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Patent "Evergreening" of Medicine–Device Combination Products: A Global Perspective

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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.

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

Healthcare Reform Is Not Yet on the Horizon

Healthcare reform is on everyone's lips these days. Persistent calls for a "difference" and "change" are becoming louder. But will these calls reach a tipping point and precipitate fundamental changes in how provinces design healthcare delivery and how they pay for it?

A number of complex and related issues may signal that meaningful healthcare reforms are afoot. There needs to be a proverbial "burning platform" that would make the political risk of overdue reforms palatable to the provincial and territorial governments responsible for healthcare delivery and quality. There also needs to be a source of money to fund provinces' reforms. Finally, there needs to be some sort of a détente between governments' perspectives of federal involvement in healthcare.

The Burning Platform

Does the current status of healthcare delivery represent a burning platform for change among the political class? That is debatable. Accessing a family doctor has been difficult for many Canadians for years, and waiting for planned surgery in provinces' hospitals has been a decades-long problem. These enduring challenges have not triggered reforms in the past, although they are worse today than they have been in recent memory.

There may be other problems that create a burning platform. Perhaps the least likely among these are the provincial medical associations and nurses' unions. Both are unarguably influential in provincial capitals, yet they have not been clamouring for or using their leverage to initiate a massive overhaul of provincial healthcare delivery. Rather, and perhaps rightly centred on their members, their focus has been on more money and hiring more people.

The more likely spark of the burning platform will come if and when doctors leave provincial health insurance programs or people die in avoidable ways. It is possible that family doctors will opt out of provincial medical insurance programs en masse, such as the Ontario

Health Insurance Plan or BC Medical Services Plan – and create more and larger "concierge" medical services companies that operate outside the province's programs and policies, leaving fewer options for residents. Alternative sparks may include medical tragedies, taking the form of failed triages in emergency departments, excessive delays in treating cancers or missed hand-offs in life-saving situations. Minus these events, the burning platform may not be "hot" enough for the political risks of healthcare reforms.

The Money

Another pillar of healthcare reform is funding. There needs to be a very significant source of money to patch over "rough" spots in the delivery system's reform. The magnitude should be in the range of $40 billion for several years as a starting place, and it should be noted that this amount is probably an underestimate (Sutherland and Forest 2021). However, as healthcare spending approaches 45% of the provincial spending, new massive spending by provinces on healthcare would mean a significant increase in provincial taxes or deficits.

The other possible source of funding could be a deep-pocketed federal government. The federal government, however, has let it be known that it does not want the same old. Unlike unmeasured goals and lack of accountability inherent in the health accords and bilateral agreements, one should expect federal money to come with strings, possibly for buying measurable, effective and patient-centred change in healthcare delivery in provinces and territories. The federal government also wants some of the credit if it puts up the money.

The Politics

For provinces' governments, accepting conditions and sharing credit are both tall orders. This tension points to the barrier of federally funded healthcare reform: political alignment between the federal government and the provincial governments' willingness to accept conditions in return for federal money. Due to the distance between federal and provincial or territorial political ideologies regarding federal involvement in healthcare delivery in some settings, federal–provincial disputes may be unavoidable, and threading the needle between ideologies will be daunting (McIntosh and DeCorby 2022).

In my opinion, the elements that would trigger a meaningful healthcare reform are not yet in place. There is neither a burning platform nor a large pot of provincial money, and there is no commonality of interest between federal and provincial governments on positions of federal involvement in provincial healthcare delivery. Until there is a change in one or more of these three pillars, I do not expect much in the way of massive reform. However, these things may change on a dime.

In This Issue

This issue is led by a research article focusing on the implications of patents on medicine–device combination products. Based on analyses of patent information, this study, authored

by Beall et al. (2022), found device patent filings to be more common in Canada, suggesting that there is increasingly more attention given to upgrading delivery devices. The findings have immediate implications regarding whether pharmaceutical manufacturers have developed new or novel devices to deliver old drugs with marginal health benefits to the patient versus significant innovations that actually improve health.

Kornelsen et al. (2022) present a scoping review of the structure and function of rural health councils from the perspective of including patients in healthcare planning and decision making. The review found a number of common themes, including the ability to participate equally, the need for transparent processes and ensuring accountability for decisions. The authors conclude that for efforts to include patients and community members in rural healthcare planning and decision making to be successful, municipal, regional and provincial collaboration is required.

A comparative study between the hospitals in Ontario and European countries by Ivanković et al. (2022) assesses the extent to which performance data are used for decision making. Using a cross-sectional survey of hospital managers, the results find that Ontario hospital managers used performance information for decision making more than their European peers. The study highlights the ability to compare countries' hospitals and outlines barriers to incorporating data into decision making.

The final article in this issue explores how Ontario homecare workers were affected by changing emergency policy measures introduced during the COVID-19 pandemic. Using a qualitative design, this study by Hopwood et al. (2022) reports that new policies focused on rapid recruitment, education and training. The study found that these policies exacerbated concerns regarding consistency in training and education, though noting that more policy research is needed to address systemic issues inhibiting durable homecare workers' employment.

JASON M. SUTHERLAND, PhD
Editor-in-Chief

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ÉDITORIAL

Toujours pas de réforme des soins de santé à l'horizon

La réforme de la santé est sur toutes les lèvres ces jours-ci. Les appels aux « changements » se font de plus en plus forts. Mais ces appels atteindront-ils un point de basculement et donneront-ils lieu à des changements fondamentaux dans la façon dont les provinces conçoivent la prestation des soins de santé et paient pour cela?

Un certain nombre de problèmes complexes et connexes peuvent signaler que des réformes significatives des soins de santé sont en cours. Il faut qu'il y ait une « situation d'urgence » qui rende le risque politique des réformes acceptable aux yeux des gouvernements provinciaux et territoriaux responsables de la prestation et de la qualité des soins de santé. Il faut aussi une source d'argent pour financer les réformes provinciales. Enfin, il doit aussi y avoir une sorte d'entente entre les perspectives des divers gouvernements sur la participation fédérale aux soins de santé.

La situation d'urgence

L'état actuel de la prestation des soins de santé représente-t-il une situation d'urgence qui justifierait le changement aux yeux des politiciens? Cela est discutable. Pour de nombreux Canadiens, l'accès à un médecin de famille est difficile depuis des années. L'attente pour une chirurgie planifiée dans les hôpitaux des provinces est un problème qui dure depuis des décennies. Ces défis persistants n'ont pas déclenché de réformes dans le passé, bien qu'ils soient aujourd'hui pires qu'ils ne l'ont été de mémoire récente.

Il y a peut-être d'autres conditions qui peuvent amener une situation d'urgence. Parmi celles-ci, les moins probables viennent sans doute des associations médicales et des syndicats d'infirmières. Les deux institutions sont incontestablement influentes dans les capitales des provinces, mais elles n'ont pas mis a profit leur influence pour lancer une refonte massive de la prestation des soins de santé. Au lieu de cela, et puisqu'elles sont axées sur leurs membres, leur objectif a été de réunir plus d'argent et d'embaucher plus de personnes.

Le déclencheur le plus probable de la situation d'urgence viendra, le cas échéant, lorsque les médecins quitteront les programmes provinciaux d'assurance maladie ou lorsque des décès évitables se produiront. Il est possible que les médecins de famille se retirent en masse des programmes provinciaux d'assurance maladie, tels que le Régime d'assurance-santé de l'Ontario ou le Régime de services médicaux de la Colombie-Britannique, et créent de plus en plus de sociétés de services médicaux « de conciergeries » qui agissent en dehors des programmes et des politiques provinciales, laissant moins de choix pour les résidents. Le déclencheur pourrait aussi venir de tragédies médicales, comme des triages ratés dans les services d'urgence, des retards excessifs dans le traitement du cancer ou des transferts manqués dans des situations vitales. Sans ces événements, la situation d'urgence ne sera peut-être jamais assez critique face aux risques politiques qui émanent des réformes des soins de santé.

L'argent

Un autre pilier de la réforme des soins de santé est le financement. Il doit y avoir une source de financement très importante pour corriger les points « difficiles » de la réforme du système de prestation. L'ampleur devrait être de l'ordre de 50 milliards de dollars pendant plusieurs années comme point de départ, et il convient de noter que ce montant est probablement sous-estimé (Sutherland et Forest 2021). Cependant, alors que les dépenses de santé frôlent 45 % des dépenses provinciales, de nouvelles dépenses massives en santé signifieraient une augmentation significative des impôts ou des déficits provinciaux.

L'autre source de financement possible pourrait être la générosité du gouvernement fédéral. Le fédéral a toutefois fait savoir qu'il ne voulait pas revenir aux mêmes vieux schémas. Contrairement aux objectifs non mesurés et au manque de responsabilité inhérent aux accords sur la santé et aux accords bilatéraux, on devrait s'attendre à ce que l'argent fédéral vienne avec des conditions, par exemple pour procéder à des changements mesurables, efficaces et centrés sur le patient. Le gouvernement fédéral veut aussi une partie du crédit s'il investit.

La politique

Pour les gouvernements provinciaux, accepter les conditions et partager le crédit constituent deux défis de taille. Cette tension met en évidence l'obstacle d'une réforme des soins de santé financée par le gouvernement fédéral, à savoir l'alignement politique entre le gouvernement fédéral et la volonté des gouvernements provinciaux d'accepter des conditions en échange de l'argent du fédéral. En raison de la distance entre les idéologies politiques fédérales et provinciales ou territoriales concernant la participation fédérale à la prestation des soins de santé dans certains contextes, les différends fédéraux–provinciaux pourraient s'avérer inévitables. Dans ce contexte, il sera décourageant de tenter de faire le lien entre les diverses idéologies (McIntosh et DeCorby 2022).

Selon moi, les éléments qui déclencheraient une réforme significative de la santé ne sont pas encore en place. Il n'y a ni situation d'urgence, ni grande cagnotte d'argent provincial, pas plus qu'il n'y a d'intérêt commun entre les gouvernements fédéral et provinciaux sur la place du fédéral dans la prestation des soins de santé. Tant qu'il n'y aura pas de changement dans un ou plusieurs de ces trois piliers, je n'attends pas grand-chose d'une réforme massive. Cependant, ces choses peuvent changer en un rien de temps.

Dans le présent numéro

Ce numéro commence par un article de recherche axé sur l'implication des brevets sur les produits mixtes de médicaments et matériels médicaux. Basée sur des analyses d'informations sur les brevets, cette étude, rédigée par Beall et al. (2022), permet de constater que le dépôt de brevets pour matériel médical est plus courant au Canada, ce qui suggère qu'on accorde de plus en plus d'attention à la mise à niveau des dispositifs médicaux. Les résultats ont des répercussions immédiates quant à savoir si les fabricants de produits pharmaceutiques ont développé des dispositifs nouveaux ou novateurs afin d'administrer des médicaments déjà connus avec des avantages marginaux pour la santé du patient, par rapport aux vrais innovations qui améliorent réellement la santé.

Kornelsen et al. (2022) présentent un examen de la portée de la structure et de la fonction des conseils de santé ruraux du point de vue de l'inclusion des patients dans la planification des soins de santé et dans la prise de décision. L'examen révèle un certain nombre de thèmes communs, notamment la capacité de participer sur un pied d'égalité, la nécessité de processus transparents et la responsabilisation des décisions. Les auteurs concluent que les efforts visant à inclure les patients et les membres de la communauté dans la planification et dans la prise de décisions en matière de soins de santé en milieu rural nécessitent une collaboration municipale, régionale et provinciale.

Pour sa part, une étude comparative entre les hôpitaux de l'Ontario et des pays européens par Ivanković et al. (2022) évalue dans quelle mesure les données de performance sont utilisées pour la prise de décision. À l'aide d'une enquête transversale auprès des gestionnaires d'hôpitaux, les résultats révèlent que les gestionnaires des hôpitaux ontariens utilisent plus que leurs homologues européens l'information sur le rendement pour prendre des décisions. L'étude met en évidence la capacité de comparer les hôpitaux des pays et décrit les obstacles à l'intégration des données dans la prise de décision.

Le dernier article du présent numéro explore comment les travailleurs des soins à domicile de l'Ontario ont été touchés par la modification des mesures politiques d'urgence introduites pendant la pandémie de COVID-19. Au moyen d'un concept qualitatif, l'étude de Hopwood et al. (2022) indique que les nouvelles politiques se sont concentrées sur le recrutement rapide, l'éducation et la formation. L'étude révèle que ces politiques ont exacerbé

les préoccupations au sujet de la cohérence de la formation et de l'éducation, tout en notant que davantage de recherches sur les politiques sont nécessaires pour résoudre les problèmes systémiques qui entravent l'emploi durable des travailleurs à domicile.

JASON M. SUTHERLAND, PhD
Rédacteur en chef

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RESEARCH PAPER

Patent "Evergreening" of Medicine–Device Combination Products: A Global Perspective

« Perpétuité » des brevets pour les produits mixtes de médicaments et dispositifs médicaux : un aperçu mondial

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Abstract

Background: Patenting medicine-delivery devices (inhalers and pens) is controversial when it extends market protections beyond that of the underlying therapeutic agent. We evaluated how common device patenting is, internationally.

Method: Using a product sample (n = 88) and an international patent database, we assessed the issue's scope.

Results: When comparing the 88 patent portfolios for each product in each country, Canada was found to be among the most impacted, with 90% of the portfolios containing at least one device patent and 35% of the portfolios containing device patents exclusively.

Conclusion: Patenting of delivery devices impacts major pharmaceutical manufacturing centres worldwide. International consensus among stakeholders (regulators and payors) is needed on which device modifications represent meaningful clinical value.

Résumé

Contexte : Le brevetage des dispositifs d'administration de médicaments (inhalateurs et auto-injecteurs) suscite la controverse quand il étend la protection du marché au-delà de celle de l'agent thérapeutique sous-jacent. Nous avons évalué à quel point le brevetage des dispositifs est courant à l'échelle internationale.

Méthode : À l'aide d'un échantillon de produits (n = 88) et d'une base de données internationale sur les brevets, nous avons évalué la portée du problème.

Résultats : Après comparaison des 88 portefeuilles de brevets pour chaque produit dans chaque pays, le Canada figure parmi les plus touchés, avec 90 % des portefeuilles contenant au moins un brevet de dispositif médical et 35 % des portefeuilles contenant exclusivement des brevets de dispositif médical.

Conclusion : Le brevetage des dispositifs d'administration de médicaments a un impact sur les principaux centres de fabrication pharmaceutique dans le monde. Il est nécessaire de trouver un consensus international entre les parties prenantes (régulateurs et payeurs) au sujet des modifications de dispositifs qui représentent une réelle valeur clinique.

Introduction

Manufacturers of medicine–device combination products (e.g., inhalers, injector pens and patches containing one or more pharmaceuticals) often make successive modifications to the delivery device for a variety of reasons (e.g., to improve performance and for convenience) after the original regulatory approval. In doing so, patent protection on revisions of the device may be obtained, which would extend well beyond any patents protecting the active drug ingredient or its therapeutic formulation or the original device. The result is a medicine–device combination product with a longer period of market exclusivity, even when patents on the medication itself have long expired. This practice has become a point of controversy in Canada and several countries around the world (Blüher et al. 2019; Christie

et al. 2021; Daubner-Bendes et al. 2021; Ferrusi et al. 2009; Kaplan and Beall 2016; Moir 2021; Radelli 2021; Simoens 2008; Strohbehn et al. 2021), particularly when the patent protection garnered by the modified device confers more years of market protection than the patents protecting the medication itself.

For example, high prices on the EpiPen, which is used to deliver lifesaving (and patent-free) epinephrine during severe allergic reactions, caused major accessibility limitations in the US after recurring price hikes. Originally approved in 1987 with an older version of the delivery device, Mylan brought a new EpiPen into the market in 2011, which is protected by patents currently set to expire in 2025. This new set of patents pertained only to the injector pen (Duhigg 2017; Eunjung Cha 2016; Kasperkevic 2016; Rubin 2016). Among the new patented features of the injector pen were two locking assemblies "to hold the needle cover in a locked retracted and extended position" (US7449012) (Google Patents n.d.). While this assembly may be beneficial to patients in terms of safety, it also contributes to constrained access, especially given that epinephrine has been used safely for more than a century using other delivery devices.

Similar to the EpiPen, 14 other US Food and Drug Administration (FDA)-approved medicine–device combination products had patent protection for the delivery device alone, extending the period of market exclusivity for the medicine–device combination by a median of 9.0 years, including another epinephrine pen (AUVI-Q) with 14.2 years of device patent protection (Beall et al. 2016). The purpose of the current study is to extend previous country-specific investigations (Beall and Kesselheim 2018; Beall et al. 2016) of device patents to evaluate (a) the international scope of delivery-device patent filings, (b) how commonly combination products only have patent filings for the device in countries and regions worldwide and (c) to understand which countries or regions are potentially the most impacted by this issue based upon such patent filings.

Methodology

Overall design

Using the European Patent Office's (EPO's) International Patent Documentation (INPADOC) database (EPO 2022), we linked all the publication numbers associated with 88 combination products delivered via an inhaler, injector pen or patch that were identified through a previous survey of the FDA patent register (also known as the "Orange Book") to locate all related patent applications globally. For each country and region globally contained in the INPADOC, we then calculated the proportion of the combination products in our sample that had (1) at least one device patent application (among all the applications for that same product) and (2) only device patent applications (i.e., no applications were found for the substance or formulation).

Ethics

Institutional review board approval for this study was not required as no patients were involved. All data analyzed are publicly available online.

Data

We began with a previously published US dataset of medicine–device combination products (observation window from 2000 to 2016) with patents pertaining predominantly to the delivery device (i.e., the patent publication's title pertained to the device itself) (Beall and Kesselheim 2018). We included only inhalers, injector pens and patches (n = 88 of 144 products) as these represented the most common types of combination products. This dataset includes information about the products themselves (e.g., their FDA approval date), and links the patent to one of three categories: (1) a device patent (i.e., the patent title refers to the delivery device), (2) a substance patent (i.e., the patent covers the active ingredient or therapeutic compound) or (3) a formulation patent (i.e., the patent covers any other feature of the product not covered by the other two categories, such as its formulation, manufacturing process or indication). We augmented this dataset with the products' therapeutic classes using the first level of the World Health Organization's Anatomical Therapeutic Chemical Classification System (WHO 2021).

We further compiled an international patent landscape by entering all US patent numbers from our previously published dataset (Beall and Kesselheim 2018) into the EPO's INPADOC patent application database (EPO 2022); this linkage is necessary because there is no equivalent medicine patent register for Europe or elsewhere (Health Canada has a similar patent listing system, but device patents for combination products are not listable by law [Government of Canada 2021]). In doing so, we derived the INPADOC extended patent family for each FDA-listed patent (EPO 2017). INPADOC's patent families include all patent applications internationally related to the same initial (i.e., "priority") patent application: in other words, these include all applications internationally that can be traced back to the initial "parent" application made by the inventors in one jurisdiction in the world before they proceeded to file a trail of subsequent "child" filings elsewhere in the world (EPO 2022). The data extraction from INPADOC was performed in April 2020. Note that the international patent data extracted from INPADOC included both national and regional applications, and that not all patent applications translate to granted patents. For the present purposes, the term "jurisdiction" means both individual countries and regional patent regimes, wherein a single filing can be adopted by all countries within that consortium, including the African Regional Intellectual Property Organization (ARIPO), the Eurasian Patent Organization (EAPO), the EPO and the Organisation Africaine de la Propriété Intellectuelle (OAPI) (a patent regime for francophone African countries).

For national patent applications, we categorized countries according to their respective World Bank Classifications as high income, upper middle income, lower middle income or

low income (World Bank 2021). Using data from the article by Gapminder (2021), we also estimated the healthcare market size for all national jurisdictions by multiplying a country's per capita income by its population and by its percent national expenditure on healthcare (Beall et al. 2017).

Analysis

We first report descriptive statistics on our product sample dataset (n = 88), including the number of combination products, the type of product and the product's therapeutic areas. We then report on the number of patent applications found in INPADOC for the 88 products, as well as the range of jurisdictions in which they were located.

For each patent jurisdiction internationally, we calculated the proportion of the 88 combination products that had at least one patent application solely directed to the device. Then, we calculated the proportion of the same 88 combination products that only had device patent filings and no other patent filings of any other kind (i.e., no unexpired substance or formulation patents were located during our observation period). We plotted our results from these two analyses on a scatterplot to visualize how jurisdictions around the world compare in terms of (1) how commonly combination product patents in the US had at least one unexpired foreign device patent filing and (2) how commonly those combination products only had foreign device patent filings. When both indicators were high for a country or region, we reasoned that those areas would have an especially high stake in the debate surrounding delivery device innovation. All analysis programming was performed in R using TidyVerse (Tidyverse 2021); plots were generated using ggplot2 and ggrepel (Slowikowski 2021).

Results

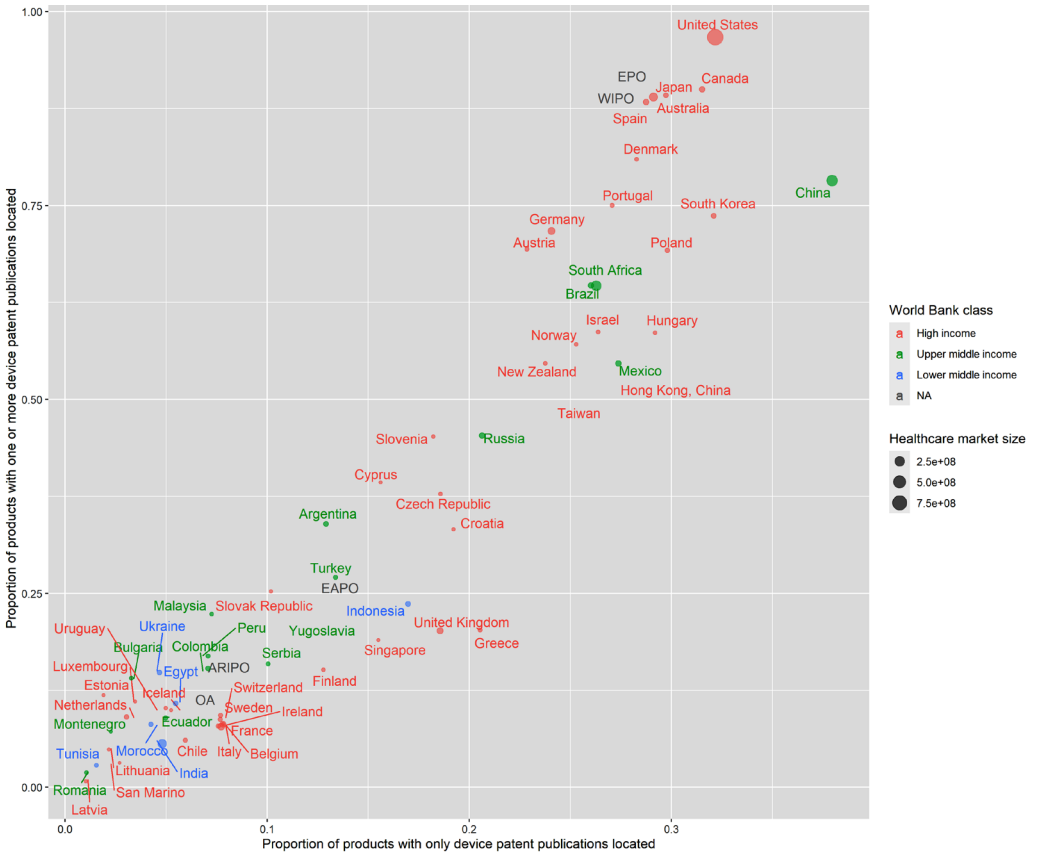
Of the 88 patented medicine–device combination products, 41 (47%) were inhalers, 31 (35%) were injector pens and 16 (18%) were patches. These products covered eight therapeutic areas, the largest of which were for respiratory disorders (37 devices, 42%), such as chronic obstructive pulmonary disease (COPD) and asthma; alimentary tract and metabolism disorders (24 devices, 27%), such as diabetes; and nervous system disorders (14 devices, 16%), including drugs for assisting with opioid dependence or tobacco cessation. We retrieved 7,622 international patent applications from INPADOC for the 431 FDA-listed patents relating to the 88 products. These patent publications were tied to 74 countries and five regional patent jurisdictions.

Proportion of combination products with at least one device patent filing

A number of countries and regions had similarly high proportions of products with device patent applications, particularly if they were in the higher income bracket (Figure 1: y-axis). For example, 90% (79/88) of the products had at least one device patent publication in Canada and the EPO (Table 1, available at longwoods.com/content/26973). This same

measure was 87% (78/88) in Australia, 87% in Japan (78/88) and 97% (85/88) in the US. Most of the original combination product sample also had at least one device patent publication in certain upper-middle-income countries (Figure 1: y-axis), including Brazil (65%, 57 products), China (78%, 69 products), South Korea (74%, 65 products) and South Africa (65%, 57 products) (Table 1). There were many other countries and regions where substantially fewer combination products had at least one patent publication specific to the device, such as ARIPO with just 14% (12/88) (Table 1; Figure 1: y-axis).

FIGURE 1. Proportion of product sample (n = 88) with at least one device patent filing versus device-only patent filings located in various locations around the world



The y-axis displays the proportion of the product sample (n = 88) in which at least one device patent filing was found in that country or region. The x-axis shows the proportion of the product sample (n = 88) for which only device patent filings were found in that country or region.
Countries are coloured by their World Bank income category and by the size of their healthcare sector, which was calculated by multiplying their per capita gross domestic product and their population size by their proportion of national spending on healthcare. As these same calculations were not possible for the regional patent regimes, only their names are displayed in the appropriate place in the plot.

Proportion of combination products with device-only patent filings

About one-third of the products (28/88) had device-only patent filings, depending on

TABLE 2. Number and proportion of products with device-only patent publications located in countries and regions around the world (n = 88)

Category	Count of jurisdictions in sample	Count of products with device-only patents detected
Income		
High	43	18%, n = 16 of 88 (IQR: 8–27%; n = 7–24)
Upper middle	22	11%, n = 10 of 88 (IQR: 7–22%; n = 6–19)
Lower middle	9	5%, n = 4 of 88 (IQR: 5–6%, n = 4–5)
Low	0	n = 0
Key countries		
Australia	1	30%, n = 26 of 88
Brazil	1	26%, n = 23 of 88
Canada	1	32%, n = 28 of 88
China	1	38%, n = 33 of 88
Japan	1	30%, n = 26 of 88
Korea	1	32%, n = 28 of 88
South Africa	1	26%, n = 23 of 88
United States	1	32%, n = 28 of 88
Regional patent filings		
ARIPO	1	8%, n = 7 of 88
EAPO	1	15%, n = 13 of 88
EPO	1	28%, n = 25 of 88
OAPI	1	7%, n = 6 of 88
WIPO (PCT)	1	28%, n = 25 of 88

Where device patents were located on one or more products within each jurisdiction, this analysis calculated the proportion of the number and of the product sample with only device patent filings. Products with only device patents are typically older products containing therapeutic substances and formulations whose patents expired before 2000 (i.e., the earliest patent register edition captured by this study).
ARIPO = African Regional Intellectual Property Organization; EAPO = Eurasian Patent Organization; EPO = European Patent Office; IQR = interquartile range; OAPI = Organisation Africaine de la Propriété Intellectuelle; WIPO (PCT) = World Intellectual Property Organization (Patent Cooperation Treaty).

the country or region (Table 2). For example, comparable proportions of products with device-only patent filings were observed for Australia (30%, n = 26 products), Brazil (26%, n = 23 products), Canada (35%, n = 28 products), China (38%, n = 33 products), the EPO (28%, n = 25 products), Japan (30%, n = 26 products), South Korea (32%, n = 28 products), South Africa (26%, n = 23 of 88) and the US (32%, n = 28 products). However, these proportions were somewhat higher than in other countries (Figure 1: x-axis) particularly in lower income settings, such as ARIPO (just 7 of the 88 products had device-only product patent publications).

Jurisdictions with device-only patent filings

Combination products with device-only patent filings were especially common in Australia, Brazil, Canada, China, the EPO, Japan, South Korea and South Africa (Figure 1: both x- and y-axes). Examples of products with device-only patent filings located in most, or all, of these top jurisdictions were typically for asthma, COPD, anaphylaxis and diabetes (Table 3, available at longwoods.com/content/26973).

Discussion

Canada is among those nations with the highest patent application filings pertaining to combination products' delivery devices worldwide, along with Australia, Brazil, China, Europe (EPO), Japan, South Korea, South Africa and the US. These areas of the world are critical centres for branded and generic pharmaceutical manufacturing for both domestic markets and export. Thus, concerns about manufacturers restricting access to older essential drug products using device patents is an international issue. Key stakeholders in these countries (e.g., public and private payors, drug regulators and health technology assessment authorities) should work collaboratively to build consensus on how to delineate the amount of innovation that would justify issuing patents on devices that deliver essential medicines, granting regulatory approval and providing reimbursement through public and private payors (Blüher et al. 2019; Daubner-Bendes et al. 2021).

The main reason why our searches only found patent applications pertaining to the delivery device for certain products is that those products are newer generations of older combination products. Any patents protecting the drug substances within these older combination products must have expired before 2000 and were thus not listed in the Orange Book to be identified by our study. Previous research has demonstrated that the life course of pharmaceutical products typically begins with the discovery and patenting of a new therapeutic substance, followed by the optimization and patenting of the substance formulation, followed by the optimization and patenting of any delivery devices (if relevant) (Beall and Kesselheim 2018; Beall et al. 2016). As a specific potentially patentable entity, delivery devices have many mechanical components, meaning it is possible to keep changing them, which could lead to many patent filings that can stretch over several decades (e.g., from an injector pen, to an injector pen with an analogue dose counter, to an injector pen with a digital dose counter, to an injector pen with a digital dose counter with audio, to an injector pen with a digital dose counter and Bluetooth connectivity to an app).

New versions of drug delivery devices can provide enhanced safety or convenience to patients. However, a superior clinical value should be demonstrated in clinical trials and not simply be assumed because changes to device technology can also disrupt patient care as healthcare providers must educate themselves and their patients on the use of the new version of the product. Discontinuation of older versions of devices can also interrupt patient adherence. Furthermore, some new versions of delivery devices have been recalled for faulty design, which also puts patients at risk for bad outcomes (Beall and Kesselheim 2018). In countries,

such as Canada, where healthcare delivery is a provincial responsibility, it is important to recognize the potential impact on patients and providers downstream. Key stakeholders, therefore, are not limited to actors at the federal level.

From an economic perspective, updating existing products' delivery devices increases product cost and the cost to society. The process of updating delivery devices may involve costly clinical trials before their approval, which must then be considered by regulatory authorities (an additional cost to society). Manufacturers must upgrade and retrofit equipment to produce the new delivery device, and quality assurance staff must be retrained. Should manufacturers withdraw original device designs from the market, the already, especially lengthy, regulatory process gets more complicated for generic drugmakers seeking to demonstrate equivalence with the now-discontinued products, for a variety of reasons (e.g., the regulatory body may be required to conduct an investigation to ensure that the product discontinuation was not made for safety reasons). Generic manufacturers seldom pursue drug-device markets, such as for inhalers, and in the absence of competition, drug prices can remain elevated (Conrad and Lutter 2019; Feldman et al. 2022). The additional patents, if challenged, must be defended in court by lawyers from both sides of the dispute. All activities such as these have cost implications that are passed onto and absorbed by patients and payors. Even a small increase in cost on a combination product can have a large impact at the health system level over time, deferring resources that could have been better spent elsewhere. This is particularly important for non-high-income settings such as those noted by our study (e.g., Brazil and South Africa). For example, an increase of just $0.25 per unit for the 36 million Americans living with an asthma or COPD diagnosis could cost upwards of $108 million per year, assuming an average of one new inhaler per month per patient. In countries such as Canada, where health technology assessment (HTA) plays an important role at the federal and provincial levels, HTA methodologies that evaluate the value of new versions of products with newly updated delivery devices against the value of older versions may play an important role in reimbursement decisions. Such evaluations are critical because new versions of combination products may not have superior clinical value for cost as compared with the original.

From an innovation policy perspective, other drug development activities might be overlooked in favour of the redevelopment of delivery devices. For example, developing new therapeutic substances occurs many years prior to regulatory approval. The substance is typically patented, then undergoes clinical trials, is considered for approval by regulatory authorities and is then approved. By the time that the product reaches the market, an average of 10 to 12 years of the 20 years of patent protection have already expired (Beall et al. 2019; Lexchin 2021). By contrast, modification of delivery devices for an existing product is more expedient, leading to fewer years of patent life lost during the pre-market phase. The upshot is that relatively more post-market patent protection is provided for delivery-device redevelopment as compared to the development of the therapeutic ingredients that they deliver. This sends a signal to developers to continue to devote increasingly more attention to

delivery-device upgrades, which may divert some resources away from other forms of pharmaceutical research and development that may have had a greater potential for a meaningful impact in those same clinical areas. Previous research has demonstrated that the number of device-only patents has come to far outnumber any other type of patent protection on these products in more recent years (Beall and Kesselheim 2018; Feldman et al. 2022). While alternatives or changes to the current patent system have been proposed elsewhere that would limit such activity (Beall et al. 2021; Feldman 2019; Vincent Rajkumar 2020), coordinating legal reform internationally would prove extremely challenging, particularly given the entrenchment of international trade agreements (e.g., the World Trade Organization's Trade-Related Aspects of Intellectual Property Agreement [WTO n.d.]). More expedient solutions may involve key stakeholders (e.g., major public and private payors) in the countries identified by our study refraining from reimbursing low-value products, including combination products that do not add clinical benefit beyond that of the original version of the device.

Our study has some important limitations. First, we did not account for regulatory exclusivities (e.g., drug regulatory bodies in some countries are barred from approving generic equivalents for a certain number of years) and other market protections (e.g., trade secrets) that may impact the combination product innovation landscape aside from patents. Second, we did not investigate predictors of where device-only patents have been filed, but the patterns observed in Figure 1 appear consistent with those noted by previous research on non-combination products, with market size and pharmaceutical manufacturing capacity being some of the most influential factors for where more patents tend to be filed (Attaran 2004; Beall et al. 2017). Third, because our methodological approach was to begin with the US market, to identify products with device patents and to extend the geographical reach by using INPADOC, our study is US- and Europe-centric. While INPADOC's patent data availability for other countries such as Australia and Canada is excellent, coverage of some key middle-income countries with high pharmaceutical manufacturing capacity, such as India, is limited. Fourth, as our US dataset had a patent register observation window extending from 2000 to 2016, many non-device patents for older products filed before 2000 would not be captured by our study. Therefore, our study has only captured the end stages of those products' innovation life courses, in which the only remaining innovation activities pertain to attempts to optimize the delivery device. Fifth, as our product sample was US-centric, many of the products in our sample may not be approved (or be relevant to general practice) in all countries as several have very specific indications in specialty care (e.g., a second-line therapy for polyarticular juvenile idiopathic arthritis). Lastly, while this study focuses on patent protection, we acknowledge the many other important challenges to generic market entry and motives for continuous delivery-device improvement, aside from intellectual property (Greene and Riggs 2015; Socal and Greene 2020). While patents may restrict a subsequent entrant from introducing an identical medicine–device combination product, this would not be the case for products for which both the device and the medicine have expired patents. For example, the originator EpiPen was introduced in the 1980s; current versions with active patents

are not the originator device, but newer versions of it. In this case, there is no patent barrier to introducing a generic delivery device, but there are other factors that discourage other market entrants, such as competition with an originator product that has benefitted from substantial marketing during its period of market exclusivity. Future research should seek to delineate patent rights from other barriers (financial, clinical evidence or others) and market forces that may disincentivize generic market entry.

Conclusion

Controversies over when pharmaceutical manufacturers have developed a new device to deliver an old drug with marginal health benefits to the patient is an international issue as the same patent families on such devices are located in important pharmaceutical markets and manufacturing centres worldwide, including Australia, Brazil, Canada, China, Europe, Japan, South Korea, South Africa and the US. While some countries are insulated from the same level of high prices on pharmaceutical products as the US (through price control policies), the same concerns still apply regarding unnecessary costs, disruption of patient care and the signal sent by the innovation system for manufacturers to continue to devote increasingly more innovation attention to delivery device upgrades. Stakeholders from within these key locations around the world should work together to build consensus on when patents for updated delivery devices should be supported through the granting of additional patents, approvals by regulatory authorities or reimbursement by public and private payors, including those at provincial or state levels.

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Competing Interests

Aaron S. Kesselheim has reported serving as an expert witness in a case against Gilead Sciences, Inc. related to patents of its Tenofovir-containing products.

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RESEARCH PAPER

Optimizing Community Participation in Healthcare Planning, Decision Making and Delivery through Rural Health Councils

Optimiser la participation communautaire à la planification, à la prise de décision et à la prestation des soins de santé par le biais des conseils de santé ruraux

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Abstract

Background: The aim of this scoping study was to understand the optimal structure and function of rural health councils (RHCs).

Methods: The study used the scoping review methodology, informed by both Arksey and O'Malley's (2005) framework and the *Joanna Briggs Institute Reviewers' Manual* (The Joanna Briggs Institute 2015).

Findings: Evidence demonstrates that the functions of RHCs range from identifying healthcare issues and priorities to local resource management. Enabling structures included the use of skills-based merit matrices to determine membership.

Conclusion: We found evidence on how to build effective models to support patient involvement in healthcare planning and service delivery to lead to care that reflects the needs of rural communities.

Résumé

Contexte : L'objectif de cet examen de portée est de comprendre la structure et la fonction optimales des conseils de santé ruraux (CSR).

Méthode : L'étude a utilisé la méthodologie de l'examen de portée, éclairée par le cadre d'Arksey et d'O'Malley (2005) ainsi que par le *Joanna Briggs Institute Reviewers' Manual* (The Joanna Briggs Institute 2015).

Résultats : Les données montrent que les fonctions des CSR vont de l'identification des problèmes et des priorités en matière de soins de santé à la gestion des ressources locales. Les structures habilitantes comprennent l'utilisation de matrices de mérite fondées sur les compétences pour déterminer l'adhésion.

Conclusion : Nous avons trouvé des données sur la manière de créer des modèles efficaces pour soutenir la participation des patients à la planification des soins de santé et à la prestation de services afin d'offrir des soins qui reflètent les besoins des communautés rurales.

Background

Involving patients in healthcare activities has emerged as an important priority in many healthcare systems internationally (Australian Commission on Safety and Quality in Health Care n.d.; NHS England 2017; Patient Safety Network 2019; WHO 2016). Although rooted in evidence showing improved outcomes when patients are involved in their own care (Arnetz et al. 2009; Loh et al. 2007; Rachmani et al. 2002), there is also a growing recognition of the important role that patients, families and caregivers play when they "… participate in quality improvement and healthcare redesign" (British Columbia Ministry of Health 2015: 2; Ontario Ministry of Health and Long-Term Care 2015). Underscoring this is the awareness of the need for productive relationships among researchers, healthcare professionals and policy makers. It is a short, although essential, step to recognize "community" – by either place or intent – as synonymous with patients and applicable to the larger patient-oriented frameworks driving healthcare improvement. This is particularly important where participation in health planning is understood through a rural lens, and the community-oriented, highly relational nature of rural communities is recognized.

Rural health councils (RHCs) or health boards are catchall phrases that refer to committees, boards and councils carrying out rural healthcare planning, decision making and/or delivery functions. Historically, prior to the widespread regionalization of health services in Canada, health boards existed as a mechanism for hearing and responding to local health concerns, which tend to be regionally variable. They were disbanded in most jurisdictions due to the cumbersome and expensive infrastructure needed to maintain them (Kornelsen and Grzybowski 2005) and in British Columbia (BC) prior to the advent of regional health

authorities. This shift in healthcare administration from a centralized entity to new regionally responsive organizational structures, echoed in most jurisdictions across Canada and elsewhere, has paradoxically increased the centralization of decision making as it concentrates decision making in a particular region. Planning and administrative efforts are applied to areas larger than individual communities. Likewise, although the original intent was to embrace democratic participation through the involvement of community members in decision making and planning to improve the health of residents, the further regional centralization, in fact, reduced such participation (Kornelsen and Grzybowski 2005).

The principles underscoring citizen-patient-community (CPC) engagement rest in a tacit understanding that health services and policy evidence must be situated in a framework inclusive of the knowledge yielded from science-based methodologies but extended also to the recognition of individual, local and community, organizational and holistic knowledge (Brown et al. 2010). In this way, incorporating CPC voices is part of a paradigm shift away from normatively valuing scientific evidence (easily measurable) at the cost of alternate forms of knowledge (not easily measurable). CPC experience is at the core of this new paradigm, and patients are encouraged to be active participants in their own care. For this vision to actualize, however, CPC involvement must be met by a system recognition of the value of such involvement and established mechanisms and accountabilities for including the yields of patient voices in decision making. Actualizing these principles is essential to ensuring authentic CPC representation in policy development.

In this article, we review relevant literature on the structure and function of health councils through a rural lens. We believe that this literature provides value to system planning across varied rural jurisdictions.

Method

Research objective and question

This pragmatic review was undertaken to strengthen our understanding of the value of CPC participation in healthcare planning, decision making and delivery through RHCs. The topic was identified through a survey by the Centre for Rural Health Research at the University of British Columbia to understand the healthcare priorities of rural residents across BC (RER 2019). We made the strategic decision to focus on RHCs due to the historical resonance with the jurisdiction in which the scoping review was undertaken. That is, we had ongoing input from the members of a robust patient advisory committee, many of whom had awareness of and direct experience with hospital boards and health councils. The research question was as follows: What is the structure, function and impact of RHCs that include patient communities in healthcare planning, decision making and delivery activities? As no human participants were involved in this review and all materials included were available in the public domain, an ethics board approval was not necessary.

Scoping review method

This literature review used a scoping methodology, informed by both Arksey and O'Malley's (2005) methodological framework and the *Joanna Briggs Institute Reviewers' Manual* (The Joanna Briggs Institute 2015) for the conduct of scoping studies. We included publications with the following criteria: those focused on systemic and sustained mechanisms of community involvement or leadership in healthcare planning, decision making or delivery through health councils; those from high-income countries as defined by the World Bank (2018) to maximize applicability to the Canadian context; those published after 1990; and English-language publications. Due to a lack of transferability, we eliminated publications describing *ad hoc* or one-off initiatives for patient involvement in health service planning, decision making or delivery through health councils. The search terms and concepts are described in Table 1. Appendix 1 (available online at longwoods.com/content/26972) describes the search strategy.

Data extraction process

The data extraction process – or "charting the results," as it is referred to in scoping studies – is intended to produce a summary of the results of each included publication, guided by the question and the objective of the scoping study. Two reviewers (CC and contributor Zeena Yesufu) performed data extraction of the included literature using a data extraction form that was developed by the study team (Table 2). The first author (JK) reviewed the data abstraction forms and resolved any discrepancies through a review of the full text of the article and a discussion with team members.

Findings

Key findings from this review describe the evidence gathered on the *structure* and *function* of RHCs, recognizing that "one size does not fit all" and that roles and applications may be different across equally effective models. There are commonalities, however, which are discussed in the following sections.

The function of RHCs

The literature described the activities of council models from international jurisdictions where CPC participation was integral to their composition and operation (Andrews et al. 2014; Bismark and Studdert 2014; Greene 2002; Hemingway and MacLeod 2004; Hudson 1996; Hurley et al. 1994; Karash 2016; Knoble 1993; Kralewski and Moscovice 1992; Larson 1999; Longley 1999; McClean and Trigger 2017; Minister's Action Committee on Health System Reform 1994; Nelson and Gauss 2016; Pickard et al. 2002; Riley and Elder 1991; Robinson et al. 2003; Rosenthal et al. 1991; Tritter and McCallum 2006; Veronesi and Keasey 2012; Weiner and Alexander 1993; Wilson et al. 1993; Wright 2013). As members of councils, there were multiple health service activities in which CPCs might participate, including but not limited to identifying and defining healthcare issues and

TABLE 1. Search concepts

Concept	Keywords	Reasoning
Rural	Keywords: Rural* MeSH: Rural Health Rural Population Rural Health Services Hospitals, Rural	The objective of the scoping study is to understand the value of community participation in healthcare planning, decision making and delivery through RHCs, specifically. For this reason, the following keywords and subject headings were applied to limit the search to publications that describe rural and remote populations and health contexts. Note that this concept was not applied during citation searching activities.
Community participation	Keywords: Community*, Public*, Consumer*, Citizen*, Local, Patient*, User*, "Civil Society" MeSH: Community Participation Community-Institutional Relations	The "community participation" concept, together with the "governing board" concept, aimed to capture the literature that addressed community involvement in healthcare activities and relations with health service organizations.
Governing board	Keywords: "Foundation Trust*", (Health* OR Hospital* OR Govern* OR District* OR Regional) ADJ3 (Authorit* OR Council* OR Board*) MeSH: Governing Board Health Planning Organizations	This concept aimed to capture the literature that addressed RHCs. The scope of the MeSH term "governing board" captures the intent of the concept, described as "The group in which legal authority is vested for the control of health-related institutions and organizations" (Medical Dictionary Online n.d.). Note that all concept keywords were limited to the last five years in the MEDLINE database. This was due to the volume of retrieved titles in the absence of the limit and time constraints on behalf of the research team and based on the assumption that articles published more than five years ago would be indexed appropriately in the database and captured through the use of the targeted MeSH terms. The keywords were not limited in the EMBASE and CINAHL databases due to the absence of targeted subject headings for this concept in the EMBASE database, and due to the small volume of retrieved citations in the absence of this limit in the CINAHL database.

CINAHL = Cumulative Index to Nursing and Allied Health Literature; EMBASE = Excerpta Medica Database; MeSH = Medical Subject Headings; RHC = rural health council.

priorities; developing strategies to address identified priorities; implementing the identified strategies; managing resources; and monitoring and evaluation (Abelson et al. 1995; Charles and DeMaio 1993; Farmer et al. 2017; Hogg and Williamson 2001; Pickard et al. 2002; Robinson et al. 2003; Tritter and McCallum 2006).

The structure of RHCs

The organization and composition of councils described in the literature were varied, with no single structure emerging as "ideal" or "best." For instance, Weiner and Alexander (1993)

TABLE 2. Data extraction form

• Bibliographic reference (Vancouver style) • Research question(s)/objective(s) • Study rationale/context • Study design/publication type • Jurisdiction
Methods • Study population • Inclusion criteria (for participants, studies, data) • Exclusion criteria (for participants, studies, data) • Study conduct (e.g., interview protocol, survey design and distribution, outcome measurement) • Analysis (e.g., statistical)
Results • Main findings (two to three points) • What is the rationale for community or patient representation or involvement?
Structure • What is the structure of the health board or council? (i.e., how is the board organized?) What is the composition of the health board or council? • How are communities or patients represented on the health board or council? • Other relevant information.
Function • What is the function (e.g., the mandate, the activities, the responsibilities, etc.) of the health board or council? • What are important considerations with regard to the effective functioning of the health board or council? • How does the health board or council make decisions? • Describe the accountability relationship of the health board or council (i.e., who is the health board or council accountable to? Who is accountable to the health board or council?). • How are communities or patients involved in the health board or council? • Other relevant information.
Impact • What is the impact of the health board or council (as a whole), or individual board members, on health services planning, decision making or delivery? (i.e., what has been their influence? What has the board accomplished? Has the board [or individual board member] been successful/effective?) • How have communities or patients influenced the effectiveness of the health board or council? • What are the advantages to community or citizen-patient representation on the health board or council? • What are the challenges or barriers to community or citizen-patient representation on the health board or council? • Other relevant information/findings.

observed that within hospital boards, board form varied according to the organizational and environmental characteristics of the hospitals. Regarding CPC representation on councils, lay individuals comprised a portion (Andrews et al. 2014; Bismark and Studdert 2014; Hemingway and MacLeod 2004; Hudson 1996; Minister's Action Committee on Health System Reform 1994) of council members and contributed alongside health service providers and local policy makers as council members (Andrews et al. 2014). In other settings, it was believed that the inclusion of healthcare providers in the council would dilute the community voice and be an inauthentic representation of CPC interests; therefore, healthcare providers were intentionally excluded (McClean and Trigger 2017).

In addition, Godbout and Leduc (1987; cf. Hurley et al. 1994) found that having a majority of CPCs on a board was necessary for meaningful participation and empowerment.

However, Checkoway (1981; cf. Hurley et al. 1994) reported that this did not ensure that CPC voices dominated or were even heard in decision making. Hurley et al. (1994) cited Steckler and Herzog (1979), who suggested that experts can dominate the discussion, intentionally or otherwise, by framing discussions technically.

Council members might be elected or appointed and identified by volunteering themselves or by being nominated (Abelson and Eyles 2002; Bismark and Studdert 2014; Hemingway and MacLeod 2004; Hogg and Williamson 2001; Hurley et al. 1994; McClean and Trigger 2017; Minister's Action Committee on Health System Reform 1994). The literature emphasized the importance of considering the experiences, skills and knowledge, as well as the demographics of the candidates, to assure a balanced and representative council (Bismark and Studdert 2014; Guzys et al. 2017; McClean and Trigger 2017; Nelson and Gauss 2016).

To address barriers related to skills and representation in CPC involvement, McClean and Trigger (2017) described the use of knowledge- and skills-based criteria and demographic requirements within the Gold Coast Primary Health Network's Community Advisory Committee (CAC). They argued that determining the membership of the CAC was critical for the success of the committee and that this selection process ensured that membership was as representative of the local CPC as possible (McClean and Trigger 2017). However, Guzys et al. (2017) cautioned that the use of skill matrices during recruitment would likely give an edge to those with higher educational attainment, thereby increasing the influence of the "elite."

Hurley et al. (1994) described BC's Community Health Councils, whereby participants were both appointed by the minister of health and elected by the public. In this case, the authors spoke positively about the processes to determine membership, suggesting that the election and appointment assured public accountability (Hurley et al. 1994). However, Abelson and Eyles (2002) warned against the electoral process, citing the experience of health boards in the Canadian provinces of Saskatchewan and Quebec, where only candidates with ulterior interests stood for election.

The role of CPCs

Hogg and Williamson (2001) distinguished the activities of CPCs at national and local levels in the UK: at the national level, CPCs were involved in, for example, government advisory committees and professional regulatory bodies whereas at the local level, CPCs served as members of hospital boards and audit committees and were appointed as chairs and non-executive directors of health authorities, trusts and primary care groups, among other activities. In addition, Charles and DeMaio (1993) discerned three decision-making contexts: treatment, service delivery (i.e., resource allocation decisions for a defined service region) and system-level decision making (i.e., macro-level healthcare allocation and policy decisions for a jurisdiction).

Who participates?

The reviewed literature emphasized the importance of particular participant attributes for the success of CPC participation, including leadership skills (Anton et al. 2007; Hart et al. 1991; Jaklevic 2002; Larson 1999; Pirani et al. 1993); trustworthiness (Anton et al. 2007; Larson 1999); experience in and commitment to local matters (Anton et al. 2007; Ramstead 1992); knowledge of the organization, health and healthcare (Anton et al. 2007; Karash 2016) including knowledge of local health needs (Guzys et al. 2017; Wright 2013); knowledge of and experience in business (Barnett and Barnett 2001; Jaklevic 2002); expertise in finance and law (Kralewski and Moscovice 1992); expertise in strategic planning (Hart et al. 1991; Kralewski and Moscovice 1992; Pirani et al. 1993); and creativity in response to resource scarcity (Ramstead 1992).

However, with regard to the selection of CPCs with experience in business, Guzys et al. (2017) cited Keevers et al. (2012) and Maier et al. (2016) who suggested that restructuring not-for-profit boards and committees to include "business-like" and professional members might reduce advocacy in favour of service provision, disempower grassroots activists and increase the influence of the elite. Similarly, Longley (1999) refuted the importance of council members with expertise in business and finance, instead suggesting that resources to communicate to council members complicated financial issues.

Abelson et al. (1995) explored the willingness and suitability of specific community groups for decision-making responsibilities. Elected officials were most willing to take responsibility for overall decision making (85% of respondents were personally willing, and 50% believed their group was suitable), and randomly selected citizens were least willing (60% of participants were personally willing, and 17% thought their group was suitable) (Abelson et al. 1995). The individuals polled favoured a combination body – including several community groups – as the most suitable overall decision-making body with representation from experts in healthcare and social services, town hall meeting attendees (i.e., "interested citizens"), and elected officials prioritized for the combined decision-making group (Abelson et al. 1995).

Finally, Pagatpatan and Ward (2017) reported the importance of "inclusiveness" for successful CPC participation, referring to the consideration of a broad range of perspectives in public participation exercises, with a particular focus on involving marginalized and hard-to-reach publics. Tritter and McCallum (2006) echoed this sentiment, suggesting that to build a successful user involvement system, diverse individuals and groups at local, organizational and national levels must be engaged. Similarly, Dunn (2007) described the importance of diversity for hospital boards, including considerations of ethnicity, age, gender, geography and occupation.

Motivation for participation

The reviewed literature presented multiple reasons for participation by CPCs that included achieving a specific outcome for their community or organization (Farmer et al. 2017), to

"have a say" or be included in decision making (Rose et al. 2014: 22), to affect service change (Farmer et al. 2017; Rose et al. 2014) or because it was "the way things were done" (Abelson et al. 1995: 407). A perception was conveyed through the literature that community members could contribute useful information (Farmer et al. 2017) and add to institutional credibility (Swapan 2016; cf. Farmer et al. 2017). Pallarito and Shinkman (1997) quoted a citizen trustee, explaining, "You do it … [because] it's part of your life" (p. 26). Included studies are summarized in Table 3, available at longwoods.com/content/26972.

Discussion

The current scoping review summarized the literature on the function and structure of RHCs, including a description of community members who participate in health planning, why they participate and what their roles and responsibilities are. We found notable similarities and differences across rural jurisdictions in the way RHCs are organized and how they function. No studies examined the efficacy of RHCs from the perspective of participating community members. To capture this literature, future studies should incorporate specific search terms that will help locate evaluation and other studies that highlight the efficacy and impact of RHCs.

The scoping review identified several themes that are reflected in the wider context of the community engagement literature. Community engagement refers to the engagement of people with lived experience in health research and program- or policy-planning processes. This engagement is guided by a set of principles (Greer et al. 2017):

- community members are experts "in the context and content of decisions that affect their daily lives" (Greer et al. 2017: 7);
- meaningful engagement of community members promotes inclusion and equity, especially among those who experience barriers and are affected by discrimination. The ability to participate equally in decision making removes power imbalances and can lead to programming that is more responsive to the needs of community members who have been historically excluded from such activities;
- processes need to be transparent, and a rationale should be provided for why decisions are made to make it less likely that the decisions are driven by personal interests or individual opinions;
- those who work with community members must be accountable and take responsibility for their actions and decisions to build trust and enhance transparency;
- "recognizing and addressing the differences in power that are entrenched at decision-making tables is paramount to the success and validity of the voices" (Greer et al. 2017: 7) of community members in community engagement work;
- through working together and sharing decision making, community and professional members build capacity by developing confidence, skills and knowledge; and

- one size does *not* fit all, and different community members might require different supports to engage (Greer et al. 2017). For example, when engaging rural community members, it is important to consider the increased time and costs of reaching people who might be geographically dispersed, be aware of issues around transportation and telephone/Internet coverage in remote areas, engagement fatigue (as requests for engagement might be fielded by a smaller number of people) and pre-existing rural–urban tensions (British Columbia Ministry of Health 2019).

It is also important that all key stakeholders understand the unique local context and community expectations, norms, customs and values. Community members should determine their desired level of engagement and be given the information, time and resources needed to engage fully. Ideally, the group should agree on the purpose and rationale for engagement early on and empower community members to co-create and co-govern processes (British Columbia Ministry of Health 2019).

Although this scoping review focused on RHCs as an established mechanism to ensure community voice in healthcare planning, we recognize that other mechanisms and frameworks for community engagement exist. For example, Boelen (2000) published a paper about the challenges and opportunities for building partnerships in health development. He noted that striking a balance and managing tensions between the values of quality, equity, relevance and cost-effectiveness are challenging; understanding the interconnectedness of these values and arriving at a consensus about how to define and enact each value among key stakeholders are important when developing and implementing health services. Boelen (2000) stressed the importance of a decentralized, community-based approach to health planning that is people-centred because understanding the "major physical, biological, social, cultural, and economic health determinants at work in a given environment is the foundation of a sound and comprehensive people-oriented health system" (Boelen 2000: 24). Factors such as housing, transportation and employment and how they affect community health need to be considered. Implementing sustainable health services that are based on community needs requires active collaboration of key stakeholders who each have different strengths, constraints, expectations and agendas. When communities, health professionals, policy makers, academic institutions and health managers share a clear vision, are cognizant of the added value of the partnership and prioritize shared values over sectoral interests, the partnership is more likely to result in health development activities that are responsive to the needs of individuals and communities (Boelen 2000).

This literature suggests a strong rationale for CPC involvement in healthcare planning, rooted in the expectation of improved decision making that incorporates the needs and preferences of end-users. This is seen most clearly in rural settings through advocacy for local services in response to perceived threats (of closure or service reduction) and also in the articulation of service gaps that may not be well understood outside the local community

population. The inclusion of community members may also enhance public trust in decision making through reassurances that local perspectives are represented. This emphasis on aspirational accountability, however, may further entrench *distrust* if it is perceived as strategic or involves citizens with allegiances to business or with interests competing with the public good. This, of course, begs the question "who represents community" and whether or not representation is inclusive of those who may be excluded from political and economic processes and discourse (the "have-nots"). For many, the realities of employment, family responsibilities and, perhaps most importantly, either distrust with the current health system or lack of confidence that involvement will lead to meaningful change, make achieving diversity difficult. When adequate representation is achieved, however, health boards and councils have the potential to increase a sense of community ownership over health services, bringing with it the conditions for "self-determining, empowered communities" (Kenny et al. 2017: 1). One of the ways that this is achieved is through, as Farmer et al. (2017) noted, the expansion of the role of community members from consumers to co-producers of healthcare.

To actualize CPC voices through health councils and boards, the most salient question is this: What is the infrastructure needed? At a macro level, system prioritization of community voices is essential (having a "receptor site" for decisions made at a local level), but actualizing input also requires capacity building in the form of orientation and training to ensure that skills and expertise on quality governance exist. Training requires flexibility to respond effectively to the needs of particular groups (Bismark and Studdert 2014) and the local healthcare priorities at hand. Furthermore, capacity development needs to be a dynamic process as board or council members, along with healthcare priorities, change over time.

The discussion of compensation for the board and council members has gained traction recently and is not without contestation. Although meaningful participation necessarily requires significant time commitments that should be honoured, some feel remuneration may also negatively affect the intent of having a true "consumer" perspective (see Kidd et al. 2007: 218). When applied to a rural context, however, the heightened importance of representing local conditions and the potential for overlapping roles of patient partners with other members of the board, council or healthcare administrators counter the commercialization of public members. In fact, the role may be seen as a transparent way of participating in community improvement and one among many ways that local citizens contribute.

Several recommendations on how to optimize the integration of patients partners into RHCs emerged from the findings. First, RHCs should be seen as an important component of healthcare planning and quality improvement initiatives and a way to make health services more patient-centred. The level and quality of patient engagement should be measured from the patient perspective and integrated as a metric for assessing healthcare quality. This is the responsibility of regional health authorities. In order for patients to make decisions that benefit their communities, they must have access to local data and the ability to collaborate with key stakeholders, including health professional divisions and community agencies. Decision

makers and other key stakeholders on RHCs must be skilled in hearing and integrating feedback from community members. The recruitment process for community members who want to participate in RHCs ideally includes a combination of appointed and elected positions and a diversity of skills, knowledge and personal characteristics. This is in the domain of municipal (local) hospital and community infrastructure.

The roles and responsibilities of council members and expected outcomes and influence of RHCs should be clearly described so that patient partners who participate in RHCs have realistic expectations. To ensure government accountability, government health policy makers should be responsible for RHCs and for the inclusion of the rural patient voices on RHCs.

Priority must also be given to Indigenous leadership in order for communities to consider the best possible mechanisms for Indigenous-specific RHCs. These structures may reflect local existing Indigenous governance structures, modified to meet the specific needs of communities in health planning. Local or regional Indigenous organizations (e.g., BC First Nations Health Authority), in collaboration with jurisdictional governments, should be accountable for ensuring the involvement of community voices. Other examples of structures that support Indigenous community participation in health planning include Aboriginal/Indigenous health improvement committees across eight communities in Northern BC. These committees include local representatives from Indigenous organizations and communities, the First Nations Health Authority, Northern Health and other stakeholders. The function of these committees is to collaboratively set healthcare priorities, find pragmatic solutions and develop local resources through relationship building, increasing cultural awareness and integrating Indigenous perspectives (Northern Health Indigenous Health n.d.).

Finally, it is essential to measure the efficacy of CPC participation in healthcare decision making to determine if the promises of community empowerment, improved decision making or improved health outcomes are actualized, particularly in rural settings. Indicators may include those that measure the efficiency of resource allocation (Abelson and Eyles 2002), whether or not participation leads to increased local services, and thus increased access to care (Andrews et al. 2014), and changes in levels of public commitment to the healthcare system (Abelson and Eyles 2002; Anton et al. 2007). As rural healthcare services are often central to the economy of communities, the impact of the health council's decision making on economic growth is a key marker. In most instances, however, measurement metrics will not be quantitative and static but, instead, best accomplished through process measures that are easily adaptable to changing circumstances and, importantly, co-determined by local stakeholders. Local research institutions should be tasked with working with patient groups on shared measures development.

Conclusion

When considering health councils and boards as mechanisms for increasing rural involvement in decision making, descriptions of structure and function provide a helpful starting place for planning. However, as much of this literature does not focus specifically on the

health councils in rural settings, we must consider implementation through a rural lens that appreciates the differences from urban centres with regard to economies of scale and local access to resources.

While the majority of recommendations are targeted at regional health decision makers, the confluence of interaction between all levels of governance is required to successfully implement a sustainable structure for community voices in healthcare planning. Specifically, a tripartite approach – that is, collaboration between municipal, provincial/territorial and regional authorities, should be used to action the recommendations, although the specifics of the agencies involved will vary between jurisdictions.

Although the nature of the implementation of health boards or councils will vary based on local political alignment, they should leverage existing political structures as a starting point for the necessary administrative infrastructure required to support health councils. However, more nuanced decisions – such as the ratio of elected to appointed representatives, role of remuneration and nature of quality improvement processes – will be required at a local level and may vary between settings. The very process of imagining how community voice can be integrated into health planning is likely to have a cathartic effect regarding attitudes to public involvement in contemporary healthcare.

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RESEARCH PAPER

Use of Performance Data by Mid-Level Hospital Managers in Ontario: Results of a Province-Wide Survey and a Comparison with Hospital Managers in Europe

Utilisation des données sur le rendement par les gestionnaires d'hôpitaux de niveau intermédiaire en Ontario : résultats d'un sondage à l'échelle de la province et comparaison avec les gestionnaires d'hôpitaux en Europe

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Abstract

This paper provides insights into the use of performance data by middle managerial staff in Ontario hospitals in 2019 and compares the results to a study conducted in Europe in the same year. A total of 236 managers working in 61 hospitals across Ontario provided responses to the survey. Compared to their European colleagues, Ontario respondents self-assessed using significantly more performance data for managerial decision making. The use of performance data in Ontario was mostly motivated by external accountability requirements, followed by internal quality improvement efforts. Ontario managers also reported accessibility, appropriateness and timeliness of data and human resources and engagement as the biggest barriers to further performance data utilization. Comparative studies, such as the one this paper is based on, provide the foundation for drawing lessons across jurisdictions. This paper also affirms the importance of hospital middle management in moving from quality assurance to quality improvement efforts and developing sustainable learning healthcare organizations and systems.

Résumé

Cet article donne un aperçu de l'utilisation des données sur le rendement par le personnel de gestion intermédiaire dans les hôpitaux de l'Ontario en 2019 et compare les résultats à une étude menée en Europe la même année. En tout, 236 gestionnaires œuvrant dans 61 hôpitaux ontariens ont répondu au sondage. Comparativement à leurs collègues européens, les répondants ontariens déclarent utiliser beaucoup plus de données sur le rendement pour la prise de décisions en matière de gestion. L'utilisation des données sur le rendement en Ontario est principalement motivée par les exigences externes en matière de reddition de comptes, suivies d'efforts internes d'amélioration de la qualité. Les gestionnaires ontariens indiquent également que l'accessibilité, la pertinence et l'actualité des données, des ressources humaines et de l'engagement étaient les principaux obstacles à une utilisation plus poussée des données sur le rendement. Des études comparatives, telles que celle sur laquelle se fonde le présent document, fournissent la base pour tirer des leçons entre les juridictions. Cet article affirme également l'importance de la gestion intermédiaire hospitalière dans le passage de l'assurance de qualité vers les efforts d'amélioration de la qualité ainsi que dans le développement d'organisations et de systèmes de santé d'apprentissage durables.

Introduction

Performance data are vital for steering improvement in healthcare (Baker and Axler 2015). Measuring and reporting on a range of indicators allows healthcare organizations, including hospitals, to take stock of current performance and guide efforts to improve care, while monitoring progress. In driving improvements, it is important not only to measure and report

performance internally but also to compare and benchmark against peers and set ambitious but achievable targets (Enticott et al. 2021). While the impacts of public reporting of performance data, such as through report cards, have received considerable attention in the literature (Prang et al. 2021; Tu et al. 2009), little attention has been paid to the challenges and enablers of the effective use of performance data by hospital managers to drive quality improvements. The challenge of transforming data into actionable indicators, which are fit for purpose and use (Barbazza et al. 2021), is largely about tying measurement information to quality improvement efforts on the front lines and closing the gap between learning from the data and actually introducing changes (Dhalla and Tepper 2018). Using performance data to support quality assurance and improvement strategies contributes to building safer, more efficient and equitable organizations and healthcare systems (Busse et al. 2019; Smith 2010). The COVID-19 pandemic additionally emphasized the role of timely, relevant and linkable performance data across healthcare services for improving organizational and system response and resilience (Kringos et al. 2020; WHO 2017).

Our previous research showed that the amount, focus and quality of performance measurement work in European hospitals did allow for sufficiently detailed performance insights (Ivankovic et al. 2020). Whether hospitals are truly equipped to turn these data into information and use them to improve outcomes for individuals and populations remains a question of paramount importance. Despite all the data available to support improvements in healthcare delivery, using it to implement innovations, even seemingly simple ones, often presents a major challenge (Alexander and Hearld 2011). Hospital executives adapting their human resource policies in order to train and support new types of roles – such as "quality managers" and "linking pin data champions" – often occupying middle managerial positions, might facilitate the use of hospital performance data to their fuller potential (Botje et al. 2016).

Hospitals in Ontario are predominantly private, not-for-profit organizations that receive most of their funding from the provincial government (Kraetschmer et al. 2014). The province carries a rich history of working with performance data and creating a culture of accountability in its acute care hospital sector. These developments are notably linked to the Ontario Hospital Report Research Collaborative, a joint effort launched in the 1990s between the University of Toronto and the Ontario Hospital Association (OHA) to develop the first province-wide performance measurement and monitoring system based on the balanced scorecard format (Baker and Pink 1995; Kaplan and Norton 1992; Pink et al. 2001). The developments in performance measurement in the past two decades were marked by a series of reforms, including the *Public Sector Accountability Act*, 2001, the 2006 formation of Local Health Integration Networks (LHINs), the *Excellent Care for All (ECFA) Act*, 2010, the *Connecting Care Act*, 2019, and, most recently, the establishment of Ontario Health Teams (OHTs) (Embuldeniya et al. 2021; MacLeod 2015; Veillard et al. 2015). Importantly, the *ECFA Act* made the development of quality improvement plans and use of performance data with targets a requirement for hospital boards in Ontario, adding a strong performance-based compensation component for the executives. Despite challenges brought about by the

COVID-19 pandemic, the introduction of OHTs aims to change the landscape in which the hospitals are operating, with increased focus on integration of care and population health management (Embuldeniya et al. 2021; Fahey-Walsh et al. 2020). These initiatives also illustrate the evolution of conceptualizing performance measurement and its use for accountability over time: from funding agreements based around service volumes through collecting, reporting and using quality of care and patient safety indicators to its current focus on patient-reported outcome and experience measures, care integration, population health management and value-based healthcare.

A study among mid-level hospital managers from 23 European countries was conducted in 2019 by the same core research team, exploring the use of performance data for managerial decision making (Ivankovic et al. 2020). Among other findings, this work also highlighted the unique role that hospital middle managers play in closing the gap between creating evidence and implementing changes to care delivery. Through adopting evidence-based managerial practices, and due to their unique position as a critical link between organizational accountability and day-to-day quality improvement work (Gutberg and Berta 2017), hospital middle managers hold a huge potential to facilitate the shift from organizational accountability toward the model of learning organizations (Ivankovic et al. 2020).

With the broad aim of gaining insights into the opportunities for strengthening performance measurement and its usefulness in driving improvement in Ontario, this study looked closely within Ontario and comparatively with Europe exploring (1) why hospital managers worked with performance data; (2) what kind of data fed into this work; (3) how performance data were used; and, additionally, (4) Ontario-specific barriers to the use of performance data.

Materials and Methods

A survey-based descriptive cross-sectional study was conducted in 2019 among mid-level managers working in Ontario hospitals. The survey elicited information on the use of performance data for managerial decision making. A similar survey, conducted by the same core research team in the European context (Ivankovic et al. 2020), provided the basis for the survey design and comparative analysis of results.

Survey design, questionnaire adaptation and piloting

The original survey questionnaire was developed, validated and used in a study among European hospital managers in 2019 as described in detail in a published scientific paper (Ivankovic et al. 2020). This study involved 125, mostly mid-level, hospital managers from 23 European countries, participants in the European Hospital and Healthcare Federation's exchange program (European Hospital and Healthcare Federation 2022). For use in Ontario, the previously developed questionnaire was amended and re-validated. To validate questions meeting their measurement goals, five individual face-to-face cognitive testing (Collins 2003) interviews were conducted between October 25 and 30, 2019, involving mid-level managers

working in Greater Toronto Area–based hospitals. The final questionnaire consisted of 29 mandatory open- and closed-ended questions and was structured in four parts as shown in the questionnaire in Appendix 1, available at longwoods.com/content/26971. The questionnaire was set up and distributed through an online surveying platform.

Study population, questionnaire dissemination and data collection

The target population of the study were mid-level hospital managers working in Ontario hospitals. In collaboration with the OHA, all 141 OHA member organizations essentially representing all the hospitals in Ontario, were contacted. Hospitals were approached directly by the OHA with an e-mail containing a brief explanation of the aim, scope and timeline of the study and the link to the online questionnaire. Invitations included a request to disseminate the questionnaire throughout organizations, specifically targeting mid-level directors and managers. Participation was voluntary, and respondents had the option to either remain anonymous or to provide contact information – only available to the OHA – if they opted to be informed on the results and included in potential follow-up work. No data on sex or gender of the participants were collected. The questionnaire was disseminated on December 4, 2019, with weekly reminders sent until December 20, 2019. Data collection was finalized on January 6, 2020.

Data analysis and the comparison to the results of the European survey

Descriptive univariate analysis of data was conducted using R (v.3.6.1) on a full sample of respondents who were, for certain segments of the analysis, grouped by their reported managerial position and the type of hospital they worked for. The OHA criteria for grouping hospitals were used for the stratified analysis (OHA n.d.).

We analyzed the survey data by addressing the broad questions of "why, what and how" of performance data use. The "why" focused on motivation, benchmarking and confidence in data. The "what" looked at data domains and sources, and was anchored in the Performance Assessment Tool for Quality Improvement in Hospitals framework developed for the World Health Organization (Veillard et al. 2005). The "how" explored the use of managerial tools and differences in patterns of use between managerial roles. Finally, Ontario-specific barriers to a more impactful use of performance data among hospital managers were analyzed.

Responses from the European study (Ivankovic et al. 2020) were used to compare survey results between Ontario and Europe for questions that were identical in both. Likert scale responses were recoded, frequency distributions calculated and statistical significance identified by observing non-overlap between 95% confidence intervals (CIs) of the means between results from the two surveys. Additionally, to validate the internal consistency of responses, a reliability coefficient was calculated using data from organization-level questions originating from hospitals with the highest number of individual responses.

Although this was primarily a descriptive, quantitative study, throughout the paper, quantitative results are illustrated and contextualized with respondents' verbatim quotations (Thorne 2021), provided in the questionnaire's open-ended questions.

Results

Characteristics of the study population

Individual respondents, working in 61 different hospital organizations in Ontario, provided 236 full responses. This made up 43% (61/141) of all OHA member hospitals, from all five Ontario health regions (Government of Ontario n.d.). The majority of responses came from community (61%, 144/236), large acute teaching (16%, 37/236) and small (8%, 19/236) hospitals.

Most survey respondents self-identified as mid-level hospital managers (82%, 193/236). Their roles equally involved managing support of care processes, such as quality, human resources, information technologies and financing (50%, 97/193), and managing clinical care processes (50%, 96/193). Less than one-fifth of all respondents (18%, 43/236) managed plans and strategies for entire organizations. Demographic characteristics of study participants in Ontario were comparable to those in the European study as shown in detail in Appendix 2, available at longwoods.com/content/26971.

Respondents from seven hospitals, six community and one paediatric, provided 42% (98/236) of all responses. This uneven sample distribution across organizations was used to assess internal consistency of responses. Cronbach's alpha values of 0.781, 0.831 and 0.852 for the three hospitals providing most responses (two community hospitals with 840 and 560 data points and a paediatric hospital with 490 data points) confirmed high internal consistency of the responses received.

Why is performance data used? Motivation, benchmarking and confidence in data

Mid-level managers reported that the primary motivation of the hospital to collect and report performance data was external accountability, specifically to ensure that externally set standards and goals are achieved. However, mid-level managers noted that their own motivation as individuals was to drive internal improvement, regardless of achieving set goals. Both organizational- or hospital-level and individual motivation to work with performance data were self-assessed to be significantly higher among Ontario participants, compared to the European cohort of hospital managers. These results are summarized in Table 1.

Respondents provided examples of using performance data for managerial decision making in their routine work. Selected free-text responses, illustrative of different managerial, are presented.

TABLE 1. Motivation to report and collect performance data on an organizational level and on the level of respondents' routine work

Levels and types of performance data use	Ontario (*N* = 236)		Europe (*N* = 125)	
	Mean (0–4)	95% CI	Mean (0–4)	95% CI
Organization level				
Internal assurance	3.38	[3.28, 3.48]	3.19	[3.05, 3.34]
Internal improvement	**3.43**	[3.33, 3.53]	3.15	[3.00, 3.30]
External accountability	**3.52**	[3.42, 3.62]	3.16	[3.00, 3.32]
External benchmarking	**3.14**	[3.03, 3.25]	2.73	[2.54, 2.92]
Routine, daily work				
Internal assurance	**3.37**	[3.27, 3.47]	3.02	[2.84, 3.20]
Internal improvement	**3.48**	[3.39, 3.57]	3.10	[2.94, 3.26]
External accountability	3.13	[2.99, 3.27]	2.91	[2.72, 3.10]
External benchmarking	**3.04**	[2.92, 3.16]	2.59	[2.39, 2.79]

Likert-scale responses were recoded (from 0 = *not important* to 4 = *very important*), and means of recoded values, with 95% confidence intervals (CIs), are presented here. Non-overlap of 95% CIs indicates statistical significance. Values of the Ontario study presented in bold indicate statistically significant differences with those from the European survey. For details on the European survey, including participating countries, please refer to Ivankovic et al. 2020.

> Performance data are utilized to determine areas of focus for our annual quality improvement plan. For example, a fall causing harm was an issue for the organization and, as such, it became an important goal as well as an indicator. (Director of quality, patient experience and patient safety)

> The preparation of the annual budget requires an understanding of the hospital's ability to overcome contractual economics and other cost pressures in balancing the budget's bottom line. This includes service volumes and understanding of the Ontario Cost Distribution Methodology results to determine if the hospital is an outlier in terms of performance and the delivery of care. In addition, an assessment of population demographics is necessary to understand the unique patient needs of our catchment area. Closing budget gaps include a review of cost per weight case by category and a comparison of areas of service to peers. (Director of finance)

> I use performance data to justify request[s] for additional resources [such as staff]. (Human resources director)

> [We use performance data] to identify program quality improvement [QI] goals and QI change initiative priorities as well as to validate that changes have led to improvements. For example, we identified the opportunity to participate in a National Baby Friendly Initiative QI Collaborative to improve our exclusive breastfeeding rates at hospital discharge for women who intend to exclusively breastfeed because our rates were 25% below benchmark. (Director of maternal and child health)

Survey results also revealed significantly more use of performance data for benchmarking purposes in Ontario, compared to the European cohort of hospital managers. More than half (57%, 130/228) of Ontario respondents replied that the performance data from their organizations get used "a great deal" or "considerably" to benchmark with other comparable organizations, while only around one-third of European respondents (36%, 37/104) replied the same way.

> We are working on making improvements in our emergency department wait time for admitted beds. We use the provincial data to contact organizations that are doing well to see which ideas worked for them and if we can implement them here. Then we look at our data the following month to see if the changes made an improvement and whether it was sustained. (Quality and patient experience manager)

Although European respondents reported less use of benchmarking, they found it significantly more useful for guiding improvement in their daily work (means of the recoded Likert scale responses were 2.66 and 2.29 with 95% CIs [2.48, 2.84] and [2.14, 2.44], respectively).

Both European and Ontario respondents expressed moderate confidence in reliability of performance data collected and used in their organizations (means of the recoded Likert scale responses were 2.47 and 2.39 with 95% CIs [2.30, 2.64] and [2.26, 2.52], respectively). Both cohorts also felt that decision making based on performance data made it significantly easier for them as managers to explain and justify their decisions (means of the recoded Likert scale responses were 3.00 for European and 2.71 for Ontario respondents with 95% CIs [2.87, 3.13] and [2.58, 2.84], respectively).

What domains of performance data, and from which sources, feed into data-driven decision making?

For most dimensions of data, considerable organizational performance data collection, reporting and use were reported, with a distinct cascading pattern. Compared to their European counterparts, Ontario managers reported significantly more work with patient and staff safety-related data, as well as patient-reported data, as shown in detail in Figure 1.

Data sources used the most for performance data, in both Ontario and Europe, were administrative and electronic health records (EHRs). Accreditation and patient-reported data were used significantly more among Ontario respondents, while population-based registry data were the least used data source as shown in Figure 2.

Almost all the respondents in Ontario reported accessing data from internal sources (99%; 234/236), with more than half additionally accessing performance data from external sources (56%; 131/236). As external sources, the majority used data provided by the Ministry of Health (77%; 101/131), LHINs (72%; 94/131) and the Canadian Institute for Health Information (70%; 92/131).

FIGURE 1. Reported collection, reporting and use of performance data through various data types

(Ontario: *N* = 236, Europe: *N* = 125). Means calculated from recoded Likert-scale responses (from 0 = *not at all* to 4 = *a great deal*) are presented on a cropped vertical axis (range 2.10–3.50). Error bars represent 95% confidence intervals (CIs) for each mean. Non-overlap of 95% CI bars indicates statistical significance.

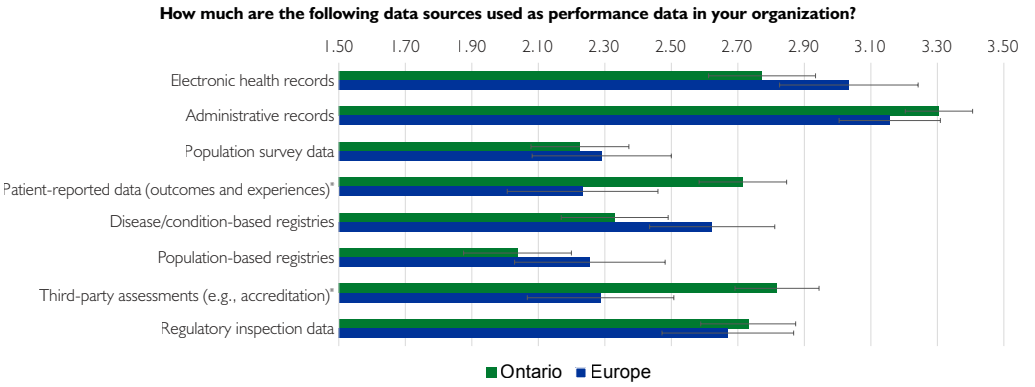
> I work as a senior analyst in decision support, so I regularly extract and present performance data from internal and external resources. Once I have extracted the data, I review them and make decisions based on the "story" that the data are telling me. I also manage the coding department, so I regularly review performance data to determine our hospital's results. If the indicators are showing negative results, I will then audit charts to determine if staff are coding according to national coding guidelines and standards, or if there is a need to reach out to physicians regarding documentation initiatives. (Decision support systems manager)

How does performance data get collected, reported and used and what are the use patterns and tools used?

Ontario managers reported moderate to considerable participation in collecting data, preparing reports and using performance data for decision making in their routine work (means of recoded Likert scale responses were 2.35, 2.39 and 3.00 with 95% CIs [2.20, 2.40], [2.24, 2.54] and [2.88, 3.12], respectively). This was significantly more than that reported by managers in Europe (means of recoded Likert scale responses were 2.09, 2.02 and 2.57 with 95% CIs [1.88, 2.30], [1.81, 2.23] and [2.38, 2.76], respectively), except for the collection dimension.

The extent of use of performance data for decision making were similar between clinical and non-clinical managerial staff in Ontario. However, non-clinical managers participated significantly more in preparing reports based on performance data (means of the recoded Likert scale responses for the reporting dimension for clinical and non-clinical managers

FIGURE 2. Reported data sources used to populate performance data and indicators



Ontario: *N* = 236, Europe: *N* = 125. Likert-scale responses were recoded (from 0 = *not at all* to 4 = *a great deal*). Horizontal axis shows cropped (range 0.00–3.50) means of recoded values. Error bars represent 95% confidence intervals (CIs) for each mean. Non-overlap of 95% CI bars and an asterisk (*) next to the label indicate statistical significance.

were 1.88 and 2.74 with 95% CIs [1.67, 2.09] and [2.55, 2.93], respectively). Results did not show significant differences in the extent of use of performance data between more (over 10 years) and less (under 10 years) experienced hospital managers in Ontario (means of the recoded Likert scale responses were 3.02 and 2.98 with 95% CIs [2.83, 3.21], [2.84, 3.13], respectively).

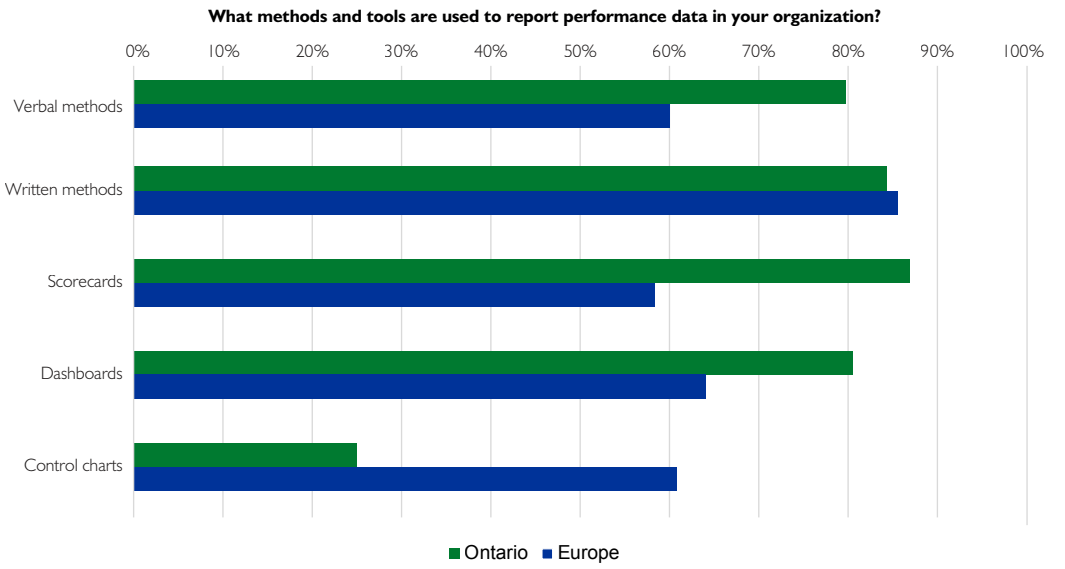
A large majority of Ontario respondents reported using business intelligence tools, such as scorecards and dashboards, to report on performance data in their organizations, significantly more than those in Europe. The exception was the use of control charts, which was more common in Europe, as shown in Figure 3.

Barriers to the use of performance data in Ontario

Timeliness and accessibility of data were recognized as the most important barriers to using performance data as shown in Figure 4. Additional barriers emerged from the free-text replies: (1) appropriateness, relevance and usefulness of performance data; (2) physician engagement, user buy-in and "audience appetite"; (3) data "overload," excessive workload, lack of time and staff to work with the data; and (4) lack of confidence in systems that collect data, their accuracy and lack of consistency.

> Poor performance on our dashboard prompted us to dive [deep] in[to] understanding what exactly was happening. We figured out that poor data quality and duplicate cases remaining open in the system were [some] of the bigger contributors. (Quality improvement specialist)

FIGURE 3. Methods and tools used to report performance data



Ontario: $N = 236$, Europe: $N = 125$. Horizontal axis presents the percentage of all respondents who replied positively for each category of reporting methods and tools.

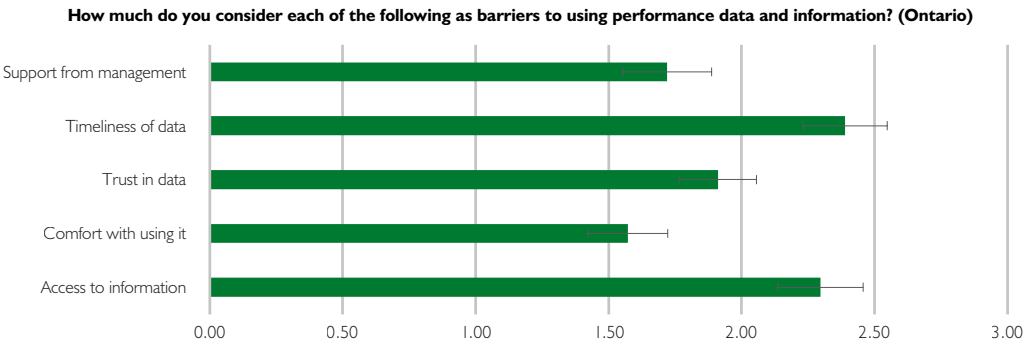
Discussion

This study aimed to provide insights into the use of performance data for managerial decision making in Ontario hospitals and to draw comparisons with Europe (Ivankovic et al. 2020). In general, the Ontario results showed considerable use of performance data among surveyed mid-level hospital managers, albeit with room for improvement. Compared to the European cohort, there seemed to be more use of performance data for managerial decision making in Ontario. Ontario managers reported accessibility, appropriateness and timeliness of data, as well as human resources and engagement to work with data, to be the most important barriers in performance data utilization.

Organization-level use of performance data was mostly motivated by external accountability and quality assurance, while the routine, daily work of mid-level hospital managers in Ontario favoured its use for driving quality improvements. Despite more extensive use of data for benchmarking among Ontario respondents, their European counterparts found benchmarking more valuable for guiding improvement efforts in their daily work. In light of the ongoing OHT Performance Measurement Framework's (Ontario Ministry of Health 2021) development and implementation in Ontario, these results indicate that summative (quality assurance) and formative (quality improvement) functions of performance data (Freeman 2002), as well as different approaches to benchmarking (Bevan et al. 2019; Ettorchi-Tardy et al. 2012; Klazinga et al. 2011), merit further research and discussion on the provincial level.

Both Ontario and European respondents showed similar cascading patterns of performance data collection, reporting and use – indicating more is collected than reported and

FIGURE 4. Barriers to the use of performance data



Ontario: *N* = 236. Likert-scale responses were recoded (from 0 = *not at all* to 4 = *a great deal*). Horizontal axis presents cropped (range: 0.00–3.00) means of recoded values. Error bars present 95% confidence intervals (CIs). Non-overlap of 95% CI bars indicates statistical significance.

finally used for managerial decision making. There seemed to be more activity with performance data use in Ontario in general, especially with data domains related to patient and staff safety and those reported by patients. Interestingly, the collect-report-use slope seems to be more pronounced for data categories that are mandatory to collect and report, such as patient and staff safety, as opposed to non-mandatory ones, such as patient-reported data.

As data sources, administrative records were used the most by both Ontario and European respondents, followed by EHRs. Interestingly, Ontario respondents reported using accreditation and patient-reported data almost as frequently as EHR data. These findings indicate that the already present, real-world and patient-reported nature of performance data sourced from different datasets needs to be carefully considered. This is especially true when discussing mechanisms to improve and appropriate indicators to capture the integration and coordination across providers and integrated care networks, such as the newly formed OHTs. Considering the care integration and population health management focus of these initiatives, a closer look into the use of population-based registries, which is more prevalent in Europe, and data linkage possibilities seems warranted. It is important to note a more homogenous nature of accreditation data across Ontario, whereas what accreditation means, if it is performed and how it is performed differs significantly between European countries (Araujo et al. 2020; Chuang et al. 2019).

Accessibility and timeliness of data emerged as the biggest barriers to performance data utilization in Ontario. Respondents also noted issues of appropriateness of existing metrics, human resources and engagement to work with data, as well as confidence in systems that collect data. These findings partially mirror the results of a recent study on barriers across European health information systems and enforce the need for sharing and learning from international experiences (Bogaert et al. 2021). In Ontario, as well as worldwide, the COVID-19 pandemic resulted in a more proactive use of performance data by hospitals, often using more timely data and predictive analytics, mostly to manage urgent capacity bottlenecks. Sustainability of these efforts, and their influence on readiness to use data

across levels of care, in line with the OHT transformation, surely merit further research (CIHI n.d.; Krylova et al. 2022).

Research on the specific role of middle management in hospitals suggests that this managerial layer is vital to successful adoption of innovation, based on data-driven managerial decision making (van Beers et al. 2022). Despite various initiatives over time, including quality improvement program-based pay-for-performance schemes for executives and managers, alignment of external reporting and internal improvement remains, according to our study findings, a challenge. It is becoming increasingly clear that in order to streamline processes, improve outcomes and reduce variation, work of middle managers needs to be better understood and supported, to which this study adds. On the other hand, increasing requirements to measure and report significantly add to the "data burden" and are becoming a questionable investment of resources. Some evidence shows that more focus on collecting and reporting data might be harmful, resource-wise, to working on patient care and improvement initiatives. Still, without performance data, it is impossible to say whether improvements work in providing better care and outcomes (Kromm et al. 2014), calling attention to the delicate balance between collecting too much and using too little.

This study has several strengths. To our knowledge, this was the first comparative study exploring patterns of performance data use among middle managers in hospitals across Canada and Europe. Working with professional organizations – OHA in Ontario and HOPE in Europe – allowed for direct access to relevant cohorts of target study participants. We also recognize potential limitations of this research. Sampling approaches differed among the two cohorts, with the European study targeting potentially more proactive participants to the professional development program. It must be acknowledged that the contexts and ways in which healthcare systems work between, and among, European countries and Ontario also differ significantly. Ontario respondents present a more homogenous cohort compared to that of European managers, working in 23 different countries and health systems around the continent. We are aware this limits the generalizability of findings and hinders certain aspects of comparison between Ontario, Canada, in general, and Europe – as does the perception- and opinion-based nature of the survey used. Also, distribution of responses in the Ontario survey showed signs of unevenness across organizations, with almost half of all the responses coming from only seven hospitals – a fact that we tried using to our methodological advantage by calculating internal consistency of the results received, but one which surely limits generalizability of our findings.

Conclusion

Comparative studies on performance intelligence production and use, such as this one, can facilitate learning across jurisdictions. Given the decades of work in Ontario preceding this study, the differences to results in Europe are far from surprising, but they still do provide

a pre-pandemic snapshot of the fast-changing performance data landscape. Our study findings also signal the importance of middle managerial staff in moving from assurance-based to improvement-based work and developing sustainable learning health systems and potentially encourage policy makers and system managers to further bridge existing gaps in use of data for continuous quality improvement. Implications for further positioning of Ontario hospitals in the patient-centred care and population health management era, emphasized by the OHT reform and challenged through the COVID-19 pandemic, remain to be seen.

Ethical considerations

Collection and analysis of data via this e-survey has been approved. Human participant ethics protocol (#38397) entitled "Survey of Hospital Managers in Ontario on the Use of Performance Data, Information and Intelligence" was submitted to the University of Toronto Office of Research Ethics and was granted approval (#17069) on November 22, 2019.

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Declaration

At the time of conducting this study, Imtiaz Daniel, Sundeep Sodhi and Tessa Dundas were employed by the OHA. The views expressed in this publication are those of the authors. They do not purport to reflect the opinions or views of the OHA or the Canadian Institute for Health Information.

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RESEARCH PAPER

Personal Support Work and Home Care in Ontario during the COVID-19 Pandemic

Services de soutien personnel et soins à domicile en Ontario pendant la pandémie de COVID-19

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Abstract

Background: Governments introduced emergency measures to address the shortage of home-care workers and unmet care needs in Canada during the COVID-19 pandemic.
Objective: This article aims to describe how policies impacted home care and identifies the potential risks for clientele and staff.

Method: Experts in home care (n = 15) were interviewed about policies that affect health and safety for homecare recipients.
Results: New recruitment strategies, condensed education and rapid hiring during the pandemic did not lead to the recruitment of sufficient workers, but increased the potential for recruitment of unsuitable workers or workers with little training.
Conclusion: It is important to consider the unintended effects of emergency policy measures and to manage the effects of such policies on homecare clients.

Résumé

Contexte : Les gouvernements ont mis en place des mesures d'urgence pour remédier à la pénurie de travailleurs à domicile et aux besoins non satisfaits en matière de soins au Canada pendant la pandémie de COVID-19.
Objectif : Cet article vise à décrire l'impact des politiques sur les soins à domicile et à identifier les risques potentiels pour la clientèle et le personnel.
Méthode : Des experts en soins à domicile (n = 15) ont été interrogés sur les politiques qui affectent la santé et la sécurité des bénéficiaires de soins à domicile.
Résultats : De nouvelles stratégies de recrutement, une formation condensée et une embauche rapide pendant la pandémie n'ont pas conduit au recrutement d'un nombre suffisant de travailleurs, mais ont augmenté le potentiel de recrutement de travailleurs inadaptés ou peu formés.
Conclusion : Il est important de tenir compte des effets imprévus des mesures politiques d'urgence et d'en gérer l'impact sur les clients des soins à domicile.

Introduction

More older Canadians are requiring more complex care at home as policies move care away from long-term care (LTC) homes and hospitals (Blay and Roche 2020; CIHI 2017; Johnson and Bacsu 2018). Worker shortages are endemic, and homecare workers are often employed part-time with inconsistent, non-guaranteed hours of work and low pay (Zagrodney and Saks 2017). The bulk of homecare services in Canada is provided by unregulated workers, who help community-dwelling clients with activities of daily living. While in this paper we use the term "personal support workers" (PSWs), they are also called by other titles, such as home support workers or home health aides (Sims-Gould et al. 2010). Homecare PSWs provide help with routine personal care activities, such as washing and bathing, and are also regularly assigned clinical tasks such as transferring clients using required equipment and assisting with medication (Denton et al. 2015; Saari et al. 2018; Zeytinoglu et al. 2014).

This paper examines the emergency policy measures related to PSW recruitment and education introduced during the COVID-19 pandemic. Taking the case of Ontario, we consider the unintended consequences of emergency policy measures in PSW-provided home care.

New risks and pandemic policy in Ontario

During the COVID-19 pandemic, the Ontario government brought in a series of orders under the *Emergency Management and Civil Protection Act* (1990) (Jeronimo 2020). These orders arose from the need to mitigate the spread of infection in the midst of a deadly crisis in LTC that accounted for 64.5% of all COVID-19 deaths in Ontario (Stall et al. 2021). They included *Limiting Work to a Single Long-Term Care Home (O. Reg. 146/20)* that required LTC workers to work at only one LTC home – or retirement home *(O. Reg. 158/20)* – to avoid spreading the virus. (These orders were in place from April 2020 to March 2022.) This contributed to a shuffling of the LTC workforce, including PSWs leaving the homecare sector for better paying and more secure jobs in LTC (Casey 2021). A separate order – *Deployment of Employees of Service Provider Organizations (O. Reg. 156/20)* – allowed for the redeployment of workers from home care and other community settings to LTC (Jeronimo 2020), although both sectors were insufficiently resourced.

Homecare recruitment and retention

There is international concern about the shortage of healthcare human resources, with increasing older populations and high turnover among workers contributing to a demand–supply imbalance (Gruber et al. 2021; Quinn et al. 2021; Strandell 2020). Turnover issues have existed for well over a decade in the Canadian homecare sector (Sayin et al. 2019; Zeytinoglu et al. 2009). In 2014, the Ontario Ministry of Health and Long Term Care reported that an estimated 60% of homecare PSWs leave their job each year (Matthews 2014).

Homecare workers are not regulated professionals in many countries, such as the UK (Saks and Allsop 2020), Sweden, Belgium, the US (Saari et al. 2018) and Canada (Afzal et al. 2018). In a context of inconsistent standards, the unclear competency of homecare workers can adversely impact client safety (Barken et al. 2020; Craven et al. 2012; Lang et al. 2014; Quinn et al. 2021; Tong et al. 2016).

During the COVID-19 pandemic, the need for PSWs in Canada was ever more pressing as the demand for home care exceeded worker availability (Casey 2021).While demand for home care dropped as much as 16% in March and April 2020, it returned to historic levels by September 2020 (Jones et al. 2021). However, PSW supply lagged. For instance, Ontario's ability to meet homecare service requests fell from 95% pre-pandemic to 60% as of October 2021 (Casey 2021) because of PSW and nurse shortages (Rodriguez 2020; Weeks et al. 2021).

Insecure work hours and low pay are widely thought to contribute to poor retention, and workers experience high rates of workplace injury, stress, burnout and turnover (Barken et al. 2018; Sayin et al. 2019; Zeytinoglu and Denton 2006; Zeytinoglu et al. 2009, 2015).

Wages

In 2014, the provincial Ontario government implemented a gradual wage increase for PSWs (Lysyk 2015). However, a recent study found that the wage increase had no discernible effect on retention (Olaizola et al. 2020).

In this paper, we highlight the ripple effects of policy developments during the COVID-19 pandemic and identify potential risks for PSW-provided homecare clients using the case of Ontario. Analysis was guided by a client-risk lens as used by the UK Professional Standards Authority (Professional Standards Authority 2016) and Saks and Allsop (2020), who described the risks in light of inadequate training, supervision and low standards of care in the UK.

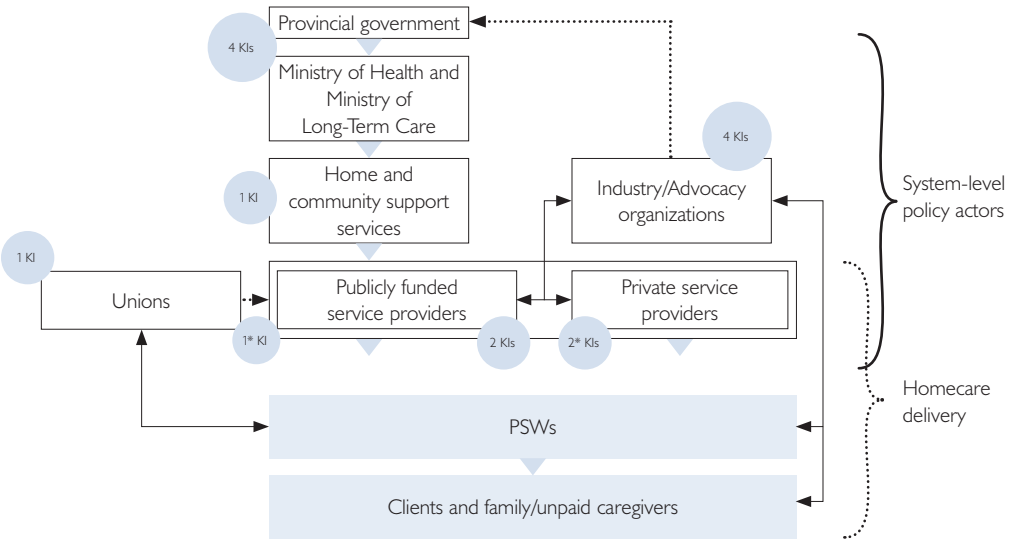
Method

We drew on interpretive policy analysis to explore data, which involves a focus on local knowledge, including an in-depth understanding of the actors and circumstances surrounding policy and the practical consequences of policies (Yanow 2000). This method is appropriate for exploring standpoints of multiple actors, their situated perspectives of policy related to PSWs and the implications for client risk. Ethics approval for this study was provided by the University of Waterloo Research Ethics Board and included informed consent, anonymity and confidentiality.

Recruitment and sample

In-depth, semi-structured interviews were conducted by PH (a former homecare PSW) from September 2020 to January 2021 and coincided with Ontario's second and third waves of the COVID-19 pandemic. Interviews were conducted with key informants (KIs). KIs were required to have close and current knowledge of homecare policy, the PSW occupation and/or client safety. KIs were identified by mapping the homecare system-level policy making through to service delivery policy (Figure 1).

FIGURE 1. KIs within the homecare system: A policy actor map



* One Union KI and one private service provider KI were also PSWs.
KI = key informant; PSW = personal support worker.

To ensure that KIs were included from each part of the homecare system, we aimed for four participants from each of the following categories: the government, industry/advocacy organizations, service provider organizations (SPOs) and four other "policy actors" based on needs identified (Yanow 2007). We had difficulty recruiting KIs from two sections of our target sample: we had zero response for the home and community care support services (HCCSS) organizations; however, these organizations were undergoing administrative transitions while also dealing with COVID-19 infections among clients and staff. We requested snowball referrals from KIs and personal contacts, and one individual was recruited by these means. For SPOs, we were unable to recruit four KIs who had experience providing publicly funded home care and expanded our recruitment to include two private service providers that employed PSWs. We used government organizational directories, submissions to governments, organizational reports and lists of homecare service providers to identify potential KIs. While PSW experience was not part of the sample inclusion criteria as the study focused on policy, two KIs who had PSW experience added depth to our sample. One KI who was also a PSW was found as a union representative with public contact information and one was found via a publicly advertised company providing homecare services. Overall, this sampling strategy allowed for purposeful selection of well-positioned individuals from organizations and the government. Individuals were contacted by phone and, in some instances, by e-mail. If a response was not received within two weeks, we followed up with an additional contact. Fifteen KIs were included in this study.

Data gathering and analysis

Prior to and alongside interviews, PH examined applicable laws and government documents in keeping with the importance of local knowledge in interpretive policy analysis (Yanow 2000). This process enhanced our ability to ask specific questions of participants and deepened our understanding of their responses. Refer to Hopwood (2021) for more details on the policy analysis process.

In-depth, semi-structured interviews were conducted via video calls or by telephone. The interview guide was based on previous policies and literature on the study topic (Yanow 2000), as well as co-authors' expertise in this area. Interview questions focused on KIs' perspectives of policies that increased risks for clients in PSW-provided care. (See Appendix 1, available online at longwoods.com/content/26970). Interviews were audio-recorded and transcribed verbatim. Memos and detailed field notes were also used to inform interpretations (Yanow 2007). Transcripts were uploaded to the NVivo-12 software (2018 version) and coded using an inductive coding process (Braun and Clarke 2006). Coding was conducted by PH, reviewed by EM and discussed with the remaining authors. In-depth analysis and team discussion of themes followed the coding process (Silverman 2015). Following Seale (2003), we used a triangulation of methods (policy analysis and interviews) and analysts (authors with different disciplinary backgrounds).

Study Findings

The 15 KIs provided senior-level insight from their positions in government departments, as senior managers in province-wide industry and advocacy organizations and as union experts. The KIs were from both provincial (n = 9) and regional (n = 6) organizations. One-quarter of the KIs had nursing backgrounds, thus also contributing clinical perspectives, while two were also PSWs. Four had 2–10 years of experience, and 11 had more than 10 years of experience (Table 1).

TABLE 1. Key informants

Participant number	Organization*	Position/role*	Scope of knowledge	Experience in years
P1	Government ministry	Senior government manager or official	Provincial	11–15
P2	Government ministry	Senior government manager or official	Provincial	>25
P3	Government ministry	Senior government managers or official	Provincial	2–5
P4	Government ministry	Policy researcher, consultant or program officer	Provincial	6–10
P5	SPO	Senior manager	Region¶ A	>25
P6	SPO	Senior manager	Region¶ A	2–5
P7	SPO	Senior manager	Region¶ B	>25
P8	SPO	PSW, entrepreneur	Region¶ A	2–5
P9	Provincial health advocacy/industry organization	Senior manager	Provincial	>25
P10	Provincial health advocacy/industry organization	Senior manager	Provincial	>25
P11	Provincial health advocacy/industry organization	Senior manager	Provincial	16–25
P12	Provincial health advocacy/industry organization	Senior manager	Provincial	16–25
P13	HCCSS§	Care coordinator	Region¶ C	11–15
P14	SPO	PSW, union representative	Region¶ D	16–25
P15	Union	Occupational health and safety specialist	Provincial	11–15

HCCSS = Home and Community Care Support Services; PSW = personal support worker; SPO = service provider organization.
* Broad categories are used to describe organizations and roles to protect participant identity.
§ HCCSS since April 2021 (formerly Local Health Integration Networks [LHINs], 2017–2021).
¶ Regions: One of the Ontario Health Regions (North, West, Central, East and Toronto); location has not been provided to protect participant identity.

We discuss findings in three main areas: (1) shortages; (2) recruitment strategies: rapid education and hiring; and (3) recruitment and retention: wages.

Shortages

Many KIs commented on worker shortages as common and increasingly problematic across health sectors during the COVID-19 pandemic. A senior government manager identified the urgent need for homecare staff, saying "We just need people. We need people. We're desperate for people." (P1)

A senior manager of a provincial health advocacy/industry organization noted a drop in the number of homecare staff provincially:

> Overall, during the height of wave one, [the homecare sector] probably lost a good 20–30% of … staff. Not only just to better paying jobs, but to government subsidies. (P9)

Several KIs linked shortages to PSW job conditions. For example, a senior government manager spoke about how improved job conditions would probably be needed to help address PSW shortages. An HCCSS care coordinator summarized the overall environment in Ontario as a dire staffing situation and noted that varying client demands made homecare staffing challenging. As clients were moved from hospitals to LTC to create hospital space during the pandemic, the number of homecare clients waiting for LTC grew from almost 35,000 before the pandemic to more than 39,000 as of January 2021 (Stall et al. 2021). Detailed quotations regarding PSW shortages are included in Table 2.

TABLE 2. Challenges regarding personal support worker shortages

KI	Role	Quotations
P5	Senior manager, SPO	" … multiple PSWs have multiple jobs. [T]hen [the] next thing you know, they're calling and cancelling their shifts because, maybe, the shifts that we had for them that they originally accepted might have been those shorter ones. But the other company now offered them those longer ones. So now they're cancelling on us and leaving the team to scramble to fill."
P6	Senior manager, SPO	"It doesn't matter if we had full-time hours to give them, but we were, you know, like a dollar shorter. You know, chances are they were going to go with another company or someone that was hiring them at an inflated price because a lot of companies were doing that."
P15	Occupational health and safety specialist, Union	"And the other thing we hear a lot from workers is that agencies are taking on patients and clients that they don't have the capacity to service, but they're taking them … just to get the funds attached."
P13	Care coordinator, HCCSS*	"So, trying to find a PSW is tough because a lot of the crunch right now for long-term-care facilities is [due to] crisis [at the] hospital because they're trying to clear out hospitals … I don't even know if we can [find] staff [for] high service needs [clients] in the [municipal] area, to be honest.
P1	Senior manager, government ministry	" … we're going to need to have better conditions … . Otherwise, we're just going to not have the people. And talking about increasing investment in home care is one thing, but to do it without putting money into the PSW side is going to be a real challenge because how do you keep up? I know some LHINs [HCCSS*] are [saying], 'we can't spend the money you give us because we cannot find people to deliver it … .'"
P7	Senior manager, SPO	"We've got shortages right now for sure. And it's something that we've grappled with for a number of years."

HCCSS = Home and Community Care Support Services; KI = key informant; LHIN = Local Health Integration Network; PSW = personal support worker; SPO = service provider organization.

* HCCSS since April 2021 (formerly LHINs, 2017–2021).

Recruitment strategies: Rapid education and hiring

KIs discussed how shortages escalated during the pandemic and drove the development of provincial policies focused on rapid recruitment, education and hiring. They described free and subsidized education for aspiring PSWs and "return of service" bonuses of $5,000 for newly graduated PSWs who completed six months' work for employers enrolled in the program (HealthForceOntario 2022). KIs also discussed SPOs offering wages above the usual minimum standards.

A KI with a senior government position in the Ministry of Health described that the lack of an adequate supply of PSWs to provide care created the potential for quality of care to be sacrificed and quick hiring to be prioritized: "The fact that some care is better than no care, I think, maybe, has driven a lot of the decision making" (P3, senior government role). Another senior government KI spoke about shortages and implications of orders to limit work to a single LTC or retirement home:

> The health human resource[s] shortages are being exacerbated during the pandemic … People have multiple jobs. This [home care] may [just] have not been the one they decided to stick with. They were told to stay in one location, and if they have a long-term care gig, they were going to stay there. (P1)

Widespread labour shortages were seen as having implications for client risk as the high staffing need led to poor staff screening. This interplay between shortages and the hiring process was described by a senior manager in a provincial health advocacy/industry organization:

> … There is such a shortage that even if a worker was to lose their job for poor practice, they would just get a job somewhere else immediately. (P10)

A senior government manager suggested that rapid hiring may contribute to the recruitment of unsuitable workers:

> … I think that happens with PSWs … You keep getting hired and moved on because the shortage means that people aren't, maybe, taking the time to do all the background checking or perhaps it's kind of out of sight, out of mind … (P3)

Ontario's tuition-free college education was seen as creating a risk of drawing in people who were unsuited to PSW work. For instance, a homecare business owner and PSW saw free education as a magnet for "anybody" irrespective of their suitability for the job: "That attracted so many *wrong* people to our profession. Being a PSW, you can't just be anybody. You need to be caring. You need to be compassionate" (P8).

Recruitment and retention: Wages

During the pandemic, policy to support recruitment and retention of PSWs included funding temporary wage increases for SPO workers; however, disparity between LTC and homecare wages remained (Ireton 2021). A senior manager in an SPO discussed how worker shortages led to an increased competition with higher paying sectors: "We [are] constantly needing individuals. It's difficult when you're competing with the long-term care homes and retirement homes" (P6). Low wage-related issues created competition, not just between LTC and homecare sectors but also among homecare service providers. Within home care, SPOs seeking to hire new workers led some organizations to offer wages above the minimum standards. Some SPO managers saw this wage increase as amplifying competition for hiring PSWs.

Discussion

This study explored how policies introduced to address PSW shortages during the pandemic may affect client safety in the home care provided by PSWs. Drawing on interpretive policy analysis and by using the case of Ontario, we focused on shortages and impacts observed by well-placed KIs in the system. Combined with the existing evidence regarding quality of care for clients, this allowed us to consider potential policy improvements. Despite KIs' heterogenous backgrounds and positions, there was surprising agreement on key policy issues, such as the need for effective strategies to attract and retain more workers well-suited to the job and the importance of adequate education.

Consequences of shortages and recruitment strategies

Healthcare workforce shortages have been problematic across sectors and international jurisdictions during the pandemic (Frogner et al. 2022; Gruber et al. 2021). International literature shows that workers faced challenges of increased workload due to absent co-workers, while limited access to personal protective equipment and risk of infection were additional concerns (Bandini et al. 2021; Markkanen et al. 2021).

We found that increased worker shortages made it challenging for SPOs to find enough PSWs to cover client care needs. Consequences of insufficient workers have been shown to include clients not receiving care and a revolving door of new workers unfamiliar with clients – with increased risk for clients' health and safety and elevated caregiver distress (Gamble 2021; Pfeffer 2020). Staff shortages also place existing workers under additional pressure, raising concern about occupational health and burnout (Agrba 2021). Lack of staffing for the provision of appropriate care has also been found to contribute to workers' moral distress (Webber et al. 2022), which, in turn, may further impact job satisfaction and retention (Panagiotoglou et al. 2017). Government managers acknowledged that providing services or spending existing care dollars was not feasible without adequate workers, despite a need for care. Our study emphasized that policies and health workforce recruitment strategies implemented during the pandemic failed to attract and retain sufficient workers.

Our study uncovered that pandemic-era policies that introduced rapid education programs had the effect of exacerbating SPO (employer) and other HCCSS stakeholders' pre-existing concerns about inconsistent education (Kelly 2017; Kelly and Bourgeault 2015). Although a minimum education standard was implemented in 2014 in Ontario by the Ministry of Training, Colleges and Universities (Kelly 2017; Kelly and Bourgeault 2015), this education is not required under provincial policy for Ontario homecare workers (Brookman et al. 2022). To ensure a high-quality workforce, mandatory education from approved programs should be considered. For example, British Columbia evaluates each program and requires that all publicly funded healthcare aides graduate from one of the approved schools (BC Care Aide and Community Health Worker Registry 2013).

Ontario's decision to limit workers to a single site was a good infection prevention and control measure: multi-site work has been identified as problematic in the US, for example (Baughman et al. 2022). Research comparing different jurisdictions' policy responses to managing worker shortages is needed. The Ontario Health agency has broad authority to set contract conditions following restructuring under the *Connecting People to Home and Community Care Act* (2020). To further reduce risk of infection spread and distribute the limited workforce more efficiently, this government agency could implement province-wide workforce policy and fund permanent, full-time PSW jobs. This could improve worker consistency and reduce multi-site work and the risk of infection transmission. Ensuring that jobs offer more consistent – for example, full-time – hours may also improve worker satisfaction and, in combination with wage parity, reduce attrition.

Wages: A barrier to hiring

Previous wage enhancements in Ontario did not make a marked difference in the supply and retention of PSWs (Olaizola et al. 2020). Our study reinforces the point that historic increases and pandemic wage enhancement alone have had insufficient lasting effect on the homecare workforce supply. Wages and intersectoral competition were viewed as a barrier to hiring and retaining homecare PSWs. Permanent wage enhancement, with home care on par with LTC, higher wages for increased skills and opportunity for advancement may be helpful policy levers for PSW staffing across Canada (Pan-Canadian Planning Committee on Unregulated Health Workers 2009) and in international jurisdictions facing similar issues.

Strengths and Limitations

Our analysis is novel in exploring how the COVID-19 pandemic policy measures to address workforce shortages impacted home care while describing potential implications for client risk. A limitation of our research is that our results do not represent all Ontario regions or provide urban–rural comparison, although six KIs had varying knowledge and roles in four different provincial regions, and the other nine participants provided insights from a provincial level.

Our study was focused on policy. We achieved a knowledgeable sample including perspectives from senior-level KIs in the government, provider and healthcare advocacy and industry organizations. A limitation of this study is that we did not include more PSWs as KIs.

Implications for future policy research

More research highlighting jurisdictions with promising practices should be considered. Future research could also investigate the expense of wage increases compared to turnover expenses, such as hiring and training 60% of the workforce every year. Including primary research with local PSWs, managers and families and considering how client care may be impacted by PSW shortages could also be examined in future work.

It will be important to learn if the recruitment schemes did impact recruitment and retention; thus, future work may consider whether workers who received the bonuses stay in the profession and in the sector. Examination of system-level data to evaluate any measurable changes to client risk during the pandemic also merits consideration.

Conclusion

In this paper, we focused on how Ontario's pandemic policy affected PSW-provided home care. By focusing on senior-level KIs' input on impacts of policy for the homecare sector, our findings contribute to identification of how the pandemic escalated key issues of concern – namely, PSW shortage, the development of more rapid education programs, accelerated recruitment and hiring and wages. Policies to recruit PSWs, reduce the length of education and subsidize tuition – while providing only temporary wage increases to existing PSWs – illustrates a short-term, "fire-dousing" approach that failed to address retention and contributed to hiring PSWs not well suited to the role. Permanent wage enhancement on par with LTC, full-time secure employment, advancement opportunity and consistent education are policy measures that may contribute to a sustainable, high-quality PSW workforce.

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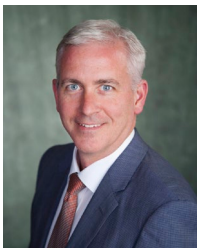

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