papers. Paris: Organisation for Economic Co-operation and Development.

Patented Medicine Prices Review Board (PMPRB). 2012. *Compendium of Policies, Guidelines and Procedures*. Ottawa: Author.

Quebec. 2012. *Règlement sur les conditions de reconnaissance d'un fabricant de médicaments et d'un grossiste* A-29.01. Quebec: Author.

Robertson, J., E.J. Walkom and D.A. Henry. 2009. "Transparency in Pricing Arrangements for Medicines Listed on the Australian Pharmaceutical Benefits Scheme." *Australian Health Review* 33(2): 192–99.

Seiter, A. 2010. A Practical Approach to Pharmaceutical Policy. Washington, DC: World Bank.

Stafinski, T., C.J. McCabe and D. Menon. 2010. "Funding the Unfundable: Mechanisms for Managing Uncertainty in Decisions on the Introduction of New and Innovative Technologies into Healthcare Systems." *PharmacoEconomics* 28(2): 113–42.

Statistics Canada. 2011. Gross Domestic Product, Expenditure-Based, by Province and Territory. CANSIM table 384-0002, Catalogue no. 13-213-PPB. Retrieved April 2, 2013. <http://www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/econ15-eng.htm>.

RESEARCH PAPER

System Integration and Clinical Utilization of the Advanced Clinician Practitioner in Arthritis Care (ACPAC) Program–Trained Extended Role Practitioners in Ontario: A Two-Year, System-Level Evaluation

Intégration dans le système et utilisation clinique des praticiens aux fonctions élargies formés dans le cadre du programme Advanced Clinician Practitioner in Arthritis Care (ACPAC) en Ontario : évaluation de deux ans au niveau du système

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System Integration and Clinical Utilization of the ACPAC Program–Trained Extended Role Practitioners in Ontario

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Abstract

Background: The Advanced Clinician Practitioner in Arthritis Care (ACPAC) program was developed in 2005 to prepare experienced physical and occupational therapists to function as extended role practitioners (ERPs) within models of arthritis care across Ontario, Canada.
Purpose: To examine the system-level integration and clinical utilization of the ACPAC program–trained ERP.
Method: A longitudinal survey was administered to all ACPAC graduates over a two-year period (n=30).
Results: The majority of ERPs were physical therapists working in urban settings. Family physicians or physician specialists referred the majority of patients. The longest median wait time to access ERPs' services was 22 days. Half of the ERPs triaged patients, and most of those who did triage (75%) worked under medical directives. Approximately half (51.6%) of the patients seen had a diagnosis of osteoarthritis, followed by rheumatoid arthritis (14.7%).
Conclusion: Understanding the system-level impact of this unique human resource can help to shape healthcare planning and delivery of care.

Résumé

Contexte : Le programme Praticiens cliniques avancés dans le traitement de l'arthrite (Advanced Clinician Practitioner in Arthritis Care, ACPAC) a été créé en 2005 pour préparer des physiothérapeutes et des ergothérapeutes expérimentés à remplir le rôle de praticiens aux fonctions élargies (PFE) au sein de modèles de traitement de l'arthrite en Ontario, Canada.
Objet : Examiner l'intégration au niveau du système et l'utilisation clinique des PFE formés dans le cadre du programme ACPAC.
Méthode : Nous avons mené une enquête longitudinale auprès de tous les diplômés de l'ACPAC pendant une période de deux ans (n=30).
Résultats : La majorité des PFE étaient des physiothérapeutes qui travaillaient dans des établissements urbains. La majorité des patients y étaient acheminés par des médecins de famille ou des spécialistes. La plus longue médiane pour le temps d'attente avant d'accéder aux services

d'un PFE était de 22 jours. La moitié des patients qui ont été dirigé par triage par un PFE, et la plupart de ceux qui ont effectué le triage (75 %), ont travaillé sous direction médicale. Environ la moitié (51,6 %) des patients traités avaient reçu un diagnostic d'ostéo-arthrite, suivi de l'arthrite rhumatoïde (14,7 %).
Conclusion : Mieux comprendre l'impact, à l'échelon du système, de cette ressource humaine unique peut aider la planification de services de santé et la prestation des soins.

Arthritis and musculoskeletal disorders are among the most common chronic health conditions in Canada, affecting more than 4.6 million people (Bombardier et al. 2011). Together, they are a leading cause of morbidity, disability and healthcare utilization. These conditions affect people of all ages, being most prevalent among seniors but also affecting children and working-age adults. The most common arthritis conditions, those with the greatest impact on the healthcare system, and those expected to increase to approximately 2% of the population in the next 30 years, are osteoarthritis (OA) and rheumatoid arthritis (RA) (Bombardier et al. 2011).

In order to help address the growing arthritis burden, the Advanced Clinician Practitioner in Arthritis Care (ACPAC) program was developed in 2005 to prepare experienced physical therapists and occupational therapists for extended practice roles and to promote the development of innovative models of arthritis care across diverse clinical settings in Ontario, Canada. Graduates of the ACPAC program represent a new cadre of extended role practitioner (ERP), having received significant additional training with formal evaluation to establish competency in advanced assessment, diagnosis and management of select arthritis conditions described elsewhere (Lundon et al. 2011). The ACPAC program is a unique clinical and academic training program offered in Toronto, Ontario. It focuses on the advanced assessment, diagnosis, triage and independent management of select musculoskeletal (orthopaedic) and arthritis-related (rheumatological) disorders (Lundon et al. 2008, 2009, 2011). Between 2005 and 2011, five cohorts (37 practitioners) of trainees have successfully completed the ACPAC program.

A need was identified to evaluate the impact of the ERPs as the graduates of the ACPAC program began to develop and implement new roles at their various institutions. The purpose of this study was to evaluate the system-level impact of ACPAC program–trained ERPs working within various models of arthritis care in diverse clinical settings across Ontario. The specific objectives were to (a) measure the extent to which ACPAC program–trained ERPs are delivering integrated and timely healthcare for patients with musculoskeletal and arthritis-related disorders throughout the province of Ontario, (b) describe the role utilization of the ACPAC program–trained ERP and (c) describe the clinical performance of the ACPAC program–trained ERP with respect to patient volumes, referral sources and diagnoses of patients seen by the ERPs.

Methods

The balanced scorecard approach (Kaplan and Norton 1996) was chosen as a framework for evaluation. This framework was used to provide stakeholders of the ACPAC program (faculty, students, graduates, healthcare organizations, policy makers) with feedback regarding performance measurement and to permit continuous improvement and strategic healthcare planning. In the province of Ontario, the Hospital Report: Rehabilitation series (Cott et al. 2005) has modeled four quadrants from the original balanced scorecard approach using the following nomenclature: (a) client perspectives, (b) clinical utilization and outcomes, (c) system integration and change and (d) financial performance and condition. This nomenclature was chosen for the ACPAC system-level evaluation, with the exception that "client perspectives" was renamed "patient and stakeholder perspectives." This study reports on the results from the system integration and change (SIC) and the clinical utilization and outcomes (CUO) quadrants.

TABLE 1. System integration and change (SIC) and clinical utilization and outcomes (CUO) indicator definitions

Indicator	Definition
System Integration and Change	
Access to care	
Wait times	The number of days from the date of referral to the date the ERP first saw the patient. The average wait time was calculated as the total wait time for all new patients seen during the fiscal quarter divided by the number of new patients seen during the fiscal quarter. Weekends and holidays were included in this calculation.
Integration of extended role practice	
Extended role practice	Working in a professional capacity that uses competencies beyond entry-to-practice–level competencies and which may be achieved through delegation or medical directives in either all or part of a full-time equivalent position.
Full-time equivalent (FTE)	The proportion of a full-time equivalent position employed as an ERP.
Title	Job title used at the ERP's primary place of employment at the time the quarterly questionnaire was completed.
Medical directives	Medical directives are defined as "indirect physician orders, used to expedite patient care by competent health professionals" (Hospital for Sick Children 2012). Elements of medical directives include the specifics of the procedure, safety conditions, the types of patient to which the directive applies and the types of professional that are authorized to implement the procedure (College of Physiotherapists of Ontario 2008).
Integration with the healthcare system	
Referral to services	The number of patients referred to institutional or community healthcare services and resources.
Communication	The number of dictations and letters completed that were related to the ERP role.

TABLE 1. Continued

Indicator	Definition
Clinical Utilization and Outcomes	
Volumes	
New consultations	The number of patients seen face-to-face for the first time by the ERP, regardless of whether this was in an initial consultation or triage capacity.
Follow-ups	The number of patient encounters seen in follow-up for either consultation or treatment. If the same patient was seen more than once, the visit was counted on each occasion.
Triage	Paper triage of faxed or electronic referrals (patients triaged during a face-to-face consultation were captured as "new consultations").
Referral sources	
Referral sources	The number of patients who were referred from the following sources: self-referral; family doctor; nurse practitioner; physician specialist; other allied health; and other.
Diagnoses	
Diagnoses	Based on International Classification of Diseases ICD-10 (World Health Organization 2010) categories related to arthritis and musculoskeletal disorders. Diagnosis was based on the ERP's assessment findings. If the patient had more than one diagnosis, the most responsible diagnosis was used. For paediatric diagnoses related to arthritis and musculoskeletal disorders, the International League of Associations for Rheumatology (ILAR) classification was used (Petty et al. 2004).

The evaluation of the SIC and CUO quadrants consisted of a longitudinal electronic survey of all ACPAC program–trained graduates (n=30) working in Ontario over a two-year period. Data were collected quarterly for the fiscal (April 1 to March 31) years 2009/2010 and 2010/2011 using SurveyMonkey® software (www.surveymonkey.com). The current cohort of ACPAC trainees (n=7) was excluded from this study. The survey consisted of indicators related to the SIC and CUO quadrants developed by a committee of ACPAC graduates and faculty. Feedback regarding selected indicators was sought from patients and parents of paediatric patients who had been recipients of healthcare provided by ACPAC program–trained ERPs and from healthcare administrators, who were familiar with or had ACPAC program–trained ERPs reporting to them. The questionnaire was then pilot tested with the ERPs on three separate occasions. ERPs were asked to provide feedback regarding face and content validity, clarity, relevance and format of the indicators included in the questionnaire. The indicators were further refined based on the feedback from each pilot. Table 1 defines the indicators related to the SIC and CUO quadrants. Variables relating to the ERP demographics were derived from the ACPAC graduate database, and from provincial and federal government websites.

Data were downloaded from SurveyMonkey® into Excel 2003, and all analyses were conducted using SAS version 9.1. Data analysis consisted of descriptive and univariate statistics to describe the variables related to demographics and the above indicators. This study received approval from the St. Michael's Hospital Research Ethics Board.

Results

A total of 30 ACPAC program–trained ERPs who graduated from the program received an electronic questionnaire each quarter during the 2009 and 2010 fiscal years. The mean response rate was 91.3% over the two-year data collection period. The quarterly response rate varied from 83.3% to 96.7%. Throughout the 2009 and 2010 fiscal years, the majority of ACPAC program–trained ERPs were physical therapists, working in urban settings and focused on adult populations. See Table 2.

TABLE 2. Description of ACPAC-trained ERPs

Variable	n (%)
Professional Designation	
Physical Therapist	25 (84%)
Occupational Therapist	5 (16%)
Geographic Location of Place of Employment	
Urban	23 (76.7%)
Rural	7 (23.3%)
Academic Status of Place of Employment	
Academic	15 (50%)
Non-academic	15 (50%)
Population Served	
Adult	26 (86.7%)
Paediatric	4 (13.6%)*

* Percentages may not add up to 100% due to rounding.

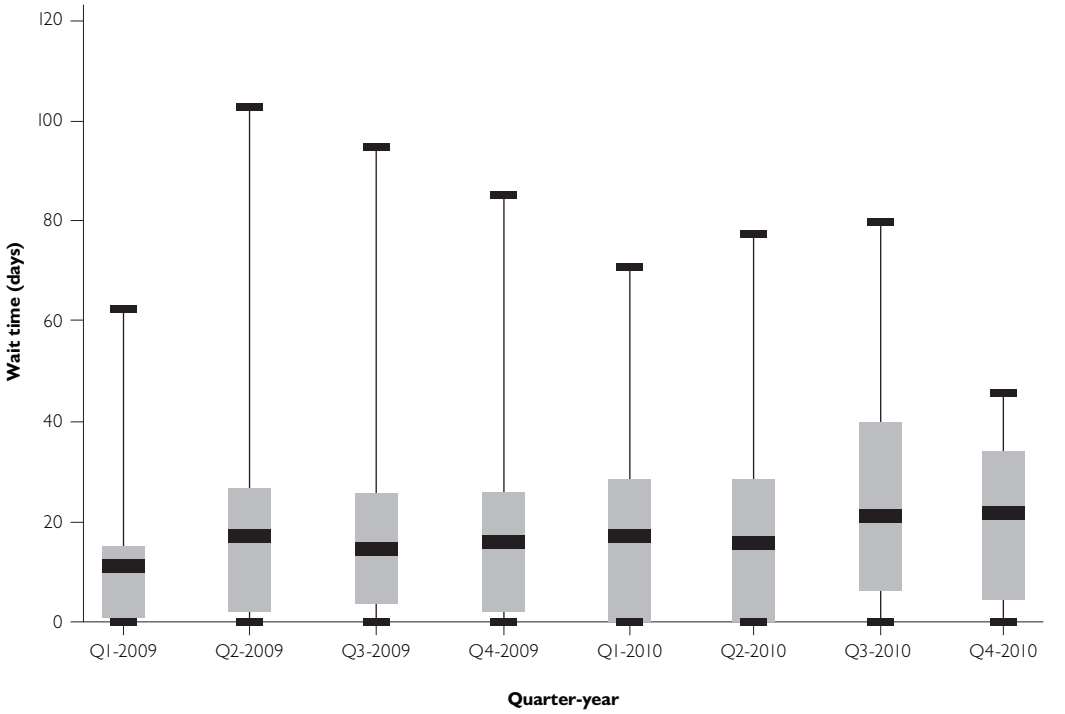
System integration

The indicators to describe the system integration of the ACPAC program–trained ERP included access to care, integration of extended role practice and integration with the health-care system.

ACCESS TO CARE

Three-quarters of ACPAC program–trained ERPs reported an average wait time of no longer than 39 days from the date when the referral was received to the date the patient was actually seen by the ERP. Over the two-year period, the longest median wait time to access ACPAC program–trained ERPs' services was 22 days. See Figure 1.

FIGURE 1. Average wait time* to access ACPAC program–trained ERPs' services



* Average wait times to access ACPAC program–trained ERPs' services were not normally distributed, making statistical estimates using the mean inappropriate. Therefore, box-and-whisker plots were used to present the data. The black line inside the box reflects the median average wait time to access ACPAC program–trained ERPs' services. This indicates that 50% of the average wait times are below the line and 50% are above the line; the upper and lower outlines of the box represent the 75th and 25th scores, respectively. The upper and lower whiskers extending from each end of the box represent the maximum and minimum scores, respectively.

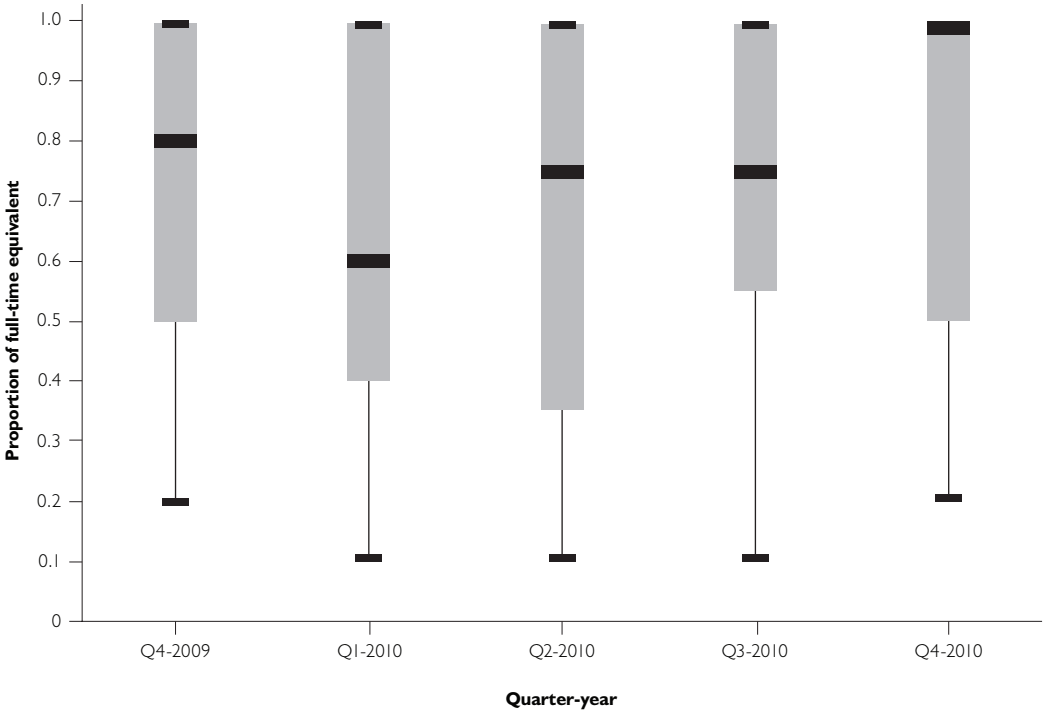
INTEGRATION OF THE EXTENDED ROLE PRACTICE

Over the 2009 fiscal year, a mean of 89.7% (n=24) of ERPs reported practising in an extended role. A similar pattern was found in the 2010 fiscal year (86.4%). Reasons for not practising in the role included lack of funding for the role, being on an extended leave of absence (including parental leave) or a change of position (for example, promotion to a management position).

There was wide variation among ACPAC ERPs regarding the proportion of their time dedicated to the extended practice role. As illustrated in Figure 2, this varied from as little as 0.1 of a full-time equivalent (FTE) (i.e., a half-day per week in a regular 40-hour work week) to as much as 1.0 FTE. However, 50% of the ACPAC ERPs reported working in a position dedicated to extended role practice at least 0.6 of a FTE.

ERPs used a variety of titles to describe their role. Overall, there were 25 reported titles being used throughout 2009 and 2010. Some examples include "advanced practice physiotherapist," "advanced clinical practitioner in arthritis care," "physiotherapist," "practitioner in rheumatology" and "advanced physiotherapist practitioner." Similar variation existed for occupational therapists.

FIGURE 2. Proportion of full-time equivalent* (FTE) ERPs who reported practising in an extended scope role

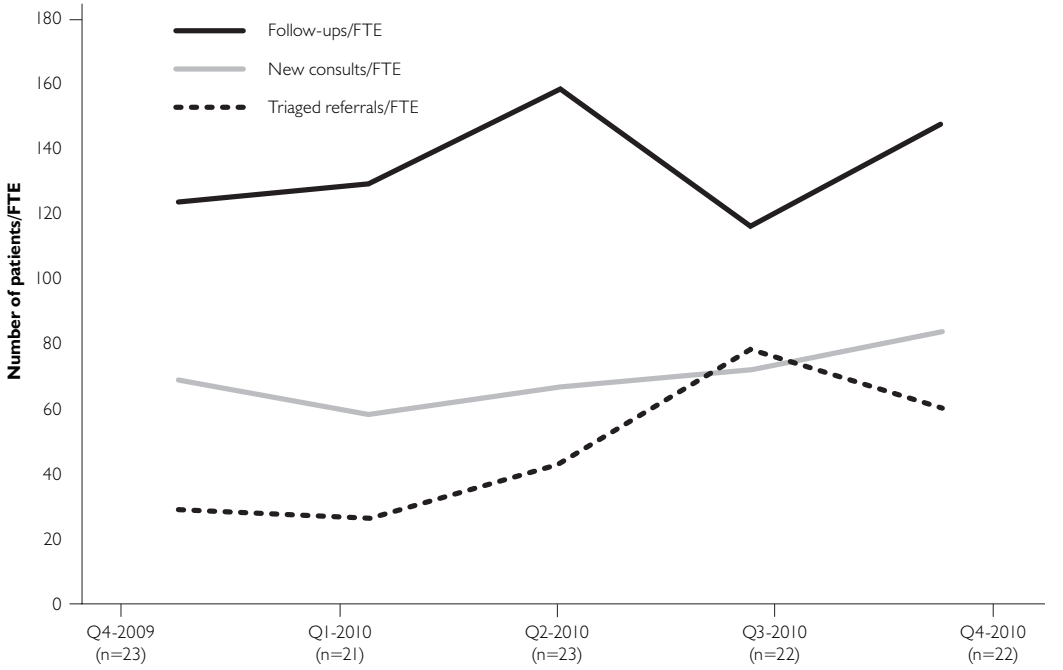


* The proportion of full-time equivalent (FTE) positions was not normally distributed, making statistical estimates using the mean inappropriate. Therefore, box-and-whisker plots were used to present the data. The black line inside the box reflects the median FTE. This indicates that 50% of the ACPAC-trained ERPs' FTEs are below the line and 50% are above the line; the upper and lower outlines of the box represent the 75th and 25th scores, respectively. The upper and lower whiskers extending from each end of the box represent the maximum and minimum scores, respectively.

With respect to the specific activities being performed under medical directives, the majority of ACPAC ERPs reported ordering lab tests (64.3%) and X-rays (82.1%) either on a daily, weekly or monthly basis during the 2009 fiscal year. A similar and slightly increased trend was observed in 2010 with respect to these specific medical directives. Approximately 40% of ERPs reported ordering diagnostic ultrasound and bone density tests over the 2009 and 2010 fiscal years.

Furthermore, about 70% of ACPAC ERPs recommended medication changes, dosage changes or both to either the patient or the referring physician, and approximately 4% of ERPs were able to make these changes under a medical directive. Similarly, 90% of ACPAC ERPs recommended joint injections to either the patient or the referring physician, with approximately 5% of ERPs having performed joint injections under a medical directive.

FIGURE 3. Number of patients/FTEs* seen by ACPAC graduates, 2009–2010



* This figure shows the sum of the total volumes divided by the sum of the total FTEs (full-time equivalents working in an extended practice role) for each quarter to give the number of patients seen/FTEs for each volume.

INTEGRATION WITH THE HEALTHCARE SYSTEM

Approximately one-third of patients seen by ACPAC program–trained ERPs were referred for X-ray, laboratory and other services. These were followed by referral to allied health services (20%) and referral to specialists (7%). Consultation letters were dictated for a third of patients. Less than 5% of patients required letters for schools, insurance agencies or Ontario Drug Benefit programs, or were related to adult transitional care.

Clinical utilization

The clinical utilization indicators included patient volumes, referral sources and patient diagnoses.

PATIENT VOLUMES

ERPs saw 4,032 and 4,679 new consultations in 2009 and 2010, respectively. The majority of the ERPs (75%) reported as many as 55 to 80 new consultations across each fiscal quarter.

With respect to patients seen in a follow-up capacity, ACPAC ERPs saw between 25% and 50% more patients for follow-up than they were seeing for new consultations. In 2009, they saw 6,563 patients for follow-up, and in 2010, 9,141 patients for follow-up.

Half of the ERPs reported being involved in triage. In 2009, 2,119 patients were triaged, and 3,506 in 2010. Of those who were actively triaging patients, the majority (75%) of ERPs triaged approximately 50 patients per quarter.

There was an overall increase in the number of patients seen per FTE for new consulta-

tions, follow-ups and patients triaged (see Figure 3). Specifically, new consultations ranged from 58 to 85 patients per FTE across the quarters; follow-ups ranged from 118 to 160 patients per FTE across the quarters, and triaged referrals ranged from 27 to 79 patients per FTE across the quarters.

The distribution of overall patient volumes over the two-year data collection period was similar with respect to the proportion of new consultations, follow-ups and triages that made up the ERPs' caseloads. Approximately half of the ERPs' caseloads were dedicated to follow-up patients.

REFERRAL SOURCES

In 2009, the greatest number of referrals came from family physicians (43.9%), followed by physician specialists (35.8%). In 2010, the reverse was the case (51.5% and 37.3%, respectively). Self-referral and referrals from nurse practitioners, allied health professionals and other sources comprised the remaining referrals.

DIAGNOSES

Most patients had non-inflammatory disorders (61.9% in 2009 and 60.1% in 2010). Approximately half of all patients seen had a diagnosis of osteoarthritis. Other common diagnoses included rheumatoid arthritis (15%) and juvenile idiopathic arthritis (10%).

Discussion

This system-level evaluation describes the integration and clinical utilization of ACPAC program–trained ERPs within the Ontario healthcare system over a two-year period. The results of this study indicate there is an opportunity to maximize the use of the ACPAC ERP, given that half of respondents reported working less than a full-time equivalent position at the end of the study period. It has been well established that there is a physician shortage throughout the province of Ontario, in terms of family physicians and medical specialists (including rheumatologists and orthopaedic surgeons) (OMA 2007; Badley et al. 2007, 2008). Given this shortage, there is a need for alternative models of healthcare delivery. Greater utilization of the ERP could (a) assist in the delivery of healthcare in geographic areas where there is lack of specialized care for specific patient populations, (b) help to improve access to care where wait times may be long, (c) enhance interprofessional care, (d) help to improve patient outcomes and (e) increase capacity for care for patients with arthritis. Further investigation into these potential system-level impacts by the ACPAC-trained ERP is warranted.

Clearly, there was no consensus among ERPs or their institutions regarding the assigned title of extended practice roles for physical therapists and occupational therapists working with people with musculoskeletal and arthritis-related disorders. The implications of multiple titles used to describe the ERP could potentially lead to difficulty in role promotion. Furthermore, consumers and colleagues from other healthcare professions may have difficulty clarifying the role. Despite foreseeable challenges, which include existing titles that have been designated

through various human resources departments, as well as regulatory body restrictions that protect professional titles, the wide variation of terminology used to describe ERP roles illustrates the need for standardization of title for ERPs.

The *Physiotherapy Act, 1991* was recently amended to include a number of acts that were previously beyond scope of practice (Government of Ontario 2011). However, the majority of ERPs are working under medical directives as they practise in institutions governed by the *Public Hospitals Act*. Furthermore, expectations of increased clinical responsibilities in the extended practice role include performing the initial assessment of a patient with undiagnosed arthritis (inflammatory or non-inflammatory), initiating orders for laboratory testing or diagnostic imaging, interpreting laboratory or diagnostic imaging test results, giving a differential diagnosis and independently managing and monitoring the follow-up for patients with an array of arthritic conditions. As an example, the practitioner is expected to identify "red flags" generated from taking a detailed history and initiate laboratory investigations based on systemic symptoms such as fever and weight loss; multisystem disease involving skin, lung, gastrointestinal and neurological symptoms; and muscle weakness. The practitioner is expected to interpret abnormal laboratory findings based on complete blood count (CBC), high erythrocyte sedimentation rate (ESR), c-reactive protein (CRP), abnormal urinalysis, liver function tests (LFT), creatine kinase (CK) elevation and abnormal proteins, all in the context of polyarthritis. With the exception of communicating a diagnosis, the additional acts do not reflect typical musculoskeletal and arthritis-related practice and therefore, many of the roles currently undertaken by ACPAC program–trained EPRs remain beyond scope, and continue to fall under the auspices of delegation or medical directive to perform. Thus, the utilization of medical directives may assist ERPs in providing comprehensive care, such as ordering appropriate investigations in a timely manner and providing efficient and effective management of musculoskeletal and arthritis-related conditions. Moreover, the use of medical directives may have the potential to help reduce unnecessary visits to specialists and may help to ensure early identification of need for specialist intervention.

Introduction of the ACPAC ERP role has demonstrated a positive impact on access to care for patients with musculoskeletal and arthritis-related disorders. The results of this evaluation showed that the longest median wait time to see an ACPAC ERP was less than three weeks. Access to appropriate healthcare is a priority for the Ontario Ministry of Health and Long-Term Care to ensure that patients are seen by the right healthcare professional, in the right place, at the right time (MOHLTC 2008). In 2007, the mean reported wait time to see a rheumatologist for non-urgent inflammatory arthritis was 13.4 weeks in the province of Ontario (Badley et al. 2008). It has been suggested that healthcare professionals working in extended roles could facilitate the early identification of inflammatory arthritis and thereby provide effective and timely intervention for this patient population (Jamal et al. 2011). Similarly, the current wait times target for orthopaedic hip and knee joint replacement surgeries in the province of Ontario is 26 weeks (MOHLTC 2011). Although orthopaedic wait times have improved in urban areas of the province, other, more rural areas still have lengthy

wait times (MOHLTC 2011). The results of this evaluation indicate that the use of ERPs has the potential to improve access to healthcare professionals who specialize in arthritis care, as they are able to see patients in a timely manner, thereby facilitating early detection and early intervention for patients with inflammatory and non-inflammatory arthritis.

The rise in patient volumes over the two-year study period likely demonstrates an increase in utilization of ERPs as their referral sources adapted to this new role. To date, there has been no benchmark set for the number of patients that should be seen in either a consultative or follow-up capacity. However, according to our findings, not all ERPs working in the province of Ontario were being utilized to their full capacity. With appropriate role promotion, the volumes of patients managed by ERPs are expected to increase over time. Further study is warranted to determine appropriate benchmarks related to patient volumes for ACPAC ERPs.

The majority of patients seen by ERPs had a diagnosis of OA. This could be attributed to the fact that the prevalence of OA (affecting 13% of Canadians), a non-inflammatory arthritis, is much greater than that of inflammatory arthritis (affecting 0.9% of Canadians) (Bombardier et al. 2011). Furthermore, the initiative of the Ontario Ministry of Health and Long-Term Care to improve access to hip and knee replacement surgery funded a number of ACPAC program–trained ERPs to develop triage programs for hip and knee replacement surgery (MOHLTC 2007). These initiatives have increased the number of patients, especially with osteoarthritis, seen by ERPs. Based on the above findings, there may be opportunities to further augment the ERP's role in improving access to care for people with inflammatory arthritis.

Limitations

This study was the first iteration of a balanced scorecard approach to measuring the impact of ACPAC program–trained ERPs on the healthcare system. As such, a number of limitations should be addressed.

First, the lack of benchmarks makes interpretation of the data difficult. A recent systematic review of Canadian and international advanced practice physiotherapists (APPs) (similar to physiotherapists and occupational therapists working in extended roles) working with patients with musculoskeletal disorders mainly examined clinical and patient satisfaction outcomes (Desmeules et al. 2012). Unfortunately, very few studies included in this review examined system-level outcomes, thus making it difficult to draw comparisons to our study. One recent study that did examine system-level outcomes, not included in the above systematic review, examined the APP role within a specialty shoulder clinic located in Ontario (Razmjou et al. 2012). This paper reports significantly shorter wait times from date of referral to date of consultation of advanced practice physical therapists compared to surgeons. The authors report a mean wait time of 147 days to be seen by the APP for shoulder consultation, compared to our finding of an average wait time of no longer than 39 days to be seen by ACPAC program–trained ERPs.

The second limitation to be acknowledged is the heterogeneity of the cohort, which makes comparisons of clinical utilization difficult, as ACPAC graduates are working in various capacities in terms of client base and clinical setting. While we have demonstrated significant pre–post change in advanced skills and knowledge and, thus, competency of the ACPAC program trainee (Lundon et al. 2011), a comparison of pre–post change in workforce measures is restricted by a relatively small cohort (n=30 ACPAC graduates) and dissimilar workplace settings that limit meaningful comparisons at this time.

Third, the unique training and system integration of ACPAC program–trained ERPs restricts the findings of this study to this particular group at this time, making the results difficult to generalize to other healthcare professionals working in alternative roles (e.g., nurse practitioner or physician assistant).

Fourth, the ACPAC program has generated a relatively small cohort of ACPAC ERP graduates since its inception (n=37). This volume reflects the extremely labour-intensive nature of this training initiative as its success relies upon establishing the necessary associations with a range of preceptors including rheumatologists, orthopaedic surgeons and other physician specialists. This is the rate-limiting step restricting the program from processing larger numbers of practitioners on an annual basis. While there is pan-Canadian interest in this program and its graduates, incorporation of this initiative at a broader academic level and across multiple sites remains at a developmental stage.

Lastly, ERPs who were consulted in the development of the indicators used in this evaluation also took part in the study. Their inclusion potentially could have led to some bias in the results. However, one could argue that the contribution of the ERPs may have actually strengthened the indicators because of a better understanding of context reflecting diverse practice settings. Moreover, administrative and physician stakeholders, as well as patients, were included in the development of the indicators to help eliminate any issues of bias.

Conclusion

Overall, this two-year, system-level evaluation yielded detailed information regarding how ACPAC program–trained ERPs are providing integrated and timely care for Ontarians with arthritis, particularly those with OA. These practitioners reported unique roles in triaging patients and working under medical directives.

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References

Badley, E.M., P. Veinot, H. Ansari and C. MacKay. 2008. "2007 Survey of Rheumatologists in Ontario." Arthritis Community Research and Evaluation Unit (ACREU). Retrieved April 12, 2013. <http://www.acreu.ca/pdf/pub5/08-03.pdf>.

Badley, E.M., P. Veinot, J. Tyas, M. Canizares, C. MacKay, A. Davis and N. Mahomed. 2007. "2006 Survey of Orthopaedic Surgeons in Ontario." Arthritis Community Research and Evaluation Unit (ACREU). Retrieved April 12, 2013. <http://www.acreu.ca/pdf/pub5/07-03.pdf>.

Bombardier, C., G. Hawker and D. Mosher. 2011. "The Impact of Arthritis in Canada: Today and Over the Next 30 Years." Arthritis Alliance of Canada. Retrieved April 12, 2013. <http://www.arthritisnetwork.ca/downloads/20111022_Impact_of_arthritis.pdf>.

College of Physiotherapists of Ontario. 2008. "Performing Controlled Acts: Guide to the Standards of Professional Practice." Retrieved April 12, 2013. <http://www.collegept.org>.

Cott, C., S. Jaglal, I. McKillop, A. Brown, P. Blackstien-Hirsch, M. Canizares et al. 2005. "Hospital Report 2005: Rehabilitation." Joint Initiative of the Ontario Hospital Association and the Government of Ontario. Toronto: Hospital Report Research Collaborative, University of Toronto.

Desmueles, F., J. Roy, J.C. MacDermid, F. Champagne, O. Hinse and L.J. Woodhouse. 2012. "Advanced Practice Physiotherapy in Patients with Musculoskeletal Disorders: A Systematic Review." *BMC Musculoskeletal Disorders* 13: 107. doi: 10.1186/1471-2472-13-107.

Government of Ontario. 2011. *Physiotherapy Act*, 1991. Retrieved April 12, 2013. <http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_91p37_e.htm>.

Hospital for Sick Children. 2012. "Definition of Medical Directives." Retrieved April 12, 2013. <http://www.sickkids.ca/medicaldirectives/101/definition/index.html>.

Jamal, S., M.H. Shabbir, E.M. Badley and C. Bombardier. 2011. "Time to Treatment for New Patients with Rheumatoid Arthritis in a Major Metropolitan City." *Journal of Rheumatology* 38(7): 1282–88.

Kaplan, R.S. and D.P. Norton. 1996. *Translating Strategy into Action: The Balanced Scorecard*. Boston: Harvard Business School Press.

Lundon, K., R. Shupak, S. Reeves, R. Schneider and J. McIlroy. 2009. "The Advanced Clinician Practitioner in Arthritis Care Program: An Interprofessional Model for Transfer of Knowledge for Advanced Practice Practitioners." *Journal of Interprofessional Care* 23(2): 198–200.

Lundon, K., R. Shupak, R. Schneider and J. Herold McIlroy. 2011. "Development and Early Evaluation of Interprofessional Post-Licensure Education Programme for Extended Practice Roles in Arthritis Care." *Physiotherapy Canada* 63(1): 94–103.

Lundon, K., R. Shupak, L. Sunstrum-Mann, D. Galet and R. Schneider. 2008. "Leading Change in the Transformation of Arthritis Care through Development of an Interprofessional Academic Clinical Education Training Model." *Healthcare Quarterly* 11(3): 62–68.

Ministry of Health and Long-Term Care (MOHLTC). 2007. "Hip and Knee Replacement Program." Retrieved April 12, 2013. <http://www.ontla.on.ca/library/repository/mon/20000/274844.pdf>.

Ministry of Health and Long-Term Care (MOHLTC). 2008. "Health Care Priorities." Retrieved April 12, 2013. <http://www.health.gov.on.ca/english/public/updates/archives/hu_08/health_care_priorities_20080424.html>.

Ministry of Health and Long-Term Care (MOHLTC). 2011. "Wait Times Provincial Trends." Retrieved April 12, 2013. <http://www.waittimes.net/Surgerydi/en/Type.aspx>.

Ontario Medical Association (OMA). 2007. "Ontario Physician Shortage." Retrieved April 12, 2013. <http://www.oma.org/Mediaroom/Backgrounders/Pages?OntarioPhysicianShortage2007.aspx>.

Petty, R.E., T.R. Southwood, P. Manners, J. Baum, D.N. Glass, J. Goldenberg et al. 2004. "International League of Associations for Rheumatology Classification of Juvenile Idiopathic Arthritis: Second Revision, Edmonton, 2001." *Journal of Rheumatology* 31: 390–92.

Razmjou, H., S. Robarts, D. Kennedy, C. McKnight, A.M. MacLeod and R. Holtby. 2012. "Evaluation of an Advanced-Practice Physical Therapist in a Specialty Shoulder Clinic: Diagnostic Agreement and Effect on Wait Times." *Physiotherapy Canada*. doi: 10.3138/ptc.2011-56.

World Health Organization (WHO). 2010. "Chapter XIII: Diseases of the Musculoskeletal System and Connective Tissue (M00–M99)." *International Classification of Diseases and Related Health Problems* (10th rev.). Retrieved April 12, 2013. <http://apps.who.int/classifications/icd10/browse/2010/en#/XIII>.

RESEARCH PAPER

Things Are Not as Bad as They Seem: Physicians' Ability to Predict Their Clinical Practice When a New Vaccine Becomes Available

Les choses ne vont pas aussi mal qu'elles en ont l'air : habileté des médecins à prévoir leur pratique clinique quand un nouveau vaccin devient disponible

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Abstract

Survey results regarding primary care physicians' likelihood of recommending a new vaccine were compared before and after the vaccine was licensed by the Food and Drug Administration for three new vaccines: herpes zoster (HZ), human papillomavirus (HPV) and rotavirus (RV), using physician networks representative of United States physicians. The main purpose of this study was to determine (a) how accurately physicians predict their eventual vaccine recommendations and the barriers they will experience in delivering the new vaccine and (b) whether physicians shift towards more or less strongly recommending a new vaccine from pre- to post-licensure. Responses from 284, 152 and 184 physicians were analyzed for the three vaccines, respectively. For all vaccines, there was a significant association between physicians' pre- and post-licensure recommendations ($p<0.05$). When responses changed from pre- to post-licensure, physicians tended to recommend a given vaccine more strongly than they had anticipated pre-licensure. Before vaccine availability, physicians tended to predict greater barriers to vaccine delivery than they eventually experienced. Surveys are useful for predicting physician practices, but may provide a slightly pessimistic view of physician adoption of new vaccines. Such data can be helpful in devising strategies to encourage vaccine delivery by physicians.

Résumé

Les résultats de sondages sur la probabilité que les médecins de première ligne recommandent un nouveau vaccin ont été comparés avant et après l'homologation de trois nouveaux vaccins par le Secrétariat américain aux produits alimentaires et pharmaceutiques (*Food and Drug Administration*) – herpès zoster (HZ), papillomavirus humain (PVH) et rotavirus (RV) –, en utilisant des réseaux représentatifs des médecins aux États-Unis. L'objectif principal de cette étude était de déterminer (a) à quel point les médecins peuvent prévoir leur éventuelle recommandation du vaccin ainsi que les obstacles qu'ils rencontreront pour son administration et (b) si les médecins recommandent plus ou moins fortement un nouveau vaccin avant et après son homologation. Les réponses de 284, 152 et 184 médecins ont été analysées pour les trois vaccins, respectivement. Pour tous les vaccins, il y a un lien significatif entre les recommandations avant et après l'homologation ($p<0.05$). Quand il y a changement de réponse avant et après l'homologation, les médecins sont plus enclins à fortement recommander un vaccin donné qu'ils ne l'avaient pensé avant l'homologation. Avant la disponibilité d'un vaccin, les médecins ont tendance à prévoir des obstacles plus grands dans l'administration du vaccin que ce qu'ils constatent éventuellement. Les sondages sont utiles pour prédire la pratique des médecins, mais peuvent donner un point de vue légèrement pessimiste sur l'adoption de nouveaux vaccins par les médecins. De telles données peuvent servir à concevoir des stratégies pour favoriser l'administration de vaccins par les médecins.

While social science literature is rich with studies examining the relationship between intentions for behaviour and actual behaviour, relatively little research has examined how well physicians' self-reported behavioural intentions predict their behaviours with respect to clinical care. This is an important question because numerous physician surveys are conducted each year and are utilized to devise strategies for improving patient care through such approaches as clinical guidelines. If physicians accurately predict their likely clinical practices in the future, then the results of surveys have value for planning strategies to influence physician behaviours. On the other hand, if physicians' intentions for practice are not sufficiently related to their actual practice, then using survey results to aid in the planning of programs would be ineffective. Literature searches uncovered only two prior studies that used pretest–posttest survey designs to examine this issue, but neither studied attitudes towards vaccine adoption (Millstein 1996; Maue et al. 2004). Because of the potential usefulness of such data to help in the planning and implementation of vaccination recommendations, we were particularly interested in how well primary care physicians' survey responses are able to predict their eventual vaccine delivery behaviour once a vaccine becomes licensed by the Food and Drug Administration in the United States.

In 2005 and 2006, three new vaccines were licensed for use in the United States. These three vaccines varied greatly in terms of targeted patient population, disease and mechanism of vaccine administration. The US Advisory Committee on Immunization practices (ACIP) recommended herpes zoster (HZ) vaccine (Zostavax®, Merck; CDC 2008) for routine use by a single intramuscular injection in immunocompetent adults ≥60 years old; human papillomavirus (HPV) vaccine for females 11–26 years old through intramuscular injection in a three-dose series (Gardasil™, Merck; CDC 2007); and rotavirus (RV) vaccine for routine use in infants and administered orally in a three-dose series (RotaTeq®, Merck; CDC 2006).

Our group administered both pre-licensure and post-licensure surveys for all three new vaccines to primary care physicians (Daley et al. 2006, 2010; Hurley et al. 2008, 2010; Kempe et al. 2007, 2009). These surveys were conducted without plans for the present analysis, with the aim to understand physicians' perceptions of a given vaccine at a particular moment. However, after collecting pre- and post-licensure survey data, the question of whether physicians' pre-licensure responses accurately predicted their eventual post-licensure recommendations for each vaccine became evident.

Therefore, our objectives for this analysis were to assess whether pre-licensure surveys were an effective tool for determining (a) whether physicians' vaccine recommendation intentions are predictive of their eventual vaccine recommendation practices, (b) whether physicians' responses pre- to post-licensure shifted towards more or less strongly recommending the vaccine, (c) whether perceived barriers before the vaccine was licensed were similar to perceived barriers after the vaccine was licensed and (d) whether physicians perceived barriers as more or less important after the vaccine was licensed.

Methods

Study setting

Pre-licensure surveys were administered from August 2005 to February 2006, and post-licensure surveys were administered from August 2007 to September 2008, resulting in a total of six surveys. These surveys were administered to national networks of primary care physicians in general internal medicine (GIM), family medicine (FM) and paediatrics (Peds). The human subjects review board at the University of Colorado Anschutz Medical Campus approved this study, and written informed consent was not required.

Population

The national networks of primary care physicians were developed as part of the Vaccine Policy Collaborative Initiative, a program designed collaboratively with the US Centers for Disease Control and Prevention (CDC) to conduct rapid-response surveys assessing physician attitudes about vaccine issues. GIM, FM and Peds physicians were recruited from the American College of Physicians, the American Academy of Family Physicians and the American Academy of Pediatrics, respectively. Quota sampling was performed to ensure that network physicians were similar to their respective memberships with regard to region of country, urban versus rural location and practice type. As described in detail elsewhere (Crane et al. 2008), demographic characteristics, practice attributes and reported attitudes about a range of vaccination issues were similar when network physicians were compared with physicians randomly sampled from the American Medical Association (AMA) master physician listing, which includes all physicians licensed in the United States.

ELIGIBILITY

To be eligible for this analysis, physicians had to receive both pre- and post-licensure surveys for a given vaccine. Owing to planned turnover in the three networks, approximately 50% of the network members were invited to complete both surveys for a given vaccine. For the HZ analysis, participants from both the GIM and FM network were eligible (n=333). The eligible Peds network was the same for both the RV (n=213) and HPV analyses (n=213).

Survey administration

Depending on each physician's preference, the survey was administered via mail or Internet. The Internet surveys were administered using web-based companies (Zoomerang MarketTools; Websurveyer Corp., Hernodon, VA; or Vovici Corp., Dulles, VA). Specific administration information for each survey has been previously published (Daley et al. 2006, 2010; Hurley et al. 2008, 2010; Kempe et al. 2007, 2009).

Survey design

Pre-licensure surveys examined physician perceptions of the disease for which the vaccine was

developed, intentions for vaccination recommendations and anticipated barriers to administering the vaccines. Physicians were also provided information describing the purpose and effectiveness of the vaccine. The physicians were then asked how likely they were to recommend the vaccine based on that information in conjunction with hypothetical Food and Drug Administration approval and routine use recommendations by the Advisory Committee on Immunization Practices (Appendix A). Post-licensure surveys assessed physicians' current vaccination practices and experienced barriers to vaccination. All responses were offered in 4-point Likert-type scales.

Reconciliation of survey items between pre-licensure and post-licensure surveys

Surveys were not designed a priori for this analysis, and consequently survey items were not always identical between pre- and post-licensure surveys. Therefore, some items were adapted to make questions and response categories comparable for analysis (see Table 1, available online at longwoods.com/content/23377 and sections below).

INTENTIONS VERSUS PRACTICE PAIRING

In order to examine whether physicians' intentions towards vaccination predicted their eventual practice, pre-licensure recommendations were compared to post-licensure recommendations as shown in Table 1. Some response and question categories were combined to make them more comparable to a response category in the parallel survey. For example, for HZ and HPV, the pre-licensure response categories "Somewhat unlikely" and "Very unlikely" were combined and compared to the post-licensure response category of "I recommend against the vaccine" for HZ and "Do not recommend" for HPV. Also, for HPV, the pre-licensure question asking how likely physicians were to recommend the vaccine for 10- to 12-year-old female patients was compared to two post-licensure questions asking how physicians recommend the vaccine to 9- to 10-year-old patients and 11- to 12-year-old patients, because the pre-licensure question included characteristics of the two post-licensure questions. For RV, pre- and post-licensure questions and categories were the same, so no groupings were necessary (see Table 1).

For two surveys (HZ pre-licensure and HPV pre-licensure), "Don't know/Not sure" options were offered. Because these responses were non-informative for predicting behaviour, these respondents were removed from the relevant analyses. Additionally, for one survey (HZ post-licensure), "I don't recommend for or against the vaccine" was offered as a response. Because this answer did not match any response category offered pre-licensure, these respondents were removed from the analysis. This resulted in 4%–14% of respondents being removed from the relevant analyses.

BARRIER PAIRINGS

To determine whether physicians were able to accurately predict the impact of barriers to vaccine administration, we compared perceptions of a given barrier pre-licensure to perceptions of the same barrier post-licensure. For HZ and HPV, we compared two barrier questions

between the pre- and post-licensure surveys. For RV, 12 questions matched between the pre- and post-licensure surveys. The response categories were the same for all three vaccines (see Table 1).

Analytic methods

For this analysis we aimed to compare physicians' pre-licensure responses to their post-licensure responses. Namely, we were first interested in whether a physician's pre-licensure response matched his or her post-licensure response. Then, if it changed, we sought to examine the direction of the shift. However, as previously mentioned, these surveys were not designed a priori for this analysis, so in some cases pre-licensure responses were aggregated and compared to aggregated post-licensure responses. All statistical analyses were performed using SAS software (version 9.1; SAS Institute, Cary, NC).

To examine whether physicians' intentions were related to their reported vaccine recommendation practices and to compare physicians' perceptions of a barrier between pre- and post-licensure, we used Kendall's tau-b (τ). This test was selected over another possible approach, repeated measures analysis, because for HZ and HPV identical language was not used between the pre-licensure and post-licensure survey questions and response categories were also not identical, a necessary condition for repeated measures analysis (see Table 1). The interpretation of Kendall's tau-b is similar to a Spearman's correlation coefficient (Field 2005). Therefore, using Kendall's tau-b, a maximum statistical score of +1 indicates that all the data pairs were 100% positively associated, and a minimum statistical score of –1 signifies that all the data pairs were 100% negatively associated (Noether 2010). A p-value <0.05 for this test indicates that a pre-licensure response was statistically significantly related to its post-licensure response. To display results, aggregate data are presented using proportions of responses in each ordinal category in Figures 1–3; however, all statistical tests were computed using the individual as the unit of analysis.

Unlike the vaccine recommendation questions for HZ and HPV, all of the barrier questions and response categories used identical wording in the paired pre- and post-licensure surveys. Therefore, Bhapkar's test was used to determine how physicians' responses regarding barriers shifted if they were not the same as their pre-licensure responses (i.e., if the response changed, did it shift towards perceiving a barrier as more or less important?). Bhapkar's test is an extension of McNemar's test, and both tests have been used for matched-pairs data for repeated measurement of subjects (Sun and Yang 2008). However, McNemar's test allows for only two outcome categories, and we often had four; therefore, Bhapkar's test was more appropriate. A p-value <0.05 for Bhapkar's test means the observed shift in the data is statistically significant.

Importantly, Kendall's tau-b and Bhapkar's test assess different aspects of the pre- and post-licensure relationship. When Kendall's tau-b is significant, indicating an association between responses pre- and post-licensure, Bhapkar's test could be non-significant (no shift) or significant (indicating a shift in responses in a consistent direction). Bhapkar's test can

also be significant (indicating a shift) when Kendall's tau-b is non-significant (indicating no relationship). For example, if physicians believed strongly that they would not recommend a vaccine but then decided to recommend it strongly once it was licensed, the Kendall's tau-b would not be significant, but Bhapkar's test would be highly significant.

Results

Survey response rate and characteristics of respondents

For HZ, of the 333 GIM and FM physicians who were surveyed both pre- and post-licensure, 254 (76%) completed both surveys. GIM and FM results were combined for the analysis, as responses to questions were very similar for these specialties. For HPV, 152 of the 213 (71%) physicians completed both surveys, and for RV, 184 of 213 (86%) physicians completed both surveys.

TABLE 2. Comparison of original sentinel networks to eligible physicians

	RV and HPV		HZ			
Characteristic	**Sentinel Peds (n=429)**	**Eligible Peds (n=213)**	**Sentinel FM (n=411)**	**Eligible FM (n=155)**	**Sentinel GIM (n=417)**	**Eligible GIM (n=178)**
Male, % (n)	54	57	NA	NA	59	59
Region of country, %						
Midwest	20	18	30	30	21	23
Northeast	28	26	15	16	25	29
South	34	38	32	23	33	25
West	18	19	24	30	20	23
Location of practice, %						
Urban, inner-city	44	45	27	28	43	46
Urban, not inner-city/suburban	44	44	45	44	43	46
Rural	12	12	28	28	13	8
Type of practice, %						
Private practice	86	90	80	79	76	83
Community- or hospital-based	12	9	18	18	21	14
Managed care organization	2	1	2	3	3	3

Peds = Paediatric medicine; FM = Family medicine; GIM = General internal medicine; NA= Not available

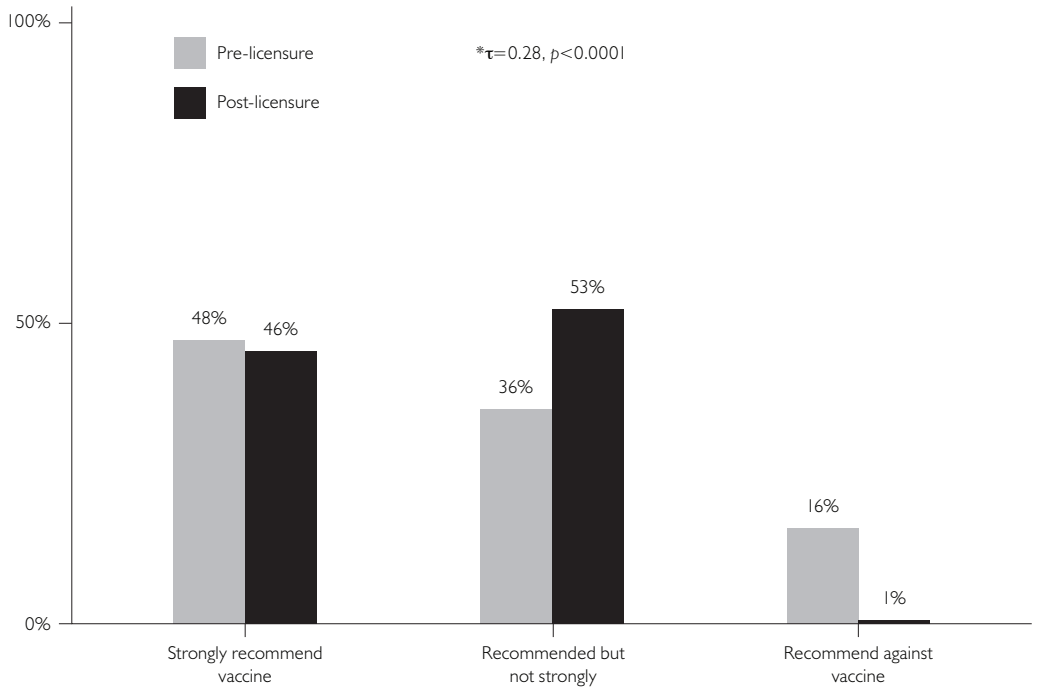
Table 2 compares the networks used in the present analysis to the sentinel networks from which they were drawn. For the RV and HPV surveys, eligible physicians were very similar to the sentinel Peds network from which they were drawn. For the HZ survey, in general,

the eligible physicians were very similar to the original networks. Physicians from the south were somewhat underrepresented in the FM and GIM respondents when compared to the networks. For GIM, rural physicians and physicians practising in community health centres or hospital settings were somewhat underrepresented among the eligible physicians when compared with the sentinel GIM network.

Pre-licensure recommendations vs. post-licensure recommendations

For HZ (adults), HPV among 9- to 10-year-olds, HPV among 16- to 18-year-olds and RV (infants), there was a significant association between physicians' pre- and post-licensure recommendations [τ range=0.21–0.37, ($p<0.05$)] (Figures 1–3). Notably, in contrast to all other vaccine recommendations, which grew in strength between pre- and post-licensure, the strong positive association for the 9- to 10-year-old female HPV recommendation was due to physicians' pre-licensure responses indicating that they did not intend to recommend this vaccine to this age group and their post-licensure consistency in not recommending the vaccine (Figure 2a).

FIGURE 1. Pre-licensure recommendations vs. post-licensure recommendations: Zoster



* τ = Kendall's tau test statistic

There were two comparisons that did not demonstrate an association pre- to post-licensure, namely, HPV vaccine recommendations for the 11- to 12-year-old and 13- to 15-year-old female age groups (τ=0.10 [p=0.20] and τ=0.13 [p=0.12], respectively).

Pre-licensure, physicians tended to believe that they would not recommend the vaccine as strongly as they reported recommending it post-licensure (Figures 2b and 2c).

In general, Figures 1–3 suggest that post-licensure, respondents were inclined to recommend a given vaccine more strongly than they had originally planned when asked pre-licensure. (This interpretation must be made with caution because the response categories were not the same pre- and post-licensure, and a shift could be due to differences in the response categories.) There were two exceptions to this statement. For the HZ recommendations, 48% of physicians reported that they were very likely to recommend the vaccine pre-licensure, and a similar proportion (46%) reported strongly recommending the vaccine post-licensure. However, 36% had reported being somewhat likely to recommend the HZ vaccine pre-licensure and 53% reported that they recommended the vaccine, but not strongly, post-licensure. Therefore, 84% of physicians reported that they were very or somewhat likely to recommend the vaccine pre-licensure and 99% were recommending the vaccine at some level post-licensure (Figure 1). The other exception was seen for the 9- to 10-year-old age group for HPV, where 45% of physicians said pre-licensure that they were not likely to recommend the vaccine and post-licensure, this figure grew to 70% who reported that they did not recommend the vaccine (Figure 2a).

Perceived barriers pre-licensure to post-licensure

For 15 out of the 16 barrier questions from all three vaccine surveys combined, physicians' perceptions of a given barrier from pre- to post-licensure were positively and significantly associated (τ range=0.24–0.46, [p-value<0.001]). The only barrier for which there was not a significant association was seen in the RV barrier of "Difficulty obtaining adequate vaccine supplies" (τ=0.10 [p=0.14]). In this case, physicians thought this would be much more of a barrier pre-licensure than they reported post-licensure (see Appendix B).

Using Bhapkar's test, when perceptions of barriers shifted from the pre- to post-licensure responses, the shift was towards reporting that a given barrier was less important for 13 out of 16 barrier questions (p<0.05). For the RV barriers of "My belief that rotavirus is not a severe disease that requires a vaccination" and "General administrative burden of rotavirus vaccine to my practice," responses were very similar pre- and post-licensure, and therefore, Bhapkar's test was not significant. The only barrier where there was a significant shift towards reporting the barrier as more important was for the HZ barrier of "The need to store the vaccine in a freezer in a separate sealed compartment" (p<0.001) (see Appendix B).

Discussion and Conclusion

This post hoc analysis examined whether primary care physicians' pre-licensure intentions to recommend a new vaccine were related to their eventual vaccination practices post-licensure and, if their responses changed, whether they shifted towards more or less strongly recommending the vaccine from pre- to post-licensure. The issue of intention–behaviour consistency among physicians has previously been studied, and the results of studies that utilized

surveys as their measurement method have been mixed. One demonstrated that surveys were effective predictors of physician-reported behaviours (Millstein 1996), while another did not find a significant relationship (Maue et al. 2004). This mix of results may be dependent on physicians' specialties and the specific behaviour being studied.

FIGURE 2A. Pre-licensure recommendations vs. post-licensure recommendations: HPV Ages 9–10

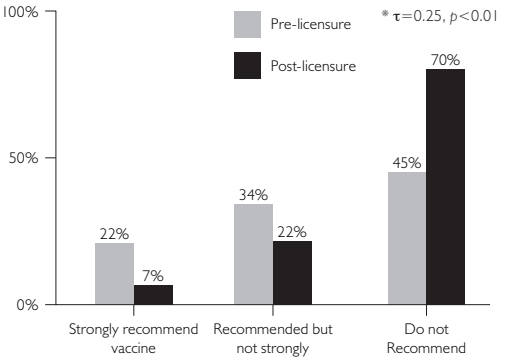
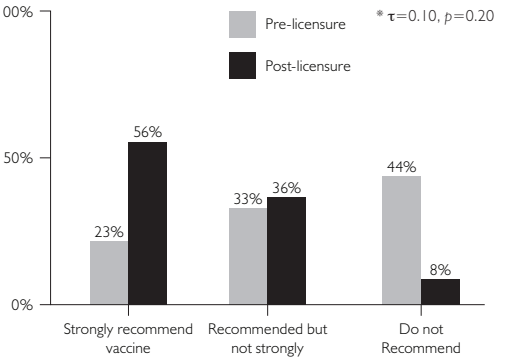


FIGURE 2B. Pre-licensure recommendations vs. post-licensure recommendations: HPV Ages 11–12



* τ= Kendall's tau test statistic

FIGURE 2C. Pre-licensure recommendations vs. post-licensure recommendations: HPV Ages 13–15

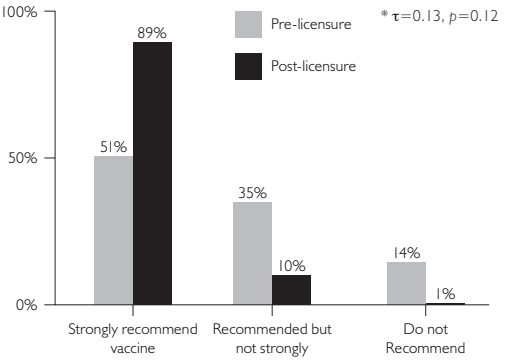
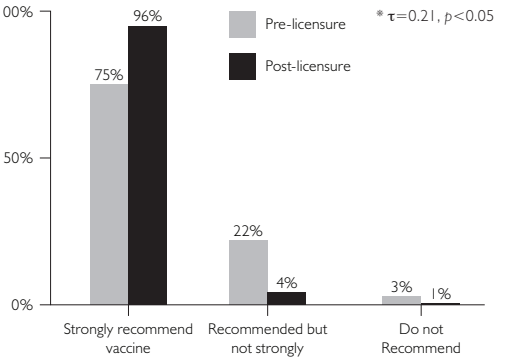


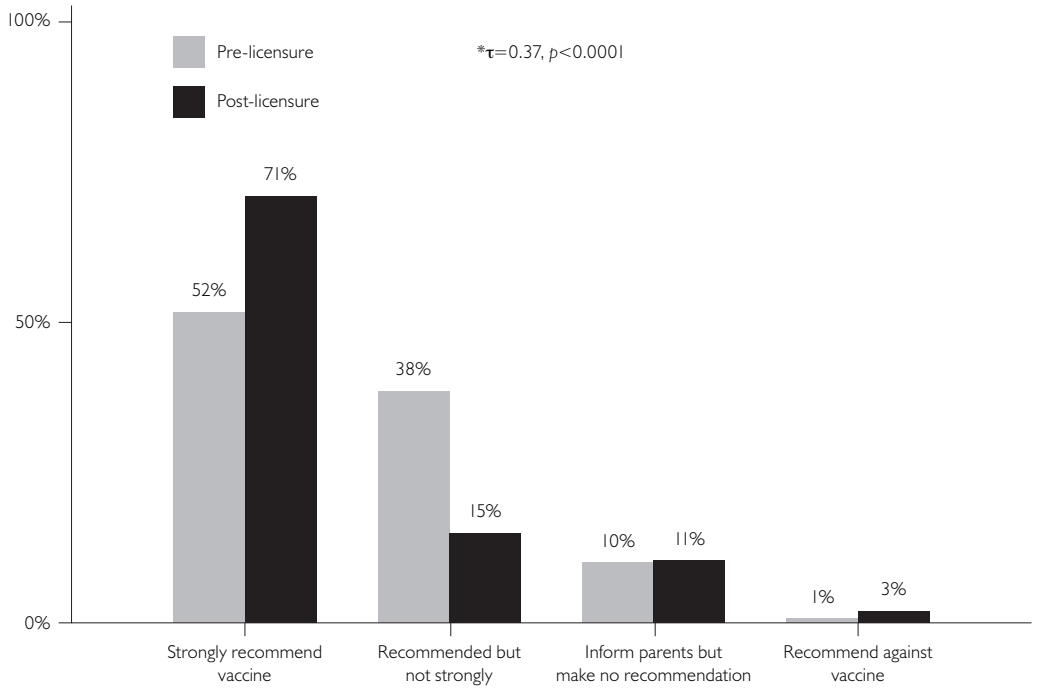
FIGURE 2D. Pre-licensure recommendations vs. post-licensure recommendations: HPV Ages 16–18



* τ= Kendall's tau test statistic

The present study determined that primary care physicians' pre-licensure recommendations were generally associated with their post-licensure recommendations, demonstrating that providers are good predictors of their eventual behaviour related to vaccine delivery. An important implication of this finding is that survey results are likely to provide useful information for guiding vaccine implementation policies and strategies, and are relatively accurate in predicting physician reactions to vaccine delivery recommendations disseminated by government agencies and organizations.

FIGURE 3. Pre-licensure recommendations vs. post-licensure recommendations: Rotavirus



* τ = Kendall's tau test statistic

Our data also suggest that the recommendations of the US ACIP have a strong influence on physician practices in that country (CDC 2006, 2007, 2008). This conclusion is demonstrated in our results for the HPV vaccine recommendations. Though the ACIP stated that the vaccine could be used in females as young as 9 to 10 years old, they did not recommend routine use in this group (CDC 2007). Seventy per cent of the physicians said they did not recommend the vaccine to this age group after publication of ACIP recommendations versus only 45% of physicians reporting that they were not likely to recommend the vaccine to this age group prior to ACIP recommendations. Conversely, for females 11 to 12 years old, the group for which the vaccine was recommended for routine use by the ACIP (CDC 2007), only 8% stated that they would not recommend the vaccine for this age group after licensure and subsequent recommendation by the ACIP, versus 44% of physicians who stated pre-licensure that they would recommend it. Another example of ACIP influence on physician vaccine recommendation practices was reported in the pre-licensure survey on RV. When physicians were asked how they would recommend the vaccine if it were recommended for permissive use instead of routine use, 33% of physicians reported they would recommend the vaccine strongly if it were permissive versus 50% who would strongly recommend the vaccine if it were routinely recommended (Kempe et al. 2007).

Additionally, physicians' perceptions of a given barrier pre- and post-licensure were positively and significantly associated, and physicians were also more likely to overestimate the

effect of a given barrier pre-licensure. More specifically, concerns about finances (e.g., upfront costs of the vaccine and reimbursement by insurance companies), vaccine safety and parents' acceptance of the vaccine lessened after licensure. This finding suggests a bit of a pessimistic bias towards the feasibility of delivering a new vaccine before one has experience with it. The finding may also reflect willingness to overcome potential barriers once a vaccine is available and has been endorsed by the ACIP.

Interestingly, physician recommendations seem to have varying correlations with national estimates of vaccine uptake in the United States. For example, the post-licensure survey on RV saw 72% of physicians strongly recommending the vaccine (Kempe et al. 2010), a figure that corresponded to an Immunization Information System (IIS) electronic registry estimate of 71% uptake in eight US states for receipt of more than a single dose in infants older than five months of age (CDC 2010). However, for HPV, 37% of girls 13–17 years of age had received at least one dose of the HPV vaccine, and only 18% had completed the three-dose series (CDC 2009), whereas approximately 93% of physicians surveyed post-licensure reported strongly recommending the vaccine for these ages (Daley et al. 2010). For HZ, approximately 7% of adults aged ≥60 had received the vaccine in the year this survey was conducted (Schiller and Euler 2009), compared to 46% of physicians surveyed post-licensure who reported they strongly recommended the vaccine (Hurley et al. 2010).

The information cited above suggests that vaccine uptake faces many different obstacles. For example, the new rotavirus vaccine has met relatively little resistance from parents and physicians. However, the HPV vaccine has received much resistance from a variety of parental groups, and even some physician groups, who believe the vaccine is associated with seizures and intellectual disability, and the suggestion that it may encourage female promiscuity (Intlekofer et al. 2012). The HPV vaccine was even part of the US Republican primary debates in 2011 (Gabriel and Grady 2011).

An issue we could not directly assess is the effect of pharmaceutical advertising. Advertising surely has an effect on physician vaccine recommendation practices, but the larger effect is most likely to be seen on patient behaviour, as has been shown with other pharmaceutical product advertising (Khanfar et al. 2007). Furthermore, for all three vaccines, the top two perceived barriers both pre- and post-licensure were financial concerns related to upfront vaccine purchase by the practice and insurance reimbursement, both of which varied greatly among the three vaccines (Daley et al. 2006, 2010; Hurley et al. 2008, 2010; Kempe et al. 2007, 2009).

Considering how very different these vaccines are in terms of the diseases that they help prevent, the patient populations targeted, clinical efficacy, route of vaccine administration and the different physician specialties that are charged with delivering the vaccines (i.e., paediatricians, family physicians and internists), our finding that the physicians surveyed were generally accurate predictors of their eventual reported vaccination practices across all three vaccines suggests that the results are generalizable to vaccines that will be introduced in the future, and possibly to the delivery of other types of medical care. This interpretation also argues that

surveys are valuable tools for understanding physicians' attitudes and behaviours. Furthermore, we believe that our results are generalizable to US primary care physicians, as the physicians who were eligible for this analysis were similar to those in the original sentinel networks.

This study has limitations. First, because we did not design the surveys with the present analysis in mind, recommendation questions and their response categories were not worded identically from pre- to post-licensure surveys, with the exception of the RV surveys. However, after data collection it became clear that our data could help answer the question of whether physicians' survey responses are accurate predictors of behaviour at a later time. In a few instances, this conclusion resulted in a need to drop a small proportion of individuals from the analysis because of their selection of "Don't know" responses or responses that could not be matched across surveys. Also, our post-licensure surveys were designed to assess practices in relation to ACIP recommendations, which had not been made at the time of the pre-licensure surveys. Therefore, wording was changed post-licensure to ensure that survey results could be interpreted in the most current environment. Additionally, with the exception of RV, only a subset of the barriers matched between the pre- and post-licensure HZ and HPV surveys (only 2/17 and 2/12 possible barriers for HZ and HPV matched, respectively). Another limitation was that although our sample of physicians appeared to be representative, there were differences between physicians who received both surveys of a pair and those who received individual surveys; further, physicians who agreed to be surveyed may have held different views on vaccine-related issues than those who were not surveyed. Finally, our findings are based on self-reports and statistical comparisons rather than actual observation of physicians' behaviours.

To our knowledge, this is the first study to assess whether pre-licensure survey responses about intentions towards administering a new vaccine accurately predict primary care physicians' reported behaviours after the vaccine is licensed. We found that pre-licensure survey responses were generally valid predictors for what a physician reports doing in terms of recommending new vaccines. Furthermore, we found that physicians tend to overestimate the impact of barriers to vaccine delivery prior to their experience of delivering the vaccine. Therefore, our results argue that physicians and policy makers should have confidence in survey results assessing what physicians predict their future practices will be, and that surveys can consequently be useful tools to assist in the development of vaccine implementation policies. Finally, our data also suggest that the recommendations of the US Advisory Committee on Immunization Practices have a strong influence on physician vaccination practices.

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References

Centers for Disease Control and Prevention (CDC). 2006. "Prevention of *Rotavirus gastroenteritis* among Infants and Children. Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *Morbidity and Mortality Weekly Report* 55: 1–13.

Centers for Disease Control and Prevention (CDC). 2007. "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *Morbidity and Mortality Weekly Report* 56: 1–24.

Centers for Disease Control and Prevention (CDC). 2008. "Prevention of *Herpes zoster*: Recommendations of the Advisory Committee on Immunization Practices (ACIP)." *Morbidity and Mortality Weekly Report* 57: 1–30.

Centers for Disease Control and Prevention (CDC). 2009. "National, State and Local Area Vaccination Coverage among Adolescents Aged 13–17 Years – United States, 2008." *Morbidity and Mortality Weekly Report* 18: 997–1001.

Centers for Disease Control and Prevention (CDC). 2010. "Rotavirus Vaccination Coverage among Infants Aged 5 months – Immunization Information System Sentinel Sites, United States, June 2006 – June 2009." *Morbidity and Mortality Weekly Reports* 59: 521–24.

Crane, L.A., M.F. Daley, J. Barrow, C. Babbel, B.L. Beaty, J.F. Steiner et al. 2008. "Sentinel Physician Networks as a Technique for Rapid Immunization Policy Surveys." *Evaluation & the Health Professions* 31: 43–64.

Daley, M.F., L.A. Crane, L.E. Markowitz, S. Black, S., B. Beaty, J. Barrow et al. 2010. "Human Papillomavirus Vaccination Practices: A Survey of US Physicians 18 Months Post-Licensure." *Pediatrics* 126: 425–33.

Daley, M.F., N. Liddon, L.A. Crane, B.L. Beaty, J. Barrow, C. Babbel et al. 2006. "A National Survey of Pediatrician Knowledge and Attitudes Regarding Human Papillomavirus Vaccination." *Pediatrics* 118: 2280–89.

Field, A. 2005. *Discovering Statistics Using SPSS* (2nd ed.). London: Sage Publications.

Gabriel, T. and D. Grady. 2011. "In Republican Race, a Heated Battle over the HPV Vaccine." *The New York Times*. Retrieved April 3, 2013. <http://www.nytimes.com/2011/09/14/us/politics/republican-candidates-battle-over-hpv-vaccine.html?_r=0#>.

Hurley, L.P., R. Harpaz, M.F. Daley, L.A. Crane, B.L. Beaty, J. Barrow et al. 2008. "National Survey of Primary Care Physicians Regarding Herpes zoster and the Herpes zoster Vaccine." *Journal of Infectious Disease* 197 (Suppl. 2), S216–23.

Hurley, L.P., M.C. Lindley, R. Harpaz, S. Stokely, M.F. Daley, L.A. Crane et al. 2010. "Barriers to the use of *Herpes zoster* Vaccine." *Annals of Internal Medicine* 152: 555–60.

Intlekofer, K.A., M.J. Cunningham and A.L. Caplan. 2012. "The HPV Vaccine Controversy." *Virtual Mentor* 14: 39–49.

Kempe, A., M.F. Daley, U.D. Parashar, L.A. Crane, B.L. Beaty, S. Stokley et al. 2007. "Will Pediatricians Adopt the New Rotavirus Vaccine?" *Pediatrics* 119: 1–10.

Kempe, A., M.M. Patel, M.F. Daley, L.A. Crane, B.L. Beaty, S. Stokley et al. 2009. "Adoption of Rotavirus Vaccination by Pediatricians and Family Medicine Physicians in the United States." *Pediatrics* 124: 809–16.

Khanfar, N., D. Loudon and F. Sircar-Ramsewak. 2007. "FDA Direct-to-Consumer Advertising for Prescription Drugs: What Are Consumer Preferences and Response Tendencies?" *Health Market Quarterly* 24: 77–91.

Maue, S.K., R. Segal, C.L. Kimberlin and E.E. Lipowski. 2004. "Predicting Physician Guideline Compliance: An Assessment of Motivators and Perceived Barriers." *American Journal of Managed Care* 10: 383–91.

Millstein, S.G. 1996. "Utility of the Theories of Reasoned Action and Planned Behavior for Predicting Physician Behavior: A Prospective Analysis." *Health Psychology* 15: 398–402.

Noether, G.E. 2010. "Why Kendall Tau?" Retrieved April 3, 2013. <http://www.rsscse-edu.org.uk/tsj/bts/noether/text.html>.

Schiller, J. and G.L. Euler. 2009. "Vaccination Coverage Estimates from the National Health Interview Survey: United States, 2008." National Centre for Health Statistics. Retrieved April 3, 2013. <http://www.cdc.gov/nchs/data/hestat/vaccine_coverage/vaccine_coverage.pdf>.

Sun, X. and Z. Yang. 2008. "Generalized McNemar's Test for Homogeneity of the Marginal Distributions." In *SAS Global Forum 2008*. Cary, NC: SAS Institute.

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RESEARCH PAPER

Meeting the Privacy Requirements for the Development of a Multi-Centre Patient Registry in Canada: The Rick Hansen Spinal Cord Injury Registry

Satisfaire les exigences en matière de confidentialité pour la création d'un registre multicentrique de patients : le Registre Rick Hansen sur les lésions médullaires

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Abstract

Privacy legislation addresses concerns regarding the privacy of personal information; however, its interpretation by research ethics boards has resulted in significant challenges to the collection, management, use and disclosure of personal health information for multi-centre research studies. This paper describes the strategy used to develop the national Rick Hansen Spinal Cord Injury Registry (RHSCIR) in accordance with privacy statutes and benchmarked against best practices. An analysis of the regional and national privacy legislation was conducted to determine the requirements for each of the 31 local RHSCIR sites and the national RHSCIR office. A national privacy and security framework was created for RHSCIR that includes a governance structure, standard operating procedures, training processes, physical and technical security and privacy impact assessments. The framework meets a high-water mark in ensuring privacy and security of personal health information nationally and may assist in the development of other national or international research initiatives.

Résumé

Les lois sur la protection de la vie privée prévoient la confidentialité des renseignements personnels; cependant, leur interprétation par les conseils de déontologie présente d'importants défis en matière de collecte, de gestion, d'utilisation et de divulgation d'informations personnelles sur la santé dans les études de recherche multicentriques. Cet article décrit la stratégie employée pour créer le Registre Rick Hansen sur les lésions médullaires (RHLM) conformément aux lois sur la protection de la vie privée et en tenant compte des pratiques exemplaires. Une analyse des lois régionales et nationales sur la protection de la vie privée a été menée afin de dégager les exigences de chacun des 31 sites du Registre RHLM ainsi que de son bureau national. Un cadre national de confidentialité et de sécurité a été créé pour le Registre RHLM. Ce cadre comprend une structure de gouvernance, des procédures d'exploitation normalisées, un processus de formation, des mesures de sécurité matérielle et technique ainsi que des évaluations d'impact sur la vie privée. Le cadre représente un important jalon pour garantir la confidentialité et la protection des informations personnelles sur la santé à l'échelle nationale et peut servir à la création d'autres initiatives de recherche nationales ou internationales.

Data related to an individual's health is one of the most sensitive types of personal information. Broadly speaking, research that utilizes such personal health information can guide healthcare policies, advance medical practices, improve healthcare outcomes and provide a better understanding of disease etiology, progression and economic costs (Black 2003). Patient registries are repositories of personal health information and have been defined as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined

by a particular disease, condition, or exposure, that serves predetermined scientific, clinical, or policy purpose(s)" (Gliklich and Dreyer 2010). Registries that contain high-quality patient data can provide important information regarding the epidemiology of health conditions and the outcomes of treatment. In Canada, the publicly funded structure of the healthcare system enables the collection of uniform and detailed information for health conditions nationally.

There are a number of Canadian patient registries that collect health information and are used by researchers, clinicians, administrators and policy makers. Most registries are developed for disease surveillance and accumulate data passively; few have been developed to facilitate prospective clinical and patient-reported data for specific health conditions.

The purpose of this paper is to describe the challenges encountered during the development of a national privacy and security framework for a prospective longitudinal patient registry of traumatic spinal cord injury (SCI), the Rick Hansen Spinal Cord Injury Registry (RHSCIR). Privacy regarding personal health information is an important aspect of the public's trust and acceptance; disclosure of collected data can lead to discrimination and emotional distress. Impairment resulting from a SCI can be highly sensitive in nature, often affecting sexual health and bladder and bowel function. National registries are an important resource for health research, but unfortunately, logistical difficulties have hindered their development. Seven years into this registry, we are in a position to describe the challenges encountered in conducting a multi-centre project and the processes we took to overcome them. It is hoped that by sharing these experiences we will assist others who face similar challenges while seeking to implement patient registries in Canada.

The Rick Hansen Spinal Cord Injury Registry

RHSCIR is a national Canadian registry of persons who have sustained a traumatic SCI, with 31 participating sites in nine provinces (Figure 1). Launched in 2004, RHSCIR is sponsored by the Rick Hansen Institute and funded by Health Canada and the governments of Alberta, British Columbia, Newfoundland and Ontario. RHSCIR was initiated as a research study and was developed to facilitate the translation of research into clinical practice and promote evidence-based care (Noonan et al. 2012).

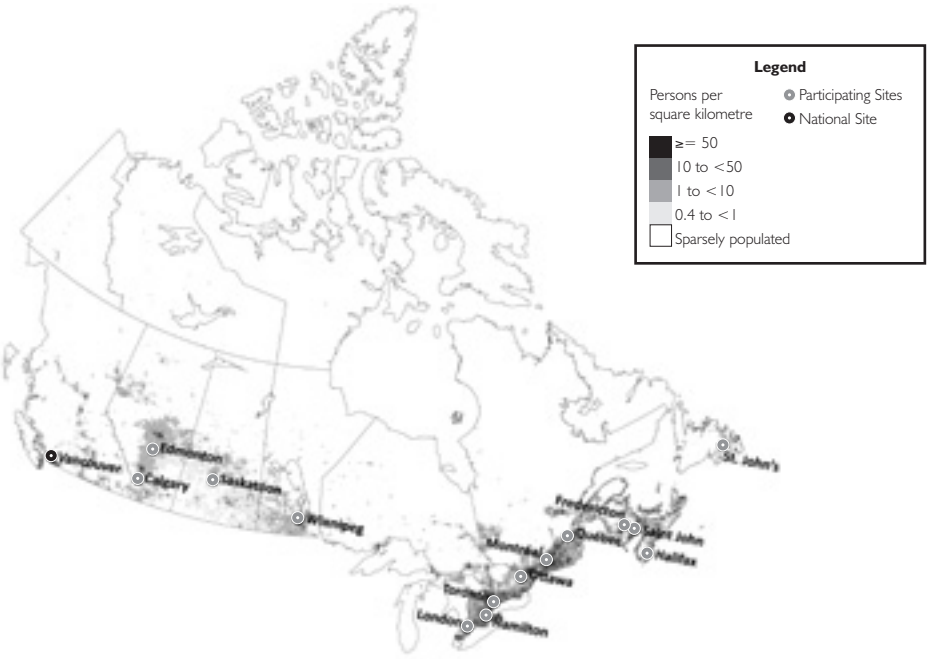
The inception of RHSCIR coincided with the enactment of federal privacy legislation governing personal health information and similar individual provincial legislation. The standardization of policies and procedures across all local RHSCIR sites has been challenging because of variation in the interpretation of legislative language. In response to these challenges, we created a national privacy and security framework to address personal privacy and security issues and operationalize the vision of RHSCIR.

Development of a Privacy and Security Framework

The development of a privacy and security framework at the Rick Hansen Institute initially required the commission of a national privacy analysis to be completed by legal experts in Canadian privacy practice. Because RHSCIR operates across several jurisdictions in Canada

and in various types of facilities (e.g., rehabilitation, acute care), the privacy analysis identified multiple and overlapping requirements for RHSCIR (see Figure 2). The requirements for each local RHSCIR site were determined by the province and the facility-specific policies, procedures and ethical/research guidelines for the local handling, transmission and storage of health data.

FIGURE 1. Rick Hansen Spinal Cord Injury Registry, national and local sites. There are 31 sites collecting data in 15 cities across 9 provinces (Noonan et al. 2012).



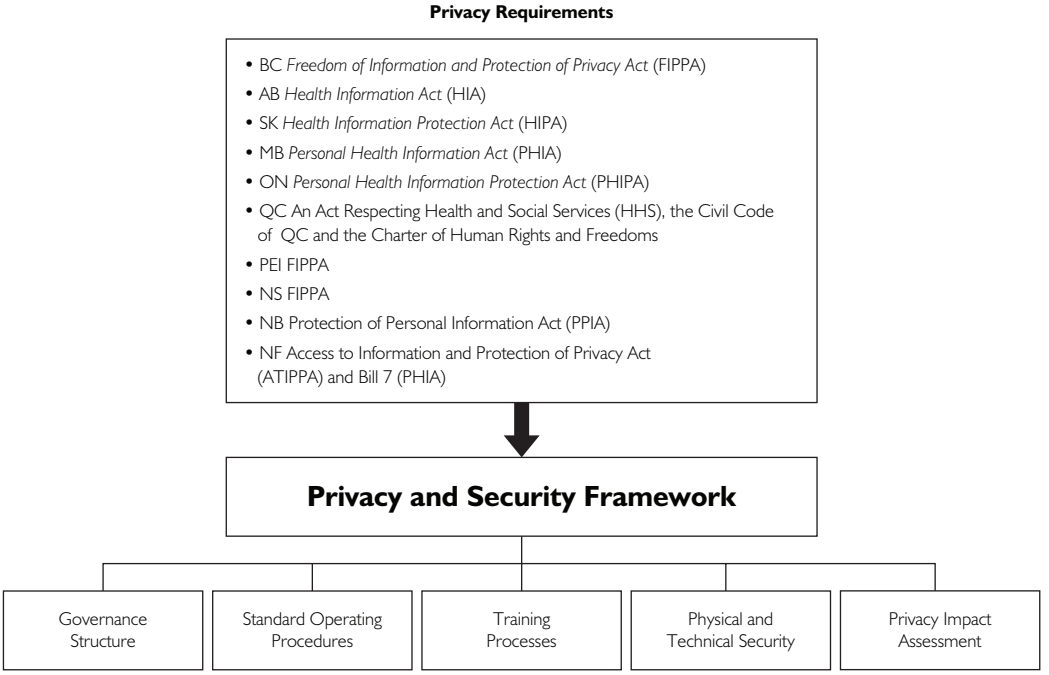
Population Source: 2001 Census of Canada. Produced by the Geography Division, Statistics Canada, 2002.

Because the national RHSCIR site handles only de-identified patient data, it is not bound by specific privacy legislation. However, to meet a high privacy standard, the national RHSCIR site complies with the federal *Personal Information Protection and Electronic Documents Act* (Department of Justice 2011) and all provincial and territorial data protection legislation, including provincial privacy laws specific to the health sector. A close working relationship exists between the national and local RHSCIR sites to ensure that privacy obligations are met.

The RHSCIR also adheres to the following research guidelines: (a) Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (CIHR 2005), (b) Canadian Institutes for Health Research: Best Practices for Protecting Privacy in Health Research (CIHR 2005), (c) ICH Guidance E6: Good Clinical Practice: Consolidated Guideline (Health Canada 2004) and (d) standards issued by the International Organization for

Standardization (ISO 2005, 2008). To ensure a gold standard of privacy compliance, the privacy requirements were benchmarked against the 10 elements of privacy best practices

FIGURE 2. Privacy requirements for the Rick Hansen Spinal Cord Injury Registry and the framework developed to meet these requirements



Abbreviations: British Columbia, BC; Alberta, AB; Saskatchewan, SK; Manitoba, MB; Ontario, ON; Quebec, QC; Prince Edward Island, PEI; Nova Scotia, NS; New Brunswick, NB; Newfoundland and Labrador, NF.

advocated by the Canadian Institutes for Health Research (CIHR 2005).

The Rick Hansen Institute developed a comprehensive framework in consultation with privacy experts that could be used by RHSCIR. The framework includes the formation of a privacy governance structure, the development of standard operating procedures, the establishment of training processes, the creation of physical and technical security, and a privacy impact assessment (see Figure 2). The framework is reviewed and updated bi-annually to ensure relevance to the current legislation, best practices and organizational structure at the Rick Hansen Institute.

Governance structure

The implementation and monitoring of privacy-related activities for RHSCIR required a chief privacy officer, reporting directly to the chief executive officer, and a Privacy Team that under the guidance of a legal expert enhanced accountability and oversight. The Privacy Team at the Rick Hansen Institute is composed of the chief privacy officer, compliance coordinator, RHSCIR project manager, director of information technology and the RHSCIR data man-

agement lead. The Privacy Team's responsibility is to foster awareness and implement, monitor and address current and potential privacy issues. Monitoring of the local RHSCIR sites is conducted regularly to ensure their compliance with all requirements, including the RHSCIR

TABLE 1. Key documents to oversee control of RHSCIR data

Document	Description
Privacy Policy	Privacy obligations at RHI and its mandate and commitment to ensuring privacy of patient information.
Data Use and Disclosure Policy	RHI's data access request and approval process applicable to requestors seeking access for authorized purposes to record-level health data stored at RHI; ensures that strict physical, technical and administrative controls are in place.
Data Storage, Retention and Destruction Policy	Physical and electronic measures required for data storage, the acceptable periods of data retention and destruction procedures.
Privacy and Information Security Standard of Conduct	Responsibilities and requirements of those associated with RHSCIR to uphold RHI's commitment to data protection, which abides by Canadian legislative requirements, international data protection standards and privacy best practices. Helps to foster an understanding of: • legal and organizational requirements that relate to privacy and information security • expectations of such staff who must ensure and protect the privacy and security of the information they create, collect, use, access, disclose or otherwise manage.
Privacy Breach Management Protocol	The procedure for managing privacy breaches in a timely and effective manner and the process for reporting, containing, notifying, investigating and remediating privacy breaches.
Handling Access Requests, Corrections and Complaints	How RHI staff must handle and respond to: • access and correction requests to be made to personal (health) data in the custody or control of RHI • complaints about RHI's personal information handling practices.
Information Security Policy	Provides high-level information on physical and electronic security measures at RHI and describes how RHI maintains the confidentiality, integrity and availability of all personal health data and other sensitive information.
RHSCIR Data Sharing Agreement	An agreement among RHI, the RHSCIR lead investigator and the relevant health authorities associated with the participating facilities/sites. It sets out the responsibilities of each party with respect to RHSCIR, the conditions for implementation funding of RHSCIR at the participating facilities/sites and an accountability framework for data sharing between the local and national sites.
Confidentiality Agreement	Describes individuals' obligation to maintain confidentiality and compliance with RHI privacy and security policies.
Data Disclosure Agreement	An agreement between RHI and the recipients of RHSCIR and other research data; outlines the obligation of the recipients to ensure security of the research data and clarifies data ownership and publication procedures.

Abbreviations: RHI, Rick Hansen Institute; RHSCIR, Rick Hansen Spinal Cord Injury Registry

study protocol and privacy legislation.

In addition to the Privacy Team, the Rick Hansen Institute has established a Data Executive Scientific Committee and a Data Access Committee to oversee the use and disclosure of the national RHSCIR data (Noonan et al. 2012). The Data Executive Scientific Committee consists of three of the lead investigators whose local RHSCIR sites contributed data to the requested data holding. This committee is responsible for reviewing data requests for scientific merit and ensuring that the use of data aligns with the permitted purposes of RHSCIR. The Data Access Committee comprises custodians from each of the local RHSCIR sites (there are currently 31) and provides approval for disclosure of the site data for each request.

Standard operating procedures

A central feature of any privacy and security framework is the system of documented policies, procedures, records and agreements/contracts that govern and allow the traceability of data handling. The key documents developed by the Rick Hansen Institute and their scopes are described in Table 1. These standard operating procedures were created under the guidance of a lawyer with privacy expertise to comply with the 10 principles of fair information practices, as outlined in the *Personal Information Protection and Electronic Documents Act* and best practices. The documents are created and managed in a document control system that is maintained by the compliance coordinator.

Training processes

The Rick Hansen Institute has an extensive training program, focused on privacy and security, in place for staff and local RHSCIR coordinators. The Privacy Team ensures that all staff members receive mandatory training annually, consistent with current policies and procedures for data and information handling. The privacy obligations of all the local RHSCIR sites are contained in the RHSCIR study protocol, and all site coordinators receive mandatory annual privacy training at RHSCIR site coordinators' meetings. These meetings also provide a forum to discuss privacy issues that arise from RHSCIR, across all the sites.

Physical and technical security

In order to maintain the privacy of participants enrolled in RHSCIR, physical and technical safeguards have been incorporated in the collection, storage, transmission of and access to data (see Table 2). These security measures have been implemented at the local and national RHSCIR sites and undergo continuous review and revision.

Privacy impact assessments

A privacy impact assessment (PIA) is a formal risk management tool used to identify the actual or potential effects that an activity may have on individuals' privacy and provides solu-

tions to eliminate or mitigate the risks. A PIA is desirable to assess the following types of risks in healthcare arising from:

- a new technology or the convergence of existing technologies;
- the deployment of existing information technology systems to new user groups;
- the use of a known privacy-intrusive technology in new circumstances; or
- a new project, or from changes to information handling practices with significant privacy effects (Cavoukian 2005).

TABLE 2. Key examples of RHSCIR-associated safeguards

Feature	Description
De-identification of local RHSCIR data during transmission and storage at the national RHSCIR site	Participants are given a unique RHSCIR ID number at the local RHSCIR site. The key matching participant name and RHSCIR ID number are stored at the local site in a separate, encrypted password-protected file, accessible only to authorized RHSCIR staff at the local site. RHSCIR data exported to the national site are identified by the RHSCIR ID number. The RHSCIR software has built-in technology to de-identify the data before they are securely transmitted to the national RHSCIR site.
Restriction of data access to authorized users	• **For data at the local RHSCIR sites:** Only the local RHSCIR sites store local RHSCIR data collected from participants in identifiable form on their internal, secure network or encrypted protected laptops, which can be accessed only by authorized RHSCIR staff with a unique username and password. • **For data at the national RHSCIR site at RHI:** No external access is available to the RHI server that stores national RHSCIR data.
Data accuracy	Data accuracy is ensured by built-in data validation checks at the local RHSCIR sites and manual inspection at the national RHSCIR site.
Data back-up	• **For data at the local RHSCIR sites:** Encrypted drives are used to securely store, manage and provide back-ups to restore data. • **For data at the national RHSCIR site at RHI:** The RHI server with national RHSCIR data is protected by regular system back-ups. Back-up tapes are stored securely off-site.
Transmission from the local to the national RHSCIR site	Data encryption software is used for electronic export of coded, de-identified RHSCIR data elements to the national RHSCIR database at RHI through a secure (https://) RHI SharePoint location.

Abbreviations: RHI, Rick Hansen Institute; RHSCIR, Rick Hansen Spinal Cord Injury Registry

The practice of conducting PIAs is becoming increasingly common, as it is an informative exercise that is mandatory for government agencies and public sector organizations (Treasury Board of Canada Secretariat 2010). Even when PIAs are not required under legislation, they are often required as a condition of funding. The Rick Hansen Institute is required by its

primary funder, Health Canada, to undertake an annual PIA. Our PIAs have been performed by an external professional service company. The PIA process assesses how the RHSCIR data are collected, used, disclosed, stored and destroyed. It involves a risk analysis and mitigation strategy for impacts on privacy through the identification of threats and vulnerabilities, and procedural technical strategies to mitigate them.

As part of the privacy and security framework, a PIA is conducted to analyze the status of data collection, use, disclosure and retention via RHSCIR and the related technical, administrative and physical safeguards in place to protect such data. The PIA reflects the current state of the privacy and security framework, the data flow and how the information technology application is currently used. Additionally, the PIA identifies and quantifies the privacy risks associated with the use of RHSCIR data by the national and local RHSCIR sites. The PIAs help identify any gaps in the privacy framework and provide an indication of the areas requiring remediation.

Key Challenges

The development of a national prospective patient registry to translate research into clinical practice and promote evidence-based care was viewed as a necessary step to improve the care of SCI in Canada. However, the creation of such a research study proved to be a daunting task, complicated by multi-centre and interprovincial challenges with the feasibility of a national site and the complexity of consent, bias and data collection. There are few national registries that are not mandated by the government and that go beyond the collection of administrative data.

Multi-centre and national scope

To capture data throughout the healthcare continuum and have a sufficient volume of data for research, the registry was required to be multi-centred, including both acute and rehabilitation facilities. As a result of the multi-centred nature, the ethics approval process was completed on a site-by-site basis, dependent on the local research ethics board (REB). Since some REBs cover more than one site, the collection of data from all 31 local RHSCIR sites (see Figure 1) required approval from 19 individual REBs, each with distinct submission and review processes.

In a study that involves several REBs in multiple provinces, interpretation of the complex legislation landscape is a time-intensive process that leads to delays in research, increased costs and protocol inconsistencies (de Champlain and Patenaude 2006; Kotecha et al. 2011; Willison 2007; Willison et al. 2008). The legal structure governing research is suited for discrete research studies with distinct goals, data sets and endpoints, not for prospective longitudinal studies, such as registries, with multiple research goals and complex national data sets (Willison 2007). In the case of RHSCIR, the REB submissions increased cost, time and human resources, and ultimately resulted in decisions that varied within a single jurisdiction.

For the RHSCIR data to be useful for national studies, the collection should be standardized across all provinces and centres. Standardization was a challenge because of the differing decisions of several REBs and the feasibility of collection among sites that have differing

standards and data collection methods. We attempted to standardize the sites as best we could to collect the same data elements; however, in some cases this was not possible, as described below.

Consent and bias

The requirement for individuals' explicit consent was intended to respect their right to privacy and control of their personal health information. However, it has been shown that consent for research purposes can reduce participation and create an ascertainment bias, such that the research sample is non-random and does not reflect the entire population for a specific health condition (El Emam et al. 2009; Harris et al. 2008; Ingelfinger and Drazen 2004; Kho et al. 2009; Tu et al. 2004). A review by El Emam and colleagues (2009) found that 32 of 37 studies reviewed reported lower recruitment rates as a result of consent and 27 found differences between consenters and non-consenters. The factors most often cited to differ were age, sex, race, socio-economic status, education and health status (El Emam et al. 2009; Kho et al. 2009). An example is the National Stroke Registry, where initial participation was 39.3% and consenting patients were younger and more likely to be mildly affected (Tu et al. 2004).

For RHSCIR, minimizing ascertainment bias was an important issue that was affected by the variability in the interpretation of provincial legislation. For consenting patients, there is a full data set of approximately 265 data elements (Noonan et al. 2012); however, to limit bias, a minimal data set is collected from individuals who have not consented or who were missed in the study. The collection of a minimal data set is permissible under privacy legislation in cases where REBs have requested a waiver of consent in research studies that utilize medical records and confer minimal or no risks. Therefore, the content of the minimal data set was decided on a site-by-site basis by the local REB. Not all REBs agreed to collect the same minimal data set; while some REBs permitted minimal data related to age, gender, details of injury, neurological assessment, diagnoses and clinical procedures, others limited collection to age, gender and date of injury. The collection of only three variables at certain sites makes determining bias beyond age and sex difficult. In theory, the idea of waiving consent is thought to reduce bias and loss of data; in practice, however, this was not the case for RHSCIR based on discrepancies between REB decisions.

Despite the efforts to reduce bias, it is still possible that the data are not entirely representative of the population of SCI in Canada. The local RHSCIR sites represent high-volume acute trauma facilities and specialized rehabilitation facilities. These sites were selected to be representative of Canadian provinces and have similar attributes whereby they provide grouping of patients with a traumatic SCI, acute and rehabilitation programs located within the same SCI centre and an in-patient SCI program. We recognize that the selection of such sites may influence the data collected, and studies are underway to compare our data to national administrative trauma data.

Data collection

A national registry required a national site to house the data and oversee operation of the RHSCIR network. The national site data do not contain identifiable patient information

owing to the challenges with identifiable data crossing provincial borders. Identifiable information is required to link SCI patient data to other data sources (e.g., hospital administrative databases and the national trauma registry), a situation that is currently unachievable at the national level. To address this challenge, local RHSCIR sites collect data from chart review, patient interviews and local hospital databases. All data are entered into the local RHSCIR site database where they are linked to local databases, assigned a unique RHSCIR identification number, de-identified and electronically sent to the national RHSCIR site. Creating data linkages at each of the local RHSCIR sites was difficult and remains an ongoing challenge. By not having identifiable data at the national level, we are not able to coordinate additional data linkages – for example, linkages to national vital statistics for information on mortality are not currently possible.

Conclusion

Today's healthcare environment is changing from the use of paper-based medical records to the implementation of computer-based documentation systems. This networking of health information has created exciting research opportunities and different privacy challenges in safeguarding personal health data. In this environment, there is a need to develop privacy architectures to protect privacy and minimize risks (Diamond et al. 2008; Lane and Schur 2010). The use of electronic health records highlights the issues surrounding secondary use of health information for research purposes and patient consent (Kosseim and Brady 2008).

The development of RHSCIR has highlighted several challenges in the creation and maintenance of a multi-centre, national, prospective registry in Canada. Specifically, the interpretation of privacy legislation by the REBs resulted in variation across RHSCIR sites. There are several provincial initiatives (Hebert and Saginur 2009) and one national initiative (CIHR 2010) for streamlining the research ethics review of multi-centre clinical studies that have brought together diverse groups of stakeholders. Based on our experience in developing RHSCIR, we support initiatives that will improve the effectiveness and efficiency of the ethics review process to enable the development of registries that collect standardized data across Canada and protect patient privacy.

The challenges encountered in launching RHSCIR are neither unique nor specific to spinal cord injury, but are applicable to any national research study requiring access to personal health information. Given the rapid advances in information technology and the need for data sharing and integration, the creation of large-scale, national research registries that collect data on whole populations and serve as platforms for future research are becoming more common. Canadian jurisprudence recognizes that patients maintain a legitimate expectation of privacy in and control over their personal health information. For RHSCIR, the development of a privacy and security framework ensured compliance and accountability, and provided assurance to patients; however, the maintenance of such a framework is an ongoing challenge and a dynamic process that continues to evolve. The lessons learned regarding the process for approval of RHSCIR may aid in the development of and collaboration with similar national disease registries in Canada and other countries.

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References

Black, N. 2003. "Secondary Use of Personal Data for Health and Health Services Research: Why Identifiable Data Are Essential." *Journal of Health Services Research & Policy* 8 (Suppl. 1): 36–40.

Canadian Institutes of Health Research (CIHR). 2005. Best Practice for Protecting Privacy in Health Research. Retrieved March 22, 2013. <http://www.cihr-irsc.gc.ca/e/22085.html>.

Canadian Institutes of Health Research (CIHR). 2010. Strategy for Patient-Oriented Research. Retrieved March 22, 2013. <http://www.cihr-irsc.gc.ca/e/41232.html>.

Cavoukian, A. 2005. "Privacy Impact Assessment Guidelines for the *Ontario Personal Health Information Protection Act*." Retrieved March 22, 2013. <http://www.ipc.on.ca/images/Resources/up-phipa_pia_e.pdf>.

de Champlain, J. and J. Patenaude. 2006. "Review of a Mock Research Protocol in Functional Neuroimaging by Canadian Research Ethics Boards." *Journal of Medical Ethics* 32(9): 530–34.

Department of Justice, Government of Canada. 2011. *Personal Information Protection and Electronic Documents Act* (PIPEDA). Retrieved March 22, 2013. <http://laws-lois.justice.gc.ca/eng/acts/P-8.6/>.

Diamond, C., M. Goldstein, D. Lansky and S. Verhulst. 2008. "An Architecture for Privacy in a Networked Health Information Environment." *Cambridge Quarterly of Healthcare Ethics* 17(4): 429–40.

El Emam, K., F.K. Dankar, R. Issa, E. Jonker, D. Amyot, E. Cogo et al. 2009. "A Globally Optimal k-Anonymity Method for the De-Identification of Health Data. Appendix A: Systematic Reviews on the Impact of Consent on Health Research." *Journal of the American Medical Informatics Association* 16(5): 670–82.

Gliklich, R.E. and N.A. Dreyer. 2010. *Registries for Evaluating Patient Outcomes: A User's Guide* (2nd ed.). Publication no. 10-EHC049. Rockville, MD: Agency for Healthcare Research and Quality.

Harris, M.A., A.R. Levy and K.E. Teschke. 2008. "Personal Privacy and Public Health: Potential Impacts of Privacy Legislation on Health Research in Canada." *Canadian Journal of Public Health* 99(4): 293–96.

Health Canada. 2004. ICH Guidance E6: Good Clinical Practice: Consolidated Guideline. Retrieved March 22, 2013. <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/guide-ld/ich/efficac/e6-eng.php>.

Hebert, P. and R. Saginur. 2009. "Research Ethics Review: Do It Once and Do It Well." *Canadian Medical Association Journal* 180(6): 597–98.

Ingelfinger, J.R. and J.M. Drazen. 2004. "Registry Research and Medical Privacy." *New England Journal of Medicine* 350(14): 1452–53.

International Organization for Standardization (ISO). 2005. ISO/IEC 27002: Information Technology – Security Techniques – Code of Practice for Information Security Management. Retrieved March 22, 2013. <http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50297>.

International Organization for Standardization (ISO). 2008. ISO 27799: Health Informatics – Information Security Management in Health Using ISO/IEC 27002. Retrieved March 22, 2013. <http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=41298>.

Kho, M.E., M. Duffett, D.J. Willison, D.J. Cook and M.C. Brouwers. 2009. "Written Informed Consent and Selection Bias in Observational Studies Using Medical Records: Systematic Review." *British Medical Journal* (Clinical Research) 338: b866.

Kosseim, P. and M. Brady. 2008. "Policy by Procrastination: Secondary Use of Electronic Health Records for Health Research Purposes." *McGill Journal of Law and Health* 2: 5–46.

Kotecha, J.A., D. Manca, A. Lambert-Lanning, K. Keshavjee, N. Drummond, M. Godwin et al. 2011. "Ethics and Privacy Issues of a Practice-Based Surveillance System: Need for a National-Level Institutional Research Ethics Board and Consent Standards." *Canadian Family Physician* 57(10): 1165–73.

Lane, J. and C. Schur. 2010. "Balancing Access to Health Data and Privacy: A Review of the Issues and Approaches for the Future." *Health Services Research* 45(5 Pt. 2): 1456–67.

Noonan, V.K., B.K. Kwon, L. Soril, M.G. Fehlings, R.J. Hurlbert, A. Townson et al. 2012. "The Rick Hansen Spinal Cord Injury Registry (RHSCIR): A National Patient Registry." *Spinal Cord* 50(1): 22–27.

Treasury Board of Canada Secretariat, Government of Canada. 2010. Directive on Privacy Impact Assessment. Retrieved March 22, 2013. <http://www.tbs-sct.gc.ca/pol/doc-eng.aspx?id=18308>.

Tu, J.V., D.J. Willison, F.L. Silver, J. Fang, J.A. Richards, A. Laupacis et al. 2004. "Impracticability of Informed Consent in the Registry of the Canadian Stroke Network." *New England Journal of Medicine* 350(14): 1414–21.

Willison, D.J. 2007. "Data Protection and the Promotion of Health Research: If the Laws Are Not the Problem, Then What Is?" *Healthcare Policy* 2(3): 39–43.

Willison, D.J., C. Emerson, K.V. Szala-Meneok, E. Gibson, L. Schwartz, K.M. Weisbaum et al. 2008. "Access to Medical Records for Research Purposes: Varying Perceptions across Research Ethics Boards." *Journal of Medical Ethics* 34(4): 308–14.

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