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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

From Global to Local: Inequalities in Health and Healthcare

This is the year that time runs out on the Millennium Development Goals (MDGs). Established following a United Nations summit in 2000, countries around the world committed to eight goals – including halving extreme poverty, stopping the spread of HIV/AIDS and reducing child mortality (United Nations 2015). While some questioned the process for establishing and monitoring the goals, the MDGs have galvanized and focused efforts from governments, civil society and other partners over the past 15 years.

There have been some remarkable achievements during this period. Globally, the number of people living in extreme poverty is down by more than half since 1990, the year against which MDG targets were benchmarked. So is under-five mortality, which dropped from an estimated 90 to 43 deaths per 1,000 live births. And maternal mortality and new HIV infections have fallen by 45 and 40 per cent, respectively. There were similar reductions in the prevalence of tuberculosis and mortality from the disease.

That said, progress towards the 21 MDG targets is uneven and not all milestones set for 2015 will be achieved. Large gaps exist between countries and within them. For example, children under five in the poorest households in developing regions are almost twice as likely to die as those in the richest, although this gap seems to be narrowing in at least some countries. However, the United Nations notes that progress in some other areas – such as measles vaccination – has stalled since 2010. Their report highlights the fact that many of the 21.6 million infants who did not receive the measles vaccine in 2013 were "from the poorest and most marginalized communities, residing in especially hard-to-reach areas" (United Nations 2015).

Similar patterns of health and disease are seen around the world; Canada is no exception. For instance, there is a 10-year gap in life expectancy at birth among provinces and territories (Statistics Canada 2013). Rates of arthritis, diabetes, hypertension, injuries and other diseases also differ among jurisdictions. Zooming in to the health region level, variations are even wider (Greenberg and Normandin 2011; Statistics Canada 2015). This "postcode lottery" represents the sobering reality that driving a few hours makes the difference between health status that is among the best in the world and one that reflects average life chances from half a century or more ago.

In this issue of the journal, Sara Allin, Jeremy Veillard, Li Wang and Michel Grignon study regional variations to understand how we can improve the efficiency with which the health system translates its resources into improved outcomes. There are no simple answers – but neither is this a simple problem. Their research highlights a combination of population, behavioural and managerial factors that help to explain variations in efficiency.

Other papers bring new perspectives to bear on equally challenging questions. The most personal explores the views of individuals designated as alternative level of care in Atlantic Canada and those of their families. Other authors examine system-level issues that have personal consequences for those they affect, such as generic drug pricing, the reimbursement of medications for rare diseases and the choice/implications of services from different types of maternity care providers.

Whatever areas of health policy you focus on, I hope that you will find food for thought, for study and for action in the journal's pages.

JENNIFER ZELMER, PhD
Editor-in-chief

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ÉDITORIAL

De l'échelle mondiale à l'échelle locale : inégalités en matière de santé et de soins de santé

Cette année commence le compte à rebours pour les objectifs du Millénaire pour le développement (OMD). Suite à un sommet des Nations Unies, en 2000, des pays du monde entier se sont donnés huit objectifs, dont réduire l'extrême pauvreté, freiner l'expansion du HIV/sida et réduire la mortalité infantile (Nations Unies 2015). Bien que certaines personnes remettent en question les processus d'établissement et de suivi des objectifs, les cibles spécifiques des OMD ont permis de galvaniser les efforts des gouvernements, de la société et d'autres partenaires au cours des quinze dernières années.

Il y a eu d'importants progrès pendant cette période. Dans l'ensemble, le nombre de personnes vivant dans l'extrême pauvreté a diminué de plus de la moitié depuis 1990, l'année de référence pour les OMD. Il en est de même pour la mortalité des enfants de moins de cinq ans, dont on estime la chute de 90 à 43 décès par 1 000 naissances vivantes. La mortalité maternelle et les nouvelles infections à VIH ont respectivement connu des baisses de l'ordre de 45 et 40 pour cent. La prévalence de la tuberculose et la mortalité liée à cette maladie ont connu des baisses similaires.

Cela dit, la progression vers les 21 cibles des OMD demeure inégale et les jalons fixés pour 2015 ne seront pas tous atteints. Il existe de grands fossés entre les pays et même à l'intérieur des frontières. Par exemple, les enfants de moins de cinq ans dans les ménages les plus pauvres des régions développées sont presque deux fois plus susceptibles de mourir que ceux des ménages les plus riches, quoique ce fossé semble se rétrécir, du moins dans certains pays. Toutefois, les Nations Unies observent que les progrès dans d'autres secteurs – tels que la vaccination antirougeoleuse – sont en perte de vitesse depuis 2010. Leur rapport souligne le fait que bon nombre des 21,67 millions d'enfants qui n'ont pas reçu le vaccin antirougoeleux en 2013 provenaient des « communautés les plus pauvres et les plus marginalisées, résidant dans des zones difficiles d'accès » (Nations Unies 2015).

On observe partout dans le monde des schémas similaires pour la santé ou les maladies, et le Canada ne fait pas exception. Par exemple, au sein des provinces et des territoires canadiens, il y a un écart de dix ans dans l'espérance de vie à la naissance (Statistique Canada 2013). Les taux d'arthrite, de diabète, d'hypertension, de blessures et d'autres maladies varient aussi entre les régions. À l'échelle des régions sanitaires, les variations sont encore plus marquées (Greenberg et Normandin 2011; Statistique Canada 2015). Cette « loterie » se traduit par le triste fait qu'il suffit parfois de rouler pendant quelques heures pour constater l'écart entre

une des meilleures situations de santé au monde et une autre qui présente des possibilités d'épanouissement semblables à celles qui prévalaient il y a plus d'un demi-siècle.

Dans le présent numéro, Sara Allin, Jeremy Veillard, Li Wang et Michel Grignon se penchent sur les variations régionales afin de trouver des moyens d'améliorer l'efficience qui permet au système de santé d'optimiser ses ressources pour obtenir de meilleurs résultats. Il n'y a pas de réponse simple, mais le problème n'est pas simple non plus. De leur recherche se dégage une combinaison de facteurs liés à la population, aux comportements ou à la gestion, qui apportent une source d'explication pour les variations observées dans les degrés d'efficience.

D'autres articles amènent de nouveaux points de vue sur des questions tout aussi complexes. L'article le plus axé sur les personnes explore le point de vue de patients (et de leurs familles) désignés pour un autre niveau de soins dans le Canada atlantique. D'autres auteurs examinent, à l'échelle du système, les enjeux qui ont d'importantes répercussions pour ceux qui en sont affectés, tels que l'établissement du prix des médicaments génériques, le remboursement des médicaments pour les maladies rares ou le choix du fournisseur de soins de maternité.

Quel que soit la politique de santé qui vous intéresse, j'espère que vous trouverez dans cette revue des idées pour nourrir votre réflexion, vos recherches et vos activités.

JENNIFER ZELMER, PhD
Rédactrice en chef

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Canada's New Generic Pricing Policy: A Reasoned Approach to a Challenging Problem

Nouvelle politique canadienne d'établissement des prix des médicaments génériques : démarche raisonnée face à un problème difficile

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Abstract
Alberta, quickly followed by other Canadian provinces, has introduced a new pricing model for generic drugs, in which prices are inversely related to the number of generic manufacturers of the drug. This paper examines the rationale for the new policy.

Résumé
L'Alberta, rapidement suivie par d'autres provinces canadiennes, a mis en place un modèle d'établissement des prix pour les médicaments génériques, modèle dans lequel les prix sont inversement liés au nombre de manufacturiers du médicament générique. Cet article étudie les fondements de cette nouvelle politique.

The Canadian Generic Manufacturing Association recently announced a new three-year agreement with the provinces and territories to establish pricing policies for generic drugs (Canadian Generic Pharmaceutical Association 2014a; Ontario Ministry of Health and Long-Term Care 2014). The proposed policies are novel within Canada, and follow the recommendations made in academic papers (Cambourieu et al. 2013; Hollis 2009; Hollis and Grootendorst 2014). The expected savings to payers are some $3.8 billion over three years (Canadian Generic Pharmaceutical Association 2014a).

The new agreement is in a contested area of drug policy in Canada, with some experts recommending tendering (Law 2013) and others reduced regulatory interference (Skinner and Rovere 2010). The starting point is, however, the status quo, which has received considerable criticism (Competition Bureau 2010; Patented Medicine Prices Review Board 2011). In the status quo system, the provinces set the prices that they pay for generic drugs dispensed to public drug plan beneficiaries, typically at a fixed percentage of the brand price. And most provinces regulate generic drug prices paid by private drug plans. Over the past seven years, the provinces have reduced prices from as high as 70% of the price of the brand drug, down to as low as 18% for some generics.

If the goal is to reduce spending, why stop at 18%? How low can prices go? The provinces are walking a tightrope. On the one side, they risk paying excessive prices for generic drugs. On the other, they risk losing generic entry, in which case they pay even higher prices. The challenge is aggravated by a pricing policy in which every generic drug is supposed to be priced at the same fraction of the brand price. The problem is that not all generic drugs are the same.

In some cases, there may be a dozen manufacturers – domestic and foreign – competing in the market. In this situation, it makes sense to beat the price down as far as possible.

In other cases, there is a single generic manufacturer in the market, who risks a substantial patent infringement liability. In these situations, the manufacturer will enter only if the price is well above the cost of production and distribution; a substantial cushion is required to make it worth bearing a significant risk. It is important to note that the parties to litigation cannot reliably predict how courts will rule. For example, in the set of decisions between Apotex and Sanofi over the validity of a patent regarding Plavix: Sanofi won in PM(NOC) cases in Federal Court, Federal Court of Appeal and Supreme Court cases; Apotex then sought to impeach the patent with the benefit of a full trial including discovery, and was successful in the Federal Court; Sanofi appealed and was successful. Apotex has discontinued its application to the Supreme Court.

In yet other cases, there is only a single generic manufacturer of an old drug with quite limited volume of sales. Here the manufacturer may find it not worthwhile to invest in maintaining spare capacity to ensure security of supply if the price is too low.

It is also evident that some generic drugs are relatively expensive to manufacture, and others are less costly. Reimbursement policy should reflect this.

The case of the cardiovascular drug ramipril is illustrative. When the generic company Apotex started selling ramipril in 2006, it generated very substantial savings for provincial

and private insurers, which purchased ramipril at the generic price, instead of the higher brand price. Apotex was immediately sued by Sanofi, the patentee, which alleged infringement and damages on lost sales valued at the full brand price. The Federal Court found Apotex non-infringing. Sanofi appealed, and lost, and then appealed to the Supreme Court, which ultimately declined to hear the appeal in 2012 (Sanofi-Aventis Canada Inc v Apotex Inc, January 3, 2012 [SCC Case No. 34600]). There was probably a big sigh of relief at Apotex, which was liable for hundreds of millions of dollars, much more than the amount it had earned from selling the drug. In 2006, had Apotex faced today's pricing environment, in which provinces refuse to allow higher prices to a generic facing patent infringement risk, it might instead have avoided entering the market until all the relevant patents had expired in 2020, 14 years after actual generic entry. The extra cost to Canadians of no generic entry is estimated at over $8 billion (Canadian Generic Pharmaceutical Association 2014b).

In some markets, the combination of small market volumes and low prices deters entry. For example, "Cuprimine" has been off patent for many years, but on the Ontario formulary, there are no listed interchangeable drugs: the profits from selling a low-volume generic drug at a low price are not enough to make it worth even going through the regulatory process. Similarly, in other markets, the risk of patent infringement may deter generic entry given a low generic price. In other cases, generic firms may find it more attractive to settle a patent dispute with the patentee, resulting in delayed entry, rather than entering at risk. The inevitable result is that the provinces will continue to pay the full brand price for an extended period.

Fortunately, there is a sensible solution to this problem. Prices should reflect the number of generic firms willing to sell. When there is only one generic firm, the reimbursed price should be relatively high – perhaps 75% of the brand. And if more generic firms are willing to enter, prices should fall to reflect this. Such a mechanism could automatically generate very low prices for high-volume competitive drugs – with no need for the drug plan to figure out the lowest feasible price. And, importantly, it would produce higher prices to stimulate generic entry in those situations where that is the only way to obtain competition at all. Essentially, the design of the scheme is such that it imitates competitive pricing. If only one firm enters, then the price stays high; if many firms enter, the price drops much lower. Firms will be attracted to enter provided that the post-entry price is greater than their average costs of production, with the result that the price is driven towards the average cost of production. The implementation of this system by the provinces should generate substantial savings (Cambourieu et al. 2013; Canadian Generic Pharmaceutical Association 2014a; Hollis 2009; Hollis and Grootendorst 2014).

Alberta's latest pricing model reflects this approach (ABC Benefits Corporation 2014). Introduced in April 2014, the current pricing policy for new generic drugs starts at 70% of the brand price if there is only one generic entrant, and falls to 50%, 25% and, then, 18% for markets with two, three and four generic entrants, respectively. The 70% pricing lasts for, at most, one year, after which, 50% pricing applies. More recently, the provinces and territories

have reached an agreement with the Canadian Generic Manufacturing Association similar to the Alberta model (Canadian Generic Pharmaceutical Association 2014a). Ontario has proposed new regulations along this line (Ontario Ministry of Health and Long-Term Care 2014). This is one of the rare situations in which a proposal made by academics was implemented by policy makers. The expected savings to all payers from the agreement is claimed to be approximately $3.8 billion over three years.

We have some reservations about the details of the agreement, which sets the lowest price at 18% of the brand, well above the cost of production for many important drugs. This will leave considerable profits available to be split between manufacturers and pharmacies. There should be additional lower price tiers that would be effective when more than four manufacturers are willing to enter. However, the agreement creates many benefits. First, it is national, which will eliminate the substantial price variations between provinces. Second, it is designed to ensure that private payers get the same prices as the public plans. Third, it creates stability and some predictability in the generic market, as the agreement is for three years. And fourth, it meaningfully relates prices to costs through firms' willingness to enter.

While it is still too early to assess the effectiveness of this scheme in practice, it is at least an effort to create pricing flexibility in a way that reflects costs and the importance of stimulating generic entry. This scheme deserves careful attention and a review once it has been fully implemented, and indeed, the provinces have committed to undertake a review within three years (Ontario Ministry of Health and Long-Term Care 2014).

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Reimbursement of Drugs for Rare Diseases through the Public Healthcare System in Canada: Where Are We Now?

Remboursement, par le système de santé public au Canada, des médicaments pour maladies rares : où en sommes-nous?

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Abstract

Introduction: Over the past 20 years, the number of therapies developed for rare diseases has rapidly increased. Often, these therapies represent the only active treatment for debilitating and/or life-threatening conditions. However, they create significant challenges for public and private payers. Because they target small patient populations, clinical evidence of efficacy/effectiveness is typically limited, while the cost per patient is high. In Canada, each province/territory establishes its own mechanisms for determining which drugs for rare diseases (DRDs) to provide.

Objectives: To compare current mechanisms across provinces and territories, and explore their impact on access.

Methods: A systematic review of relevant published and unpublished documents was performed. Electronic bibliographic databases, the internet, and government websites were scanned using structured search strategies. Information was extracted independently by two researchers, and included aspects such as program type, condition/patient/therapy eligibility criteria, role of health technology assessment (HTA), decision options, ethical assumptions, and stakeholder input. It was validated through member-checking with provincial/territorial policy experts and tabulated to facilitate qualitative analyses. Impact on access was assessed through a cross-province/territory comparison of the coverage status of all non-cancer therapies reviewed by the Common Drug Review for indications affecting <1/2,000 Canadians using the Kappa statistic. Reasons for variations were explored using qualitative techniques.

Results: Each province/territory has formal and informal mechanisms through which such therapies may be accessed. In most cases, formal mechanisms constitute the centralized HTA processes that also apply to common therapies. While several provinces have established dedicated processes/programs, whether they have affected access is not clear. Despite broadly comparable approaches, there is less than perfect agreement on publicly funded DRDs across jurisdictions.

Conclusions: Individual jurisdictions have developed different approaches to providing access to these therapies. However, as the number increases, a more systematic approach to decision-making may be needed.

Résumé

Introduction : Au cours des vingt dernières années, le nombre de thérapies pour les maladies rares a augmenté rapidement. Ces thérapies représentent souvent le seul traitement actif pour des personnes aux prises avec un état débilitant ou mettant la vie en danger. Cependant, il y a d'importants défis pour les gouvernements et les tiers payant privés. Étant donné que ces thérapies visent un petit nombre de patients, il y a souvent peu de données cliniques sur leur efficience et leur efficacité, tandis que le coût par patient demeure élevé. Au Canada, chaque province ou territoire conçoit ses propres mécanismes pour déterminer quels médicaments pour les maladies rares (MMR) seront fournis.

Objectifs : Comparer, entre les provinces et les territoires, les mécanismes en place et étudier leur impact sur l'accès.
Méthodes : Nous avons mené une revue systématique des documents pertinents publiés et non publiés. Au moyen de stratégies de recherche structurées, nous avons scruté les bases de données bibliographiques, l'Internet et les sites Web des gouvernements. Deux chercheurs indépendants ont recueilli les données, notamment à l'aide de critères tels que le type de programmes, les critères d'admissibilité pour l'état, le patient ou la thérapie, le rôle de l'évaluation des technologies de la santé (ETS), les choix de décisions, les questions d'éthique et les commentaires exprimés par les intervenants. Les données ont été validées auprès d'experts des provinces ou territoires, puis tabulées afin d'en faciliter les analyses qualitatives. Nous avons évalué l'impact sur l'accès en comparant, entre les provinces et les territoires, la couverture pour toutes les thérapies pour les états non cancéreux, et ce, à l'aide du Programme commun d'évaluation des médicaments pour les indications touchant un nombre de Canadiens <1/2 000, au moyen de l'indice Kappa. Les causes des variations ont été explorées au moyen de techniques qualitatives.
Résultats : On trouve, dans chaque province et territoire, des mécanismes officiels et non officiels qui permettent d'accéder aux thérapies. Dans la plupart des cas, les mécanismes officiels sont les mêmes processus d'ETS centralisés qui s'appliquent également aux thérapies communes. Bien que plusieurs provinces aient mis en place des processus et des programmes particuliers, on ne sait pas clairement s'ils ont une influence sur l'accès. Malgré des démarches similaires dans l'ensemble, il n'y a pas vraiment d'accord entre les divers gouvernements sur le financement public des MMR.
Conclusions : Chaque province et territoire a développé une démarche différente pour ce qui est de l'accès à ces thérapies. Toutefois, alors que le nombre de cas augmente, la prise de décisions devrait adopter une démarche plus systématique.

The last two decades have seen the development and introduction of a number of innovative drugs for rare diseases (DRDs) (i.e., orphan or ultra-orphan drugs). In many cases, they comprise the first disease-modifying treatment for a life-threatening or chronically debilitating complex disease. Therefore, patients and families want access to them as soon as possible. However, for payers, the risks associated with coverage decisions on DRDs are considerable. Clinical evidence is typically limited to small short-term trials relying on surrogate rather than hard clinical outcomes (Picavet et al. 2013). The annual treatment costs, most of which are life-long, can exceed $300,000 CDN per patient (Hollis 2005). Thus, given uncertainty in the value proposition, payers are reluctant to reimburse DRDs. Often, a positive coverage decision follows an extensive media campaign highlighting the plight of desperate patients and demonizing payers. Kalydeco® for some types

of cystic fibrosis provides a recent Canadian example of the tensions between patients and payers (CTV News 2014). In Canada, the absence of national pharmacare has been cited as one factor contributing to those tensions, as there may be disparities in access to DRDs across provinces/territories that potentially create inequities in the health of patients with rare diseases. In response, provincial and territorial ministers of health have announced plans to consider a national approach to reimbursement decision-making on DRDs (Canadian Intergovernmental Conference Secretariat 2015). However, before exploring what that approach might look like, it is important to understand how these decisions are currently made and the extent to which access to DRDs actually varies across Canada.

While published literature describing Canada's centralized processes for providing reimbursement recommendations to participating federal and provincial drug plans exists (Grima and Samjoo 2013; Rocchi et al. 2012; Spitz 2013), a comprehensive review of how decisions on DRDs are made and through what mechanisms DRDs are accessed at the provincial and territorial drug plan level has yet to be published.

Objective

The objectives of this paper are:

1. To compare current mechanisms for making reimbursement decisions on DRDs across provincial and territorial publicly funded drug plans in Canada.
2. To examine the extent to which reimbursement of DRDs through publicly funded drug plans varies across provinces and territories.

Background

In Canada, new drugs (including DRDs) being considered for reimbursement through provincial (except for Quebec), territorial or federal drug plans (i.e., outpatient) must first be evaluated by one of two centralized drug review processes: the Common Drug Review (CDR) for non-oncology drugs and the pan-Canadian Oncology Drug Review for oncology drugs. Both are managed by the Canadian Agency for Drugs and Technologies in Health (CADTH) and evaluate the clinical and economic implications of drugs submitted for review and provide reimbursement recommendations to participating drug plans. Currently, there are no separate centralized review processes or explicit special considerations within the two existing ones for DRDs. Decisions on whether to reimburse a drug remain with each plan. Therefore, this paper focuses on decision-making processes at the provincial and territorial levels. Further, since most of the life-long drugs with annual per-patient costs exceeding $100,000 Canadian dollars target non-cancers, only processes for non-cancer drugs are described.

Methods

The project was conducted in two parts. The first involved the identification of different ways in which patients access DRDs through the publicly funded healthcare system in each

province and territory and through the federal government's Non-insured Health Benefits (NIHB) program. The second examined variations in access to specific DRDs across provinces and territories, and explored whether those variations may be related to differences in decision-making processes.

In this project, a DRD was defined as a drug intended to treat a disease with a prevalence of <1/2,000 persons, the rate recently proposed in the draft regulatory framework for orphan medicinal products prepared by Health Canada (Health Canada 2012a).

Part 1: Identification of mechanisms for accessing DRDs through the publicly funded healthcare systems

To identify current mechanisms through which reimbursement decisions on DRDs are made, three methods were used:

1. a comprehensive review of published papers and government documents describing provincial and territorial approaches to providing access to DRDs;
2. analyses of relevant ministerial websites; and
3. a survey of drug plan managers in each of the provinces and territories.

COMPREHENSIVE LITERATURE REVIEW

The literature search included the following bibliographic databases: PubMed, The Cochrane Library, the Centre for Reviews & Dissemination (DARE, NHS EED and HTA) databases, EMBASE, Web of Knowledge, EconLit, PAIS International, Sociological Abstracts, Canadian Business and Current Affairs, ABI/INFORM Global, Scopus, Proquest Dissertations & Theses and Canadian Newsstand Complete. The databases were searched in February–March 2013. The search was restricted to publications from 1990 to date, and English or French language publications (where possible). Search terms used controlled vocabulary, such as the Medical Subject Headings (MeSH) terms: Rare Diseases, or Orphan Drug Production, as well as additional MeSH and free text keywords (to capture the concepts of decision-making, reimbursement, etc.). Monthly PubMed update searches were run throughout the project (to March 2015).

Searches for grey literature included the following Internet sources: KU-UC (Quebec Population Health Research Network), Google.ca and the websites of rare diseases associations and Canadian federal and provincial government agencies. The reference lists of relevant papers were scanned to identify additional references. Full details of the search terms and sources used are included in Appendix A. For each of the Internet searches, the first 300 "hits" were examined. Citations identified through the various searches were imported into a Reference Manager database. Two researchers independently reviewed all of the citations using a set of pre-defined selection criteria that included the names of the provinces and territories and discussion of coverage or reimbursement for specific DRDs/orphan drugs or DRDs/orphan drugs, in general. Agreement between researchers was assessed using the

kappa statistic, and discrepancies were resolved through discussion. This statistic, which measures agreement beyond chance between sets of observations (i.e., which papers to include in the review), was used. Kappa values range from −1 to 1, and strength of agreement is interpreted as follows: $K < 0$ (poor); $0 < K < 0.20$ (slight); $0.21 < K < 0.40$ (fair); $0.41 < K < 0.60$ (moderate); $0.61 < K < 0.80$ (substantial); and $0.81 < K < 1.0$ (almost perfect) (Fleiss 1981). Information on key elements from papers selected for inclusion was extracted using a standard "data abstraction form." The key elements, identified as relevant by senior policy makers from several provinces involved in a Canadian Institutes for Health Research (CIHR)-funded team grant on policies for managing rare diseases in Canada, included: type of reimbursement program (e.g., listing on a formulary or case-by-case/exceptional funding), decision options, condition/patient/therapy eligibility for consideration under a particular reimbursement program, role of clinical and economic evidence in reimbursement decision-making around DRDs and opportunities for stakeholder input (e.g., patients and specialists in rare diseases). These were defined on the basis of consultations with provincial drug plan managers and knowledge users in a CIHR-funded emerging team grant on policies for managing technologies for rare diseases. The extracted information was tabulated to facilitate qualitative comparative analyses.

ANALYSES OF MINISTERIAL WEBSITES

The website of each provincial and territorial ministry of health was scanned independently by two researchers to identify reimbursement processes for DRDs. The same data abstraction form as that developed for the literature review was used to systematically extract information from each website. The information was then combined with data collected from the literature review into a single set of tables.

SURVEY OF DRUG PLAN MANAGERS

Provincial/territorial/NIHB drug plan managers were contacted by e-mail to identify one individual from each jurisdiction who would be able to complete a self-administered survey. One representative from each jurisdiction participated. For each jurisdiction, a table of information about programs specific to DRDs and processes through which reimbursement decisions are currently made (obtained from the literature review and ministry websites) was prepared. This was sent to drug plan managers or their delegates for verification and updating. Based on feedback received, the tables were revised and then analyzed qualitatively. The survey questions from which these tables were prepared are shown in Appendix B.

Part 2: Access to specific DRDs across provinces and territories

To compare inter-provincial/territorial access to DRDs, a list of potential drugs was first compiled. It contained all DRDs (non-cancer) submitted to the CDR since its inception until February 2014. Because drugs must first go through these processes before being considered by provincial and territorial drug plans, CDR submissions were used as the information

source for identifying possible drugs. Canadian estimates of prevalence for the condition/disease indicated on each drug submission were obtained through targeted searches of Orphanet and published literature, as well as contact with patient organizations. Only drugs for which the prevalence of their indication was less than 1 in 2,000 individuals in Canada were selected. As no common definition of a "rare" disease exists in Canada, this prevalence rate, which is enshrined in European Union legislation, and being considered within the proposed Orphan Drug regulatory framework for Canada, was used. The selected drugs were then categorized by Anatomical, Therapeutic and Chemical (ATC) Classification.

Publicly funded coverage for/access to each included DRD across the provinces and territories was determined through a review of the contents of publicly available formularies and benefits lists and a survey of provincial and territorial drug plan managers. The survey listed all of the DRDs and asked respondents to indicate the reimbursement status of each one.

To assess variations in access to DRDs across jurisdictions, the kappa statistic, which measures agreement beyond chance between sets of observations (i.e., reimbursement status of drugs in each jurisdiction), was used. Kappa values were calculated for all of the included DRDs, as a whole, as well as for specific ATC Classification groups. The latter analysis was performed to assess whether concordance across plans varied across drug classes.

Results

Part 1: Identification of mechanisms for accessing DRDs through the publicly funded healthcare systems

There was "almost perfect" agreement between the two reviewers in the sources of information selected (K = 0.92). Information on current mechanisms through which DRDs are considered for reimbursement was found for all 10 provinces, Nunavut, Yukon, the Northwest Territories and the NIHB program of the federal government. Although the searches of grey literature provided a considerable amount of information on specific jurisdictional processes, the survey of the jurisdictions yielded considerably more information from Alberta, British Columbia, Newfoundland, Nova Scotia, Saskatchewan and the NIHB program. The reimbursement decision-making mechanisms were grouped into three categories: (1) general reimbursement; (2) case-by-case review; and (3) DRD-specific plans or processes.

GENERAL REIMBURSEMENT

General reimbursement refers to processes established for making formulary decisions (i.e., decisions around whether or not to add a drug to the list of publicly insured drugs) for outpatient drugs, in general. All jurisdictions have such processes, which typically accept submissions from manufacturers following completion of a review by the CDR (Table 1). Thus, drugs (including DRDs) eligible for consideration are those for which a CDR recommendation is available. Across jurisdictions, possible outcomes of these processes are: (1) provide coverage through public funding, (2) provide coverage with conditions (e.g., specific patients

or prescribing physicians) and (3) do not provide coverage (Table 1). All require information on the disease/condition for which the drug is indicated, clinical evidence addressing safety and effectiveness and economic evidence related to cost-effectiveness, price and budget impact (Table 2). Most of this information is contained within the original manufacturer's CDR submission. Requirements do not differ between DRDs and drugs for common conditions/diseases. In British Columbia (BC Ministry of Health 2010a), Ontario (MOHLTC 2013a) and Quebec (INESSS 2014b), perspectives of patients and families, provided through submissions from patient organizations, also comprise an information input. These submissions are accepted for all drugs under review, regardless of their indication. Some jurisdictions require letters from manufacturers confirming their ability to supply the drug based on the anticipated demand, e.g., Alberta (Alberta Health and Wellness 2012), Ontario (MOHLTC 2000) and Saskatchewan (Saskatchewan Health 2014c). In most jurisdictions, information inputs are collectively scrutinized by an expert committee, whose membership, at a minimum, comprises pharmacists and physicians (Table 3). In Ontario (Ontario Public Appointments Secretariat 2013b), British Columbia (BC Ministry of Health 2010a) and Quebec (INESSS 2014b), the committee also includes representatives from the public, referred to as "lay" members or "citizen" members depending on the jurisdiction. Each committee considers a set of decision factors/criteria and formulates a listing recommendation. In almost all jurisdictions, final decisions are made by the minister. Factors/criteria considered by all committees include recommendations from the CDR, therapeutic advantage, clinical safety and effectiveness, availability of alternatives and value for money (Table 3). Additionally, several committees explicitly consider: impact on patients (Alberta, Alberta Health and Wellness 2012; British Columbia, BC Ministry of Health 2014d; Ontario, MOHLTC 2013c; Quebec, INESSS 2014b; and Saskatchewan, Saskatchewan Health 2014c), current clinical practice/utilization patterns (Alberta, Alberta Health and Wellness 2012, and British Columbia, BC Ministry of Health 2014d), affordability (Alberta, Alberta Health and Wellness 2012; Manitoba Health 2014a; New Brunswick, Government of New Brunswick 2014f; Newfoundland, Newfoundland & Labrador 2013d; and Ontario, MOHLTC 2013e), alignment with government goals/priorities (Alberta, Alberta Health and Wellness 2012; New Brunswick, Government of New Brunswick 2014f; Newfoundland, Newfoundland & Labrador 2013d; Ontario, MOHLTC 2013e; and Saskatchewan, Saskatchewan Health 2014c), impact on health services (Ontario, MOHLTC 2013e; Newfoundland, Newfoundland & Labrador 2013d; and Quebec, INESSS 2014b) and social values/ethical implications (British Columbia, BC Ministry of Health 2010a; Ontario, MOHLTC 2012m; and Quebec, INESSS 2007a). Importantly, in all jurisdictions, factors/criteria considered are the same for all drugs (including DRDs). Similarly, where formal opportunities to appeal decisions exist (British Columbia, BC Ministry of Health 2014g; Manitoba Blue Cross 2014c; Newfoundland, Newfoundland & Labrador 2013d; Ontario, MOHLTC 2012m; Quebec, RAMQ 2014i; Saskatchewan; and the Yukon, Government of Yukon 2005), they apply to all drugs, regardless of their indication (Table 4). While decisions arising from general reimbursement review processes are made publicly

available (usually through ministry websites) in most jurisdictions, rationales are not, with the exception of Alberta, Ontario and Quebec (INESSS 2007a). Tables 1 through 4 can be seen at www.longwoods.com/content/24360.

CASE-BY-CASE REVIEW

In almost all jurisdictions, drug plans have established processes for considering funding requests for drugs not included on the benefit list/formulary for individual patients (i.e., case-by-case review). Typically, requests are made by the prescribing physician, who completes an application form. Some jurisdictions have defined eligibility criteria related to the patients or drugs for review through these processes (Alberta, CTV News 2012; Manitoba Health 2008; MOHLTC 2011a; Prince Edward Island, PEI Ministry of Health and Wellness 2013f; Quebec, INESSS 2014j). With respect to patient-related criteria, all of these jurisdictions have a "lack of available treatment alternatives" condition, where patients considered are those who were unable to tolerate standard therapy or who did not achieve a satisfactory response to standard therapy. Drug-related criteria include drugs without regulatory approval, those yet to be reviewed through the general reimbursement process (Alberta, CTV News 2012, and Ontario, MOHLTC 2011a) or those failing to receive a positive recommendation through the general reimbursement process (New Brunswick, Government of New Brunswick 2014f; Newfoundland, Newfoundland & Labrador 2013d; Ontario, MOHLTC 2011a). In Alberta, the annual cost must also exceed $100,000 Canadian. "Rarity" of the disease is explicitly taken into account in Manitoba (Manitoba Health 2008) and Saskatchewan (Saskatchewan Health 2014k), where "exception status drugs" can include those "not ordinarily prescribed or administered" in the province because the condition is "rarely found" there. However, it does not constitute an eligibility criterion. Across all jurisdictions, potential decision options/outcomes comprise "provide coverage with conditions" or "do not provide coverage." The "conditions" are generally clinically based. In several jurisdictions, a "provide coverage with conditions" is an interim decision, granting temporary funding/access for a fixed period (Table 1). In all jurisdictions, the decision applies to the individual patient for whom the DRD was requested (i.e., DRD is not added to the formulary).

Information requirements of case-by-case requests are less explicit, except in Alberta and Ontario (34), where submission of relevant peer-reviewed clinical studies is specified (Table 2). Procedures for making case-by-case decisions are also less explicit. In both Alberta and Ontario (MOHLTC 2011a), decision-making involves senior-level staff (executive directors), who seek advice from external clinical experts (Table 3). In most jurisdictions, decision criteria/factors considered during deliberations are not specified.

DRD-SPECIFIC PLANS AND PROCESSES

Five provinces have established specific programs for DRDs. These programs take the form of coverage plans enabling access to a defined set of DRDs on a separate formulary in Alberta (Alberta Health 2012b) and New Brunswick (Government of New Brunswick 2014l) or

dedicated reimbursement decision-making processes for DRDs (British Columbia; Ontario, MOHLTC 2013c; and Saskatchewan). Alberta's program covers CDR-reviewed drugs for genetic lysosomal storage disorders affecting fewer than 1 in 50,000 individuals in Alberta (Alberta Health 2012b). Similar to a case-by-case review, a physician who specializes in these disorders completes a Rare Disease Drug Coverage application on behalf of a patient. The application is considered by the same committee as that involved in the general reimbursement process, but with advice from an expert clinical panel on rare diseases (Alberta Rare Diseases Clinical Review Panel). Two recommendations are possible: "provide coverage with conditions" or "do not provide coverage." A "provide coverage with conditions" involves coverage conditional upon regular monitoring of clinical outcomes. If his/her condition worsens, coverage is discontinued. A "do not provide coverage" recommendation is made if a patient has an additional significant illness that is likely to substantially reduce life expectancy (Table 1). Final decisions rest with the Minister of Health. Importantly, this program only applies to a set of drugs that have already been deemed eligible. Since 2009, it has included drugs for the following diseases: Gaucher, Fabry, MPS II (Hunter Syndrome) and Pompe. Like Alberta's program, the recently announced Drugs for Rare Diseases Plan in New Brunswick also applies to a defined set of drugs/separate formulary (Government of New Brunswick 2014l). That set comprises five drugs for the following diseases: MPS I, MPS II, Cryopyrin-Associated Periodic Syndrome, Pompe disease and Niemann Pick Type C (Government of New Brunswick 2014, 2014u). Similar to Alberta's program, coverage is considered for individual patients whose physician has submitted a request on their behalf. However, the plan will adopt criteria from Ontario's Drugs for Rare Diseases Evaluation Framework (DRDEF) (Government of New Brunswick 2014l, 2014u). This framework represents one of two provincial reimbursement decision-making processes dedicated to rare diseases only. Drugs eligible for review through the DRDEF are those that treat diseases (non-cancer-related) with an annual incidence of <1/150,000 individuals and those for which clinical trials measuring clinically important outcomes have not been possible (Fraser 2013). Requests for consideration of an eligible drug may be submitted by manufacturers or physicians using a standard template (MOHLTC 2011c). Unlike the plans in both Alberta (Alberta Health 2012b) and New Brunswick (Government of New Brunswick 2014l), requests relate to access for all patients for whom the drug is indicated, rather than access for an individual patient. Required information includes a description of the disease (incidence, natural history, subtypes and available treatment alternatives), proposed drug benefit price, letter confirming ability to supply anticipated demand, clinical trial data and a budget impact analysis (Fraser 2013). Submissions are reviewed by the Drugs for Rare Diseases Working Group (DRDWG), comprising physicians, a pharmacist and a health economist (Winquist et al. 2012). The DRDWG confirms disease prevalence and that adequately powered studies are infeasible; reviews the pathophysiology, natural history and health implications; considers the mechanism of action of the drug and its potential and actual treatment effects; reviews available clinical data and develops a decision model that incorporates variability in treatment effects;

and evaluates the budget impact of the drug. It also considers patient submissions prepared by registered patient advocacy groups (MOHLTC 2013c). Based on this information, the DRDWG makes a funding recommendation, which is forwarded to the Executive Officer for a decision (Fraser 2013; Winquist et al. 2012). Two decision options exist: "provide coverage with conditions" (regular monitoring of patient outcomes) and "do not provide coverage." While there is no formal appeals mechanism, patient organizations, physicians and manufacturers may provide feedback to the Ministry and DRDWG, who, in turn, determine whether a re-evaluation is necessary (Winquist et al. 2012). In contrast to the rare disease plans in Alberta (Alberta Health 2012b) and New Brunswick (Government of New Brunswick 2014l), the status of submissions and decisions are publicly available on the ministry's website (MOHLTC 2013c). As in Ontario, British Columbia's Expensive Drugs for Rare Diseases (EDRD) program also comprises a process for making reimbursement decisions on DRDs. However, unlike the DRDEF, reimbursement requests are made by physicians for specific patients and reviewed on a case-by-case basis. Drugs eligible for review must have an annual cost of >$50,000/patient and be indicated for a non-cancer-related condition with a prevalence of <1.7/100,000 Canadians (Table 1). Requests are reviewed by an expert committee (EDRD Advisory Committee), comprising pediatric and adult rare disease specialists, a medical geneticist, pharmacists, health administrators, a health economist and an ethicist. The committee considers severity of the disease, clinical effectiveness of the drug and availability of alternatives (Table 3). Recommendations are either: "provide coverage with conditions" or "do not provide coverage," and final decisions are made by the minister. Decisions are not posted on the ministry's website. Saskatchewan's EDRD process is similar to British Columbia's program, except that eligible drugs are those used to treat conditions with an annual incidence of <1/150,000 individuals in Canada. As in British Columbia, requests relate to individual patients and are made by their physicians. The Saskatchewan Drug Plan and its Drug Advisory Committee review requests, considering an explicit set of factors that include recommendations from the CDR, criteria from the Ontario EDRDEF and reimbursement status of the drug in other Canadian jurisdictions (Table 3). Decision options are "provide coverage with conditions" and "do not provide coverage" to the patient. "Conditions" comprise fixed periods at the end of which a progress report describing the patient's treatment response must be provided (Table 3).

Part 2: Access to specific DRDs across provinces and territories

A total of 33 DRDs met the selection criteria and were included in the analyses (Table 5). While 11 (33%) were available through one of the above three types of reimbursement mechanisms in at least 10 of the jurisdictions, 12 (36%) were available in fewer than three of the jurisdictions. Of those 12, over half fell within the Alimentary Tract and Metabolism Products ATC Classification. Overall, there was moderate agreement (pooled K = 0.48) on DRD accessibility across the jurisdictions. However, kappa scores ranged from 0.11 (between Yukon and Ontario) to 1.0 (between Nunavat and Northwest Territories) (Table 6).

Among pair-wise jurisdictional comparisons, the proportion of kappa scores indicating "substantial," "moderate" and "slight" agreement was ~20%, ~40% and ~5%, respectively (Table 6). Based on kappa patterns, level of agreement did not appear to vary with the presence of a DRD-specific reimbursement process (i.e., higher scores were not observed between jurisdictions with such processes). When agreement across jurisdictions was assessed by ATC Classification, over half of the kappa scores were less than 0.2, indicating "slight" agreement across jurisdictions (Table 7). The lowest scores related to Alimentary Tract and Metabolism Products (which include the enzyme replacement therapies) and Respiratory System Agents (ivacaftor). Tables 5 through 7 can be seen at www.longwoods.com/content/24360.

Discussion

In this paper, the landscape of approaches used by publicly funded drug plans to make reimbursement decisions on DRDs across provinces and territories is described. All jurisdictions use a combination of general reimbursement review processes through which formulary listing decisions are typically made and "safety-net" programs through which case-by-case requests for access for individual patients are determined. Moreover, all use similar types of clinical and economic evidence (usually provided by the CDR) to inform listing decisions. Despite broadly comparable approaches, there is less than perfect agreement on publicly funded DRDs across jurisdictions. This may be explained in part by variations in factors considered during decision-making beyond clinical and economic implications. As many rare diseases are genetic and found predominantly within certain communities and geographic locations, demand for specific DRDs may differ across jurisdictions. Therefore, the lack of coverage in a particular province or territory may reflect a lack of patients for whom the DRD is indicated. For example, the prevalence of Fabry Disease in Nova Scotia (which has a founder population with the disease) has been reported to be 1 in 15,000 (West et al. 2002), while the prevalence in a general population ranges between 1 in 40,000 and 1 in 117,000. Therefore, a drug may receive a higher priority for funding from decision-makers in some jurisdictions where the disease is more prevalent (or the drug may not even be considered in a province where there are no patients with the disease). It may also be related to cost. DRDs around which variations in access across Canada were found to be the greatest include some of the most expensive drugs currently marketed (ivacaftor, with annual costs estimated at over $US300,00, and eculizumab, with annual costs exceeding $US500,000).

Variations in access to drugs across Canada have been previously documented in the literature (Chafe et al. 2011; Glass-Kaastra et al. 2014; Menon et al. 2005). These differences raise questions around inequities in access because of the limited treatment choice. For common diseases, a number of treatment options exist, at least one of which is available in jurisdictions. Variations in access may also be related to media coverage of individual patients seeking reimbursement for a particular DRD in a specific jurisdiction. A national approach may address some of these inter-jurisdictional disparities, as well as other issues related to rare diseases, such as an inconsistency in the definition of a rare disease, and challenges related to

establishing patient registries with small numbers of patients in each jurisdiction (Panju and Bell 2010).

In April 2008, the House of Commons passed a motion to create a national plan for rare diseases (49). While such a plan has yet to be developed, federal, provincial and territorial governments have begun to examine ways to address issues around DRDs collaboratively. Under the umbrella of the Council of the Federation, premiers have established a working group to explore ways to manage the cost of DRDs with evidence-based approaches (Canadian Intergovernmental Conference Secretariat 2015). At the federal government level, the Minister of Health announced in 2102 that an Orphan Drug Regulatory framework would be established for the pre-market review and post-market monitoring of new DRDs (Health Canada 2012a). However, this framework has yet to be implemented.

Another Canadian initiative has been the creation of the pan-Canadian Pharmaceutical Alliance (pCPA) by the provincial and territorial governments. The pCPA has the authority to decide whether pan-Canadian negotiations should occur after a new drug, including a DRD, has undergone the common drug review. Such negotiations may involve proposals of "managed access programs," in which a drug is funded with the requirement that additional evidence be collected during its use (i.e., access with evidence development). Given that many DRDs are launched with limited clinical evidence, this might be the most appropriate approach to providing more DRDs through public drug plans. As these initiatives move forward, it will be important to ensure that they take into account inter-jurisdictional differences in the needs of patients. The results of this study could inform further development of the pCPA as well as policies related to managed access programs.

Limitations

This project relied on publicly available information and survey responses. Although copies of tables were sent to each jurisdiction to ensure their accuracy and comprehensiveness, it is possible that some information may have been missed. Also, processes may have changed in the months following completion of data collection. Finally, some of the more subtle aspects of decision-making may not have been captured through the data collection that was undertaken from the jurisdictions.

Conclusion

Despite broadly similar coverage review processes for DRDs across Canada, listing decisions and, in turn, access vary considerably. Given the recent interest expressed in orphan drug policy by both levels of government in Canada, an opportunity might exist to build on these review processes and create a pan-Canadian approach.

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RESEARCH PAPER

How Can Health System Efficiency Be Improved in Canada?

Comment peut-on améliorer l'efficience des systèmes de santé au Canada?

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Abstract

Improving value for money in the health system is an often-stated policy goal. This study is the first to systematically measure the efficiency of health regions in Canada in producing health gains with their available resources, and to identify the factors that are associated with increased efficiency. Based on the objective elicited from decision-makers that the health system should ensure access to care for Canadians when they need it, we measured the efficiency with which regions reduce causes of death that are amenable to healthcare interventions using a linear programming approach (data envelopment analysis). Variations in efficiency were explained in part by public health factors, such as the prevalence of obesity and smoking in the population; in part by characteristics of the population, such as their average income; and in part by managerial factors, such as hospital readmissions.

Résumé

L'amélioration de l'optimisation des ressources dans les systèmes de santé est un des objectifs souvent énumérés dans les politiques. Cette étude est la première à mesurer systématiquement, parmi les régions sanitaires au Canada, l'efficience de l'utilisation des ressources disponibles pour obtenir des gains sur le plan de la santé, et à déterminer les facteurs associés à un accroissement de l'efficience. En fonction des objectifs établis par les décideurs, à l'effet que le système de santé devrait pouvoir assurer l'accès aux soins pour les Canadiens au moment où ils en ont besoin, nous avons mesuré l'efficacité avec laquelle les régions parviennent à réduire les causes de décès attribuables à des interventions, et ce, au moyen de la programmation linéaire (méthode d'enveloppement des données). Les variations dans l'efficience s'expliquent en partie par des facteurs liés à la santé publique, tels que la prévalence de l'obésité et le tabagisme; en partie par les caractéristiques de la population, telles que le revenu moyen; et en partie par des facteurs liés à la gestion, tels que les réadmissions à l'hôpital.

Annual spending on healthcare represented an estimated 11.2% of annual income (gross domestic product, GDP) in 2013 in Canada, compared to 7% in 1975 (CIHI 2013b). This long-term trend of increasing spending on healthcare is common to other industrialized countries; however, there is no clear relationship between high levels of spending on healthcare
and improvements in health outcomes. For instance, Australia spent 9.1% of its GDP on healthcare in 2011, while key indicators of health status improved at a faster pace and surpassed most indicators for Canada in the past 20 years (OECD 2014). The same holds true within Canada: the average resident of Alberta spends 23% more than the average resident of Quebec on healthcare, without better health outcomes (CIHI 2013a, 2013b). It is therefore not surprising that questions would be raised about the value created by such expenditures.

The goals of doing more with resources available are recognized by federal and provincial governments, and professional organizations alike, as a priority for ensuring the sustainability of the Canadian health system (CMA 2010; Health Canada 2013; MOHLTC 2012). This view is also shared by Canadians: a recent public survey placed efficiency higher than increased funding as priorities for health system reform (Environics Research Group 2011).

In the past few years, national and international experts, professional organizations and policy makers across the country have made numerous recommendations for reducing waste and improving efficiency in healthcare, for the most part by improving the way services are organized and delivered (Ontario Ministry of Finance Commission on the Reform of Ontario's Public Services 2013; The Council of the Federation 2012). However, to date, there has not been any attempt to measure systematically what expenditures buy in the Canadian healthcare system, nor to identify factors associated with higher levels of efficiency. Still, measuring health system efficiency has been the focus of several high-profile international studies, but these have limited application for decision-makers in general and have had limited impact in Canada (Joumard et al. 2010; WHO 2000). Among other issues, these studies make use of national indicators of the organization of healthcare (such as payment schemes or financing mechanisms) that do not take into consideration Canada's highly decentralized responsibility for healthcare delivery and administration.

This paper presents the results of a study that measured health system efficiency in Canada at the health region (sub-provincial) level (CIHI 2014). The aim of this study was to provide actionable results for decision-makers by identifying some of the factors that are associated with higher levels of efficiency. The focus was on technical efficiency, which refers to the extent to which objectives are achieved by health systems given available resources: it addressed the question of whether we could get more given what we spend. It is important to note that we use efficiency in a neutral sense here, referring to the ability of a health region to get more outcomes with the same level of resources; such ability can be the result of better management in the health region, but it can also result from environmental constraints beyond their control. Through the systematic measurement of health system outputs and inputs, we were able to measure inefficiencies in each region in Canada, and based on these findings, we gained insight into the factors explaining inefficiencies and the interplay among environmental, public health and managerial factors influencing efficiency.

Methods

In this study, the unit of analysis of health system efficiency was the health region. There are over 100 health regions in Canada, and this study included 89 regions for which data were available (territories were not included). Health regions are administrative bodies that are legislated by the provincial ministries of health. Even though the legislated roles of health regions, and their relationship with local hospitals and other providers, vary across provinces, health regions have a degree of responsibility (relative to the province where they are located) for improving the health of their respective populations. They are also responsible for

providing health and healthcare services to their populations. There are important variations across regions that may affect efficiency, for instance in terms of the size and characteristics of the populations they serve, the range of resources available (CIHI 2013a; Statistics Canada 2013) and the strategies they adopt to coordinate and plan services for their populations. In 2010, the average population size of health regions in this study was over 400,000 people, with a range from 26,400 (Zone 5 in New Brunswick) to nearly 2 million (Région de Montréal, Québec).

This research proceeded in three steps. The first step was to define the objective (output) and resources (inputs) of the healthcare system. In the existing literature on health system efficiency we could identify, researchers often defined health systems objectives and resources on the basis of data availability. We were not able to identify studies that attempted to confirm whether decision-makers or citizens accepted these assumptions about what the healthcare system should be measured against. In contrast, in this study, we solicited decision-maker and other stakeholder perspectives, through a scoping review of public documents (archival work); a series of in-depth, qualitative, open-ended interviews with senior Canadian health ministry officials (Abelson and Pasic 2013); and, finally, a facilitated dialogue (which is akin to a focus group) with health system leaders and stakeholders (Lavis 2013). In the second step of this study, we gathered regional data on what these stakeholders had indicated were legitimate outputs and inputs from their perspective, and we calculated efficiency scores using a sophisticated version of a common approach in the health economics literature – data envelopment analysis (DEA). DEA uses linear programming that determines that a region is inefficient when any linear combination of observed regions yields more output with the same level of inputs (Jacobs et al. 2006). It simply describes the data, as opposed to assuming any specific relationship between the inputs and outputs as required for regression-based approaches such as stochastic frontier analysis. Not imposing any relationship gives DEA the advantage that it is less prone to misspecification bias than regression-based approaches. The weakness of the standard DEA, however, is that it has no stochastic component (it is entirely deterministic) and, as a result, imposes an assumption that at least some regions must be perfectly efficient (scores of 1). To alleviate this, we used a recently developed methodological improvement based on a procedure akin to a bootstrap analysis. Following bootstrapping, although no region attains a score of 1, an efficiency score of 0.8 would still be interpreted as 80% efficient because it relates to the maximum *attainable* efficiency as opposed to the maximum *observed* efficiency score.

The last (third) step in this study was to conduct a regression analysis of the logarithm of the efficiency scores for each region on a set of explanatory variables to identify the factors that were significantly associated with variations in efficiency scores across regions. We used a backward step-wise regression to select variables to be included in the final regression model.

Data

There are three main components to an efficiency analysis: the *inputs* (system resources) and the *output* (or system objective) of the healthcare system, which were used to calculate efficiency scores using DEA, and the *factors* that can explain how well inputs are used to produce the output, which were included in the third step-wise regression on efficiency scores. All data were ecological and measured at the level of the health region.

Based on the results of the qualitative study of stakeholder perspectives on the healthcare system, we defined the *output*, or objective, of the healthcare system as ensuring that Canadians have access to timely and effective healthcare when they are sick or need care. The concept of avoidable mortality provides the closest measurable indicator of this stated objective, as it measures the outcome of timely and effective healthcare being received (CIHI 2012b; Nolte and McKee 2004, 2008). Other possible measures of accessibility include waiting times and self-reported unmet need. Indicators such as these provide a partial picture of effective healthcare being received. Moreover, these indicators can be considered to be included in a summary measure like avoidable mortality, as longer wait times and other barriers to accessing appropriate care can help to explain why we observe premature deaths from treatable causes. Avoidable mortality can be divided into two components: causes of death that should have been prevented with effective public health interventions (e.g., vaccine-preventable deaths and smoking-related deaths) and causes of death that should have been treated with effective healthcare interventions. Some examples of treatable causes of death include sepsis, pneumonia, colorectal cancer, breast cancer in women, hypertensive diseases, asthma and most other respiratory diseases, renal failure, pregnancy and childbirth (CIHI 2012b). For this study we used the treatable potential years of life lost (PYLL), an indicator that calculates the number of years of life that are lost prematurely (here, before age 80) to causes of death that are considered to be treatable by healthcare interventions (CIHI 2012b; Nolte and McKee 2004, 2008). The underlying idea is that if Canadians had access to timely care when they need it, no person should die before age 80 of (the small set of) causes of death that are considered to be treatable. In practice, this means that a person who died at age 65 from a treatable cause of death would have lost 15 potential years of life. These values of the difference between the actual age of death and age 80 are then summed over the population and divided by the population count.

The choice of age 80 as the cut-off for considering a death to be premature was based on stakeholder feedback, in large part owing to the observation that about half of all deaths occur after age 80. However, sensitivity analyses were conducted using different cut-offs, including the conventional cut-off of 75. Sensitivity analyses using an alternative measure of treatable mortality – the age-standardized mortality rate from treatable causes of death – were also conducted. Results were robust to these changes in both the age cut-off and the choice of mortality rate versus the years of life lost.

In contrast to what we found in the stakeholder consultation, the majority of studies of efficiency have chosen measures of average population health, such as improving life expectancy or disability-adjusted life expectancy, and reducing infant mortality as the desired objective of the health system (CIHI 2012a). Only one other study that we identified measured efficiency across OECD countries in terms of reducing avoidable mortality (Joumard et al. 2010).

Also based on stakeholders' perspectives, *inputs* were measured as the dollar value spent on the major components of healthcare: hospital costs, physician payments, pharmaceutical spending, cost of residential care facilities and community care. Spending data were from the Canadian Institute for Health Information administrative databases (the Canadian MIS database for hospital spending and the National Physicians Database for physician spending), Statistics Canada (the Residential Care Facility Survey and the 2006 Census to estimate spending on community care) and IMS Brogan Canada (community prescription drug spending). It is important to note that the estimates of hospital and specialist spending at the regional level were adjusted to account for the fact that residents of more rural regions likely travel to nearby urban regions that have more hospitals. Specifically, hospital and specialist spending were both divided by a modified version of the inflow–outflow ratio produced by the Canadian Institute for Health Information that accounted also for the average cost of delivering care in the region (using the average cost per in-patient) (CIHI 2014).

The environment in which a health system operates can significantly affect its ability to bring about health improvements with a given set of resources (Jacobs et al. 2006). For instance, the prevalence of health conditions that are considered to be amenable to health system interventions, such as asthma or pneumonia, can be affected by broader health determinants, such as education level. This study controlled for three external determinants of health – education level, and concentration of recent immigrants and individuals identifying as Aboriginal – by including them as additional inputs in the analysis. These three external determinants of health were chosen on the basis that they could be considered outside of the control of health system managers, and that they were significantly associated with the outcome measure (treatable PYLL). This ensured that comparisons were made only among health regions with similar operating environments.

Table 1 provides the mean, dispersion and range of inputs and outputs included in the calculation of the efficiency scores.

TABLE 1. Description of variables included in the DEA

	Mean	Standard deviation	Range	
			Minimum	Maximum
Inputs – spending per capita, $				
Hospitals	1,718.93	520.40	951.32	3,826.39
Prescription drugs	545.60	123.50	288.53	884.25
Physicians	471.15	122.42	177.01	816.72
Residential care facilities	336.42	164.00	74.20	901.83
Community nurses	54.49	18.51	19.59	98.68
Inputs – environment				
Education (% with high school or more)	82.33	6.85	63.30	94.00
Recent immigrants (%)	3.16	4.21	0.10	16.70
Non-Aboriginal (%)	92.74	9.21	49.50	99.60
Output				
PYLL from treatable causes (before age 80), per 100,000 population, age-standardized	1,666.34	317.92	1,066.6	2,452.6

Finally, the *factors* that were considered in the third step of the analysis (factors explaining efficiency scores) included the characteristics of the environment that are not adjusted for in the calculation of efficiency scores. These include the age and sex structure of the population, because they were not significantly associated with the outcome measure, which is not surprising given that treatable PYLL is age-standardized. Also considered were public health factors that could affect efficiency (such as the level of smoking and obesity in the population, and the proportion of the population reporting to have three or more chronic conditions), which reflect both past investments in health system as well as the current challenges that health system managers face. By not including these public health factors as inputs in the calculation of efficiency scores with DEA, the implication is that the prevailing burden of disease in the regions is within the responsibility of health system leaders. Moreover, variations in the population health of regions may then help to explain variations in the efficiency with which regions are able to transform health system dollars into health gains, as measured by fewer treatable causes of death. The remaining factors included those that are directly within the control of health system managers, such as hospital readmissions and lengths of stay. Table 2 provides the mean, dispersion and range of the variables that were considered in the step-wise regression analysis of efficiency scores.

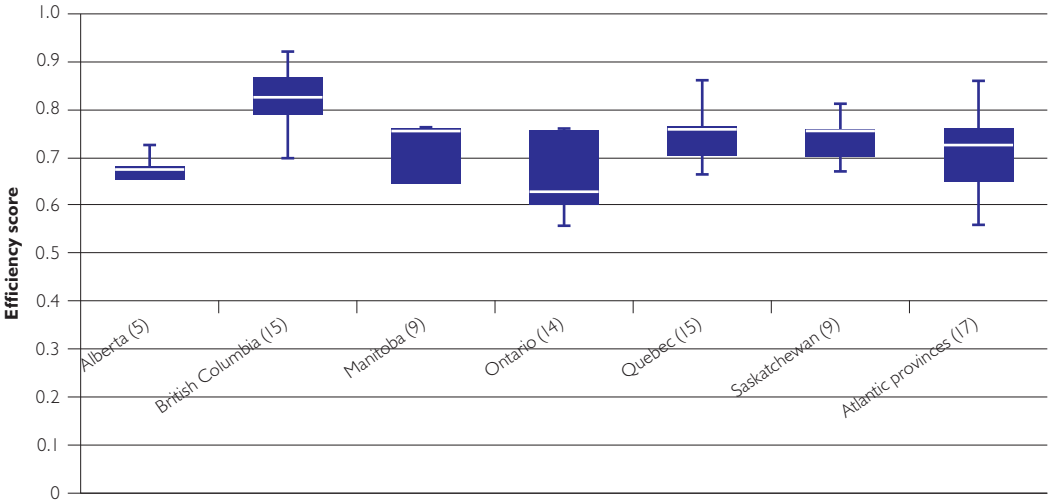
TABLE 2. Description of variables considered in the step-wise regression analysis

	Mean	Standard deviation	Minimum	Maximum
Environmental factors				
Men	0.5	0.01	0.48	0.52
Population aged 65 years and older	0.14	0.03	0.08	0.22
Population density	249.08	896.03	0.13	5,679.00
Long-term unemployment	4.1	2.85	1.3	16
Average income ($)	32,164	5,287	23,611	50,111
Income-related inequality in likelihood of a physician visit	0.02	0.01	−0.02	0.05
Income inequality (Gini index)	0.26	0.14	0.04	0.65
No teaching hospitals in the region	0.8	0.4	0	1
Public health factors				
Daily smoking (per cent of population aged 12 and over)	18.78	3.59	10.3	26.6
Obese (per cent of population aged 18 and over)	19.91	5.06	6.3	30.8
Overweight (per cent of population aged 18 and over)	35.65	3.31	23.7	43.7
Three or more chronic conditions (per cent of population aged 12 and over)	24.34	3.7	16.5	32.2
Physically inactive (per cent of population aged 12 and over)	49.16	5.85	29.4	61.3
Management factors				
ACSC admissions per 100,000 population	415.66	151.74	185.67	880.33
Repeat hospitalizations for mental illness (per cent of patients with at least one hospitalization for mental illness)	10.93	2.68	4.1	18.1
C-sections (per cent of total births)	23.58	7.04	0	37.36
VBAC rate (per 100 births)	15.64	7.39	2.97	34.71
Overall 30-day readmission rate (per cent of all hospital discharges)	9.33	1.84	6.24	15.96
30-day readmissions (surgical)	6.72	1.57	1.2	14.12
30-day readmissions (paediatric)	5.54	1.46	1.56	9.44
30-day readmissions (medical)	13.64	1.64	10.38	18.53
Operational factors				
GPs (per cent of total physicians)	63.75	14.37	34.53	98.93
Nursing in-patient services total worked hours per in-patient case	50.99	7.43	39.63	72.74
Average typical length of stay in acute hospital (days)	4.77	1.61	2.55	11.68
Average ALC length of stay in acute hospital (days)	9.28	8.73	3.84	68.67
ALC cases (per cent total in-patient cases)	4.86	5.52	0.45	33.4
Average occupancy rate in acute hospitals	81.1	12.89	22.4	96.71
Average spending on administration as a per cent of total hospital spending	5.32	1.23	3.2	8.9
Average cost per weighted case ($), acute hospitals	5,123.27	711.34	3,555.22	7,197.14

Results

We found significant variations in health system efficiency across regions, even though comparisons were made only among regions that shared some key characteristics (in terms of concentration of recent immigrant, educated and Aboriginal populations). On average, the level of efficiency in Canada was 0.73 (compared with an optimal efficiency level set at 1.0), with a range across different model specifications between 0.65 and 0.82 across the 84 regions included in the study (after excluding five regions that were statistical outliers). This suggests that PYLL from treatable causes of death could be reduced by between 18% and 35% if all regions were operating efficiently in Canada. Figure 1 reports the efficiency scores summarized by province, showing a wide range of efficiency scores within every province (or group of provinces in the case of Atlantic Canada), with only British Columbia showing relatively higher scores than the rest of the country.

FIGURE 1. Summary of efficiency scores by province, including median, 25th and 75th percentiles (the number of regions in parentheses)



Note: Atlantic provinces include Newfoundland, New Brunswick, Nova Scotia and Prince Edward Island

Table 2 reports the results of the step-wise regression on efficiency scores. The regression results suggest that the variations in efficiency scores across regions relate in part to public health factors (here, measured by the prevalence of traditional risk factors for common diseases) and in part to more managerial factors related to the appropriate use of hospitals (e.g., Alternate Level of Care length of stay), hospital readmissions and investment in nurses and primary care physicians. Two of the environmental factors were also significantly (negatively) associated with efficiency: the average income of the population (richer regions use resources less efficiently) and the level of income-related inequity in the use of physician services in the region (regions that make sure the lower-income families can access services according to

their needs have fewer deaths from treatable causes). It is important to note that sensitivity analyses indicated the results presented here were robust to alternative model specifications (CIHI 2014) (Table 3).

TABLE 3. Results of the regression on the logarithm of efficiency scores

Variables	Coefficient	Standard. error	$P > \|t\|$
Contextual factors			
Average income (logarithm)	-0.304*	0.098	0.003
Inequity in the likelihood of visiting a physician in past 12 months	-1.737**	0.862	0.047
Clinical factors			
Daily smoking (%)	-0.010**	0.004	0.015
Physical inactivity (%)	-0.007*	0.002	0.004
Multiple (three or more) chronic conditions (%)	-0.013*	0.004	0.001
30-day overall readmission (rate per 100)	-0.021**	0.009	0.028
Operational factors			
GPs (% of all physicians)	0.005*	0.001	0.000
ALC length of stay (days)	-0.002*	0.001	0.003

*Significant at $p < 0.01$
**Significant at $p < 0.05$

Discussion

This study was the first to measure the level and determinants of health system efficiency in Canada based on quantitative and qualitative research involving key decision-makers. The findings suggest that significant health improvements could be gained without additional spending, and that some of the factors that could help bring about efficiency gains include interventions targeting the health of the population, such as reducing smoking and physical inactivity, as well as policies directed at the organization and delivery of health services, such as reducing hospital readmissions, or reducing length of hospital stay among patients designated as alternate level of care patients.

The range of efficiency scores that this study yielded is consistent with the (few) international studies that have included Canada. For instance, a recent OECD study found the level of inefficiency in Canada to be 20% (Joumard et al. 2010). Moreover, we found that health systems operating in populations with poorer risk factors (smoking, obesity, inactivity) were less efficient. In other words, these findings indicate that more money is being spent in these regions to treat a more complex population, but outcomes are worse than in other regions with healthier populations. These results suggest that system managers can bring about

improvements in value for money by addressing some of the important causes of illness and treatable conditions through targeted prevention efforts. This suggestion is consistent with reports and consultations stressing the importance of these determinants of health (CMA 2013; Lalonde 1974).

In addition, this study confirms the important role of organizational factors in achieving efficiency gains (Ontario Ministry of Finance Commission on the Reform of Ontario's Public Services 2013): reducing alternate level of care days and readmissions helps the health system managers direct healthcare dollars to more effective treatments to reduce causes of death due to treatable conditions, thereby improving efficiency. The findings from this study suggest that marginal investments in primary care may be more efficient than marginal investments in specialized care. This is consistent with the literature on the efficacy of primary care services (Marmot et al. 2008; Starfield et al. 2005; WHO 2008).

Interestingly, the study found that efficiency and equity may work in the same direction: because individuals with lower income need more care, on average, ensuring that these populations access primary care may be a good way of increasing efficiency. This finding is in line with the literature on equity and recent debates about health financing and universal health coverage suggesting that healthcare should be distributed according to need, not ability to pay (Marmot et al. 2008).

There are several strengths to this study that are worth noting. First, the theoretical model of health system efficiency we used was informed by stated preferences of decision-makers who are responsible to take action on the findings. Second, we were able to use extensively a wealth of data on spending and outcomes, even though there were still some limitations. Third, the sensitivity analyses we conducted showed that the study results were robust to changes in model specifications, such as to changes to the age cut-off for defining premature death, and to the choice of outcome measure as PYLL versus the age-standardized mortality rate from treatable causes of death. Finally, we were successful at estimating relative levels of inefficiency and explaining a significant portion of the variations observed.

However, there were also some important limitations to this study. First, the variables included in the final regression model accounted for just half of the variation in efficiency scores. The unexplained variation could relate to population characteristics that we were not able to measure and/or to indicators of clinical practice and system management that are difficult to measure with existing data sources. Second, with existing limitations in timeliness of mortality data in Canada, we were only able to measure health system efficiency at one point in time and with historical data. Third, the outcome measure we used in this study included only deaths and not a measure of health and well-being. Finally, we encountered some challenges in measuring spending in all categories of health system expenditures (e.g., public health spending is not easily measured at the regional level), and in measuring physician spending given the increasing role of alternative payments.

Conclusions

A major conclusion of this study is that any policy action aiming at reducing the efficiency gap needs to include both interventions related to traditional sources of inefficiency and those focused on the prevention of disease and health promotion interventions. Practically, an implication for provincial and territorial governments in Canada is that focusing on operational efficiency and indicators of good management will not substantially reduce the efficiency gap measured. A diversity of interventions on healthcare services, health promotion and disease prevention and broader determinants of health is required to improve efficiency. In addition, the results suggest that investments in primary care and advanced access to healthcare services for lower-income individuals may be effective in improving health system efficiency.

There are several avenues for future research that could improve our understanding of efficiency in Canada. These include improving our understanding of how some health regions have achieved higher efficiency scores than other regions, for instance, with in-depth qualitative analysis such as case studies. It would also be important to better capture some of the factors that may affect efficiency that we cannot easily measure at present, such as indicators of management style, workplace conditions and patient experience. Finally, future research could consider including morbidity variables (e.g., the Health Utilities Index) in the model of efficiency to capture the impact of the health system on *quality* of life in addition to more readily available measure of *quantity* of life (e.g., with measures of years of life lost).

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RESEARCH PAPER

Mix of Maternity Care Providers in Canada

Composition des fournisseurs de soins de maternité au Canada

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Abstract

Objective: To identify the factors influencing women's choice of maternity care providers in Canada.

Method: Using the Maternity Experience Survey and a multinomial logit model, this paper examined the influence of various socio-economic and demographic factors on the mix of maternity care providers, while controlling for maternal risk profiles. Additionally, provinces were interacted with maternal age to assess the extent to which regional variations in mix of maternity care providers is influenced by pregnant women's needs.

Results: Besides maternal risk factors, province of prenatal care and the place of residence were found to be statistically significant determinants of choice of maternity care providers. Analysis involving interaction terms indicated wide regional variations in the mix of providers by maternal age.

Conclusions: The results suggest a wide provincial variation in the mix of maternity care providers. New provincial government initiatives are needed to enhance the supply and capacity of care providers.

Résumé

Objectif : Déterminer les facteurs qui influent sur le choix, par les femmes, du fournisseur de soins de maternité au Canada.

Méthode : S'appuyant sur l'Enquête sur l'expérience de la maternité et à l'aide d'un modèle logistique multinomial, cet article examine l'influence de plusieurs facteurs socioéconomiques et démographiques sur la composition des fournisseurs de soins de maternité, tout en contrôlant les profils de maternité à risque. De plus, nous avons considéré le lien entre les provinces et l'âge à la grossesse pour évaluer à quel point les besoins des femmes enceintes influencent les variations régionales dans la composition des fournisseurs de soins de maternité.

Résultats : Mis à part les facteurs liés à une maternité à risque, la province où sont donnés les soins prénataux et le lieu de résidence s'avèrent des déterminants statistiquement significatifs du choix quant aux fournisseurs de soins de maternité. L'analyse des interactions démontre une grande variation régionale dans la composition des fournisseurs de soins de maternité, et ce, en fonction de l'âge pendant la grossesse.

Conclusions : Les résultats font voir une grande variation entre les provinces dans la composition des fournisseurs de soins de maternité. Les gouvernements provinciaux devraient adopter de nouvelles initiatives pour accroître la présence et la capacité des fournisseurs de soins.

Over the past two decades, there has been a change in the mix of providers in the provision of maternity care in Canada. While family physicians are involved in many aspects of maternity services, fewer are providing prenatal and intra-partum care than before (CIHI 2004; Godwin et al. 2002; Reid et al. 2000; Zelmer and Leeb 2004). On the other hand, despite the well-developed evidence that midwives are safe and effective in managing low-risk pregnancies, regulation and public funding of midwifery as autonomous providers is currently limited to only some Canadian provinces (Born et al. 2014; Kornelsen 2003; O'Brien et al. 2011). Each type of health provider offers a different style of care in terms of routine screening and diagnostic care, with obstetricians tending to rely more on medical and surgical interventions such as ultrasounds, labour inductions and caesarean section than other providers (Fraser et al. 2000; Guliani et al. 2013; Klein et al. 2009; Monari et al. 2008; O'Brien et al. 2011; Rosenblatt et al. 1997). The scope of practice among providers also varies widely across the country (CIHI 2004; Reid et al. 2000). Despite different practice styles among care providers, few appreciable differences are seen in birth outcomes for women with low-risk pregnancies (Hutton et al. 2009; Jackson et al. 1996; Khan-Neelofur et al. 1998; O'Brien et al. 2011). Indeed, studies suggest that low-risk pregnant women who received their prenatal care from midwives are more likely to have positive maternity

experiences and are less likely to access non-obstetric services such as the emergency department during pregnancy than those who were cared for by family physicians or obstetricians (Harvey et al. 2002; Metcalfe et al. 2013; O'Brien et al. 2011).

The resources required to provide maternity care services vary depending on who provides the care as well as the range of services and tests that are performed. A recent pilot study evaluating the costs and outcomes of integrating independent midwifery care with existing healthcare services in the province of Alberta suggested that choice of regulated and publicly funded midwifery care by low-risk women was a cost-effective intervention without adversely affecting maternal or neo-natal outcomes (O'Brien et al. 2010). It is, therefore, imperative to understand what factors influence women's choice of prenatal care provider. Most research to date has looked at the factors that go into patient's provider choice decision in the context of health-seeking behaviour in general (Bernard et al. 2006; Victoor et al. 2012), but studies on determinants of prenatal care provider choice are virtually non-existent in Canada and elsewhere. Existing studies examining the choice of provider in developed countries are mainly concerned with the factors influencing patients' choice of primary care physicians (Bernard et al. 2006; Bornstein et al. 2000; Grytten and Sorensen 2009; McGlone et al. 2002; Victoor et al. 2012) and the relative importance of physicians' gender in patients' selection of obstetrics and gynaecology provider (Johnson et al. 2005; Makam et al. 2010; Plunkett et al. 2002). To the best of this author's knowledge, only one Canadian study by Liva and colleagues (2012) examines the factors influencing nurses' choice of care provider for their own maternity care. However, little is known about the factors influencing women's choice of various types of maternity care providers.

Using the Maternity Experience Survey (MES) of Statistics Canada, and a multinomial logit model (MNL), this paper assessed the influence of various socio-economic and demographic factors on the mix of maternity care providers, while controlling for maternal risk profiles. Specifically, this study aimed to answer two questions. First, what factors influence women's decision to seek care from alternate types of maternity care providers? Second, are there regional variations in the mix of providers for a given risk factor? Regional variations in the mix of maternity care providers may highlight the effect of policies within provinces and can be used to better understand and improve maternity care services.

Methods

Data

This study utilized the data set of the MES conducted by Statistics Canada in 2006 and sponsored by the Public Health Agency of Canada. The MES is the only available nationwide survey that assessed pregnancy, delivery and postnatal experiences of mothers and their children. Participants eligible for the study were women aged 15 years and older, who had singleton live births and who lived with their babies at the time of data collection. After excluding incomplete information, the sample size reduced to 4,829. These missing observa-

tions accounted for less than 3% of the responses for most of the variables except household income. The socio-demographic and maternal risk profiles of the respondents with missing observations revealed few differences to those included in the analysis. However, in the case of household income, young and low-income respondents were more likely to have missing data. Therefore, an additional missing category for household income was used in the analysis.

Analysis

In the event of pregnancy, a woman is assumed to seek care from a healthcare system characterized by a variety of healthcare providers. It is further assumed that a woman knows all provider-specific characteristics and will choose a healthcare provider that would yield maximum expected utility (Bolduc et al. 1996; Canaviri 2007). As women's choice of prenatal care provider is a discrete decision, an MNL was used to assess the association between socio-demographic and maternal risk factors on the choice of prenatal care providers. For the MNL model to be a valid framework for inference, the well-known assumption of the independence of irrelevant alternatives (IIA) must be satisfied. To test for the IIA assumption, the Hausman and McFadden specification test was run, and the results suggest that IIA has not been violated in this study. To account for the complex sampling design, the model was estimated using population and bootstrapping weights. All analyses, including bootstrapping, were conducted using STATA (version 13.0) statistical software.

Measures

The dependent variable – types of providers – was grouped into three major categories: obstetricians/gynaecologists (OB/GYNs), family physicians/general practitioners (FP/GPs) and midwives/nurses/nurse practitioners. The reference alternative in this study was OB/GYNs. The theoretical and empirical literature suggests that a patient's demand for healthcare in general and the choice of providers in particular is influenced by various socio-economic and demographic factors such as age, education, income, distance and transportation, health status of an individual and accessibility of care (Bernard et al. 2006; Guliani et al. 2013; Victoor et al. 2012). These independent variables were grouped into: (1) the maternal risk profile, (2) the reproductive history, (3) prenatal care history and (4) socio-economic and demographic factors. Table 1 provides the summary statistics for all variables used in the estimation.

TABLE 1. Summary statistics for the dependent and independent variables

Variable name	N (%)
Dependent variable	
Type of healthcare provider	
Obstetricians and/or gynaecologists (the reference category)	2,857 (56.0)
Family doctors/general practitioners/doctors (unspecified)	1,920 (37.7)
Midwives/nurses/nurse practitioners	321 (6.3)

TABLE 1. Continued

Variable name	N (%)
Independent variables	
Maternal risk profile	
Maternal age at selected birth	
15–34	4,271 (83.8)
≥35	827 (16.2)
Health problems before pregnancy	
Yes	813 (16.0)
No	4,285 (84.0)
Use of medications or technical procedures to get pregnant	
Yes	253 (5.0)
No	4,845 (95.0)
Body mass index before pregnancy	
Under weight	284 (5.6)
Normal weight (the reference category)	2,956 (58.0)
Overweight	1,113 (21.8)
Obese	745 (14.6)
Planned caesarean for medical reasons	
Yes	601 (11.8)
No	4,497 (88.2)
Reproductive history	
Any miscarriage, tubal or ectopic pregnancy or stillbirth history	
Yes	1,595 (31.3)
No	3,503 (68.7)
Any premature birth before	
Yes	490 (9.6)
No	4,608 (90.4)
Parity	
1 (the reference category)	2,432 (47.7)
2	1,913 (37.5)
3	544 (10.7)
4	147 (2.9)
5+	62 (1.2)

TABLE 1. Continued

Variable name	N (%)
Prenatal care history	
Received prenatal care as early as wanted	
Yes	4,554 (89.3)
No	544 (10.7)
Number of prenatal visits	
1–4	51 (1.0)
≥5	5,047 (99.0)
Socio-economic and demographic factors	
Area of residence	
Rural	1,103 (21.6)
Semi-urban (the reference category)	1,435 (28.2)
Urban	2,560 (50.2)
Province of prenatal care	
Atlantic	918 (18.0)
Quebec	992 (19.5)
Ontario (the reference category)	1,578 (31.0)
Manitoba	291 (5.7)
Saskatchewan	269 (5.3)
Alberta	525 (10.3)
British Columbia	525 (10.3)
Maternal education	
Less than high school	359 (7.0)
High-school graduate	702 (13.8)
Post-secondary diploma (the reference category)	2,194 (43.0)
University graduate	1,843 (36.2)
Household income	
<20,000	411 (8.4)
$20,000–$39,000	921 (18.9)
$40,000–$59,000	988 (20.2)
$60,000–$79,000	933 (19.1)
≥$80,000 (the reference category)	1,631 (33.4)

TABLE 1. Continued

Variable name	N (%)
Nativity	
Canadians (the reference category)	4,080 (80.0)
Aboriginals	210 (4.1)
Immigrants	808 (15.9)
Marital status	
Married (the reference category)	3,460 (67.9)
Common-law partner	1,229 (24.1)
Divorced	69 (1.4)
Single	340 (6.7)
Employment status during pregnancy	
Employed	3,518 (69.0)
Not employed	1,580 (31.0)

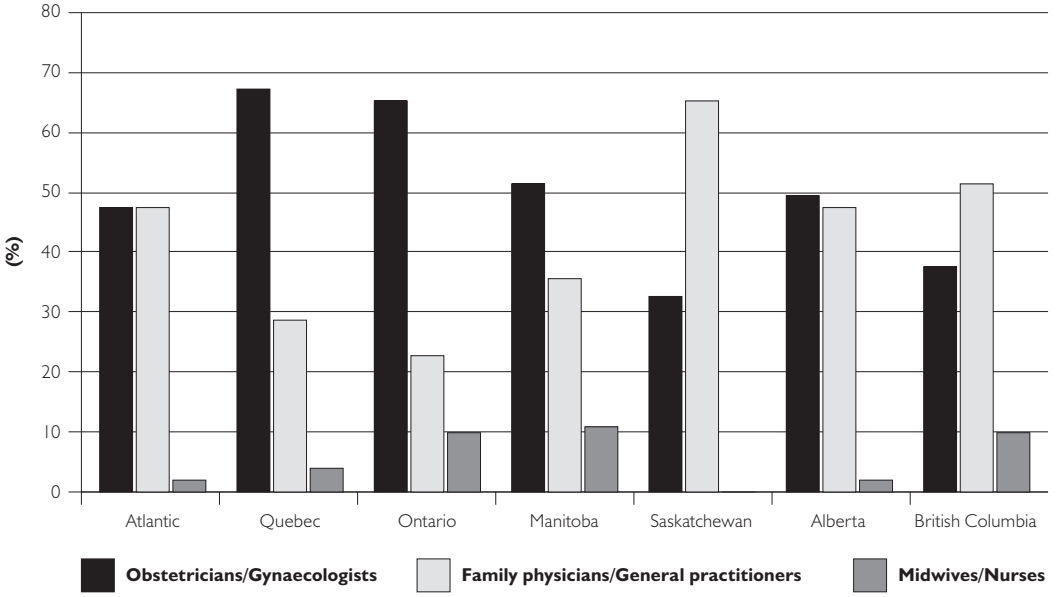
Potential maternal risk factors included the maternal age at selected birth, any health problems before pregnancy that required taking medication for more than two weeks, use of medications or technology to get pregnant and having a planned C-section owing to medical reasons. Another risk indicator was the woman's body mass index before pregnancy, which was here categorized into four groups: underweight, normal weight (the reference category), overweight and obese. A pregnancy was considered to be risky if the woman was obese or overweight before pregnancy. Reproductive history was represented by parity and a history of complications in a prior pregnancy associated with miscarriage, tubal/ectopic pregnancy, stillbirth and premature birth. Similarly, prenatal care variables were included to capture the relationship between choice of prenatal care provider and the timings and frequency of prenatal care. The socio-economic and demographic factors included in this study were the province of prenatal care, an urban or rural place of residence, maternal education, the total household income, the marital status, employment status and the residency status of the woman. Because of the smaller number of observations, the four Atlantic provinces were grouped into one category. The place of residence was classified into three groups: rural, semi-urban (population 30,000–<499,999) and urban (population ≥500,000) (the reference category). Maternal education was measured according to four broad categories: less than high school, high-school graduate, post-secondary diploma (the reference category) and university graduate. The annual household income was categorized into five groups: <$20,000, $20,000–<$40,000, $40,000–<$60,000, $60,000–<$80,000 and $80,000 or more (the reference category). Nativity/ethnicity was measured according to three broad categories: aboriginal Canadians, non-aboriginal Canadians and immigrants.

Results

Descriptive statistics

At the national level, 56% and 38% of women, respectively, reported receiving care from OB/GYNs and FP/GPs for their prenatal care, whereas only 6% percent received care from midwives/nurses. These national averages, however, masked wide variations in the mix of maternity care providers across provinces (Figure 1). The percentage of women who received care from OB/GYNs ranged from 66% to 68% in Quebec and Ontario; 49% to 51% in Atlantic Provinces, Alberta and Manitoba; and 34% to 38% in Saskatchewan and British Columbia. Similarly, the percentage of women who received care from FP/GPs ranged from 52% to 66% in British Columbia and Saskatchewan to 48% to 49% in Alberta and the Atlantic Provinces and 24% to 38% in Ontario, Quebec and Manitoba. The proportion of women who received care from midwives/nurses ranged from 2% in the Atlantic provinces to 10% to 11% in British Columbia and Manitoba. Inter-provincial variations in the provision of maternal care were also noticeable by maternal age.

FIGURE 1. Mix of maternity care providers by province (%)



Note: The Statistics Canada disclosure control rules preclude from reporting the estimates for midwives/nurses for Saskatchewan owing to less than minimum required observations.

Econometric results

The regression results from the multinomial model are presented in Table 2. To facilitate interpretation, the estimated coefficients were converted to odds ratios. As expected, choice of healthcare provider was responsive to need. Maternal risk factors such as higher maternal age (≥35), health problems before pregnancy, use of medical procedures to get pregnant and planned caesarean for medical reasons decreased the odds of receiving care from FP/GPs over

OB/GYNs (the reference category). Similarly, women who received their prenatal care as early as they wanted were 78% more likely to receive care from FP/GPs over OB/GYNs, but the effect was insignificant for midwives/nurses.

TABLE 2. Multinomial regression results for the choice of three types of provider: OB/GYNs (the reference category), FP/GPs and midwives/nurses

	Prob (Y) = FP/GPs		Prob (Y) = midwives/nurses	
	Odds ratio	**95% CI**	**Odds ratio**	**95% CI**
Maternal risk profile				
Maternal age at selected birth	0.81*	0.66, 0.98	1.40	1.00, 1.96
Health problems before pregnancy	0.71**	0.58, 0.87	1.06	0.77, 1.47
Technical pregnancy	0.55**	0.40, 0.77	0.49*	0.24, 0.98
Body mass index before pregnancy (ref. category: normal weight)				
Underweight	1.34	1.00, 1.80	0.90	0.49, 1.64
Overweight/Obese	1.06	0.92, 1.23	1.05	0.79, 1.38
Planned caesarean	0.61**	0.49, 0.75	0.37**	0.22, 0.64
Any premature birth before	1.06	0.84, 1.33	1.00	0.63, 1.58
Any previous miscarriage, tubal/ectopic pregnancy or stillbirth	0.85*	0.73, 0.98	0.90	0.69, 1.19
Parity (ref. category: first birth)				
2	1.00	0.86, 1.16	0.83	0.64, 1.08
3	1.14	0.90, 1.45	0.73	0.45, 1.19
4	1.25	0.82,1.91	0.72	0.28, 1.91
≥5	1.09	0.56,2.13	2.10	0.82, 5.37
Prenatal care history				
Early prenatal care	1.78**	1.43, 2.23	1.20	0.78, 1.85
Five or more visits (ref. category: <5 visits)	0.30*	0.13, 0.69	1.97	0.27, 14.23
Socio-economic and demographic factors				
Province of residence (ref. category: Ontario)				
Atlantic	1.81**	1.50, 2.16	0.18**	0.10, 0.30
Quebec	1.09	0.89, 1.34	0.31**	0.21, 0.47
Manitoba	1.63**	1.24, 2.12	1.36	0.90, 2.06
Alberta	2.39**	1.93, 2.95	0.36**	0.20, 0.66
British Columbia	4.20**	3.33, 5.30	2.00**	1.41, 2.84

TABLE 2. Continued

	Prob (Y) = FP/GPs		Prob (Y) = midwives/nurses	
	Odds ratio	**95% CI**	**Odds ratio**	**95% CI**
Area of residence (ref. category: urban)				
Rural	2.00**	1.67, 2.39	1.32	0.93,1.88
Semi-urban	2.12**	1.80, 2.49	1.42*	1.04,1.94
Household income (ref. category: ≥$80,000)				
<$20,000	1.16	0.83, 1.61	1.66	0.91, 3.03
$20,000-<$40,000	1.02	0.82, 1.27	1.79**	1.22, 2.63
$40,000-<$60,000	0.96	0.79, 1.16	1.23	0.85, 1.77
$60,000-<$80,000	0.80*	0.66, 0.97	1.01	0.70, 1.44
Education (ref. category: post-secondary diploma)				
Less than high school	1.12	0.84, 1.51	0.66	0.36, 1.20
High-school graduate	1.35*	1.09, 1.67	0.73	0.46, 1.16
University graduate	1.15	0.98, 1.35	1.99**	1.48, 2.66
Marital status (ref. category: married)				
Common-law partner	0.93	0.77, 1.11	1.25	0.87,1.79
Divorced	0.72	0.38, 1.34	1.16	0.35, 3.89
Single	0.98	0.71, 1.35	0.94	0.50,1.76
Nativity (ref. category: Canadian)				
Aboriginal	1.06	0.75, 1.51	1.85*	1.05, 3.28
Immigrant	0.57**	0.46, 0.70	0.52**	0.36, 0.75
Employment status	0.95	0.80, 1.11	0.68*	0.51, 0.91

*Significant at $p < 0.05$

**Significant at $p < 0.01$

OB/GYNs = obstetricians/gynaecologists; FP/GPs = family physicians/general practitioners

Among the socio-economic and demographic factors, the province of prenatal care and the geographic area of residence were found to be the strongest predictors of choice of prenatal care provider, even after controlling for maternal risk factors. The estimated odds ratios on the province of prenatal care were statistically significant (at 1%) for all but Quebec in the FP/GPs model and Manitoba in the midwives/nurses model. The odds of receiving care from FP/GPs over OB/GYNs were 1.6–2.4 times more for women in Manitoba, Atlantic provinces and Alberta compared with women in Ontario (the reference category). The odds of receiving care from FP/GPs over OB/GYNs were more pronounced for British Columbia,

where pregnant women were 4.2 times more likely to receive care from FP/GPs than women in Ontario. While women in most provinces were less likely to receive care from midwives/nurses over OB/GYNs, in British Columbia, pregnant women were two times more likely to consult midwives/nurses over OB/GYNs than their counterparts in Ontario (the reference category). Saskatchewan was excluded in our multinomial regression model owing to very few numbers of observations on midwives/nurses for this province. However, the results were robust to the exclusion of Saskatchewan in seeking care from two dominant types of providers – FP/GPs and OB/GYNs. As expected, rural and semi-urban women were two times more likely to receive care from FP/GPs over OB/GYNs than urban women (the reference category). Semi-urban women were also 42% more likely to receive care from midwives/nurses than urban women. No clear pattern was observed between income and the types of prenatal care provider. The odds of receiving care from midwives/nurses over OB/GYNs were 99% more for university graduates compared with post-secondary diploma (the reference category). Compared with non-aboriginal Canadians (the reference category), immigrant women were 43% and 48%, respectively, less likely to receive care from FP/GPs and midwives/nurses over OB/GYNs. The odds of receiving care from midwives/nurses (over OB/GYNs) were 85% more for aboriginal Canadians than non-aboriginal Canadians. However, these results should be interpreted with caution, given that the sample size on aboriginal was very small and heterogeneous, covering only those living off reserves.

TABLE 3. Logistic regression results for interaction terms between the maternal age and province of prenatal care for the choice of two types of providers: OB/GYNs (the reference category) and FP/GPs[a]

	If age <35		If age ≥35	
Maternal age × province (ref. category: Ontario)	**Odds ratio**	**95% CI**	**Odds ratio**	**95% CI**
Province				
Atlantic	0.58*	0.47, 0.70	0.44*	0.28, 0.69
Quebec	0.92	0.74, 1.14	1.11	0.60, 2.04
Manitoba	0.56*	0.42, 0.75	0.96	0.41, 2.28
Saskatchewan	0.27*	0.21, 0.36	0.31*	0.14, 0.68
Alberta	0.45*	0.36, 0.57	0.26*	0.15, 0.43
British Columbia	0.24*	0.18, 0.31	0.24*	0.15, 0.38

[a] Other regressors in the model correspond to those listed in Table 2.

*Significant at $p < 0.05$

**Significant at $p < 0.01$

OB/GYNs = obstetricians/gynaecologists; FP/GPs = family physicians/general practitioners

To assess whether inter-provincial variations in the mix of providers vary in strength for a given risk factor, the regression model was further extended by interacting provinces with maternal age (Table 3). As there were very few observations by age for midwives/nurses in

some provinces, the extended model compares the choice of two dominant types of providers (OB/GYNs and FP/GPs) by maternal age across provinces using logistic regression. Overall, the results suggested that mothers living in Ontario, irrespective of their age, were more likely to receive care from OB/GYNs than their counterparts in other provinces. Compared with Ontario, higher age (≥35), pregnant women in Atlantic, Saskatchewan, Alberta and British Columbia were 56%–76% less likely to receive care from OB/GYNs than FP/GPs. The results for interaction terms between younger women (age <35) and provinces indicated even more widespread differences in receiving care from alternative providers. Low-risk pregnant women (<35) in Western provinces were 44%–76% less likely to receive care from OB/GYNs than their counterparts in Ontario.

Discussions and Conclusions

This study empirically assessed the influence of various socio-economic and demographic factors on the mix of maternity care providers in Canada, while controlling for various maternal risk factors. The results suggested that besides maternal risk factors, province of prenatal care and the place of residence were found to be statistically significant determinants of mix of maternity care providers. The results were more noticeable in the choice of OB/GYNs versus FP/GPs than for midwives/nurses. Additional analysis involving interactions between provinces and maternal age indicated wide interprovincial variations in the mix of providers for a given risk factor.

Province and area of residence were found to be the strongest predictors of mix of prenatal care providers. A study from the US also suggests that economics and geography are stronger predictors of a woman's initial choice of provider than medical and obstetric risk factors (Dobie et al. 1994). Compared with Ontario, women in all other provinces were more likely to receive care from FP/GPs over OB/GYNs, with the odds being particularly more pronounced for residents of British Columbia and Alberta. Similarly, except for British Columbia, women in all other provinces were more likely to choose OB/GYNs over midwives/nurses. The results also suggested that FP/GPs were the preferred form of care in rural and semi-urban areas than in the urban area. These provincial and geographic variations reflect differences in the distribution and characteristics of alternative providers and the scope of practice among these providers in a given region or healthcare policies in these regions (Wennberg and Gittelsohn 1982; Zuckerman et al. 2010). The supply of FP/GPs and OB/GYNs varies across provinces, with Alberta and British Columbia having the lowest number of OB/GYNs per 100,000 (CIHI 2013). Given the higher proportion of OB/GYNs in Ontario and to the extent that patient's perception of quality of care is equated with the provision of high-tech care, women in this province are more likely to choose OB/GYNs irrespective of their maternal risk (Guliani 2013; Ikegami and Campbell 1999). Similarly, the number of midwives per 100,000 ranges from five in Manitoba to one in Saskatchewan (CIHI 2014). These numbers have not changed substantially over the past

decade. Even though midwifery has now been regulated in most provinces (with the exception of Prince Edward Island and Yukon), progress to formally integrate them into the health system has been slow and uneven across the country (Born et al. 2014; CAM 2012). For instance, despite the approval of the *Midwifery Act* in 2010, New Brunswick had no practicing registered midwives until 2013 (CAM 2013). Similarly, Newfoundland and Labrador had no licensed or practicing midwives regardless of incorporation of midwives in the *Health Professions Act* (Born et al. 2014; CAM 2013). Access to any type of maternity care providers has always remained limited in rural areas of Canada, and the picture is getting bleaker every year with more and more FPs opting out of maternity care practice as well as a national shortage of midwives. Thus, even though care is publicly funded and women may choose their care providers, choices may be limited in practice owing to unequal distribution of various providers across the country (O'Brien et al. 2011). The results from the interaction terms also suggested that OB/GYNs were the dominant type of maternity care provider in Ontario, irrespective of maternal age. Regional variations for a given risk factor further highlighted variations in the availability and distribution of providers, differences in provider style of practice or healthcare policies in these regions.

Some caveats are in order. First, the timing of interviews in the MES varied from 5 to 14 months postpartum, which might have influenced both maternal recall and perceptions of some events and experiences. Second, the data did not allow us to control for providers' practice characteristics, nor for the supply of providers in the region. However, to the extent to which the supply of providers varies by province, the inclusion of a province dummy variable may capture, at least partly, the relationship between the supply of providers and women's use of maternity provider. Third, results may have been subject to endogeneity bias, if there were unobserved factors such as the perception of the quality and service of the provider, preference for certain medical procedures or just a preference for being treated in a certain way may influence the mix of provider.

In conclusion, the results of this study have important policy implications with respect to the utilization of maternity care in Canada. New provincial government initiatives are needed to support collaborative and integrated care for expectant mothers. Policies aimed at enhancing the supply and capacity of FPs and midwives/nurses in providing a broad range of clinical services to low-risk patients will make a greater contribution to maternity care (CIHI 2004; Kornelsen 2003). By increasing the availability and widening the mix of providers, these initiatives will broaden the choice set of low-risk pregnant women and their families in the birthing process.

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RESEARCH PAPER

A Cost-Effectiveness Analysis of Low-Risk Deliveries: A Comparison of Midwives, Family Physicians and Obstetricians

Analyse coût-efficacité des accouchements à faible risque : comparaison entre sages-femmes, médecins de famille et obstétriciens

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Abstract

Objective: To investigate the cost-effectiveness of in-hospital obstetrical care by obstetricians (OBs), family physicians (FPs) and midwives (MWs) for delivery of low-risk obstetrical patients.

Methods: Cost-effectiveness analysis from the Ministry of Health perspective using a retrospective cohort study. The time horizon was from hospital admission of a low-risk pregnant patient to the discharge of the mother and infant. Costing data included human resource, intervention and hospital case-mix costs. Interventions measured were induction or augmentation of labour with oxytocin, epidural use, forceps or vacuum delivery and caesarean section. The outcome measured was avoidance of transfer to a neonatal intensive care unit (NICU). Model results were tested using various types of sensitivity analyses.

Findings: The mean maternal age by provider groups was 29.7 for OBs, 29.8 for FPs and 31.2 for MWs – a statistically higher mean for the MW group. The MW deliveries had lower costs and better outcomes than FPs and OBs. FPs also dominated OB.s The differences in cost per delivery were small, but slightly lower in MW ($5,102) and FP ($5,116) than in OB ($5,188). Avoidance of transfer to an NICU was highest for MW at 94.0% (95% CI: 91.0–97.0), compared with 90.2% for FP (95% CI: 88.2–92.2) and 89.6% for OB (95% CI: 88.6–90.6). The cost-effectiveness of the MW group is diminished by increases in compensation, and the cost-effectiveness of the FP group is sensitive to changes in intervention rates and costs.

Conclusions: The MW strategy was the most cost-effective in this hospital setting. Given data limitations to further examine patient characteristics between groups, the overall conservative findings of this study support investments and better integration for MWs in the current system.

Résumé

Objectif : Étudier le rapport coût-efficacité des soins obstétricaux offerts à l'hôpital par les obstétriciens (OB), par les médecins de famille (MF) et par les sages-femmes (SF) pour les accouchements à faible risque.

Méthodes : Analyse coût-efficacité, selon l'angle du ministère de la Santé, au moyen d'une étude de cohorte rétrospective. La période de temps visée s'étendait de l'admission à l'hôpital d'une patiente enceinte à faible risque jusqu'à l'obtention du congé par la mère et l'enfant. Les données sur le calcul des coûts comprenaient les ressources humaines, les interventions et les coûts d'hospitalisation du groupe clients. Les interventions retenues pour les mesures étaient le déclenchement ou l'accélération du travail à l'aide de l'ocytocine, le recours à l'épidurale, l'emploi du forceps ou de la ventouse obstétricale et la césarienne. Le résultat mesuré était l'évitement d'un transfert vers l'unité de soins intensifs néonatals (USIN). Divers types d'analyses de la sensibilité ont été employés pour tester les résultats modélisés.

Résultats : L'âge moyen à l'accouchement, selon les groupes de fournisseurs de soins, était de 29,7 pour les OB, 29,8 pour les MF et 31,2 pour les SF – une moyenne statistiquement plus

élevée pour le groupe des SF. Les accouchements avec SF présentaient des coûts moins élevés et de meilleurs résultats que ceux avec les MF et les OB. En ce sens, les MF obtiennent de meilleurs résultats que les OB. La différence du coût par accouchement était peu marquée, mais légèrement plus petite pour les SF (5 102 $) et pour les MF (5 116 $) que pour les OB (5188 $). L'évitement du transfert à l'USIN était plus élevé chez les SF, soit à 94,0 % (95 % IC: 91,0–97,0), comparé aux MF avec 90,2 % (95 % IC: 88,2–92,2) et aux OB avec 89,6 % (95 % IC: 88,6–90,6). Le rapport coût-efficacité pour le groupe des SF est réduit grâce à l'accroissement des avantages. Le rapport coût-efficacité pour le groupe des MF est sujet à changement en raison des taux et coûts des interventions.
Conclusions : La stratégie des SF présente le meilleur rapport coût-efficacité en milieu hospitalier. Malgré la limite des données permettant d'approfondir les caractéristiques des patientes selon les groupes, les résultats d'ensemble de cette étude appuient le financement des SF ainsi qu'une meilleure intégration des SF dans le système en place.

Childbirth represents a significant share of total healthcare expenditures in Canada. In 2011–2012, there were over 373,000 childbirths in hospitals across the country (Canadian Institute of Health Information 2013). The majority of newborns are delivered by obstetrician/gynecologists (OBs) (69.6%), followed by family physicians/general practitioners (FPs) (14.6%), midwives (MWs) (4.3%), nurses or nurse practitioners (4.7%) and other (6.8%) (Public Health Agency of Canada 2009). Systematic reviews and cohort studies have shown that clinical effectiveness is comparable between these three groups (Birthplace in England Collaborative Group et al. 2011; Villar et al. 2001). However, a cost-effectiveness analysis (CEA) comparing the costs and outcomes of childbirths by the different providers could offer new information for healthcare decision-makers regarding the optimal management of low-risk obstetrical patients in the current fiscal climate.

Medical interventions such as epidurals, induction and augmentation of labour, assisted vaginal delivery techniques (vacuum and forceps delivery) and caesarian sections are increasingly being used during labour and delivery (Betran et al. 2007). However, prior studies have shown that the rates of medical intervention vary by provider. A retrospective chart review in Toronto, Ontario, showed that the intervention rates for artificial rupture of membranes, induction, augmentation, low forceps plus vacuum extraction, episiotomy and epidural anaesthesia were all higher in OB deliveries compared with FP (Reid et al. 1989). No difference was observed in the caesarean section or maternal and newborn outcome rates (Reid et al. 1989). A prospective cohort study in British Columbia showed that MW deliveries had lower rates of narcotic analgesia, episiotomy and artificial rupture of membranes, though no difference in adverse neonatal outcomes compared with physicians was detected (Janssen et al. 2007; Rosenblatt et al. 1997). A recent Cochrane review showed that MW patients were

less likely to experience regional analgesia (epidural/spinal), and instrumental vaginal deliveries (vacuum/forceps), but there were no significant differences between groups for caesarean section or adverse neonatal outcomes (Sandall et al. 2013).

Different rates of intervention use between provider groups during labour and delivery could have cost implications where a fee-for-service payment scheme is used for physician services. Midwifery services are still in a nascent stage of development in the Canadian healthcare system. The scope of practice and payment scheme for this group varies across provinces and territories. In Ontario, MWs are remunerated for a course of care scheme instead of by fee-for-service. Despite recent investments in MWs as a low-cost provider, there are few Canadian cost-effectiveness studies on MW services and none that examine obstetrical care across OBs, FPs and MWs. Differences in intervention rates, remuneration schemes, scopes of practice and transfers of patient care from MWs or FPs to OBs present challenges when comparing the cost-effectiveness of the three provider groups or multiple sites and jurisdictions.

The objective of this study was to evaluate the cost-effectiveness of obstetrical care for low-risk women by OBs, FPs and MWs during the labour and delivery period in a hospital setting. The study used intervention rates and neonatal outcome rates (avoidance of transfer to the neonatal intensive care unit [NICU]) from a Canadian hospital. In-hospital costs were calculated from the provincial Ministry of Health perspective.

Methodology

Retrospective cohort study methods

A cost-effectiveness study was based on a retrospective cohort of low-risk deliveries from Brampton Civic Hospital (BCH) of the William Osler Health System located in the province of Ontario. BCH is a full-service community hospital with practicing privileges available to OBs, FPs and MWs. The retrospective data obtained through BCH for this study are part of the Better Outcomes Registry & Network Ontario (BORN) database, which collects information on every birth in Ontario. Research Ethics Board approval was granted in November 2013 for access to all the aggregated and anonymized BORN data specific to deliveries performed in-hospital at BCH from April 2012 to September 2013.

The exclusion criteria were based on the College of Midwives of Ontario indications for mandatory consultation and transfer of care (College of Midwives of Ontario 1999), and previous studies evaluating low-risk obstetrical care. Patients were considered high-risk and excluded from the study cohort if they met any of the following criteria: maternal pre-existing hypertension or diabetes (Janssen et al. 2007; Reid et al. 1989; Rosenblatt et al. 1997), gestational hypertension or diabetes (College of Midwives of Ontario 1999), greater than a singleton pregnancy (Janssen et al. 2007; Rosenblatt et al. 1997); previous caesarian section (Rosenblatt et al. 1997), previous stillbirth (Reid et al. 1989; Rosenblatt et al. 1997), placental abruption or placenta previa after 28 weeks' gestational age (GA) (College of Midwives

of Ontario 1999), GA less than or equal to 36 weeks at the time of delivery (College of Midwives of Ontario 1999) or malpresentation of the baby at the time of the delivery (Janssen et al. 2007). Two investigators (A.G. and A.E.N.) independently applied the exclusion criteria to ensure data agreement and validity.

The retrospective cohort was stratified by the provider group under which the patient was admitted to compare intervention and neonatal outcomes rates. Maternal age, the only relevant patient-level characteristic with data available in the data set, was analyzed. Intervention variables analyzed were induction or augmentation of labour with oxytocin, epidural use, caesarean section, assisted vaginal delivery with forceps or vacuum and, finally, spontaneous vaginal delivery. These were the most common interventions with an effect on cost, and costing data readily available. Neonatal outcomes were defined by the avoidance of transfer to the NICU. As newborns admitted to the NICU are the most vulnerable and critically ill, transfers to the NICU provided a useful, albeit crude, marker to denote "healthy" versus "unhealthy" babies. Admission to NICU would capture infants who experienced other outcomes of interest such as low APGAR score at five minutes, need for resuscitation at birth or intubation (Janssen et al. 2007; Reid et al. 1989; Rosenblatt et al. 1997; Sutcliffe et al. 2012). Outcomes such as small for GA or low birth weight were not included, as they were not a direct consequence of labour and delivery, but more so of the entire pregnancy (Janssen et al. 2007; Reid et al. 1989; Sutcliffe et al. 2012; Villar et al. 2001). Maternal outcomes such as postpartum haemorrhage requiring hysterectomy and fourth-degree tears were analyzed but not included in the CEA owing to low prevalence and lack of statistically significant differences between providers. Two investigators (A.G. and A.E.N.) independently analyzed intervention and outcome rates for each provider group to ensure data agreement and validity.

All statistical analyses were conducted using SAS (version 9.4) software (SAS Institute Inc. 2013). Relative risks of interventions and neonatal outcomes in FPs and MWs were compared with OBs (the standard provider). A normal binomial distribution was assumed for all intervention and outcome variables.

Economic methods

This economic evaluation was conducted from the Ministry of Health perspective, which includes the overwhelming majority of hospital costs. The time horizon of analysis was hospital length of stay (time of admission of the pregnant patient to the time of discharge of mother and infant) to account for in-hospital decisions pertaining to care. Patient costs as well as intervention and outcome rates were attributed to the admitting provider (even for those patients transferred to OBs) to yield a conservative set of cost–outcome estimates. For example, if an FP or MW patient was transferred to an OB during the care process owing to a complication in labour, the interventions used by the OB and their costs were allocated to the admitting provider. This method was used to account for patient choice of provider regardless of subsequent transfers. TreeAge Pro (version 2015) was used to run the CEA decision tree model and sensitivity (TreeAge 2015).

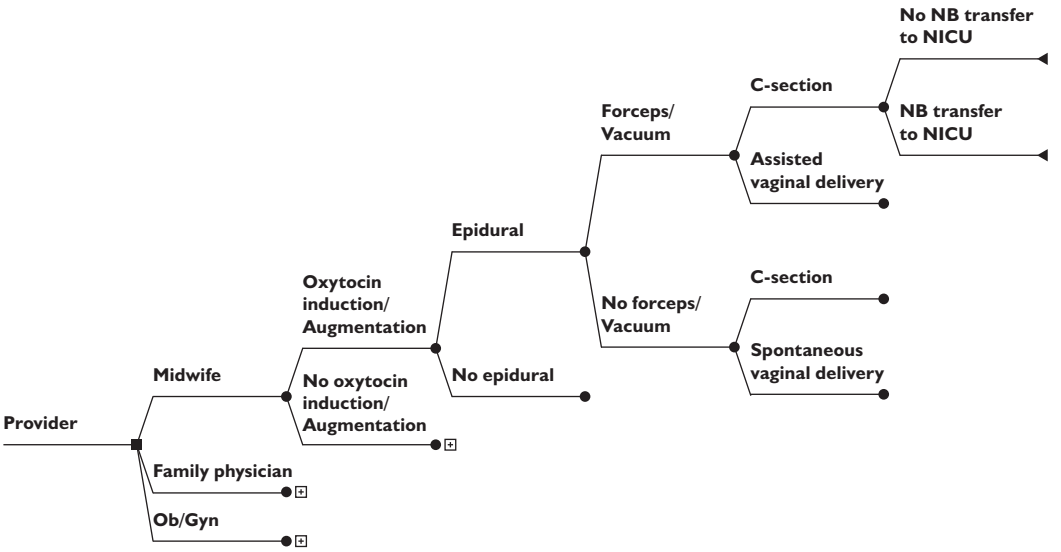
Costs were obtained from two different sources. Human resource costs were micro-costed. Hospital costs were based on case costing. Human resource unit costs for interventions, labour and delivery were retrieved from the Ontario Schedule of Benefits for Physician Services (MOHLTC 2013), the Compensation Review of Midwifery (Courtyard Group 2010) and documents related to the current Association of Ontario Midwives, (AOM) lawsuit for pay equity (Durber 2013). Owing to the differences in payment methods between MWs (course of care for entire pregnancy) and fee-for-service for both groups of physicians, the cost for a MW attending delivery was calculated by allocating 48% of the total course of care fee. This was estimated by calculating a total cost of care for physicians (OBs and FPs) using the fee-for-service costs for the typical number of antepartum and postpartum visits in a healthy pregnancy and calculating the percentage of that total cost that was made up of attending delivery for the physician group (MOHLTC 2013). Time allocations for physician fees during time-dependent procedures like caesarean section (Petrou et al. 2001) and epidural maintenance (MOHLTC 2013) were based on clinical standards for the procedures.

Case costing is an accounting method that captures the full cost of specific procedures and episodes of care by calculating all direct and indirect costs. The Canadian Institute of Health Information (CIHI) maintains case-costing methodology called Case Mix Group (CMG+) (CIHI 2013). CMG+ categorizes acute care in-patients with similar clinical and resource-utilization characteristics, and is based on codes for the most responsible diagnosis and the primary procedure for each admission. It is often referred to as "patient-level costing" and is similar to the American Diagnosis-Related Groups methodology. CMG+ case costs for this study were provided directly from William Osler Health System – BCH 2012/2013 data. As there were a few BCH CMG+ case costs that were not available owing to Freedom of Information regulation – because there were fewer than five cases – data from the CIHI Patient Cost Estimator for all Ontario hospitals were used to supplement the CMG+ case costs (CIHI 2012). The CMG+ groups of interest within our study were: caesarean section with/without induction (#558–559), vaginal birth with/without anaesthetic and with/without non-major obstetrical interventions (#562–565), singleton delivery (#576) and caesarean delivery (#577). Additionally, the cost of newborn transfer to the NICU was calculated as a weighted average for all CMG+ groups indicating neonatal birth weight greater than 2,500 g with major complications (#589–599). Because the population was low-risk pregnancies, it was less likely to have a neonate <2,500 g. All unit costs and case costs were reported in 2013 Canadian dollars ($1.00 USD = $0.91 CAD) for this study (Bank of Canada 2014); therefore, no adjustment for inflation was necessary.

Within the variables selected for this study, a decision tree model was developed that outlined the possible combinations of human resources, interventions, method of delivery and outcomes associated with each provider group (Figure 1). The probabilities for interventions used in the model were obtained from the retrospective cohort (including oxytocin for

induction and augmentation, epidural and forceps/vacuum) and method of delivery (caesarean section, spontaneous vaginal delivery and assisted vaginal delivery). Model costs were obtained from both the human resources costing and CMG+ groups described above. As the outcome of interest was defined as the avoidance of newborn transfer to the NICU, the model branches ending in a transfer to the NICU were assigned an effect equal to 0, and branches with no transfer to the NICU were assigned an effect equal to 1 (Sandall et al. 2013).

FIGURE 1. Decision tree model



One-way sensitivity analyses were conducted for all three providers by varying case costs and probabilities at the 95% confidence intervals. Values for the sensitivity analysis of cost and probability variables were retrieved from the literature, provincial data and probability point-estimates (Aenhaim et al. 2007; CIHI 2012; Durber 2013; Janssen et al. 2007; Krikke and Bell 1989; MOHLTC 2013; Reid et al. 1989; Sandall et al. 2013). Additionally, the cost of MW attending birth was varied up to a high value equivalent to the compensation level requested by MWs in a current Ontario lawsuit (Association of Ontario Midwives [AOM] 2013). The results of the one-way sensitivity analyses of key variables for MWs are presented in an Incremental Cost-Effectiveness Ratio Tornado diagram, which demonstrated the influence of varying key costs and probabilities to high and low values from literature, provincial averages and a current labour dispute. Probabilistic sensitivity analyses (Drummond et al. 2005), using a Monte Carlo Simulation of 10,000 cases with means and standard deviations for all variables, were conducted for the MWs and FPs versus OBs. Costs were assigned a gamma distribution and probabilities were assigned a beta distribution (Briggs et al. 2001). An Incremental Cost Effectiveness Plot Report was used to determine the portion of scenarios cost-effective under $1,000 and $5,000 willingness-to-pay thresholds.

Results

Retrospective cohort study

A total of 4,693 low-risk deliveries were eligible for inclusion in this study. By provider, this included 3,601 (76.7%) births to mothers admitted by OBs, 844 (18.0%) admitted by FPs and 248 (5.3%) admitted by MWs. The mean maternal age for mothers was 29.7 for OBs (CI: 29.56, 29.88), 29.8 for FP (CI: 29.48, 30.89) and 31.2 for MW (CI: 30.72, 31.69). There was both a statistical difference in means between MW and other providers ($p < 0.0001$). From the overall low-risk birth cases, 15.1% (n = 708) delivered by caesarean section and 10.1% (n = 474) of newborns were transferred to the NICU. The intervention rates were reported as the following: induction with oxytocin at 12.8% (n = 601), augmentation with oxytocin at 41.7% (n = 1,959), epidural at 71.4% (n = 3,353) and forceps or vacuum delivery at 10.0% (n = 491). The comparative proportions of interventions and maternal and neonatal outcomes in the three providers are shown in Table 1.

TABLE 1. Intervention and neonatal outcome rates in OBs/FPs/MWs and relative risk of interventions/outcomes in FPs and MWs versus OBs

Intervention/outcome	OB (n = 3,603)	FP (n = 845)	MW (n = 248)	FP vs. OB	MW vs. OB
	% (95% CI)	% (95% CI)	% (95% CI)	RR (95% CI)	RR (95% CI)
Induction and/or augmentation with oxytocin	58.0 (56.4–60.0)	48.1 (44.8–51.6)	25.0 (19.6–33.4)	0.83 (0.77, 0.89)*	0.43 (0.35, 0.54)*
Epidural	72.8 (71.3–74.2)	75.1 (72.2–78.1)	38.7 (32.7–44.8)	1.03 (0.99, 1.08)	0.53 (0.45, 0.62)*
Forceps and/or vacuum	10.8 (9.8–11.8)	10.3 (8.4–12.5)	5.2 (2.5–8.0)	0.95 (0.76, 1.19)	0.48 (0.28, 0.83)*
Caesarean section delivery	16.2 (15.0–17.4)	12.4 (10.3–14.8)	7.3 (4.0–10.5)	0.77 (0.63, 0.93)*	0.45 (0.29, 0.70)*
Spontaneous vaginal delivery	75.1 (73.4–76.2)	79.6 (76.3–81.8)	87.1 (84.3–92.3)	1.06 (1.02, 1.10)	1.16 (1.10, 1.22)*
Neonatal outcomes**	89.6 (88.6–90.6)	90.2 (88.2–92.2)	94.0 (91.0–97.0)	1.01 (0.98–1.03)	1.05 (1.01–1.08)*

*Statistically significant ($\alpha = 0.05$).

**Avoided transfer to neonatal intensive care unit (NICU)

The relative risks (RR) of all interventions and outcomes in FP and MW compared with OB are also shown (Table 1). Patients in the FP group were more likely to experience spontaneous vaginal delivery (RR: 1.06; 95% CI: 1.02–1.10) and were less likely to receive induction/augmentation (RR: 0.83; 95% CI: 0.77–0.89) and caesarean section (RR: 0.77; 95% CI: 0.63–0.93). Patients in the MW group were more likely to experience spontaneous vaginal delivery (RR: 1.16; 95% CI: 1.10–1.22) and less likely to receive any of the interventions analyzed in this study: induction/augmentation (RR: 0.43; 95% CI: 0.35–0.54), epidural (RR: 0.53; 95% CI: 0.45–0.62), forceps/vacuum (RR: 0.48; 95% CI: 0.28–0.83) and caesarean section (RR: 0.45; 95% CI: 0.29–0.70). Newborns delivered in the FP group had comparable results in avoiding neonatal transfer to the NICU (RR: 1.01; 95% CI: 0.98–1.03), while the MW group showed a slight, but statistically significant, improvement (RR: 1.05; 95% CI: 1.01–1.08).

Costs

The decision tree model (Figure 1) assisted in determining the cost for each care pathway based on intervention, method of delivery and outcome variables attributed to each provider. According to the Ontario Schedule of Benefits (April 1, 2013), physician course of care cost was $1,025 (Table 2) for a low-risk obstetrical patient, including all antepartum and postpartum appointments as well as vaginal delivery (MOHLTC 2013). The portion of the course of care cost specified for vaginal delivery is 48%. Using the same portion, the cost for MWs attending a delivery was calculated at 48% of the course of care cost. Given that MWs have varying costs for courses of care depending on practice site (urban/rural) and seniority (Courtyard Group 2010), the course of MWs attending a delivery was calculated as $1,043 (0.48 × $2,147.50), with a range between $860 and $1,227 for the purposes of this CEA (Table 2). There was little difference in costs between FPs and OBs for the decision tree pathways, with the exception of caesarean section billings. For patients admitted under OBs who require caesarian sections, the OB fee for caesarean delivery (P018) plus a surgical assistant fee will be billed (P018B). However, for patients admitted under FPs, the FP fee for attendance at the delivery (P009) will be billed in addition to the OB fee for caesarean delivery (P018) but without a surgical assistant fee. Notably, in cases admitted under MWs requiring a caesarean delivery, each of the MWs course of care cost, the OB fee for caesarean delivery (P018) and surgical assistant fee (P018B) was attributed to the midwife branch. Additional costs for other interventions, referral, attendance by physicians, anaesthesia or a second MW were attributed to the admitting providers.

TABLE 2. Cost variables

Description	Cost	Reference
Caesarean section with induction (case cost)	$5,639	BCH CMG+ 558
Caesarean section with no induction (case cost)	$3,461	BCH CMG+ 559
Vaginal delivery with anaesthetic and with non-major intervention (case cost)	$3,874	BCH CMG+ 562
Vaginal delivery with anaesthetic and without non-major intervention (case cost)	$2,938	BCH CMG+ 563
Vaginal delivery without anaesthetic and with non-major intervention (case cost)	$2,478	BCH CMG+ 564
Vaginal delivery without anaesthetic and without non-major intervention (case cost)	$1,936	BCH CMG+ 565
Newborn, singleton birth (case cost)	$790	BCH CMG+ 576
Newborn, caesarean birth (case cost)	$977	BCH CMG+ 577
Newborn, transfer to ICU (case cost)	$2,436	BCH CMG+ 589–599 weighted average
Midwife costs for attending delivery	$1,043.68	Prorated (48%) midwife course of care

TABLE 2. Continued

Description	Cost	Reference
Midwife second attending a birth	$214.00	Ontario midwife compensation guide 2010
Midwife referral for anaesthesia	$106.80	Ontario physician schedule of benefits April 1, 2013 A816
Midwife referral for physician assessment	$101.70	Ontario physician schedule of benefits April 1, 2013 A813
Physician costs for vaginal delivery	$498.70	Ontario physician schedule of benefits April 1, 2013 P006
Physician costs for forceps or vacuum delivery	$535.60	Ontario physician schedule of benefits April 1, 2013 P020
Physician costs for caesarean section delivery of a patient admitted by an obstetrician (time assumed to be one hour for assistant)	$700.20	Ontario physician schedule of benefits April 1, 2013 P018 + P018B
Physician costs for caesarean section delivery of a patient admitted by a family physician	$1,078.50	Ontario physician schedule of benefits April 1, 2013 P018 + P009
Human resource cost of caesarean section delivery of patient admitted by midwife (time assumed to be one hour for assistant)	$1743.88	Prorated (48%) midwife course of care + Ontario physician schedule of benefits April 1, 2013 P018 + P018B
Physician costs for induction or augmentation of labour with oxytocin	$67.75	Ontario physician schedule of benefits April 1, 2013 P023
Anaesthesia costs for inserting and maintenance of epidural (time assumed to be six hours [maximum])	$270.18	Ontario physician schedule of benefits April 1, 2013 P014C + P016C
Anaesthesia costs for attendance at caesarean section (time assumed to be one hour)	$165.11	Ontario physician schedule of benefits April 1, 2013 P018C
Anaesthesia costs for attendance at caesarean section with no epidural (time assumed to be one hour)	$90.06	Ontario physician schedule of benefits April 1, 2013 P013C

Case costs for method of delivery at BCH ranged from a total average cost of $1,936 for vaginal delivery without anaesthetic and without non-major intervention to $5,639 for a caesarean section with induction (Table 2). In addition, the case costs for outcome ranged from $790 for singleton delivery to $2,436 for newborn transfer to the NICU. The BCH CMG+ costs varied from 19% (caesarean delivery) to 25% (vaginal delivery with anaesthetic and with non-major intervention) in comparison with the provincial averages.

Cost-effectiveness

In the CEA model, MW care dominated the other two providers, as it was both more effective (fewer NICU admissions) and less costly. As well, FPs dominated in relation to OBs. It is important to recognize that there are small differences in both the total cost per delivery by provider ($5,188 [OB], $5,116 [FP] and $5,102 [MW]) and the difference in NICU admissions (Table 3).

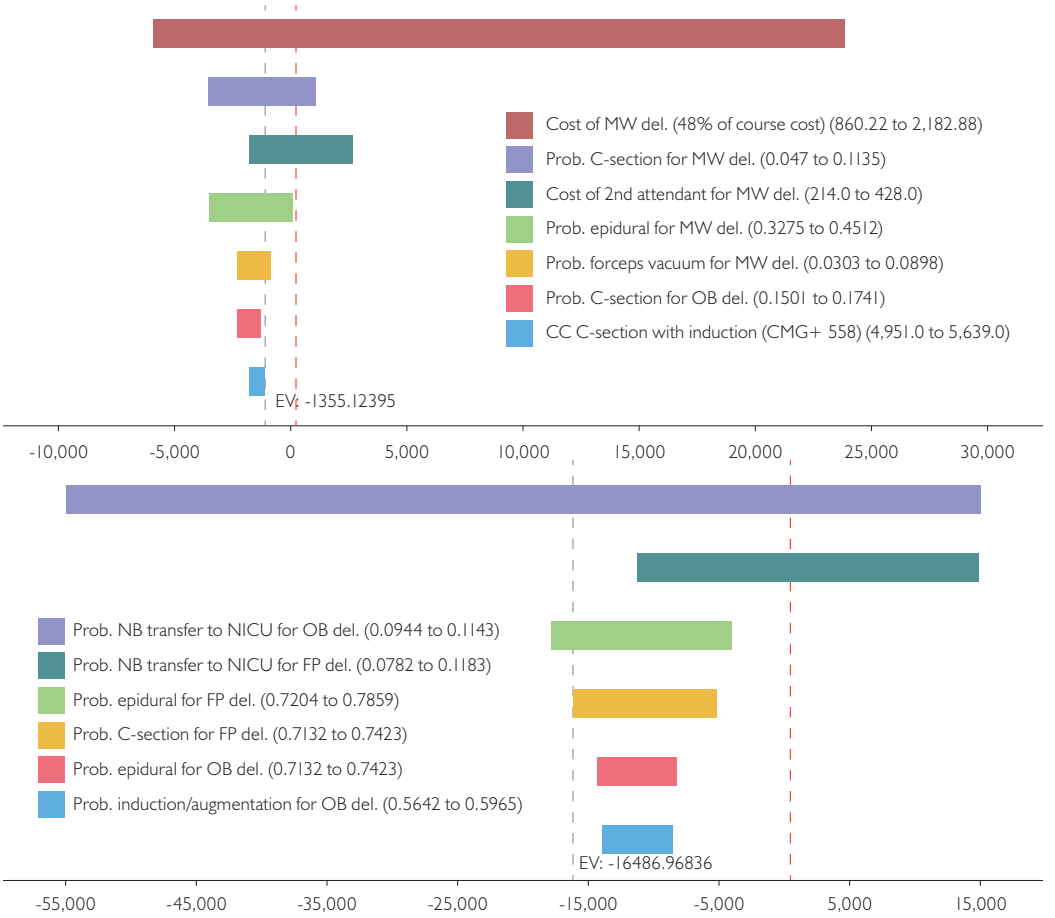
TABLE 3. Cost-effectiveness analysis results

Ministry perspective							
Provider	**Cost**	**Incremental cost**	**Effectiveness**	**Incremental effectiveness**	**Incremental C/E**	**NMB**	**C/E**
Midwife	$5,102		0.9395			−5,102	5,431
Family physician	$5,116	14	0.9018	−0.0377	−361	−5,116	5,673
Obstetrician	$5,188	86	0.8956	−0.0439	−1957	−5,188	5,793

Sensitivity analysis

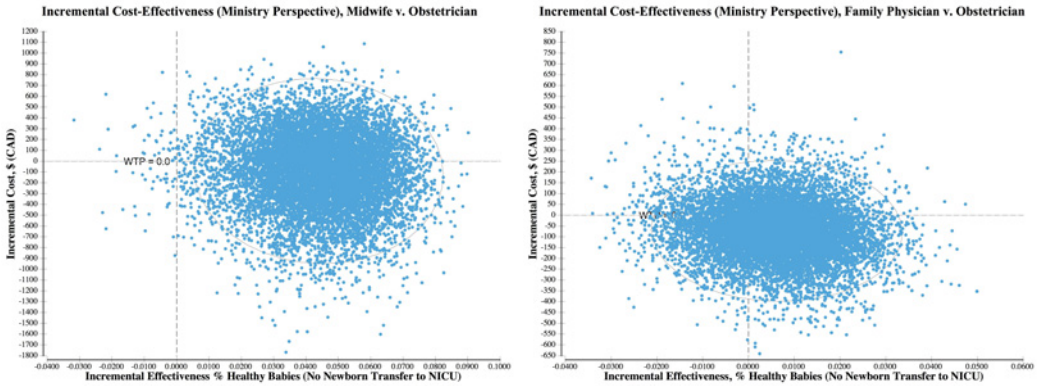
Results of the one-way sensitivity analysis for MW versus OB as well as FP versus OB are shown in a Tornado diagram (Figure 2). The Tornado diagram shows that MW and FP strategy has a positive cost-effectiveness relative to OB, but that varying certain costs and intervention rates to values from the literature or provincial estimates could reduce the difference between providers or eliminate all advantage. Most notably, varying the MW compensation to the increased level recommended by a pay equity consultant – a 75% compensation increase – for the AOM lawsuit (calculated as $2,182 for MW costs for attending delivery, which represents 48% of requested course of care fee) negated the MW dominance as a cost-effective strategy for low-risk births (Figure 2). This is an important finding because it demonstrates the impact of human resource costs in the model. The probability of receiving a caesarean section for a mother admitted by MW and the cost of the second attendant in MW deliveries also had an effect. Varying the probabilities of newborn transfer for both the FP and OB had a greater positive effect on FP cost-effectiveness compared with OBs.

FIGURE 2. One-way sensitivity analysis – Tornado diagram – Ministry perspective – MW versus OB and FP versus OB



The results of the probabilistic sensitivity analysis show that the MW sample is stable with respect to effect size for the primary health outcome (Figure 3). Based on the variance around both the MW and OB group, the model has a 95% certainty that MW newborns are transferred less often than OB patients. However, the cost estimate has a large variance and the 95% confidence interval is −$900 (savings) and +$700 (increased costs). Overall, the MW strategy cost less than $5,000 per NICU transfer avoided in 80% of scenarios and less than $1,000 per NICU transfer avoided in 63% of scenarios compared with the OB strategy. Within the FP versus OB analysis, the model was sensitive to both cost and effect variations for this population.

FIGURE 3. Probabilistic sensitivity analysis – Ministry perspective – MW versus OB and FP versus OB



Discussion

The model shows that MWs and FPs were more cost-effective than OBs in performing deliveries in low-risk obstetrical patients. Notably, MWs have demonstrated significantly lower intervention rates, which are accompanied by lower costs. The sensitivity analyses showed the MW model to be sensitive to increases in the compensation for attending the delivery. If MW compensation increases, they may no longer be the cost-effective strategy.

BCH was a model hospital for this study because all three groups provide obstetrical care in this institution and MWs have the capacity to practice to their full scope of practice (College of Midwives of Ontario 1999). In contrast to other hospitals in Ontario, the scope of MW practice includes managing the care of clients who have received an epidural or whose labour has been induced or augmented (Ontario Hospital Association et al. 2010), which enables MWs to continue as primary provider for a larger proportion of patients without transferring such patients to another provider. As all births in this study took place in BCH, this study did not include home births attended by MWs or deliveries at birthing centres.

Strengths and limitations

A strength of this study is that it was based on real data and included almost 5,000 patients. While the 248 MW births may appear small, the hospital has among the most MW-led

deliveries for any institution in Ontario under the current limited scale of midwifery in the province. This model attributed all interventions and outcomes and their associated costs for a particular patient to the admitting provider instead of the providers who applied interventions, and this may have inflated intervention rates and associated costs for FP and MW providers. The strength of the CMG+ methodology is in its generalizability across Ontario; it is a good way to look at populations of patients within the same hospital or health system. The limitation is the use of an average cost; costs for providers who are not using resources such as nursing staff are overestimated, and costs for providers who use more resources are underestimated. For example, MWs may not have nursing staff present during labour and delivery, which may result in lower direct costs. Together, it is reasonable to suggest that these factors have resulted in even more conservative cost-effectiveness estimates in support of the MW strategy. It is uncertain whether higher-than-average CMG+ cost at BCH for case types is a reflection of being higher-than-average or rather simply a larger facility or having a concentration of specialists than other community-based health facilities.

The cost-effectiveness results should be viewed with caution, however, as costs and outcomes differed by narrow margins. It is also unknown whether the findings here are generalizable to MW care in other delivery settings such as homes and birth centres, as outcomes may vary (Grunebaum et al. 2014). A potential bias of the study is that lower-risk patients may have self-selected a MW. Previous studies showed that patients who choose a MW have a desire to avoid technology and intervention, while some women perceive childbirth as a process with inherent risks and are more likely to choose a physician and be more accepting of technology and intervention (Howell-White 1997), but this level of analysis is not possible using data from the comprehensive BORN database. Other than age of mothers, it was not possible to examine patient-level characteristics such as ethnicity, education level or socioeconomic background, which may have influenced the types and number of interventions used during labour and delivery. Even though the mean maternal age was higher in the MW group by 1.5 years, this difference is not expected to change the results. It is conceivable that the slightly older MW patients resulted in a more conservative estimate for cost-effectiveness. Attributing costs, however, to the original provider helps to mitigate the potential bias of only having very healthy patients in the MW group. This model was designed to reflect, as closely as possible, the consequence of patients choosing their preferred provider for pregnancy care, labour and delivery.

The time frame selected for analysis was from hospital admission of the pregnant patient until discharge of mother and baby. The CEA only accounted for the costs of labour and delivery, as opposed to the entire course of care that typically also includes antenatal and postpartum care. This is relevant to MWs because they are paid in the form of one course of care fee for the entire pregnancy, in contrast to physicians who are paid by fee-for-service. Using a percentage of total MW costs for calculating the cost for attending delivery in our model was necessary to compare disparate funding models. Further assumptions made when costing specific interventions may also have led to some biases. With respect to physician costing, it was

assumed that all instrumental deliveries were mid-cavity extractions and were priced at the premium delivery code of P020, as opposed to P006 (MOHLTC 2013), which increases the cost of delivery by $36.90. However, this only occurred in 10.2% of cases for FPs and 10.8% for OBs (Table 1) and, therefore, has a negligible effect on total cost. Furthermore, physician-led birth costs may have been underestimated because allowable evening/night/weekend premiums were not included.

Summary and future directions

This study shows that MWs are the most cost-effective provider group for low-risk obstetrical care during delivery in this hospital setting. All three provider groups were similar with respect to the cost per delivery. In November 2013, the AOM initiated legal action against the MOHLTC under the Human Rights Tribunal of Ontario, claiming systematic discrimination in MW remuneration on the basis of gender (Association of Ontario Midwives [AOM] 2013). Based on our findings, if compensation for MWs is increased to the levels recommended in the pay equity lawsuit, MWs would no longer be the most cost-effective provider group. Currently, MWs are only meeting 65% of the demand for their services (Ontario Hospital Association et al. 2010). This study's findings support greater integration and collaboration between MWs, FPs and OBs for providing obstetrical care in hospital settings under the current provider compensation schemes. Finally, the model developed may be used for future larger research studies across multiple settings and can inform governments on funding frameworks for obstetrical care.

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RESEARCH PAPER

The Untold Story of Being Designated an Alternate Level of Care Patient

Ce qu'on ne dit pas sur le fait d'être désigné pour un autre niveau de soins

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Abstract

Introduction: Much of the research and policy reports on Alternate Level of Care (ALC) in Canada have focused on the impact ALC has on acute care services. To date, the experiences and opinions of those who must wait in hospital for alternate services have been largely absent from discussions.

Method: A qualitative study was conducted with patients and families designated as ALC in one urban and two rural hospitals in Atlantic Canada. Data were analyzed using content analysis.

Results: Three themes emerged from the data: a perception of normalcy, being old but not sick and anticipating relocation to another facility.

Conclusions: ALC is an important issue for patients and their families. Policy directives aimed at addressing the causes and impacts of ALC, identification and provision of appropriate supportive care in the community and sensitivity to the impact of ALC for individuals designated as ALC are needed.

Résumé

Introduction : La plupart des recherches et des rapports de politiques sur les autres niveaux de soins (ANS), au Canada, ont trait à leur impact sur les soins de courte durée. À ce jour, l'expérience et l'opinion de ceux qui doivent attendre à l'hôpital pour obtenir d'autres services ont été plutôt absentes des discussions sur le sujet.
Méthode : Une étude qualitative a été menée auprès de patients (et leurs familles) désignés pour un ANS dans un hôpital urbain et deux hôpitaux ruraux du Canada atlantique. Les données ont été traitées au moyen de l'analyse du contenu.
Résultats : Trois thèmes se dégagent des données : une perception de normalité, le fait d'être vieux sans être malade et l'attente d'un transfert vers un autre établissement.
Conclusions : L'ANS est un enjeu important pour les patients et leurs familles. Il est nécessaire de doter les politiques de directives qui permettent d'aborder les causes et l'impact de l'ANS, d'identifier et d'apporter les soins de soutien appropriés dans la communauté et de tenir compte de la sensibilité à l'impact chez tous les patients désignés pour un ANS.

There has been increasing concern over the growing number of people who must wait in hospital for more appropriate settings to have their needs met. The Canadian Institute of Health Information (CIHI) refers to the level of care required by these individuals as Alternate Level of Care (ALC). To be classified as ALC, there must be a notation on the patient's hospital record indicating that the person no longer requires acute care services (CIHI 2009). Although there has been concern about the consistency of data reported on patients designated as ALC (Cancer Care Ontario 2011; CIHI 2009), there is a general consensus that ALC is a complex issue that negatively impacts hospitals' ability to operate efficiently (Canadian Health Services Research Foundation 2011; CIHI 2012; Costo et al. 2012; Sutherland and Crump 2013).

Across Canada, clinicians and policy makers have been struggling to understand ALC from both a system and individual perspective. CIHI has produced several reports on ALC over the years with the hope of "understanding the extent of the ALC challenge in hospitals" (CIHI 2009, 2012; Walker et al. 2009). Others have attempted to explore possible strategies to respond and reduce ALC within Canadian hospitals (Costa and Hirdes 2010; Ontario Hospital Association 2012; Sutherland and Crump 2011; Walker 2011). Despite these efforts, ALC continues to be of concern, with reports of as many as 25% of acute care beds being occupied by people designated as ALC (McCloskey et al. 2014).

Notably absent from discussions on ALC is the patients' perspective. Yet, if the goal of ensuring Canadians receive the right care in the right place is to be achieved, those affected by ALC must be heard. Patients and their families have first-hand knowledge of the issues surrounding ALC and by drawing on these experiences, policy makers and clinicians may have a better understanding of how to respond to ALC. The purpose of this study was to speak with ALC patients and their family members to understand the ALC experience from their unique perspective.

Methods

A qualitative study was conducted with hospital patient's and family members who were designated as ALC. Open-ended interviews were conducted to collect data about the ALC experience and questions such as "what is it like to be waiting in hospital" and "tell me more about that" were used. Data were analyzed using content analysis. The focus of content analysis is to discover the underlying meaning and significance of an experience from the perspective of those directly affected (Hsieh and Shannon 2005; Rodgers 2000).

Sample

The study utilized a convenience sample of patients designated as ALC and their families in New Brunswick, Canada. Participants were recruited from one regional and two community hospitals within one health authority. When the study was initiated, 118 patients were classified as ALC in the three hospitals, including 92 (20.7%) in the regional hospital and 16 (35.6%) and 10 (40.0%) in the community facilities.

Hospital staff distributed letters of invitation to patients and families of people designated as ALC who were English-speaking and able to provide informed consent. A research assistant met with those who expressed interest in the study to explain the study and to answer questions. All 20 people who expressed an interest in the study agreed to participate (Table 1). Half (10) of these participants were from the regional facility and half were from one of the two community facilities. All interviews took place between May 2012 and November 2012.

TABLE 1. Study participants

Patients (n = 16)	
Admitted to hospital through the emergency department	16
Mean age	85.1 years (SD = 11.1)
Sex	
Male	5 (31.3%)
Female	11 68.7%)
Admission diagnosis	
Dysphagia	1
Pain	1
Urinary tract infection	1
Cardiac	3
Respiratory	2
Social admission	2
Fall	3
Neurological	2
Cellulitis	1
Living arrangements prior to admission	
Home with family	10 (62.5%)
Home alone	6 (37.5%)
Formal supports prior to admission	9 (56.3%)
Discharge plan	
Long-term care facility (nursing home)	15 (93.7%)
Special care home*	1 (6.3%)
Family members (n = 4)	
Husband	1
Daughter	1
Son	1
Friend	1

*A special care home is a 24-hour assisted living facility staffed by unregulated workers.

Data collection

All interviews took place in an in-patient hospital room and were tape-recorded and transcribed verbatim. Participants were encouraged to discuss the events that led to the current hospital admission and what it was like to be in hospital or to have a loved one in hospital for a prolonged stay. Interviews ranged from 20 to 45 minutes in length. Data were entered in NVivo 7, and a constant comparison analysis was used to analyze data. The study was approved by the Research Ethics Boards at University of New Brunswick Saint John and Horizon Health Network.

Findings

Three themes emerged from the data, including a perception of normalcy, being old but not sick and anticipating relocation to another facility.

Perception of normalcy

Life was described by 18 participants prior to the hospitalization as one of a decline in physical function and difficulty in managing at home. With the exception of one patient, ALC patients and the family members were satisfied with their pre-hospitalization living conditions, despite the fact that 12 patients/family members described a home situation that was marked by compromised safety, social isolation and increasing dependency. Thom, the husband of one ALC patient, described how he "lifted" his wife "in and out of bed every day" and how she would "roll out of the bed or slip out of the chair or slip out of the bed." Frank, a 55-year old with a debilitating neurological condition, talked about being confined to his home for two years prior to admission to hospital because of functional impairment and reliance on his sister to "get my mail, get my groceries, and wash all my clothes."

Ten participants spoke of their trust in the healthcare system and of their perception that a healthcare provider was aware of their living situation pre-hospitalization. The underlying assumption was their living situations were "normal" and that initiation/augmentation of supportive services was not required because the need was never introduced by a healthcare provider. John described the home care nurse who came to his house to monitor his wife's colostomy by saying, "she was aware she was spending her days and nights in that chair and didn't do anything, so I just assumed it was normal." Even those who did not have community supports in place prior to the hospitalization did not consider services because they were unaware of what was available or because they were waiting for a healthcare professional to direct them to do so. When Thom was asked about lifting his wife in and out of bed and picking her up off the floor, he responded by saying that the healthcare professionals who were involved in his wife's care were "aware of what we were dealing with at home."

Every family participant spoke of an unquestioned role of providing informal care to the patient that was marked by a gradual increase in emotional and physical demands. Each family member interviewed accepted the fact that they played a central role in their loved one's ability to remain at home for as long as they did. Surprisingly, family members did not feel relieved of their duties as caregivers after their loved ones were hospitalized. Family members continued to visit frequently and support their family member who was designated as an ALC patient. Mary, whose mother was in hospital for five months at the time of the interview, stated: "I work Saturday, Sunday, Monday and Tuesday and then I have Wednesday, Thursday and Friday off so I come here in the city and I stay with my family so I can visit with Mom."

With the exception of one participant, all spoke matter-of-factly about the ALC status. They acknowledged that the demand for long-term care beds seemed to exceed the supply. They accepted the fact that they would have lengthy hospital stays before "getting to the top of

a [nursing home] list." Seven participants were aware of other ALC patients who were waiting longer than themselves for a bed in a long-term care facility.

Old but not sick

A reoccurring topic in the interviews was the feeling that they were using a hospital bed unnecessarily, which participants were aware were in short supply. Although most participants spoke of "being sick" during the early days of the hospitalizations, all four family members and eight patients were mindful of the fact that they no longer required acute hospital services but were unable to leave the hospital because of the unavailability of long-term care services. For these 12 participants, the need to occupy a hospital bed unnecessarily was a source of guilt. Under these conditions, participants spoke of often engaging in activities that minimized the work they created for staff, thus not taking valuable time away from "the sick patients." One participant said she rarely left her room during her 11-month hospitalization because it would require the staff's assistance; another spoke of accepting a bedpan rather than walking to the bathroom because it "was easier for the nurses."

Participants appeared to be acceptant of the fact that "not being sick" meant patients designated as ALC were not a priority for staff and therefore not deserving of staff's time or attention. Several participants talked about the staff "always being in a rush" and not always having time to engage in meaningful dialogue or to meet some of the patients' basic needs. Alice, a lady who had been designated as ALC for three months, described her frustration in getting a regular bath:

> I do realize that some people need more attention than others. But you're only allowed a bath every so often. They couldn't fit everybody in.
>
> I'm going to beg for a bath tomorrow because really you only get one [a bath] once a week if you're lucky.

Nine participants discussed the financial implications of being in hospital when they were not sick. Every family member interviewed discussed the charges their loved one incurred as a result of waiting in hospital for alternate services. Family members compared the monthly hospital fees associated with those they will incur when their loved one moves into a long-term care facility. None of the family members disputed the monthly charges and one family member referred to the expenses as a "win-win. This way she gets looked after while she waits, and we pay for the care she gets." Alternately, participants were less acceptant of the expenses associated with family members' regular hospital visits, including gas and parking expenses. These expenses created financial and emotional difficulties for some participants. One family member stated: "It costs me about $38.00 a day. I was coming [to visit] every day but I can't afford to anymore." Five participants anticipated these expenses would decrease after entry

into a long-term care facility home because of the expectation of placement in a facility within their own community and the absence of parking fees.

Anticipating relocation to a long-term care facility

Only one of the participants was apprehensive about the pending relocation to a long-term care facility. Although most admitted initially resisting the idea of long-term care, at the time of the interviews, every participant was anxious to leave the hospital and to move into a long-term care facility. Eight participants were so eager to enter long-term care that they described efforts in trying to expedite the process, with the most frequent activity being regular phone calls to their chosen facility and contacting friends and people perceived to have influence in placement decisions. Some talked about calling the Director of Nursing in their preferred facility, and one reported calling a family friend who worked in their preferred facility. When asked about contacting the facilities, three participants admitted being "advised by a staff member" to make regular phone calls, as one family member stated: "they said to call at least once a week because the homes pick who they admit. If you call, they are less likely to forget about you and you might get a bed quicker." However, sometimes, this strategy was not effective, as one daughter stated that staff in her mother's preferred facility were no longer accepting her calls:

> Well, they told us here that we should call the home every week and ask them how much longer mum has to wait. They won't accept my calls anymore, guess they are tired of hearing from me. But I keep calling anyway.

When asked about what they thought it would be like to live in a long-term care facility, participants described a life where they would have more autonomy, improved quality of life and less social isolation. Many believed the routines of the hospital would not exist in a long-term care setting. They anticipated life would be flexible and staff would have more time to spend with them. One participant was looking forward to the daily baths she would get when she finally entered the long-term care facility; others believed that long-term care would help them to regain some of the functional ability lost during the long hospital stay, and still others were looking forward to the social stimulation.

Discussion

Although it is widely recognized that ALC is an important issue for healthcare administrators and policy makers, what this study highlights is that ALC is an equally important issue for patients and families. The patients who were designated as ALC in this study were waiting up to 11 months in hospital for long-term care services, and some spoke of other people designated as ALC who were waiting much longer than themselves. While patients and family members likely have different perspectives regarding being designated as an ALC patient, the issues they discussed during the interviews were strikingly similar. It is noteworthy that

lengthy waits for long-term care for both patients and families have become normalized – they were largely unquestioned by participants. This finding is consistent with that of others who assert that limited access to long-term care is a key factor in the ALC issue (Costa and Hirdes 2010; Zhang et al. 2012). Although wait times within the Canadian healthcare system are frequently discussed and monitored, these discussions are generally limited to acute care services (Shamian et al. 2006). Access to long-term care has been largely ignored in governmental wait-time policies. This may be owing to the fact that long-term care does not fall under the *Canada Health Act* and, therefore, is not subject to the same level of political scrutiny as publicly funded hospital services. Yet, for many Canadians, long-term care is a necessary component of healthcare (CIHI 2013).

Limited access to long-term care services is not only an issue impacting those waiting for a nursing home bed, but also has a significant effect on those requiring acute care in hospitals. According to CIHI (2011), on any given day, there are upwards of 7,550 Canadian hospital beds occupied by people who are waiting for long-term care services. In other words, access to an acute care hospital bed is compromised for 7,550 Canadians each day because of the unavailability of a hospital bed. Limited access to long-term care is an issue that has far-reaching effects and deserves the same attention as
the pan-Canadian priority areas identified in the 2004 Health Accord (Government of Canada 2006). Until improvements are made in accessing long-term care services, hospitals will continue to struggle with trying to achieve targets set for wait times in the identified priority areas.

In the province where this study took place, individual facilities choose who they will admit from a provincially approved long-term care wait-list. Selection from this list is based on an individual facility's perception of their ability to meet an individual's needs and not on wait times or individual circumstances. The fact that participants were advised to make regular phone calls to their preferred facility to ensure they were "not forgotten about" suggests healthcare providers were concerned about the wait-list management process in place. Surprisingly, family members did not question the recommendation of making regular phone calls. It is possible that making regular contact with the preferred facility helped family members to feel they were contributing to the admission process. A review of long-term care wait-list management processes found wait-list policies generally involve some combination of need and first-come-first-serve philosophies (Chafe et al. 2010). The effectiveness of facility-based management of long-term care wait-lists has been largely ignored in the literature. There may be benefit in exploring alternate strategies to manage the wait list for long-term care within the province where this study took place.

Home care is often cited as a possible alternative to ALC (Health Council of Canada 2012). It is estimated that over one million Canadians currently receive publicly funded home care services (Canadian Home Care Association 2015). McCloskey and colleagues (2014) recently reported that 46.2% of patients designated as ALC received publicly funded home care prior to being hospitalized. An estimated 53.3% of the home care

provided in provinces contributing to the 2013–2014 CIHI home care reporting system was initiated during a hospital admission (CIHI 2014). Yet, the provincial nature of home care compromises its ability to serve as a national response to ALC. For example, each province has its own unique basket of home care services that vary by type of service available. In addition, while residents in some provinces are subjected to income-testing to assess eligibility for publicly funded home support, those in other provinces may be eligible irrespective of income or assets (Blomqvist and Busby 2012; Mery et al. 2014). New Brunswick residents must undergo an income assessment to identify eligibility for publicly funded services and a functional assessment to determine the amount of service. Residents of New Brunswick may qualify for publicly funded home care in the form of supportive home services for a maximum of 7 hours per day or 49 hours per week. The broad range of terminology, services, funding structures as well as the different methods of assessment used to determine eligibility are major obstacles in comparing this level of home care with that available across the country (Health Council of Canada 2012). Irrespective of the differences that exist, there are no guarantees that home care will be available or sufficient to meet the needs of those designated as ALC. Home care should not be provided as an alternative to ALC solely because it is more convenient and possibly less expensive. Rather, home care should be available only because it is the most appropriate option based on individual need.

Contrary to existing literature on wait times (Harold and Jackson 2011; Webster et al. 2014), our participants did not express feelings of frustration with the need to wait for appropriate care. This may be explained by the fact that participants were waiting in hospital and may have perceived themselves already receiving needed care. Yet it is acknowledged that waiting in hospital unnecessarily is not an appropriate use of hospital resources (Canadian Health Services Research Foundation 2011; Zhang et al. 2012). While it is accepted that the healthcare system cannot be expected to provide immediate access to all services, it is not unreasonable to anticipate reasonable access to health and social services. In the case of people waiting for long-term care services, what constitutes reasonable access needs to be determined. Similar to benchmarks established for cancer treatment, joint replacement and the other priority areas within the Canadian healthcare system, benchmarks for wait times for long-term care facilities and home care services across Canada should be considered. These guidelines must reflect the needs and the realities of the entire healthcare system along with those of individual patients and families. Benchmarks should include prioritization and urgency categories, thus helping to ensure resource allocation is based on need and not on financial resources or the ability of a family member to make regular contact with a preferred facility.

This study also highlights the financial implications of having to wait in hospital for long-term care. Remaining in hospital after being medically discharged by a physician is not a medical necessity and, therefore, meets the criteria of an uninsured hospital service according to the *Canada Health Act* (Parliament of Canada 2005). Hospitals have the authority to charge patients a daily or monthly rate to cover the cost of their hospitalization. This rate is equivalent to the rate of long-term care. In New Brunswick, the maximum daily cost for

long-term care is $113 per day or about $3,437 each month. For those who cannot afford this, the government provides a subsidy that includes the difference between this rate and the individual's Old Age Security and Guaranteed Income Supplement (Province of New Brunswick 2015). Participants in this study readily accepted the per diem rate charged by the hospital, and many rationalized that this fee was comparable with what they would pay if they, or their loved one, moved to a long-term care facility. Yet, hospitals are not long-term care facilities and despite efforts to establish "transitional care units" or "ALC units," hospitals are designed to provide care that is fundamentally different than that provided in long-term care facilities (Ostry et al. 2004) Organizational supports that enable staff to provide quality care to older adults with long-term care needs are often missing in acute care settings (Nilsson et al. 2012). For example, New Brunswick long-term care facilities are required to provide rehabilitative, recreational and social activities, and residents must be provided the opportunity to have input into standards of care and the management of each facility through a Resident Council (Province of New Brunswick 2015). Unlike hospitals, parking in long-term care is provided free of charge. Yet, if fees comparable with long-term care are to be applied to people designated as ALC, efforts should be made to ensure they receive the full scope of services they have paid for. Hospital standards should be developed to guide administrators who are developing specialized units for the growing number of people who wait in hospital for alternate services.

Another important finding was the fact that people designated as ALC are sensitive to the fact that they are in a setting where they do not belong and they feel they are utilizing a resource that could be better utilized by others. For many, waiting in hospital for alternate services generated feelings of unworthiness for care. Many did not feel they deserved the attention of hospital staff and made a concerted effort to minimize the work they created for staff. While these actions may have reduced the time staff had to be with them, they likely led to deconditioning and functional declines (Boltz et al. 2012; Mudge et al. 2010; Zisberg et al. 2011). This underscores the need for staff to engage patients waiting in hospital in activities that promote function and independence. Knowledge and understanding about supporting function and independence among staff working in units designated for ALC is an understudied area that warrants investigation.

Another surprising finding was the fact that the many participants acknowledged that a care provider was aware of the challenges they faced living at home prior to the admission, but did not suggest changes in the care environment. Of the nine participants who were receiving formal home supports prior to admission, only one did not acknowledge any unmet hygienic, nutritional or social needs. Participants assumed that because additional supports were not introduced that their current situations were acceptable. A possible reason for the failure to recognize the need for additional supports is the fact that up to 80% of home care is provided by unregulated care providers (Berta et al. 2013). Unregulated healthcare providers follow a clearly defined plan of care developed by others (New Brunswick Nurses Association 2011). Although skilled in assisting with activities of daily living, they do not always have the skills

to think critically, modify plans of care or to advocate for needed services. Competencies and training standards are needed for this essential group of healthcare workers to ensure they have the necessary skills to support the work they are expected to perform.

It is also possible that healthcare workers did speak about increasing supports but participants did not understand what was being discussed. Similarly, it is possible that supports were offered and denied to the three participants who did not receive assistance at home but who described a living situation suggestive of need. Participants may not have understood that they may have qualified for publicly funded home care, or that additional home care could have been available at no cost. Healthcare workers need to recognize that those not directly involved in the health sector may have difficulty discerning services available, and understanding the different roles and terminology used within healthcare. Many were unaware of the differences between home care, assisted living and long-term care; still others could not identify the government department/agency to contact to request community-based supports. Finally, care must also be taken to ensure that discussions surrounding ALC are not framed in a way that casts blame on the patients themselves. The issue of ALC should be presented in a way that acknowledges the difficulties and challenges related to limited access to long-term care and the effects that this has on everyone including patients, families, health and social services.

There are a number of limitations with the current study. The use of a convenient sample limits generalizability of findings. The inclusion of only English-speaking patients who could provide informed consent precluded those with cognitive impairment or non-Anglophone from participating. A recent study conducted in the province where this study took place reported that 63.6% of people designated as ALC had a diagnosis of dementia (McCloskey et al. 2014). It is possible that patients who did not meet this study's eligibility criteria had very different experiences that are not reflected in these findings. Reliance on interviews as the primary method of data collection limits information obtained to participant accounts of past and current events and functional abilities. Differentiation between actual and perceived abilities to perform activities of daily living was also not possible in this study. Data from patients and family members were analyzed together owing to the small number of patients and family members recruited into the study. Although it is recognized that both patients and families may each have a very unique perspective on ALC, it was not possible to analyze each group separately because of the small sample size. Future studies should consider alternate recruitment strategies, including the use of multiple hospitals, those with cognitive impairment and focusing separately on patient's and family's perceptions.

Finally, knowledge about the patients' length of stay – both the number of acute care days and ALC days – would have provided important information. However, this study design did not provide access to patient's hospital records, and therefore, information on acute and ALC hospital days was not available. The fact that six participants had also been transferred between two different facilities during the ALC stay further impeded the collection of

accurate data on the total length of hospital stay. Without these data, relationships between length of stay and experiences could not be made.

Conclusions

Engaging patients and family members in discussions about being an ALC patient offers some insight into the personal perspective of the scope and depth of the ALC situation in Canada. A lack of long-term care services and the need for improvements in how hospital beds are utilized is a concern not only for hospitals but for patients and families as well. An important finding from this discussion is that much can be learned from ALC patients and families about how our health and social systems respond to the high demand for long-term care services. It is unclear from this study if home care alone is a viable solution to ALC in Canada. It appears that the complex ALC issue requires a multifaceted response that includes a comprehensive strategy of appropriately subsidized home care, case management that will assist individuals' transition across the care continuum in a timely manner, additional long-term care beds, a long-term care wait-list management plan that allocates resources based on clearly identified indicators and the development of best-practice guidelines for caring for people in hospital who are designated as ALC.

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RESEARCH PAPER

Barriers to the Adoption of Safety-Engineered Needles Following a Regulatory Standard: Lessons Learned from Three Acute Care Hospitals

Obstacles à l'adoption des aiguilles sécuritaires conformément à une norme réglementaire : leçons tirées de trois hôpitaux de soins de courte durée

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Abstract

Background: A number of jurisdictions have introduced regulation to accelerate the adoption of safety-engineered needles (SENs). This study examined the transition to SENs in three acute care hospitals prior to and following the implementation of a regulatory standard in Ontario. This paper focuses on the ongoing barriers to the prevention of needlestick injuries among healthcare workers.

Methods: Information from document review and 30 informant interviews were used to prepare three case studies detailing each organization's implementation activities and outcomes.

Results: All three hospitals responded to the regulatory requirements with integrity and needlestick injuries declined. However, needlestick injuries continued to occur during the activation of safety devices, during procedures and during instrument disposal. The study documented substantial barriers to further progress in needlestick injury prevention.

Conclusions: Healthcare organizations should focus on understanding their site-specific challenges that contribute to ongoing injury risk to better understand issues related to product limitations, practice constraints and the work environment.

Résumé

Contexte : Bon nombre d'autorités ont mis en place des règlementations pour accélérer l'adoption d'aiguilles sécuritaires. Cette étude examine la transition vers l'utilisation d'aiguilles sécuritaires dans trois hôpitaux de soins de courte durée, avant et après la mise en place d'une norme réglementaire en Ontario. Cet article porte sur les obstacles courants face à la prévention des blessures par piqûres d'aiguille chez les travailleurs de la santé.

Méthode : Les renseignements tirés d'une revue de la documentation et obtenus auprès de 30 informateurs ont été utilisés pour mener trois études de cas qui présentent les activités et résultats de la mise en œuvre de la réglementation dans chacune des organisations.

Résultats : Les trois hôpitaux ont chacun tenu compte des exigences réglementaires et il y a eu une réduction des blessures par piqûres. Cependant, il y a encore des blessures par piqûres lors de l'activation des mécanismes de sécurité, lors de la procédure et lors de la disposition des instruments. Cette étude a permis de documenter d'importants obstacles à l'amélioration de la prévention des blessures par piqûres d'aiguille.

Conclusions : Les organismes de santé devraient se pencher sur les défis qui contribuent aux risques dans leur établissement particulier, et ce, afin de mieux comprendre les enjeux liés aux limites des instruments, aux contraintes pratiques et à l'environnement de travail.

Worldwide it has been estimated that healthcare workers suffer 2 million needlestick injuries annually (Wilburn and Eijkemans 2004). Needlestick injuries have the potential to result in the transmission of blood-borne pathogens (e.g., hepatitis B, hepatitis C, human immunodeficiency virus) between patients and healthcare workers. In 2007, the province of Ontario (Canada) established a regulatory standard requiring the adoption of safety-engineered needles (SENs) in the provincial healthcare system as a measure to reduce the incidence of needlestick injuries (Ontario Regulation 474/07 Needle Safety 2007). Prior to the regulatory standard, a Canadian survey on the health of nurses found that nearly half of the nurses reported being injured by a needle or other medical sharp at some point during their career and 11% within the previous year (Shields and Wilkins 2006). Following the introduction of the regulatory standard, the decline in needlestick injury rates in the province of Ontario has been less than expected (Chambers et al. 2015). Over a nine-year period (2004–2012), needlestick injury rates in Ontario's health and social sector declined by 38%, and by 30% specifically in the hospital sector (Chambers et al. 2015). There was an expectation that the mandatory use of SENs could eliminate up to 90% of injuries in the province (Bill 1279 2005). Controlled studies that have examined the efficacy of SENs have documented considerable variation in outcomes (Lavoie et al. 2014; Tuma and Sepkowitz 2006). Less-than-optimal outcomes have also been documented in other jurisdictions that have established regulatory standards to promote the adoption of SENs (Chambers et al. 2015; Jagger et al. 2008, 2010; Stringer et al. 2011). However, these studies have not provided any contextual information on implementation issues associated with the use of these devices.

This paper presents findings from a qualitative case study that describes the experiences of three Ontario hospitals following the implementation of a regulatory requirement to implement SENs, with a specific focus on describing ongoing barriers to the prevention of needlestick injuries among healthcare workers.

Methods

Design

A qualitative case study design (Stake 2005) was carried out in three acute care hospitals in the province of Ontario, Canada, over a 24-month period (April 2011–March 2013).

Sampling and recruitment

Geographic sampling was used to identify 17 community and teaching hospitals that were within 40 km of our research offices. From this roster, hospitals were randomly sampled to participate.

At each site, staff were purposefully recruited to obtain a broad range of perspectives. Staff that were involved in the implementation of SENs were initially recruited through referrals made by the health and safety staff at each hospital. An e-mail invitation was

distributed to nurses in select departments where SENs were in frequent use, including the emergency department or critical care unit.

Data collection

The two main sources of data used in this study were document records and face-to-face interviews. A range of topics were addressed during the interviews with staff. To examine ongoing implementation efforts, both document records and interviews were used to describe what measures were in place and also perceptions towards ongoing investment in this area. Ongoing needlestick injury risk was understood through analyses of incident reports and through interviews with nurses who were able to comment on their own personal injury experience or those that they had observed in practice.

Informants in the department of occupational health and safety assisted with the collection of supporting documents including: evaluation reports, written policies and procedures, incident reports, inspection orders, safety product lists, training materials and administrative documents from the sharps safety committees.

Data analysis

Case studies were prepared for each hospital site detailing the organization's implementation history, relevant activities and outcomes. The case reports were based on accounts from interviews, observations from field notes and information extracted from organizational documents (Braun and Clarke 2006). A thematic analysis was carried out to identify patterns and themes within and across the three case sites. The analysis considered both retrospective reflections of the implementation experience and reflections on current and future conditions. When analyzing interviews, attention was placed on practices, understandings and conditions at the workplace level, to examine not only what they reported about the use of safer needle technology but how they talked about it. There was also an attempt to think through some of the implications of shared views or divergent perspectives and underlying assumptions through an in-depth review of the accounts.

The research protocol was approved by the ethics review board at the University of Toronto and by ethics review boards at the three participating hospitals.

Results

The complete data set included 30 semi-structured interviews, 55 document summary forms, 36 case summary forms and 32 field notes. The interviews were conducted with healthcare professionals (57%) and hospital managers and administrative staff (43%). Half of the interviews were carried out with staff who currently or previously had a health and safety role in the organization. This paper focuses on two primary themes from the case studies: the influence of technology, practice and the work environment on ongoing needlestick injury risk and organizational constraints to further invest in needlestick injury prevention.

Table 1 summarizes key attributes of the participating hospitals. The three hospitals provided acute care services in cities serving primarily large urban populations. Different types of SENs were available across the three hospitals. Manual SENs, which require the user to directly manipulate the safety component on the device, were available at all three hospitals. Semi-automatic SENs were also in use. These devices have a retractable component but are not considered truly passive, as some form of user activation is required (e.g., press of a button). Hospital C was the only site to integrate fully automatic or passive SENs in select high-risk areas. While needlestick injuries declined following the integration of SENs, there was considerable variation in outcomes. Needlestick injury rates declined by 28%, 60% and 81% at Hospitals A, B and C, respectively.

TABLE 1. Summary of implementation processes and outcomes in the three acute care hospitals

	Hospital A	Hospital B	Hospital C
Characteristics	Large teaching hospital	Multi-site community hospital	Large teaching hospital
Transition to safety needles	2007, in response to safer needle regulation	2006, in response to a workplace inspection order	2003, voluntary transition
Training	Group-based training	Train-the-trainer strategy	Group-based + train-the-trainer strategy
Types of SENs	Mix of semi-automatic and manual	Mix of semi-automatic and manual	Mix of semi-automatic, manual and passive
Ongoing implementation policies and practices	Written policies and procedures Ongoing monitoring of incidents Resources on the intranet	Written policies and procedures Ongoing monitoring of incidents	Written policies and procedures Annual review of exceptions Ongoing monitoring of incidents
Rate of NSIs per 100 beds			
Time 1*	11.9	15.3	8.3
Time 2**	8.6	6.2	1.6
% change	↓28%	↓60%	↓81%

*One year prior to the transition

**Three years post-implementation

Pathways for ongoing needlestick injury risk

At all three hospitals, needlestick injuries declined following the implementation of SENs; however, needlestick injuries continued to be documented in incident reports. While Hospital C was observing less than 20 needlestick injuries annually at the time of the field work, both Hospital A and B were continuing to document between 40 and 100 needlestick injuries each year. As healthcare workers reflected on their own injury experiences and injuries that they had observed in practice, they were able to contextualize a number of product limitations and environmental constraints that limited the effectiveness of SENs, including unpredictable patient interactions, downstream risks of exposure and safety device activation and design.

UNPREDICTABLE PATIENT INTERACTIONS

The most common explanation for ongoing injury risk focused on injuries that occur before SENs are activated, during a procedure and as a result of patient action. In these situations, patients were described as being "aggressive," "combative" or "not-cooperative." The risk of exposure prior to the activation of SENs is heightened as a result of these unpredictable patient interactions. Workers acknowledged how their work environment and interactions with patients can be unpredictable:

> Maybe a patient becomes very anxious or just swats their hand very quickly and catches the nurse completely off guard whereas the needle can end up sticking them instead of a patient. Sometimes you really just don't know what may happen and it may not be preventable in a sense because it just happens so sudden.

The notion of being able to evaluate and plan for difficult patient interactions was challenged by workers. One of the nurses recounted her own recent needlestick injury experience to explain how challenging it can be to anticipate these types of interactions. Based on her initial assessment, she had determined that her patient was "compliant" and "coherent." Her injury happened during the second injection; the first injection gave no indication that the patient would resist.

There was a shared perspective that safety needles that needed to be manually activated are limiting in these types of situations. The manual SENs were described by some workers as more challenging to activate. An injured worker recounted her experience using a manual SEN with a patient who was not cooperating with the procedure. This was a safety device that the worker felt was effective in reducing risk of injury only when used in a "contained and stable environment." This pathway for ongoing injury risk represents an important limitation with respect to both the work environment and limitations in the ability of SENs to reduce risk of exposure at all stages of care.

DOWNSTREAM RISK OF EXPOSURE

A number of the organizational informants also linked ongoing injury risk to improper sharps disposal practices, including the use and replacement of overfilled sharps disposal bins. The examples that were provided emphasized how these practices did not only impose a risk of injury to oneself but also to other nurses and housekeeping staff working in the same area. These types of injuries were perceived to be concerning, as the source patient would be unknown, complicating the post-exposure testing protocol. This pathway for ongoing injury risk also draws attention to the lack of control over the work environment, emphasizing the implications of individual practices on the health and safety of co-workers.

SAFETY DEVICE ACTIVATION AND DESIGN

In reference to ongoing needlestick injuries, nurses and managers emphasized not only the potential for needlestick injuries to occur before safety devices were activated but also during

activation. The most common SEN in use across all three sites had an active design where a safety cap had to be manually flipped over the needle. The potential for injury arises when healthcare workers attempt to use their finger to flip and lock the safety cap into place rather than using a stable surface such as a bed frame or table to activate the device.

There were a number of incidents described by informants that emphasized that not all SENs are equally effective, easy to use or able to eliminate needlestick injuries. Informants at Hospital A described what they referred to as a "non-functional safety." The device, which was a manual safety butterfly needle, resulted in an increase in needlestick injuries. Staff found the safety device too cumbersome and, thus, the safety component was not being used. Informants attributed the more bulky design of the device as an important contributor to the ongoing injuries that were being reported. It was interesting to note that the needlestick injury data collected from Hospital C demonstrated that needlestick injuries occurring during a procedure actually doubled following the implementation of SENs but then slowly declined over time. These two examples demonstrate the potential for some SENs to be limited in reducing risk of exposure or in some cases requiring a period of adaptation. An important consequence of using manual SENs is that they put a demand on the user to maximize the safety potential of the device. Manual activation can then be hampered by environmental demands and unpredictable interactions.

PERCEIVED CONTROL AND RESPONSIBILITY OVER ONGOING INJURY RISK

There were a number of explanations as to why needlestick injuries continue to occur and how they could be further prevented. These explanations can be organized under two perspectives: the individual blame perspective that emphasized the importance of staff compliance and "being more careful" and the environmental constraints perspective. Explanations that centred on the inevitability of injury were reflected in the accounts above that focused on unpredictable patient interactions, reliance on the health and safety practices of co-workers and product limitations.

The description of ongoing injury risk attributed to proper adherence to the timing of activation eludes to the important role that point-of-care health professionals have in creating a safe work environment. Other references to the importance of staff compliance were more direct. The following quote provides an example of how nurses attributed ongoing injury risk to individual action. In this case, there was an emphasis on the importance of taking personal control over the situation:

> I tell nurses you are the one in control, you have the needle in your hand, make sure the patient stays still which means either you hold them still or you tie them down, get another nurse to hold them down because if they flinch, it's going in through him and you.

There were select reports from the informants that described continued poor compliance with the use of SENs. One representative from health and safety who was routinely monitoring injury data emphasized that while usage had improved over time, there were still issues and injuries. Nurses were able to speak to the types of "bad practices" that were ongoing, which were most commonly linked to SENs not being activated prior to disposal. As one nurse emphasized, "at the end of the day the issue isn't what the hospital has, the issue is how the staff use it."

Constraints to further investment in needlestick injury prevention

A common finding across all three hospitals was limited ongoing investment in needlestick injury prevention. Some informants expressed reservations about the value of future investments to promote consistent use of SENs and the need to adopt more advanced SENs. For example, organizational informants at Hospital B felt that the time investment involved in re-examining lists of non-safety needles that continue to be used in select areas would unlikely result in any product changes. Across all three cases, there was no momentum for an increased use of passive safety needles. The following quote is from a worker who did express positive views towards the added value of passive SENs but also emphasized that staff are content with the current stock:

> I do think that staff are quite happy with their safety-engineered devices, I am not saying that, that they wouldn't be happier if they have had their retractable, I would certainly think in certain cases it would be better, but what we've got is certainly helping.

Some informants presented a different perspective, expressing strong support for the use of more advanced safer needle technology and the need for more emphasis on needlestick injury prevention. These informants had all recently reported a needlestick injury. Some workers used the interview as an opportunity to share how their own injury could have been prevented with the use of a passive safety device. While this group could be considered "experts" on account of their experience, they did not feel they were in a position of power to advocate for improvements.

Another barrier to furthering prevention efforts in this area was the lack of investment in the ongoing review of needlestick injuries and efforts to share information with staff. There were a number of nurses who were not aware that needlestick injuries were continuing to occur. There was also limited information available to identify where additional prevention efforts should be targeted.

Informants also spoke of "change fatigue" as a barrier to implementing new preventive measures to further reduce injury risk. At Hospital A, where SENs were integrated within a very short period, resistance to change was in part attributed to employees responding

more generally to an overload of changes at the hospital. The following quote is from an organizational informant who felt that the initial resistance to SENs arose in part from working in an environment that is under constant change:

> Hospitals are going through so much change right now universally that people are almost balking at anything, people get a little fed up with change so I think that's confounding what they really feel about the product or its safety. If it's something different, it's a change and they don't want it.

Other informants spoke of "change fatigue" as a barrier to considering new SEN technology or to the implementation of additional training opportunities. Perceptions of financial constraints were also a barrier to further prevention efforts. SENs are more expensive than conventional non-safety needles and syringes, and the initial adoption of SENs following the regulatory standard had significant cost implications for hospitals. Occupational health informants noted financial issues were a constraint in their efforts to integrate more advanced safer needle technology at Hospital A and B. Nurses also reported a reluctance to advocate for better technology based on their understanding of constrained hospital resources.

Discussion

A qualitative case study of the implementation experience in three acute care hospitals described outcomes of a hospital-wide transition to SENs and a number of product limitations and environmental constraints that reduced the effectiveness of SENs. Needlestick injuries did decline at all three sites following the transition to SENs; however, a number of injuries continued to be reported. Ongoing injuries following the mandatory use of SENs have been described in a number of jurisdictions (Chambers et al. 2015; Jagger et al. 2010; Jagger and Perry 2003; Stringer et al. 2011; WorkSafeBC 2011) and in studies of SEN efficacy (Lavoie et al. 2014; Tuma and Sepkowitz 2006). As revealed in this study, there are a number of barriers to completely eliminating needlestick injuries under current conditions. There are gaps in the ability of SENs to prevent injuries during activation, during a procedure and during instrument disposal.

With respect to the generalizability of the case study findings to other hospitals in the province, the variation in the outcomes observed across the three cases following the integration of SENs suggests we would see variation in the levels of success with respect to declines in needlestick injuries across hospitals in the province. Despite variation in processes and outcomes, there were consistent themes across the three hospitals specific to implementation challenges, ongoing needlestick injuries and organizational constraints impeding further progress in this area. The consistency of these themes resonated with stakeholder groups who have attended presentations on the case study findings.

It is important to reflect on what can be achieved. Hospital C was able to reach a point where less than 20 injuries were being reported annually. There is likely considerable variation across hospital organizations in terms of the types of SENs provided, the quality of training and other supports, the health and safety culture and various other organizational characteristics (e.g., staffing, workload demands, crowding) that will influence injury risk. There does appear to be opportunities to further enhance prevention in this area, particularly among sites that continue to observe elevated rates of needlestick injuries. There is a need to strive to ensure that healthcare workers across the province have comparable access to the best safety devices and a safe work environment.

There are a number of recommendations that can be made to further needlestick injury prevention for both hospitals that have already integrated SENs and those that are in the process of doing so. In 2013, a European Union (EU) directive on sharps safety came into effect, providing member states three years to adopt the requirements outlined in the framework. There is an opportunity to share best practices and lessons learned regarding effective implementation practices with hospitals that are in the early implementation planning stage. For organizations that are in the process of integrating SENs, there is a need to invest in a comprehensive implementation planning process to support the successful integration of this technology (PSHSA 2012). This might involve looking for guidance on how best to establish an implementation team (The National Implementation Research Network 2015). Multidisciplinary implementation teams should undertake a comprehensive assessment or diagnostic analysis of some of the anticipated barriers and facilitators to practice change across the organization to inform the types of supports that will be needed (Moore et al. 2014).

This study has also suggested that there is a need for organizations who have already integrated SENs to continue to consider needlestick injury prevention as an important occupational health and safety issue and to promote sustained adherence to safer needle use. For example, organizations need to continue to collect sufficient information from ongoing needlestick injuries to identify which of the remaining pathways is most responsible for ongoing injury risk.

Despite a number of gaps in the effectiveness of SENs and ongoing reports of issues with safer needle use, needlestick injury prevention was not reported as an ongoing priority. There was a lack of awareness regarding ongoing injury risk and divergent views over whether ongoing injuries could be further reduced. Perceived financial constraints and competing health and safety priorities also appear to be influencing further progress in this area.

There are a number of small measures hospitals can adopt to continue to enhance prevention in this area, including opportunities to increase awareness that needlestick injuries continue to occur, which may involve opportunities to discuss recent injuries that have been reported during staff meetings to identify opportunities for prevention. The recommendations made here are in line with the Consensus Statement and Call to Action that was drafted by members of a multi-stakeholder steering committee attending the tenth anniversary of the

US Needlestick Safety and Prevention Act (International Healthcare Worker Safety Center 2010). The call to action acknowledged that while substantial progress has been made, preventable sharps injuries and blood exposures continue to occur. They argued that not all issues have been resolved by the enactment of regulatory standards to promote the uptake of SENs and that renewed commitment was needed to achieve further progress.

Conclusion

In conclusion, there appear to be a number of product limitations and environmental conditions that can help explain ongoing reports of needlestick injuries following the implementation of a regulatory standard. It is recognized that investment in this area will be challenged by other important health and safety priorities; however, a renewed interest in needlestick injury prevention among healthcare workers and managers is necessary to make further progress.

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