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

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

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

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

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

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

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EDITORIAL

When Small Changes Add Up to System Transformation

Just as sandy beaches are the result of uncountable individual waves crashing on a shore, fundamental shifts in the health sector often reflect the cumulative result of hundreds – perhaps thousands – of individual decisions. Each, on its own, may seem to have only local effect. But together, they represent a transformation in how care is delivered.

Take hospital services, for instance. In 1975, patients spent 43.1 million days in Canada's hospitals. Shortly thereafter, Statistics Canada analysts were interested in the effect that the baby boom generation would have on hospital use (Lefebvre et al. 1979). They asked: if the population grew and aged but healthcare utilization by age and sex stayed the same, how many hospital days would there be in 2016? Their answer: 76.7 million days. Actual use was less than a third of this amount, according to data from the Canadian Institute for Health Information (CIHI 2019).

Why the discrepancy? Was it because the original population projections were too high? No, that was not the case, and in fact, the 2016 Canadian census enumerated almost 5 million more people than the analysts projected in the 1970s (Statistics Canada 2017). Rather, the way we use hospitals has profoundly changed over the last four decades.

Adoption of new surgical techniques that enabled faster recovery and a switch to day surgery. Streamlining pre-surgical preparations or discharge planning. Supporting people with chronic conditions to manage them at home, reducing the need for hospital stays. Earlier discharge after giving birth. Due to these types of changes and many more, today's hospital care looks very different from care in the past.

It is clear that it wasn't one particular decision that changed the system, but rather a multitude of smaller ones made by local teams, hospitals, regional authorities, and provinces/territories.

Because change is often incremental and cumulative, it can be hard to perceive wider, long-term trends. As a result, it's helpful to mark milestones along the way. With this in mind, I am delighted to announce that *Healthcare Policy/Politique de Santé* recently received its 1,000th submission – what a great way to start the 15th year of the journal!

The articles published in this issue of the journal illustrate the diversity of papers that we have received over the years. Some focus on methodological advances in the field, as Shoemaker and colleagues do in this issue. Their paper describes development of clinical cohorts of people living with HIV in two provinces that have been linked with administrative data. Other authors use a variety of qualitative and quantitative methods to illuminate topical healthcare policy issues. In this issue, for instance, authors address issues that matter to the young and the old – from children's oral health to dementia care – as well as those that affect people of all ages, such as opioid prescribing, orphan drug pricing, and technology assessment and adoption.

Regardless of your particular health policy interests, we hope that you will find food for reflection in this issue of *Healthcare Policy/Politique de Santé* and that you will contribute insights of your own by submitting papers describing novel methods, relevant research, and insightful policy commentary for potential publication in future issues.

JENNIFER ZELMER, PhD
Editor-in-Chief

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ÉDITORIAL

Quand les petits changements mènent à une transformation du système

À l'instar des plages qui sont le fruit d'un nombre incalculable de vagues se brisant sur la côte, les grands changements du secteur de la santé sont souvent le résultat cumulatif de centaines, voire des milliers, de décisions ponctuelles. Chacune d'elles peut sembler n'exercer son effet qu'à l'échelle locale, mais ensemble elles se traduisent par une transformation de la prestation des soins.

Considérons, par exemple, la question des services hospitaliers. En 1975, il y a eu 43,1 millions de journées d'hospitalisation dans les établissements canadiens. À l'époque, des analystes de Statistique Canada se sont intéressés aux effets des baby-boomers sur les taux d'occupation des hôpitaux (Lefebvre et al. 1979) en se posant la question suivante : si la population croît et vieillit mais que l'utilisation des services de santé selon les groupes d'âge et de sexe demeure la même, combien de journées d'hospitalisation seront nécessaires en 2016? Leur réponse : 76,7 millions. Dans les faits, selon les données de l'Institut canadien d'information sur la santé (ICIS 2019), l'occupation réelle pour cette année-là représente moins du tiers du chiffre projeté.

Pourquoi y a-t-il une telle différence? Est-ce parce que les projections de population étaient trop élevées? Non, car selon le recensement de 2016 la population canadienne a dépassé de près de 5 millions la projection calculée par les analystes dans les années 1970 (Statistique Canada 2017). En réalité, c'est plutôt l'usage des hôpitaux qui a profondément changé au cours des quatre dernières décennies.

Les nouvelles techniques chirurgicales qui favorisent un rétablissement plus rapide ou permettent les chirurgies d'un jour. La rationalisation des préparations préopératoires ou la planification des sorties de l'hôpital. La gestion à domicile pour les personnes aux prises avec un état chronique, réduisant ainsi les séjours hospitaliers. Les congés obtenus plus rapidement après un accouchement. En raison de tous ces types de changements, et de plusieurs autres, les soins hospitaliers d'aujourd'hui sont bien différents de ce qu'ils étaient auparavant.

Il est évident que le changement du système ne découle pas d'une seule décision, mais bien d'une multitude de petites décisions prises par les équipes, les hôpitaux, les autorités régionales ainsi que les provinces et territoires.

À cause de sa nature souvent incrémentielle et cumulative, il est difficile de percevoir les tendances à long terme d'un changement. Ainsi, il est pratique d'en marquer les jalons en cours de route. C'est dans cet esprit que je suis heureuse d'annoncer que *Politique de Santé/Healthcare Policy* a récemment reçu le 1 000e article soumis pour publication : quelle belle façon de commencer la 15e année de la revue!

Les articles qui paraissent dans le présent numéro illustrent la diversité des sujets que nous recevons année après année. Certains d'entre eux portent sur les avancées méthodologiques, comme le font Shoemaker et al. En effet, leur article décrit l'évolution de cohortes cliniques de personnes qui vivent avec le VIH dans deux provinces dont les données administratives ont été couplées. D'autres auteurs ont recours à une variété de méthodes qualitatives et quantitatives pour éclairer certains enjeux liés aux politiques des soins de santé. Par exemple, dans le présent numéro, des auteurs se penchent sur des enjeux qui concernent les jeunes et les aînés – allant de la santé buccodentaire des enfants aux soins pour les personnes atteintes de démence – ou qui ont des répercussions pour les gens de tous âges, comme la prescription d'opioïdes, le prix des médicaments orphelins ou l'évaluation et l'adoption des technologies de la santé.

Quels que soient vos intérêts en matière de politiques de santé, j'espère que vous trouverez matière à réflexion dans ce numéro de *Politique de Santé/Healthcare Policy* et que vous contribuerez à trouver des solutions en proposant des articles qui décrivent de nouvelles méthodes, qui relatent des résultats de recherche pertinents ou qui présentent des commentaires inspirants pour les prochains numéros de cette revue.

JENNIFER ZELMER, PhD
Rédactrice en chef

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DISCUSSION AND DEBATE

Creating Clinical Cohorts: Challenges Encountered in Two Canadian Provinces

Constituer des cohortes cliniques : défis rencontrés dans deux provinces canadiennes

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Abstract

In 2013, the Living with HIV (LHIV) Innovation team established clinical cohorts of people living with HIV in Manitoba and Newfoundland and Labrador, and they linked the data to provincial health administrative databases. Access to these data enabled researchers to conduct studies across provincial borders; contribute to a national dialogue on HIV health system performance; and give recommendations for evidence-based healthcare, health policy and public health. However, research funding is episodic; maintaining cohorts requires stable funding. We support the establishment of a cross-jurisdictional approach to facilitate streamlined data collection and linkage without interruption and to allow for meaningful analysis in order to inform national policies.

Résumé

En 2013, l'équipe d'innovation Vivre avec le VIH constituait des cohortes cliniques de personnes vivant avec le VIH au Manitoba et à Terre-Neuve-et-Labrador. L'équipe a couplé ses données aux bases de données administratives provinciales. L'accès à ces données a permis aux chercheurs de mener des études transprovinciales, de contribuer au dialogue national sur le rendement du système de santé quant au VIH et de formuler des recommandations pour des politiques de santé, des soins et des mesures de santé publique éclairés par les données probantes. Toutefois, le financement de la recherche est sporadique, alors que la continuité d'une cohorte dépend de la stabilité du financement. Nous appuyons la mise en place d'une approche pangouvernementale afin de simplifier la cueillette et le couplage des données sans interruption et de permettre des analyses approfondies pour éclairer les politiques nationales.

To make evidence-informed policy and public health decisions, stakeholders, including federal, provincial and regional policy makers, practitioners and community organizations, require high-quality information and access to valid and reliable data to measure the impact of their decisions (Plsek and Greenhalgh 2001). In Canada, although there is a growing imperative to measure HIV health system performance (Johnston et al. 2015) and strengthen existing data management and infrastructure (Law et al. 2007), significant gaps remain with respect to comprehensive, population-level data that could guide resource allocation and healthcare delivery, including prevention, treatment and care for people living with HIV (PLWH). Despite the universality of coverage for medically necessary services delivered in hospitals or by physicians in Canada and the fact that the federal government transfers funding to the provinces and territories to support such coverage, the majority of these services are paid for directly by the provinces, and therefore, the majority of health administrative data are housed provincially, with varying degrees of completion and comprehensiveness (Widdifield et al. 2013). As the Council of Canadian Academies states, "in Canada ... those who need access to data must navigate a 'complex environment of heterogeneous entities,' often including numerous data custodians, privacy offices and research ethics boards, whose collective governance and operational practices fall short of constituting a well-defined and coherent system" (Council of Canadian Academies 2015).

Over the past five years, a number of research-funded initiatives focusing on different areas of health, such as the Canadian Longitudinal Study on Aging and the Canadian Partnership for Tomorrow Project, have sought to develop systems or platforms to link data collected through large cohort studies across different Canadian provinces to administrative health data (Doiron et al. 2013; Dummer et al. 2018). They are working to devise access protocols that respect jurisdictional requirements while supporting rigorous and effective harmonization practices (Fortier et al. 2017), but these are still nascent and are not yet in a position to provide researchers with access to multi-province data. It is thus heartening to see the Canadian Institutes of Health Research (CIHR) award $39 million over seven years to the Pan-Canadian Real-World Health Data Network (Smith et al. 2018) to create the Strategy for Patient-Oriented Research (SPOR) National Data Platform that can "receive multi-jurisdictional service requests and enable a single portal of access" to provincial and territorial health data, and "provide leadership and a forum to harmonize data access requirements and processes across jurisdictions" (CIHR 2017, 2019a), a sum which has recently been increased to $81 million by the federal government (CIHR 2019b).

In the absence of such a single portal of access, however, researchers wishing to establish cohorts in more than one province/territory that are linked with administrative health data must still work one jurisdiction at a time, which is more costly and less efficient. This paper describes how we used research funding to create linked cohorts in two provinces to address

data gaps, opportunities and challenges encountered in doing so and sustainability of bolstering national capacity around the HIV health system performance by using this approach.

Cohorts as a Response for Measuring Health System Performance

Measurement of the HIV cascade, a framework that incorporates testing for HIV diagnosis, presentation to and engagement in care and successful treatment to reach full virologic suppression, is one example of health system performance and an urgent public health priority (Levi et al. 2016). To fully characterize the HIV cascade and implement actionable policies, it is essential to know who is accessing care, who is providing care and the extent to which care is optimized (Rice et al. 2018). However, there is no national consensus about whether administrative, clinical cohort or electronic health data sources best capture cascade data; who holds accountability regarding data integrity and validity; and who is responsible for resourcing comprehensive data collection and analysis for sustainability and monitoring/evaluation (National Collaborating Centre for Infectious Diseases 2017).

The Public Health Agency of Canada collates and reports provincial and territorial public health data on HIV-relevant variables, including age, sex, ethnicity, country of birth, geographic location, transmission risk groups and HIV viral loads (Public Health Agency of Canada 2017). Although critical to the HIV cascade picture, these data may not reflect the broader health complexities and health services needs of PLWH (Johnston et al. 2015). Administratively collected data, on the other hand, are limited to routinely collected health services data, with varied linkage to social and other data across jurisdictions, and these do not include important patient characteristics or health system indicators to facilitate policy and provider responses (Tu et al. 2014). This gap has led research teams in Ontario (Ontario HIV Treatment Network 2018), British Columbia and Quebec (Canadian Observational Cohort Collaboration [CANOC] 2008; Klein et al. 2010; Loutfy et al. 2017) to create provincial clinical cohorts of PLWH by comprehensively linking public health, administrative and cohort data.

Until recently, comparable cohorts did not exist in Manitoba or Newfoundland and Labrador. As part of a five-year CIHR–funded program of research, "Advancing Primary Health Care for Persons Living with HIV in Canada" (LHIV), and building on our Ontario experience, new clinical cohorts of PLWH were created in Manitoba and Newfoundland and Labrador and linked to provincial administrative databases. This linkage created a repository of population-level clinical, administrative and public health data that could facilitate comparisons across provinces and contribute to a national dialogue on the HIV health system performance. In addition to cascade measures, these data can be used to assess the proportion of patients using primary or specialized healthcare services given provincial geographic disparities and to provide insight into how services are being used and how they can be optimized.

TABLE 1. Summary of information obtained through clinical cohorts from Manitoba and Newfoundland and Labrador*

	Manitoba (*N* = 871) *n* (%)		Newfoundland and Labrador (*N* = 251) *n* (%)
Sex			
Male	620 (71.2)		189 (75.3)
Female	251 (28.8)		61 (24.3)
Other/missing			1 (0.4)
Age at diagnosis			
<25	126 (14.5)		34 (13.5)
25–34	308 (35.4)		78 (31.1)
35–44	235 (26.9)		55 (21.9)
45–54	136 (15.6)		36 (14.3)
≥55	66 (7.6)		14 (5.7)
Missing	0		34 (13.5)
Ethnicity			
Caucasian	373 (42.8)		180 (71.7)
Indigenous	358 (41.1)		–
African Caribbean Black	94 (10.8)		13 (5.2)
Asian	31 (3.6)		–
Other/missing	15 (1.7)		58 (23.1)

	Manitoba Regional Health Authorities		Newfoundland and Labrador Health Regions	
	Region of residence	***n* (%)**	**Region of residence**	***n* (%)**
	Southern	35 (4.0)	Central	21 (8.4)
	Prairie Mountain	33 (3.8)	Western	18 (7.2)
	Winnipeg + Churchill	00 (80.4)	Eastern	202 (80.5)
	Interlake-Eastern	48 (5.5)	Grenfell-Labrador	≤6
	Northern	33 (3.8)	Unknown	≤6
	Unknown	22 (2.5)		
Primary care access		621 (71.3)		232 (92.4)
Co-infections/co-morbidities				
Hepatitis C		152 (17.5)		6 (2.4)
Asthma/COPD		123 (14.1)		29 (11.6)
Hypertension		104 (11.9)		48 (19.1)
Type II diabetes		92 (10.6)		17 (6.8)
Ischemic heart disease		29 (3.3)		7 (2.8)
Receiving antiretroviral treatment		823 (94.5)		81 (32.3)
Suppressed viral load (<200 copies/ml)		128 (14.7)		66 (26.3)

* data from June 2017

Creation of LHIV Provincial Clinical Cohorts

Recruitment for Manitoba's clinical cohort began in October 2013. We sought consent during clinical encounters at two Winnipeg-based sites of the Manitoba HIV Program, the primary provider of HIV care in the province. Clinical data are regularly collected manually from charts or electronic medical records. Anonymized and de-identified clinical data are linked to provincial administrative health databases housed within a division of Manitoba Health, Seniors and Active Living. Manitoba is well positioned to undertake large population-based studies given its strong infrastructure of linkable, population-based administrative health databases (University of Manitoba 2017). Currently, data from 871 PLWH living in Manitoba are included in the cohort, representing the first comprehensive source of health data among PLWH in Manitoba. This cohort will facilitate more sophisticated epidemiological analyses that can inform HIV care programming and provincial policy, for example, by establishing which populations are currently underserved.

Similarly, a cohort of PLWH was developed in Newfoundland and Labrador in September 2013. Because the majority of PLWH are referred to and receive care at the St. John's nurse-practitioner–led HIV clinic, a clinical cohort was developed similar to the Manitoba cohort. Further, an iterative approach was used to extract variables from three different databases – provincial laboratory data, HIV clinic data and administrative health data – using validated algorithms (Nosyk et al. 2013). The extraction and compilation of these databases were approved and completed by a trusted third party, the Newfoundland and Labrador Centre for Health Information. The cohort currently includes data from 251 PLWH, including demographics, laboratory tests, hospitalization visits, physician claims, mortality, cancer and co-morbidity information, pregnancy status, smoking status, country of origin and medication use. With cohort data access, researchers in Newfoundland and Labrador are able to identify the number of PLWH in the province and how many are accessing care at the HIV clinic. Table 1 provides preliminary demographic and clinical data acquired from these cohorts.

Challenges to Cohort Creation

The development of these cohorts was not without challenges. In Manitoba, some potential participants expressed apprehension regarding the kinds of data collected and how they will be used and concerns regarding confidentiality. The idea of using provincial administrative health data for research is a new concept to many individuals, and the study staff spent considerable time explaining the processes through which the study is able to link clinical and administrative data while maintaining anonymity and confidentiality. Potential participants were assured that they would never be contacted by the research team outside of the clinic setting to maintain confidentiality and that access to the master list containing study identification numbers and names was highly secured and restricted to two members of the research team. At the institutional level, it is challenging to integrate the cohort enrolment protocols into established clinic operations. In the context of an over-burdened healthcare

system, it is difficult to ask busy providers to incorporate additional procedures related to research studies into their routine encounters with clients. The Manitoba LHIV study team engages regularly with providers to emphasize the benefits of the cohort for their own practice and for Manitoba HIV Program's ability to meet the needs of its clients. Furthermore, because enrolment protocols are clinic-based, the clinical cohort under-represents PLWH who are sub-optimally engaged in care, thereby limiting the generalizability of cohort findings.

In Newfoundland and Labrador, there are risks to confidentiality among its predominantly rural population (Statistics Canada 2011), and a number of steps and ethical considerations had to be considered to ensure the cohort remained anonymous. Newfoundland and Labrador developed a data governance model that united researchers, data custodians, clinicians, patients, trainees and data experts, who met regularly to discuss any challenges and to develop mitigation strategies (Asghari et al. 2019). Inconsistencies across databases (provincial laboratory, clinic and health administrative data) posed another challenge, as PLWH were not necessarily identified by all three sources. Continuous data quality is a challenge for any clinical cohort; administrators and policy makers need to adopt the latest coding standards and diagnostic systems and ensure coders and physicians are trained to use them correctly (Nicholls et al. 2017). Some provincial databases were transitioning to an electronic medical system during cohort development, and the data of patients whose files had not yet been transferred may have been missed. Thus, the cohort was developed to be an interactive database that is retrospectively updated bi-annually with new PLWH data.

Our processes of stakeholder engagement, cohort development, data linkage and cross-system alignment of variable and outcome definitions have been undertaken entirely using research funds, as the research questions answered by the LHIV team could not have been addressed before the creation of clinical cohorts in these two provinces and their linkage with established administrative data. Leveraging research funds was beneficial during cohort development because it provided the flexibility of using innovative approaches guided by scientific evidence, but such funding is time-limited and therefore cannot ensure the sustainability of the cohorts.

Conclusion

Research funding has allowed the LHIV research team to develop clinical cohorts of PLWH in Manitoba and Newfoundland and Labrador, and it has created platforms for linking these cohorts to provincial health administrative databases. The established clinical cohorts will, for the first time, allow us to use rich individual-level clinical data to understand population-level healthcare delivery to PLWH in these provinces. One aim of the LHIV team was to compare HIV epidemics across provinces, but the unique provincial challenges experienced with respect to data collection and linkage, as well as the complexity of and time required to pool cohort data of multiple provinces into one repository, mean comparisons will have to be conducted at the aggregate level. Further, for these cohorts to be developed and

maintained, a more stable and sustainable source of funding is required than research funding, which is time-limited and episodic. LHIV funding ends in 2020, and it is unclear how the linked cohorts we have established will be maintained thereafter. Without meaningful multi-stakeholder investment in data collection, linkage and analysis, system-level measures of comprehensive HIV performance measurement in Canada are unlikely in our foreseeable future (Low-beer et al. 2018). We urge stakeholders, including researchers, public health and stewards of administrative data at the provincial and national levels, to collaborate across silos, collect data in Canadian jurisdictions that are generally under-represented and commit to action on infrastructure such as the SPOR National Data Platform. This will facilitate rigorous harmonization across studies and will inform the direction of the evidence-based health system for the care of PLWH and other chronic conditions.

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Review of Coroner Inquest Recommendations into Opioid Prescribing Practices in Ontario: Ongoing Health Policy Gaps

Examen des recommandations issues de l'enquête du coroner sur les pratiques de prescriptions d'opioïdes en Ontario : lacunes dans les politiques de santé

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Abstract

The rate at which opioids are being prescribed and the safety of prescription opioid use are serious and ongoing problems for individuals, communities and health systems across Canada. In 2011, a coroner's inquest was held in Brockville, Ontario, Canada, to examine the issue of prescription opioid diversion and abuse. Following the inquest, the jury provided 48 recommendations pertaining to prescribing and monitoring of opioids. The ensuing discussion highlights health policy gaps that remain to be addressed seven years after the inquest, in educational resource-sharing, high-dose prescribing, development and use of abuse-resistant formulations and coordination and monitoring of policy interventions.

Résumé

Le taux de prescription d'opioïdes et la sécurité liée à l'utilisation d'opioïdes d'ordonnance constituent de sérieux problèmes pour les personnes, les communautés et les systèmes de santé du Canada. En 2011, une enquête du coroner a été effectuée à Brockville, en Ontario (Canada), afin d'examiner la question du détournement et de l'abus des opioïdes d'ordonnance. Suite à cette enquête, le jury a formulé 48 recommandations concernant la prescription et la surveillance des opioïdes. La présente discussion met en relief les lacunes des politiques de santé auxquelles il faut remédier sept ans après la tenue de l'enquête, notamment dans le partage des ressources didactiques, dans la prescription de fortes doses, dans le développement et l'usage de formules prévenant une utilisation abusive ainsi que dans la coordination et la surveillance des interventions stratégiques.

Introduction

The rate at which opioids are being prescribed and the safety of prescription opioid use are serious and ongoing problems for individuals, communities and health systems across Canada. In 2011, a coroner's inquest was held in Brockville, Ontario, Canada, to examine the issue of prescription opioid diversion and abuse (Ministry of Community Safety and Correctional Services [MCSCS] 2011). Following the inquest, the jury provided 48 recommendations involving 18 agencies at federal and provincial levels. These recommendations pertain to the prescribing and monitoring of opioids and demonstrate the need for a comprehensive chronic non-cancer pain management strategy in Ontario. The jury recommendations have created an opportunity for policy intervention in the opioid epidemic that Ontario has been facing over the past two decades.

Background

When measured in milligrams of morphine or equivalent (MME) dispensed, Canada has the highest rate of opioid prescribing in the world (Busse 2017). In 2016, an estimated 21.5 million prescription opioids were dispensed, or 595 opioid prescriptions per 1,000 population (Canadian Institute for Health Information [CIHI] 2017). As the highest

dispensing province in Canada, an estimated one in seven people in Ontario received a prescription opioid in 2015/2016 (Gomes et al. 2017a).

This is concerning, as the rate of opioid prescribing in Ontario has been found to be positively correlated with opioid-related mortality (Fischer et al. 2014; King et al. 2014). The number of annual opioid-related deaths in Ontario increased from 127 in 1991 to 1,265 in 2017 (Gomes et al. 2017b; Public Health Ontario [PHO] 2018). The impact of problematic opioid use is most impactful among vulnerable populations including youth, seniors and First Nations and those living in poverty (Dhalla et al. 2011).

A main issue identified by the inquest was the increasing rate of high-dose opioid prescriptions for chronic non-cancer pain and the associated diversion and abuse of prescribed opioids leading to high levels of opioid-related mortality. The recommendations resulting from the inquest provided an opportunity for Ontario to develop an integrated health policy framework for chronic non-cancer pain management and opioid use. The inquest called for the use of a variety of policy instruments, including legislation, regulation and guidelines to address issues of problematic prescribing, monitoring and diversion of opioids. Despite expert-driven policy recommendations to address the epidemic, prescribing habits in Ontario have not changed significantly. In fact, opioid-related morbidity and mortality rates have increased (PHO 2018), and the ongoing epidemic demonstrates the failure to implement effective health policy in a timely fashion.

Though there has been progress in several drug policy areas, the opioid epidemic continues and shows no signs of abating. Since the time of the inquest in 2011, the rate of opioid-related deaths in Ontario has continued to rise; from 4.2 deaths per 100,000 in 2011 to 8.9 deaths per 100,000 in 2017 (PHO 2018). This pattern suggests that interventions have not been effective at reducing mortality, and further policy development is required to prevent additional harm. Indeed, no agency can tackle the opioid epidemic alone, and this process will involve ongoing teamwork and coordination across all levels of the government. This article highlights some major initiatives that have occurred since the inquest, as well as policy gaps that remain to be addressed including gaps in educational resource-sharing, dosing guidelines, development and use of abuse-resistant formulations and coordination and monitoring of the effectiveness of interventions. Policy gaps as discussed in this paper are defined as the lack, or ineffectiveness, of current policies. It should be noted that policy recommendations discussed here address opioid prescribing for chronic non-cancer pain management specifically, as one of several important contributors to the opioid epidemic.

Summary of major initiatives

Since completion of the inquest, several major initiatives have been implemented in Ontario to mitigate some of the potential harmful risks associated with opioid use and assist in surveillance and monitoring of opioid prescribing. In 2012, the Narcotics Monitoring System (NMS) was implemented to collect information from dispensers about all prescribed monitored drugs dispensed to people in Ontario. In 2016, a province-wide opioid strategy was

launched, which included publicly funded naloxone distribution programs, needle exchange programs and fentanyl patch-for-patch return program. In 2018, the Ministry of Health and Long-Term Care (MOHLTC) began accepting applications for overdose prevention sites to support harm reduction services, and the Ontario Drug Policy Research Network (ODPRN) launched the Ontario Prescription Opioid Tool, which collects data from the NMS to assist in monitoring opioid prescriptions across Ontario. Health Quality Ontario (HQO) has launched an opioid strategy that includes evidence-based quality standards, increased capacity for quality improvement, measurement and reporting on variations in quality while engaging with partners. Other provinces in Canada have developed and implemented similar initiatives.

Education and resource-sharing

Several recommendations from the 2011 inquest relate to mandating education on safe opioid prescribing and dispensing. To date, educational interventions for physicians have been provided in the form of in-person sessions and sharing of online resources and tools. A report by the ODPRN found that voluntary education programs are not as effective as physician-directed interventions for prescribing habits. Upon assessing the effect of a two-day course designed to promote appropriate opioid prescribing habits, the ODPRN found that "voluntary enrolment in the course was not shown to decrease opioid prescribing rates during the two-year period following course attendance." The report further stated that "if a physician was referred to attend the course by the College of Physicians and Surgeons of Ontario (CPSO) (e.g., following a complaint), there was a marked decrease in opioid prescribing following referral by the CPSO, but prior to the prescriber completing the course" (ODPRN 2016: 16).

Although continuing education is essential, this finding suggests voluntary education alone, without monitoring and regulation, may fail to achieve the intended outcomes. To address the current policy gap, a mentorship-style educational plan could be implemented in consideration of the new Canadian Guidelines for physicians and pharmacists to receive consistent educational programming surrounding the prescription, dispensing and utilization of opioids. To complement education efforts, HQO has made it possible for primary care physicians to access confidential *MyPractice* reports to compare their opioid prescribing patterns to their peers across the province. These include measurement on several indicators such as opioids dispensed, opioids and benzodiazepines dispensed and high-dose opioids dispensed.

High-dose prescribing

Several recommendations pertain to mandated limits on the volume of MME per day that can be prescribed based on evidence from the Canadian Guidelines around a "watchful dose" (Busse 2017). The Centre for Disease Control and Prevention (CDC) guidelines report that higher opioid doses are associated with increased risks for motor vehicle injury, opioid use disorder and overdose resulting in death (Dowell et al. 2016). Overall, there is evidence

to suggest that high-dose opioid dispensing has continued to decline since 2013 (ODPRN 2018). However, there has been reluctance to mandate dosing limits by physician regulatory bodies, suggesting physicians should use their best judgment on a per-patient basis.

The latest CDC guidelines, released in March 2016, recommend that "when opioids are started, clinicians should prescribe the lowest effective dosage" (Dowell et al. 2016). Evidence suggests that harms associated with doses of >200 MME outweigh the benefits and increase the risk of opioid-related mortality (Gomes et al. 2011). Both the CDC and the Canadian Guideline for Opioid Therapy and Chronic Non-Cancer Pain clearly indicate that clinicians should use caution when prescribing opioids at any dosage and should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 MME/day and avoid increasing dosage to ≥90 MME/day without careful justification (Busse 2017; Dowell et al. 2016). The College of Physicians and Surgeons of British Columbia and Nova Scotia have adopted the CDC guidelines as far as the dose recommendation is concerned (College of Physicians and Surgeons of British Columbia [CPSBC] 2016; College of Physicians and Surgeons of Nova Scotia [CPSNV] 2017).

To encourage appropriate prescribing, resources have been shared to educate physicians on safe dosing practices. However, as previously mentioned, voluntary education may not change behaviours, especially for those whose prescribing practices fall outside what is recommended by guidelines. An alternative could include a regulation whereby physicians are required to submit a referral to a pain specialist before prescribing a dose beyond what is recommended by the guideline. Limits to quantities prescribed must be made gradually, and with caution, to prevent unintended negative consequences.

Abuse-resistant formulations

Policy changes have been made to formulations of certain opioids to limit abuse and increase safety. For example, OxyContin was delisted from the Ontario Drug Benefits Formulary in 2011 and replaced with a tamper-resistant formulation called OxyNeo. Since this change, overall prescription rates and opioid-related mortality have continued to increase, likely as a result of dependence on oxycodone simply substituted by other potent medically prescribed and illicit drugs such as heroin (Hedegaard et al. 2015). Indeed, there is a temporal link between the decrease in oxycodone-related mortality following its removal from the formulary and the rise in fentanyl- and hydromorphone-related mortality (PHO 2018). This finding most likely reflects the transition of OxyContin users to other powerful opioids.

Abuse-deterrent formulations (ADF) of opioids have not been proven to reduce the harmful effects of opioid abuse. It has been reported that "ADFs represent a 'gimmick' of primary benefit to the pharmaceutical industry and that undue focus on them may undermine more meaningful policy measures" (Gomes and Juurlink 2016; Leece et al. 2015). This highlights the importance of policy evaluation and aligning the change or shift in policy instruments to predetermined health indicators and measurable outcomes.

Coordination and monitoring

Although the jury recommendations set out action items for specific agencies, there is a need for a collaborative structure to help coordinate efforts at national, provincial and local levels. Given the complexity of the opioid epidemic, collaborative efforts between agencies could be streamlined through a central stakeholder. Regional health organizations, in collaboration with local public health agencies, are well positioned within communities to lead collaborations. The Southeastern Ontario region can be used as an example, having formed a mentorship and support network that acts as a resource and provides physicians a platform to seek second opinions and troubleshoot various opioid-related scenarios they may face in practice. This model can be replicated in other local public health agencies or at a minimum in those communities with high rates of opioid prescribing and opioid-related morbidity and mortality (Moore et al. 2017).

The provincial governments could implement a centralized secretariat to coordinate a consistent, evidence-based response across all levels of the government. The secretariat should be given the mandate, staffing, budget and required data outlets or surveillance dashboard to enable them to accomplish a decrease in the overall community opiate load and a subsequent decrease in opioid-related morbidity and mortality. In addition, a dashboard could help monitor the effect of various interventions and could integrate numbers of intravenous drug use and related infections, the NMS prescribing data and the maps and analysis provided in the Ontario Narcotics Atlas. Such mechanisms could provide a greater ability to collect, analyze and report on the prescribing and dispensing of narcotics, and assist in identifying and addressing the systemic challenges that may lead to addiction and death.

Limited scope of the coroner jury recommendations

We must acknowledge the limitations in the process of coroner jury recommendations in and of themselves. Though well intentioned and based on expert advice, the recommendations provided by the jury may not be possible to implement or be within the mandate of the organization to which they were directed. There are also organizations not mentioned in the jury recommendations that make important contributions to mitigate risks associated with prescription opioids (i.e., street health centres and overdose prevention sites). Despite this, the process of the coroner jury recommendations was integral in identifying key issues relating to prescription opioids and setting clear goals. Agencies can work to achieve the overall intent of the recommendations, even if done through alternate means than specifically suggested.

The recommendations from the inquest relate specifically to the safe prescribing and dispensing of opioids. However, the opioid epidemic has many other causes and presents many other challenges, such as the entry of illicit fentanyl to the drug supply. Efforts should also focus on primary prevention to address underlying causes of the opioid epidemic. For example, we must advocate for, and improve, equitable access to addiction and mental health

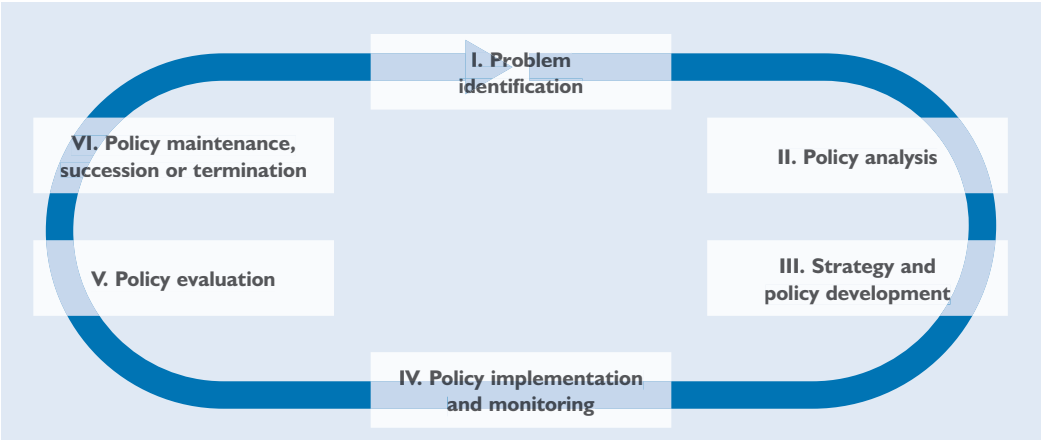
services, non-pharmaceutical treatment of chronic pain and the integration of trauma-informed care, among other upstream interventions. Addressing social determinants of health on a population basis must be integral to any approach.

Canada has faced years of opioid overprescribing that has contributed significantly to the harms caused by the opioid epidemic. Sensible reductions in amounts of opioids prescribed and provision of substitution therapy are needed to decrease the levels of opioids circulating in our communities and thereby reduce morbidity and mortality. Still, we must look for unintended harms in reducing medical supply of opioids. Such changes could result in the increased use of illicit drugs as those dependent on opioids try to avoid withdrawal, including use of illicit heroin and fentanyl. If suddenly cut off from their medical supply, those with existing opioid use disorders could lose tolerance and be at risk of overdose.

Conclusion

Several challenges may inhibit the implementation of the jury recommendations including a lack of central coordination between agencies necessary to adopt, implement, evaluate and continuously improve policy measures. This may result in delayed and disjointed efforts to bring the opioid epidemic under control. There is an urgent need for decisive action and implementation of evidence-based health policy. As with any policy intervention, the policy cycle (Figure 1) should be followed – from problem identification, to policy evaluation and improvement – to monitor and measure policy outcomes using indicators for performance management and continuous quality improvement principles.

FIGURE 1. Health policy process adapted from the heuristic policy cycle (Cairney 2013)



A public health crisis of this magnitude calls for a robust response from federal, provincial and territorial governments with focused, integrated, long-term intervention plans. All organizations and agencies involved have a responsibility to acknowledge their role and prevent further opioid-related harm.

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RESEARCH PAPER

Children's Oral Health and Barriers to Seeking Care: Perspectives of Caregivers Seeking Pediatric Hospital Dental Treatment

Santé buccodentaire des enfants et obstacles dans la recherche de soins : point de vue des parents ou tuteurs légaux à la recherche de traitements dentaires pédiatriques en milieu hospitalier

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Abstract

Objectives: To investigate the demographics of children (and their caregivers) requiring hospital-based tertiary dental care, oral health services use and perceptions of and barriers to oral healthcare in Nova Scotia.

Method: A questionnaire was administered to caregivers (N = 62) on behalf of their child (N = 62).

Results: Nearly half (45.8%, N = 27) of the caregivers experienced difficulty seeking oral healthcare for both themselves and their children. Less than a quarter (23.2%, N = 13) of the caregivers sought care for their child by the recommended age of one (mean age of first visit = 2.69 years). Alternate delivery in a school, community or primary healthcare setting was preferred by 53.3% (n = 32) of the caregivers for children's oral healthcare. Low-income families (53.8%, n = 28), rural areas (47.4%, n = 27) and Indigenous children (9.7%, n = 6) were over-represented in the study's sample.

Conclusion: Socio-economically disadvantaged populations are more vulnerable to oral diseases. Oral health of priority populations in Nova Scotia appears to be inadequately addressed.

Résumé

Objectifs : Étudier les données démographiques concernant les enfants (ainsi que celles de leurs parents ou tuteurs légaux) qui nécessitent des soins dentaires tertiaires en milieu hospitalier; étudier l'usage des services de santé buccodentaire et la perception vis-à-vis des soins dentaires, ainsi que les obstacles pour l'obtention de services dentaires en Nouvelle-Écosse.

Méthode : Les parents ou tuteurs légaux (N = 62) ont répondu à un questionnaire au nom des enfants (N = 62).

Résultats : Près de la moitié (45,8 %, N = 27) des parents ou tuteurs légaux ont connu des difficultés dans la recherche de soins dentaires pour eux-mêmes ou leurs enfants. Moins du quart (23,2 %, N = 13) des parents ou tuteurs légaux ont tenté d'obtenir des soins pour l'enfant dès l'âge d'un an, tel que recommandé (âge moyen de la première consultation = 2,69 ans). Un peu plus de la moitié, 53,3% (n = 32) des parents ou tuteurs légaux ont préféré d'autres modes de prestation de soins dentaires pour les enfants, soit à l'école, dans les services communautaires ou dans les établissements de soins de santé primaires. Les familles à faible revenu (53,8 %, n = 28), les secteurs ruraux (47,4 %, n = 27) et les enfants autochtones (9,7 %, n = 6) étaient surreprésentés dans l'échantillon de l'étude.

Conclusion : Les groupes défavorisés sur le plan socioéconomique sont plus vulnérables aux maladies buccodentaires. La question de la santé buccodentaire des populations priorisées en Nouvelle-Écosse ne semble pas être abordée adéquatement.

Despite the advances in oral health due to the widespread use of fluorides and a shift to a focus on prevention (Petersen and Ogawa 2016), dental caries (cavities) continue to be the most common chronic childhood disease (CIHI 2013; Rowan Legg 2013). Dental treatment for decay is the most common reason for day surgery for children in Canada (CIHI 2013).

Among those who suffer the greatest burden and experience the most barriers to care in Canada are the socio-economically disadvantaged, including children living in low-income or in poorly educated families, Indigenous peoples, refugees and immigrants, those with special needs and those living in rural areas (CAHS 2014; Health Canada 2010). Dental decay can result in acute or chronic pain that may affect a child's ability to eat, sleep, communicate and socialize and may ultimately influence optimal growth and development (i.e., failure to thrive) (CDA 2010; CIHI 2013; Ismail and Sohn 2001; Rowan Legg 2013).

A review of the oral health status of children in the province of Nova Scotia (NS) analyzed data from a 1995–1996 cross-sectional study of first-grade children in NS (Ismail and Sohn 2001). The authors recommended (1) a multifactorial approach to prevention and treatment of oral disease that addresses social determinants of health, (2) community-based preventive services and (3) health promotion programs such as school-based education and media promotion. Despite Ismail and Sohn's recommendations, dental public health human resources have since declined in NS, as there are fewer dental hygienists working in public health (Shaw and Farmer 2016).

Currently, the Fluoride Mouthrinse Program is the primary initative of public health dental hygienists in NS and is offered to select schools across the province. Some municipalities in NS fluoridate the public water supply, though information regarding whether a public water supply is fluoridated is not widely available to the public. The Children's Oral Health Program (COHP) is an insurance program (payer of last resort) provided by the NS Provincial Government since 1974. It focuses on publicly financed oral healthcare, diagnostic, preventive and treatment services, delivered primarily in private offices for all children until age 15 (Oral Health Advisory Group 2015; Shaw and Farmer 2016). According to the MSI (Medical Services Insurance) Annual Statistical Tables, the most recent data (fiscal year 2017/2018) showed that only 42% of the eligible children used the COHP (Nova Scotia Department of Health and Wellness MSI Health Information Department 2018).

The objectives of this cross-sectional descriptive study were to determine the demographic profiles of both children requiring tertiary oral healthcare and their caregivers, the perceptions of the caregivers of pediatric oral healthcare in NS and their children's utilization of these services and the barriers to oral healthcare. Ultimately, the goal was to investigate if inequities in oral health status continue to exist in NS despite the oral health policies and programs implemented by the provincial government and, if so, to identify contributors to those disparities. The results of this study will add to the limited body of knowledge on children's oral health in NS.

Methods

Setting and population

This study was conducted at the Izaak Walton Killam (IWK) Health Centre in Halifax, NS, which is the only pediatric hospital in Atlantic Canada. The IWK treats oral disease in children who are unable to be treated in private dental clinics because of a variety of medical and dental concerns, though only children who were primarily referred to the clinic for an unmet dental need, a key indicator of poor oral health, were included in the study. Although the children were the focus of the study, their caregivers – as the responsible decision-makers – were the study's eligible participants. The minimum target sample size for this study was 46, which was calculated using an online sample size calculator. This calculation was based on a population of ~52 eligible patients (derived from clinic records during the study period of July–August 2015), a confidence level of 95% and a confidence interval of 5%. In total, a sample of 62 participants was recruited via quota sampling over a three-week period in August 2016. Ethics approval for this research was obtained from the Research Ethics Boards at Athabasca University and the IWK Health Centre.

Inclusion and exclusion criteria

Caregivers were eligible to participate in the study if their child was entitled to coverage under the NS COHP and caregivers were seeking or had sought care at the IWK pediatric dental clinic for their child's unmet needs such as visible tooth decay, dental abscesses or facial cellulitis. Excluded were caregivers whose child's underlying medical condition or behaviour management was the primary inhibitor to seeking care in a private dental clinic.

Design

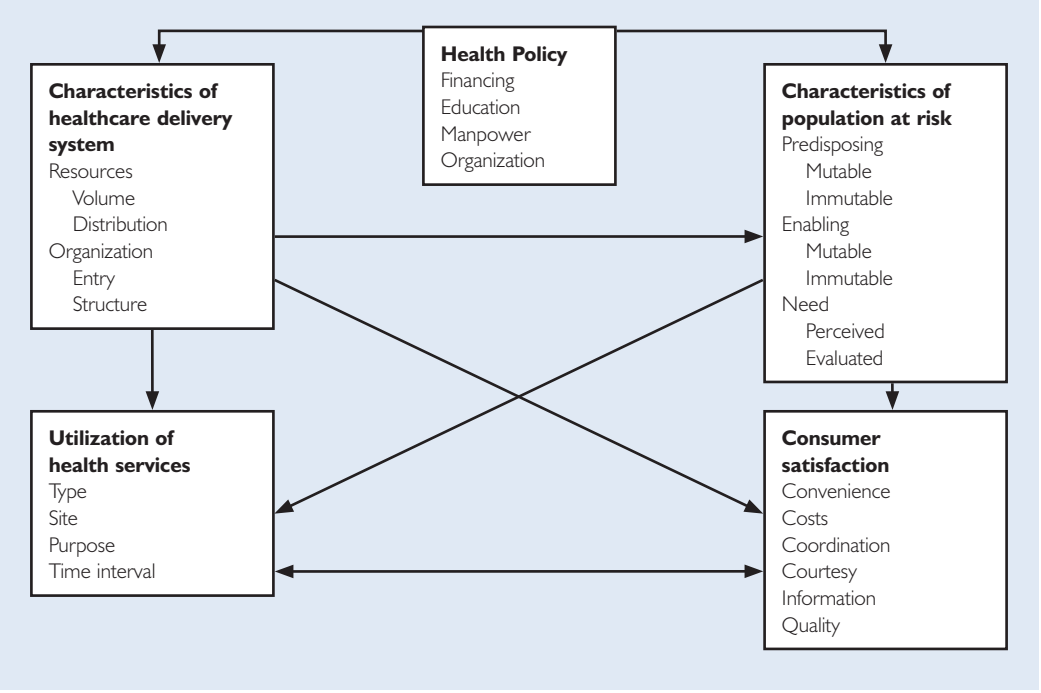
The study used a cross-sectional descriptive design. The research tool was a 52-item questionnaire (Appendix 1, available at longwoods.com/content/25940) adapted from a previously tested questionnaire (Lai et al. 2012) based on Aday and Andersen's (1974) framework for the study of access (Figure 1). This widely accepted model has been used as the framework for numerous studies on access and utilization of oral healthcare services (Beil and Rozier 2010; Crowder 2015; Jang et al. 2014). Each element of the conceptual model was used to inform the study's questionnaire. Eligible caregivers were invited to complete the online questionnaire on a portable computer tablet, using LimeSurvey™ survey software, while visiting the IWK pediatric dental or day surgery clinic for their child's dental appointment in August of 2016.

Analysis

The data were exported from LimeSurvey™ to IBM SPSS™ Statistics v23 software. Participants were classified as low-income using Statistics Canada's (2012) low-income cut-offs (LICO) 2013 base before tax table, which combines family size and community size to

determine the low-income threshold. Descriptive statistics (frequencies, measures of central tendency and variance) were calculated for each variable. A series of bivariate inferential comparisons were run using the chi-square test to examine whether demographic variables (such as community size, education level or income level) had an impact on respondents' perceptions of availability of dental services. Independent sample t-tests were used to look for differences in child's age at first visit among each of the following: insurance status (private, dual private, public or none) of caregiver's child, caregivers with differing perceptions of the importance of dental care (very important, important, somewhat important, somewhat unimportant, unimportant or very unimportant) and caregivers whose children had differing oral health status (those with or without a cavity and/or abscess) at first visit.

FIGURE 1. Framework for the study of access



Results

All eligible caregivers (N = 62) were willing to participate in the study. Each caregiver was participating on behalf of a child (N = 62) requiring hospital-based tertiary dental care. Although the study included 62 participants, not all caregivers responded to all of the questions. The denominator for variable changes based on the number of respondents for each question. All responses are based on the perceptions and knowledge of the caregivers.

Table 1 addresses the pillar "Characteristics of Population at Risk" in Aday and Andersen's framework for the study of access. The pillar "Utilization of Oral Healthcare Services" is addressed in Table 2. Table 3 bridges pillars "Characteristics of Population at

Risk" and "Consumer Satisfaction," and pillars "Characteristics of Health Delivery System" and "Consumer Satisfaction" are represented in Table 4. These tables available online at longwoods.com/content/25940.

Demographic profile

The mean age of children in the study was 6.21 years (+/–3.06 SD), and there was nearly even distribution of male and female children. The most commonly selected ethnicity was Caucasian (75.8%, n = 47), followed by Indigenous (9.7%, n = 6). Caregivers were predominantly female (86.0%, n = 49). Almost half of families (47.4, *n* = 27) lived in towns or communities with a population of fewer than 30,000 people with a significant proportion having a high school education or lower (41.1%, *n* = 23). The majority (61.7%, *n* = 32) had a total household income of less than $50,000. Just over half (53.8%, *n* = 28) of the families lived below the LICO threshold.

No statistically significant differences in the caregivers' perceptions of availability of dental services were found between respondents from different community sizes, education levels, genders, income levels or immigration status (chi-square tests; $p > 0.05$).

Utilization of oral healthcare services

Most caregivers (79.1%, *n* = 49) reported being made aware of the recommended age of first dental visit by a dental professional. Fewer than one-third (27.4%, *n* = 17) had been instructed by a doctor or nurse, and only one respondent (1.6%) had been advised of this by a prenatal instructor. Several (14.5%, *n* = 9) reported they had never been informed of the recommended age. Only 23.2% (*n* = 13) of the children visited a dental professional by the recommended age of one. A majority (63.6%, *n* = 35) of the caregivers perceived the appropriate age of the first dental visit to be higher than the recommended age, 2.29 +/–1.36 years (mean +/– SD), while the mean age at which caregivers had actually first sought dental care for their child was 2.69 +/– 1.29 years (mean +/– SD). Many of the children (44.1%, *n* = 26) already had decay at that time. Caregivers reported that 72.9% (*n* = 43) of the children had experienced a toothache (pain) and 23.3% (*n* = 10) had missed school because of this pain. Most caregivers (86.4%, *n* = 51) had experienced a toothache and 36.7% (*n* = 18) had missed work because of tooth-related pain. Nearly half (42.1%, *n* = 24) of the caregivers had not sought preventive dental care, described as a "cleaning or check-up," for themselves in the previous year.

Most respondents had received instruction about oral hygiene homecare for their children and information about cariogenic (cavity-causing) foods and drinks from a dentist (66.1%, *n* = 41) or a dental hygienist (38.7%, *n* = 24), followed by a prenatal instructor (4.8%, *n* = 3) and a nurse (1.6%, *n* = 1), and 8.1% (*n* = 5) of the respondents had not received any instruction or information about cariogenic foods and drinks from a health professional.

Television and the Internet were the two most common media sources of oral health information, although 29.0% (n = 18) of the caregivers reported not receiving any oral health information via the media.

No statistically significant differences in child's age at first visit were found between respondents with different insurance status, respondents with differing perceptions of the importance of dental care or respondents whose children had different oral health status at first visit (independent sample t-tests; $p > 0.05$).

Barriers to care

Nearly half (45.8%, n = 27) of the caregivers reported experiencing difficulty in seeking oral healthcare for both their children and themselves. The most common barriers to seeking oral healthcare for children were cost (17.7%, n = 11), lack of cooperation by the child (16.1%, n = 10) and inability for the caregiver to miss work (9.7%, n = 6). The most common barriers to caregivers seeking oral healthcare for themselves were cost (35.5%, n = 22), no insurance or uncertainty about insurance coverage (14.5%, n = 9), inability to miss work (8.1%, n = 5) and anxiety regarding dental treatment (8.1%, n = 5).

Perception of oral healthcare in NS

Given the choice, 53.4% (n = 32) of the caregivers reported they would prefer an alternate dental care setting for their children's dental care over a private dental clinic, for example, community-based clinics (26.7%, n = 16), primary healthcare-based clinics (15.0%, n = 9) and children's school-based clinics (6.7%, n = 4).

Discussion

Characteristics of population at risk and consumer satisfaction

The percentage of caregivers and children who fell below the LICO threshold (53.8%, n = 28) was eight times higher than the 2011 NS provincial average (7%) and four times higher than the 2007–2011 Canadian national average (12.9%) (Nova Scotia Department of Community Services 2018; Statistics Canada 2013). Cost was one of the most commonly reported barriers (17.7%, n = 11) for children accessing dental care, which signifies that the financial burden of oral healthcare is still a concern and a barrier to care for some children, despite the existence of a children's public oral health insurance program.

The proportion of children in this study who identified as Indigenous was disproportionately high compared to the provincial population (9.7% compared to 4.3%) (Statistics Canada 2008, 2012). This finding of disproportionate numbers of Indigenous peoples seeking tertiary oral care is an indicator of inequitable poor oral health. The 2008–2010 First Nations Regional Health Survey found that First Nations children had a disproportionately

high rate of decay: 18.7% of infants and 30.9% of preschoolers had teeth affected by early childhood caries. In part, the First Nations Regional Health Survey attributed the high burden of oral disease to socio-economic and geographic challenges. Despite publicly financed dental care (through the federal Non-Insured Health Benefits program and the provincial programs such as COHP), utilization of oral healthcare services is lower among First Nations people than the general Canadian population (First Nations Information Governance Centre 2012).

Families living in small towns or rural communities were over-represented in the study sample: 47.4% (n = 27) lived in communities of fewer than 30,000 people, compared to 38% of similarly aged adults in the overall Nova Scotian population. Similarly, families living in medium-sized communities (30,000 and 99,999 people) were also over-represented in the study's sample compared to the provincial population (12.3% versus 2%) (Statistics Canada 2012, 2013). Conversely, families living in large centres were under-represented in the study sample. This distribution may reflect the challenges of accessing dental care outside of urban areas where dental professionals are concentrated (Emami et al. 2016).

Characteristics of health delivery system and utilization of health services

For prevention and early detection of oral diseases, the CDA recommends that a child's first dental visit be within six months of the eruption of the first tooth or by age one, whichever is earliest (CDA 2018). Only 14.5% (n = 9) of the caregivers reported never being educated on the age of first visit (dental professionals were the most commonly reported educators), yet the mean ages that caregivers perceived to be appropriate and the actual age that dental care was first sought for their children were both over two years of age. A low percentage (23.2%, n = 13) of caregivers actually took their children to a dental professional by the age of one year. Depending on the extent or severity of oral disease, young children ranging in age from 1 to 14 (M = 6.21) required specialty dental treatment and, in many cases, surgical intervention. Among the most likely contributors to these discrepancies are inadequate delivery of key messages and inadequate translation of knowledge into action. Studies have shown the oral health benefits of initiatives that involve both medical and dental professions (Biordi et al. 2015; Braun and Cusick 2016; Clark et al. 2016). Non-dental primary care health professionals are well positioned to improve access to dental care (Bernstein et al. 2017). More initiatives in early oral health screening and referrals, education and intervention for children and their caregivers by non-dental professionals who have access to priority populations may reduce the inequities in oral health.

Despite Ismail and Sohn's (2001) recommendation for media promotion, 29% (n = 18) of the caregivers reported never receiving oral health-related information through the media, including television, radio, Internet, social media and print.

The results of this study support the existing evidence that priority populations, including low-income families, Indigenous peoples, those residing in rural communities and those with a lower education level, are more likely to be burdened by oral diseases. The results

also suggest a need to further evaluate the accessibility of oral healthcare in NS for those who need it most according to Aday and Andersen's fifth pillar of the study of access model "Health Policy." Most dental treatment is provided in private dental offices (Health Canada 2010), yet contrary to this policy, alternate dental care settings for children's dental care were preferred by over half (53.4%, $n = 32$) of the caregivers. Quiñónez et al. (2010) found that low-income Canadians prefer seeking dental care in a public setting and suggest that the private dental practice model of delivery is a major contributor to unequal access to care. Accordingly, more initiatives in early oral health screening and referrals, education and intervention for children and their caregivers by dental professionals in non-dental settings that are frequented by priority populations can also reduce the inequities in oral health status.

Limitations

Although the results of this study show disparities in oral health for a portion of children in NS, because of the nature of non-probability sampling and the sample size, it is difficult to make inferences about all children in the province. The current study did not include an investigation of oral health status; the study findings are based on caregivers' perceptions and knowledge only. The results do indicate a need for further research to determine the current oral health status of children across the province of NS, along with a review of current evidence-based public oral health programs, and an evaluation of the effectiveness of the provincial policies and programs to prevent, reduce or eliminate oral diseases among children in NS.

Conclusion

For many Nova Scotians, the oral health system appears to be working well, as the rate of oral disease continues to decline across Canada. Though the publicly funded, privately delivered oral healthcare model may be failing the children who are most in need (CAHS 2014; CIHI 2013; Health Canada 2010), the realities of priority populations and evidence-based oral health strategies are disconnected from current decision-making. This study confirms that disparities in income, education, geography and ethnicity continue to impact the oral health of children and their caregivers seeking hospital-based tertiary dental care in NS. Caregiver perceptions of the oral care services and barriers to care reinforce the inadequacy of current oral care policies in achieving optimal oral health for Nova Scotians, regardless of socio-economic status.

Oral health screening and surveillance measures are needed to determine the current oral health status of children throughout NS. This information combined with what is known regarding effective public policy and programming can be used to evaluate the current oral health initiatives. Government oral health policy with consideration of the impact of the social determinants of health and equitable evidence-based strategies is required to meet the needs of those children who are most burdened by oral disease.

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RESEARCH PAPER

Impact of Deferring Critically Ill Children Away from Their Designated Pediatric Critical Care Unit: A Population-Based Retrospective Cohort Study

L'impact d'une réorientation des enfants gravement malades hors de leur unité de soins intensifs pédiatriques désignée : une étude de cohorte rétrospective

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Abstract

Background: The impact of deferring critically ill children in referral hospitals away from their designated pediatric critical care unit (PCCU) on patients and the healthcare system is unknown. We aimed to identify factors associated with deferrals and patient outcomes and to study the impact of a referral policy implemented to balance PCCU bed capacity with regional needs.

Methods: We conducted a population-based retrospective cohort study of admissions to a PCCU following inter-facility transport from 2004 to 2016 in Ontario, Canada.

Results: Of 10,639 inter-facility transfers, 24.8% (95% confidence interval [CI]: 23.5–26.1%) were deferred during pre-implementation and 16.0% (95% CI: 15.1–16.9%) during post-implementation of a referral policy. Several factors, including previous intensive care unit admissions, residence location, presenting hospital factors, patient co-morbidities, specific designated PCCUs and winter (versus summer) season, were associated with deferral status. Deferrals were not associated with increased mortality.

Conclusions: Deferral from a designated PCCU does not confer an increased risk of death. Implementation of a referral policy was associated with a consistent referral pattern in 84% of transfers.

Résumé

Contexte : On ne connaît pas l'impact, sur les patients et le système de santé, d'une réorientation des enfants gravement malades hors de leur unité de soins intensifs pédiatriques (USIP) désignée. Nous voulions dégager les liens entre les réorientations et les résultats pour les patients ainsi qu'étudier l'impact d'une politique d'aiguillage des patients mise en place pour assurer l'équilibre entre le nombre de lits en USIP et les besoins de la région.

Méthode : Nous avons mené une étude de cohorte rétrospective des admissions à l'USIP suite à un transfert inter-établissements entre 2004 et 2006 en Ontario, au Canada.

Résultats : Parmi les 10 639 transferts inter-établissements, 24,8 % des cas (95 % intervalle de confiance [IC]: 23,5–26,1 %) ont été redirigés avant la mise en œuvre de la politique d'aiguillage et 16,0 % (95 % IC: 15,1–16,9%) après sa mise en œuvre. Plusieurs facteurs sont liés à une situation de réorientation, notamment les admissions antérieures à l'unité de soins intensifs, le lieu de résidence, les facteurs d'hospitalisation, la comorbidité des patients, les USIP désignés et les saisons (hiver ou été). Les réorientations ne sont pas associées à un accroissement de la morbidité.

Conclusions : Le fait d'être redirigé hors de l'USIP désignée ne présente pas un risque accru de mortalité. Nous observons un lien entre la mise en œuvre de la politique d'aiguillage et un schéma d'aiguillage cohérent dans 84 % des cas de transfert.

Background

Regionalized care networks with centralized expertise make inter-facility transfers a necessary element of modern healthcare. Critically ill pediatric patients have improved outcomes when treated in a tertiary care centre rather than a community hospital (Holmes and Reyes 1984; Newgard et al. 2007; Pearson et al. 1997; Pollack et al. 1991; Pracht et al. 2008), providing a compelling rationale for the centralization of care. Inter-facility transfers have increased in frequency in Ontario and elsewhere (Franca and McManus 2018; Tijssen et al. 2019). Ideally, children requiring critical care are transferred to their designated pediatric critical care unit (PCCU); however, when this is not possible, they are deferred to an alternate PCCU. The designated PCCU is usually the PCCU closest to the referring hospital; there is usually some familiarity by the receiving PCCU and transport teams with the referring hospital and its clinicians. Alternatively, the non-designated PCCU may have a required service that is not available at the designated PCCU, for example, cardiovascular surgery. The impact of PCCU deferrals on patients and the healthcare system has not previously been studied and is unknown.

In 2014, there were 85 beds in four PCCUs for critically ill children in Ontario, Canada. Of these, 65 were equipped to manage children who require mechanical ventilation (CritiCall Ontario b). To administer critical care services in Ontario, an official referral policy was implemented in 2010 to guide the inter-facility transfers of critically ill children based on regions, distance and predicted bed capacity. Prior to 2010, referral patterns were based on shortest distance and informal relationships between hospitals and/or clinicians. The new referral policy was based on the 14 local health integration networks (LHINs) in the province, which are regional networks of healthcare institutions through which funding flows with an aim to improve patient access and experience. It is not known whether this new referral policy made patient transfers more consistent and improved healthcare outcomes.

Our study's objectives were to identify factors associated with deferrals of critically ill children away from their designated PCCU, evaluate patient outcomes as they related to deferrals away from a PCCU and study the impact of the 2010 referral policy implementation. We hypothesized that season, presenting diagnosis, presence of specific co-morbidities and specific designated PCCUs would be associated with deferrals. We also hypothesized that deferrals would not be associated with increased risk of mortality and that the policy would lead to more consistent referral patterns.

Study design and setting

We conducted a population-based retrospective cohort study of all inter-facility transports of children to PCCUs using administrative healthcare data in Ontario, Canada. Ontario has four Level 3 and above PCCUs, and all residents of Ontario (population approximately 14 million) obtain healthcare services from a government-administered single-payer system. A PCCU is a ward within a hospital that specializes in caring for critically ill children from

newborn to 18 years of age, and Level 3 units are capable of providing the highest level of service to meet the needs of patients who require advanced or prolonged respiratory support or basic respiratory support together with the support of more than one organ system (Critical Care Services Ontario). A unique, encoded identifier permits linkage across several administrative databases, which were then analyzed at the Institute for Clinical Evaluative Sciences (ICES). This report follows the RECORD (REporting of studies Conducted using Observational Routinely-collected health Data) statement (Benchimol et al. 2015).

Data sources

Data sets included the Canadian Institute for Health Information's (CIHI) Discharge Abstract Database, Same-Day Surgery Database and National Ambulatory Care Reporting System; the Registered Persons Database; census; and LHIN databases (Supplement Tables 1 and 2 available online at longwoods.com/content/25939). This study was approved by the institutional review board at Sunnybrook Health Sciences Centre, Toronto, Canada.

Study cohort

Our study cohort included all eligible transports of patients who were of age <18 years and were transported directly from a referral centre to one of Ontario's four Level 3+ PCCUs between January 1, 2004 and December 31, 2016. Patients who did not reside in Ontario at the time of transport, patients who did not have a valid Ontario Health Insurance Plan number during the study period and patients with missing information on age or sex were excluded from the final cohort.

Patient factors and outcomes

We identified the following patient characteristics: age, sex, rural dwelling, distance traveled from the referral hospital to the PCCU, originating location within the referral centre (ward, emergency department [ED] or operating room), time spent in the ED (for those who originated in the ED), most responsible diagnosis, time and season of PCCU admission, fiscal year of transport, total acute care days, prior intensive care unit (ICU, not specifically pediatric) admission in previous 12 months, prior hospitalization in the previous two years, co-morbidities and designated PCCU. Rurality was determined using the Statistics Canada (2011) definition of rurality with coding based on the Statistics Canada Postal Code Conversion Files (Wilkins 2009). Distance was calculated using straight-line distance from latitude and longitude values. The time to definitive critical care was calculated as the time between ED registration and PCCU admission for patients who presented to the ED. Most responsible diagnosis was based on the International Classification of Diseases 10th revision coding associated with the PCCU admission and collapsed into nine categories (congenital malformations [for newborns]/genetic abnormalities, respiratory, psychiatric/neurologic, perinatal complications [for newborns], accidents or ingestions, acquired cardiac/circulatory,

infection, hematology/oncology, infection and other) (Supplement Table 3). The time of admission to the PCCU was defined as daytime (08:00–16:00), evening (16:00–24:00) or night (24:00–08:00). The seasons of the PCCU admission were defined as winter (January, February, March), spring (April, May, June), summer (July, August, September) and fall (October, November, December). The "total acute care days" were calculated as the sum of days with ED visits, hospitalization and same-day surgeries in the six months prior to transfer. The following co-morbidities were identified for patients who required acute care in the one year prior to transfer: malignancy, cerebral palsy, tracheostomy, congenital cardiac malformation, heart failure, chronic liver failure, chronic renal failure or history of an organ transplant (Supplement Table 4). The four designated PCCUs were randomly assigned letters A, B, C and D.

Our primary outcome was deferral status. Secondary outcomes included mortality in the PCCU, mortality in the PCCU within 24 hours of transfer, mortality within six months of transfer and PCCU and hospital lengths of stay (at the receiving hospital, LOS), defined as long if the LOS was greater than the median LOS for all transferred patients. Our main predictor of interest was the patient's transfer status (deferred or not) based on the 2010 referral policy. According to the policy, a deferred patient is one who requires a PCCU admission but is transferred to a PCCU other than their designated centre (Supplement Table 5). A deferral could occur if the designated centre is at full bed capacity or has other resource shortages (e.g., insufficient nurses or no available pediatric neurosurgeon), there are weather restrictions on travel or because of patient preference or specific individual needs (e.g., patient requires a cardiac surgical evaluation not offered at each PCCU centre).

Statistical analysis

Transfers were the unit of analysis in this study. We compared patient characteristics between deferred and non-deferred transfers, using the chi-square test for categorical variables and Student's t-test or Kruskal–Wallis for continuous variables where appropriate. We used multivariable logistic regression models to examine factors associated with deferrals in the pre-implementation and post-implementation periods. The generalized estimating equation (GEE) estimation method was used to account for the potential within-patient clustering among children who experienced more than one transfer during the study periods. Factors included age, sex, previous ICU stay, rurality, designated PCCU, distance from referral hospital to designated PCCU, presentation to local hospital, originating location in referral hospital, transfer time of day, transfer season, total acute care days in the previous six months, previous case of cancer, chronic respiratory failure, congenital cardiac malformation, heart failure and transplant and most responsible diagnosis of the PCCU admission.

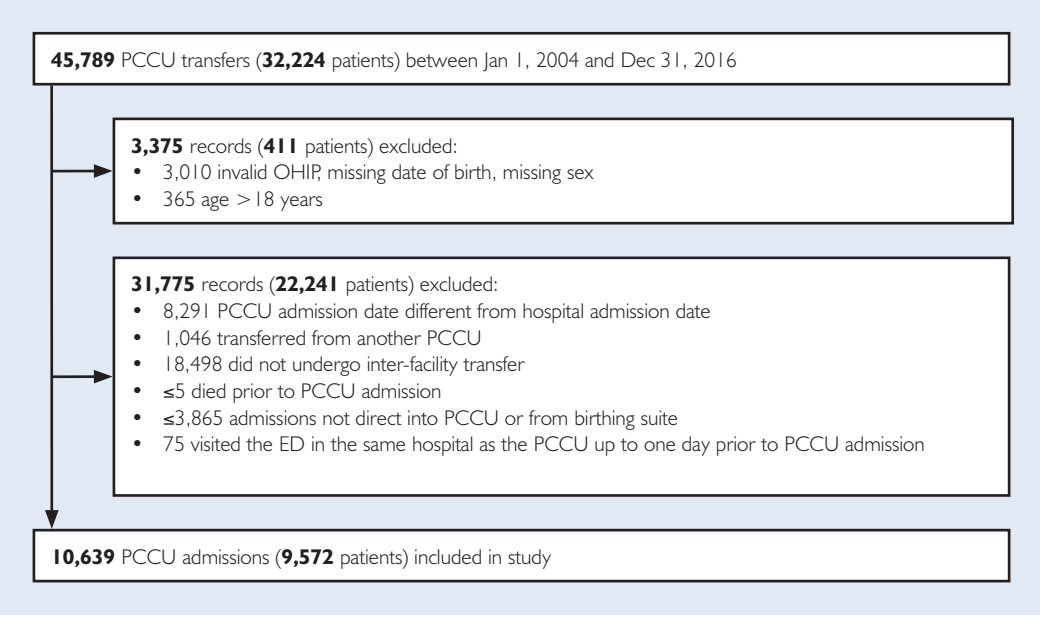
Similarly, we used the GEE to examine the risk of deferral on our primary and secondary outcomes of interest: mortality in the PCCU, mortality in the PCCU within 24 hours, mortality within six months and PCCU and hospital LOS. Model covariates included: age,

sex, rurality, previous PCCU stay, origin in referral hospital, transfer time of day, total acute care days in previous six months, most responsible diagnosis of the PCCU admission and the absence of co-morbidities identified in the previous year.

Sensitivity analyses were completed for all outcomes in the period following the introduction of the referral policy (January 1, 2010). This was done to assess whether observed effects were consistent after implementation of the referral policy.

All analyses were performed using SAS Enterprise Guide version 7.1 (SAS Institute Inc., Cary, NC). The 95% CIs reported for deferral rates in the pre- and post-implementation periods were calculated using Wilson's score method. $p < 0.05$ was considered statistically significant.

FIGURE 1. Study flow diagram



OHIP: Ontario Health Insurance Plan

Results

Over the study period, there were 10,639 inter-facility transfers for 9,572 patients, with 713 patients (7.4%) experiencing more than one transfer during the study period (Figure 1). The median age of transported patients was 17 months, and the interquartile range (IQR) was 1–103 months, with 5,720 (53.8%) transports for children of age less than two years (Table 1). 40.3%, (n = 4,284) were transferred from an ED, and 1,533 (14.4%) lived in a rural setting. The median (IQR) distance from the referral hospital to the admitting PCCU hospital was 50 (21–105) km. The most common diagnosis was respiratory (n = 2,298, 21.6%), followed by congenital malformations/genetic abnormalities (n = 2,006, 18.9%) and other (n = 1,749, 16.4%). More transfers occurred in the evening and winter. Patients had a

median (IQR) of 1 (0–3) previous acute care days in the six months prior to transport, and 5,296 (49.8%) had no previous hospitalizations in the previous two years and 9,653 (90.7%) had no co-morbidities.

Factors Associated with Deferrals

Comparing all deferred and non-deferred patients (Table 1 available online at longwoods.com/content/25939), it was noted that deferred patients were younger (median = 10 months; IQR = 1–78 months) than non-deferred patients (median = 20 months; IQR = 1–107 months). On average, deferred patients had more previous acute care days, more co-morbidities and presented more often in winter and from a non-ED area of the hospital (compared to an ED). However, among those presenting from the ED, median time to definitive critical care was 109 minutes longer for patient who were deferred. Patients presenting with congenital malformations/genetic abnormalities or acquired cardiac diagnoses were more often deferred, whereas those with psychiatric/neurologic, accidents or ingestions and other diagnoses were less frequently deferred. Those with the following co-morbidities were more likely to be deferred: congenital cardiac malformation, heart failure, chronic respiratory failure, transplant history, cancer and liver failure. Sex, time of day and rural status were not significantly associated with deferral status. Deferred patients were transported a median difference of 104 km more than those who were not deferred.

Regression models identified that previous ICU admissions, non-rural dwelling, patients not presenting to their local hospital, non-ED origin in the referral hospital, winter (versus summer) and a history of congenital cardiac malformation or a transplant and designated PCCU "B" and "C" (compared to "A") were associated with a higher risk of deferral in both the complete study period and the post-implementation period. Designated PCCU "D" (compared to "A"), a history of chronic respiratory failure and a most responsible diagnosis of congenital malformation/genetic abnormalities were significant for the post-implementation period only. A history of heart failure was not significant for the post-implementation period only (Table 2 available online at longwoods.com/content/25939).

Patient outcomes

MORTALITY OUTCOMES

Of all transported patients, 526 (4.9%) died in the PCCU (Table 3). Of these, 167 (1.6%) died within 24 hours of PCCU admission. Six-month mortality was 8.5% (903 transports). In the fitted regression models for the mortality outcomes, deferral status was not associated with increased mortality and was associated with decreased 24-hour mortality ($p = 0.02$) (Table 4).

The median (IQR) PCCU LOS was 52 (25–127) hours or 2.2 days and receiving hospital LOS was 7 (3–15) days. In the fitted regression models for LOS outcomes, deferral status was significantly associated with a longer PCCU LOS (greater than 2.2 days) ($p < 0.0001$) (Table 4).

TABLE 3. Primary and secondary outcomes by deferral status

Outcome	Transfer status		Total (n = 10,639)	p-value
	Deferred (n = 2,077)	Non-deferred (n = 8,562)		
Mortality within PCCU, n (%)	91 (4.4)	435 (5.1)	526 (4.9)	0.187
Mortality within 24 hours of transfer, n (%)	20 (1.0)	147 (1.7)	167 (1.6)	0.013
Mortality within six months of transfer, n (%)	188 (9.1)	715 (8.4)	903 (8.5)	0.304
PCCU LOS, days, median (IQR)	3 (1–7)	2 (1–5)	2 (1–5)	<0.001
Hospital LOS, days, median (IQR)	8 (4–17)	6 (3–15)	7 (3–15)	<0.001

PCCU = pediatric critical care unit; IQR = interquartile range; LOS = length of stay.

TABLE 4. Multivariable regression models for deferral status and outcomes*

Outcome	Complete study period (2004–2016)		Post-implementation period (2010–2016)	
	OR (95th CI)	p-value	OR (95th CI)	p-value
Mortality within the PCCU	0.81 (0.63–1.04)	0.1	0.74 (0.51–1.07)	0.1
Mortality within 24 hours of transfer	0.56 (0.34–0.92)	0.02	0.41 (0.18–0.91)	0.03
Mortality within six months of transfer	0.89 (0.74–1.07)	0.22	0.91 (0.7–1.19)	0.49
Longer than average hospital stay	0.95 (0.85–1.06)	0.38	0.99 (0.84–1.16)	0.86
Longer than average PCCU stay	1.26 (1.13–1.4)	<0.0001	1.28 (1.09–1.49)	0.002

*OR compares outcomes for deferred to non-deferred transfers.
All models adjusted for age, sex, ICU admission in previous year, rurality, origin in the referral hospital, transfer time of day, total number of previous acute care days, most responsible diagnosis and absence of co-morbidities.

Impact of referral policy implementation

In total, 2,077 (19.5%) transports were deferred based on the 2010 referral guide definition: 24.8% (95% CI: 23.5–26.1%) pre-implementation and 16.0% (95% CI: 15.1–16.9%) post-implementation of the 2010 referral policy (Supplement Figure 1). Since the introduction of the formal referral guide in 2010, the inter-facility transfers have followed the health region-based guide more frequently in all four PCCU designated regions (Supplement Figure 2). Despite the policy implementation, a significant number of transfers associated with two PCCUs were still being deferred after 2010 (>25% for one PCCU and 10–25% for the other).

Discussion

The 2010 referral policy was introduced in an effort to improve efficiency and clarity when transferring a critically ill child from a community healthcare centre to a PCCU in Ontario, Canada. If the care pathway of a critically ill child is pre-emptively organized, then the time spent seeking an accepting physician and a PCCU bed can be minimized. In turn, this allows the physician more time to focus on the patient's medical management. Furthermore,

ensuring that the patient gets transferred to their closest PCCU can be helpful for the provision of psychosocial support to the patient and their family. However, despite the policy's best intentions, it may not always be possible (e.g., bed capacity issues) or in the best interest of the patient (e.g., required specialized services not offered at the designated PCCU) to avoid a deferral.

The four main findings of this study were as follows: (1) previous ICU admissions, non-rural dwelling, patients not presenting to their local hospital, non-ED origin in the referral hospital, winter (versus summer) and a history of congenital cardiac malformation or a transplant and certain designated PCCUs were associated with a higher risk of deferral; (2) there was no increased risk of mortality for deferred patients compared to non-deferred patients; (3) deferred patients (from the ED) had to wait almost two hours longer for definitive critical care (i.e., PCCU admission) and had a longer PCCU LOS; and (4) implementation of the referral policy led to a more consistent inter-facility transfer process.

We found a number of associations for deferrals, both patient- and system-related. History of a congenital cardiac malformation or transplantation was associated with a higher risk of deferral. This is not surprising, as one centre serves as the provincial transplant and cardiac centre; thus, children with a history of one of these conditions were likely bypassing the designated PCCU and being sent directly to this centre if a complication related to their medical history arose. While controlling for this, we were surprised to find that children with a history of a PCCU admission in the previous year were more likely to be deferred. In addition, patients originating in a non-ED setting (e.g., hospital ward) were more likely to bypass their designated PCCU. Perhaps, because these patients were already admitted, they had more time to present a clearer indication for specialized care only offered at a non-designated centre. Another explanation may be that some ward patients were deemed stable enough to transfer to a farther PCCU. Perhaps these patients were being treated by a pediatrician (because the hospital had pediatric admitting capabilities), and thus also deemed to have "more time." This fact indirectly contrasts the findings of the study by Gregory et al. (2008), who demonstrated that patients transferred from an in-patient ward were sicker than those transferred from an ED. A future area of study would be to better understand the decision framework for these patients.

As for system-related factors, patients were more likely to be deferred in the winter. Unit capacity is more strained in the winter when there are more respiratory illnesses. We also found that patients who presented to a hospital other than their local hospital were more likely to be deferred. This finding likely accounts for one aspect of the decision of where to transfer a patient that cannot be guided by a referral policy. A patient and family may be outside of their usual health region at the time of critical illness onset and thus may advocate for transfer to a PCCU that is closer to their home because of familiarity with that hospital, for social supports and the practical benefits of being closer to home. Interestingly, patients who lived in a rural setting were less likely to be deferred, independent of the distance to the designated PCCU. The increase in transport distance for deferred patients may be important.

There was a 2% increase in critical events for every 10-minute increase in transport duration for critically ill adults transported by air in Ontario, which may also be relevant for children (Singh et al. 2009).

When clinicians are faced with determining the best pathway for a patient, they assess the patient's characteristics and medical requirements with transport and hospital resources. The patient's best interest is always the guiding principle. We did not find deferrals to be associated with increased mortality. Results support clinicians and the current referral process, suggesting that patients were appropriately selected for deferral. The finding that deferred patients had a lower 24-hour mortality following transfer maybe speaks to a lower severity of illness that they had at the time of transfer decision and the appropriateness of the decision to defer when faced with capacity issues. Alternatively, we did not have data on patients who died prior to transfer, thus introducing an immortal time bias that may have preferentially affected the deferred group.

The finding that deferred patients from the ED spent an average of almost two hours longer waiting for definitive critical care may be important. This may mean more time without proper equipment, pediatric expertise and definitive PCCU care. Patients awaiting transfer, particularly if delayed, may benefit from ongoing remote support via telemedicine (Labarbera et al. 2013). Though deferral status did not result in increased mortality, it was associated with prolonged PCCU LOS while controlling for past ICU admissions and acute care contact, origin in the ED, diagnosis and presence of co-morbidities. It is difficult to reconcile this with reduced early mortality, as PCCU LOS reflects the patients' need for PCCU resources and is thus often a surrogate for severity of illness. A better understanding of the course of disease in the transported population is indicated.

The 2010 referral policy was successful in ensuring that most (84%) inter-facility transfers followed the designated referral patterns and the proportion of deferred patients decreased. The most significant decline in deferrals appeared to occur after 2007 (Supplement Figure 1), which might be explained by the introduction of a formal PCCU consultation service ("CritiCall") in 2006. This service was designed to help connect referring physicians to accepting physicians in PCCUs in Ontario. This suggests that the 2010 referral policy did little else than to reinforce pre-existing relationships that had been established from about 2007. The fact that the rate of deferrals appears fairly constant since 2010 suggests that there are reasons beyond policy adoption that dictate whether a patient will be deferred. Although hospital referral capabilities dictate the need for transfers with metrics designed to track patient trajectories (Franca and McManus 2017), it is largely the ICU capacity that dictates where the patient is transferred to. ICU capacity has been studied at great length to predict and manage patient flow. Several mathematical models exist to do so for adult critical care, as capacity prediction is more complex than simply a function of the number of annual admissions, illness severity and LOS (Konnyu et al. 2011). For example, seasonality appeared to be the most influential factor in bed shortage risk for a hypothetical hospital in England following modelling of emergency admissions (Bagust et al. 1999).

There are a number of limitations. As discussed, though we managed to control for a number of patients, disease, transport and hospital factors associated with deferrals, we did not have data on severity of illness, PCCU bed capacity, the weather and availability of a given transport team. Measures of severity of illness were not available and surrogates of severity of illness (such as use of vasoactives or mechanical ventilation) either do not exist in the database or have not been validated. Although there is conflicting evidence on whether available scores can be accurately applied to this population (Freishtat et al. 2004; Orr et al. 1994), we used other variables in lieu of scores. Further, we did not have data on deferrals to out-of-province PCCUs from centres close to Manitoba, Quebec or the US.

Conclusion

We conducted a 13-year study using health administrative data of critically ill children who underwent inter-facility transfer to a PCCU in Ontario to describe patients who were deferred away from their designated PCCU. Patients with a previous PCCU admission, non-rural dwelling, patients presenting to their local hospital, non-ED origin in the referral hospital, winter (versus summer) and a history of congenital cardiac malformation or a transplant and designated PCCU were associated with higher risk of deferral. Deferrals were not associated with an increased risk of death but were associated with a prolonged PCCU LOS and a delay in definitive critical care for the ED patients. We found that implementation of a referral policy was associated with a consistent referral pattern in 84% of transfers. Further study is indicated to better understand additional factors associated with deferrals as well as their impact on resource utilization and quality of life.

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RESEARCH PAPER

Key Lessons Learned in the Strategic Implementation of the Primary Care Collaborative Memory Clinic Model: A Tale of Two Regions

Principales leçons à retenir de la mise en œuvre stratégique du modèle des cliniques collaboratives de la mémoire en soins primaires : l'histoire de deux régions

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Abstract

Background: Primary care collaborative memory clinics (PCCMCs) address existing challenges in dementia care by building capacity to meet the needs of persons living with dementia within primary care. This paper describes the strategic implementation of the PCCMC care model in two regions within Ontario.

Methods: Evaluation of this initiative included the completion of individual interviews (N = 32) with key informants to identify impacts associated with the PCCMCs and tracking of all referrals and assessments completed in the first nine months of clinic implementation.

Results: The qualitative analysis of interview transcripts generated five major themes: (1) earlier identification of dementia and intervention; (2) increased capacity for dementia care within primary care; (3) better patient and caregiver experience with care; (4) improved continuity, integration and coordination and improved care; and (5) system efficiencies. Across both regions, 925 patients were referred to PCCMCs, of which 631 (68%) had been assessed during the evaluation period.

Conclusions: Strategic, regional implementation of PCCMCs provides a significant opportunity to support better integrated and coordinated dementia care.

Résumé

Contexte : Les cliniques collaboratives de la mémoire en soins primaires (CCMSP) s'intéressent aux défis en matière de soins aux personnes atteintes de démence, et ce, en renforçant les capacités au sein des soins primaires afin de répondre aux besoins de ces personnes. Cet article décrit la mise en œuvre stratégique du modèle de soin des CCMSP dans deux régions de l'Ontario.

Méthode : L'évaluation de cette initiative comprenait la tenue d'entrevues individuelles (N = 32) auprès d'informateurs clés afin de déterminer l'impact des CCMSP ainsi que le suivi de tous les cas dirigés et des évaluations complétées durant les premiers neuf mois de la mise en œuvre desdites cliniques.

Résultats : L'analyse qualitative des transcriptions des entrevues a permis de dégager cinq grands thèmes : (1) diagnostic et intervention précoces; (2) capacité accrue des services primaires pour les soins aux personnes atteintes de démence; (3) une meilleure expérience patient-soignant; (4) meilleures continuité, intégration et coordination ainsi que des soins améliorés; et (5) rendement du système. Dans les deux régions, 925 patients ont été dirigés vers les CCMSP, dont 631 (68 %) ont été évalués au cours de la période étudiée.

Conclusions : La mise en œuvre stratégique régionale des CCMSP constitue une bonne occasion pour mieux intégrer et coordonner les soins aux personnes atteintes de démence.

Introduction

To address the well-documented challenges associated with managing dementia in primary care (Aminzadeh et al. 2012; Bradford et al. 2009; Pimlott et al. 2009), the primary care collaborative memory clinic (PCCMC) care model was created to increase capacity within

primary care to assess and manage persons with memory concerns (Lee et al. 2010, 2017a). PCCMCs are family physician-led interprofessional teams that provide comprehensive evidence-informed assessments and person-centred care management plans for persons living with dementia and other memory disorders and for their family members. PCCMCs support referring family physicians to provide quality dementia care through a shared-care collaborative approach. The goal of this program is to build capacity and skills for primary care practitioners to better manage memory disorders within the family practice setting, efficiently streamlining appropriate referrals to specialist care for cases that are the most complex. Partnerships with local community services such as the Alzheimer Society ensure timely patient and caregiver access to education, support services and system navigation. More information about this care model is presented elsewhere (Lee et al. 2010, 2014b, 2017a).

The first PCCMC was created and implemented in 2006 in the Centre for Family Medicine Family Health Team, in Kitchener, Ontario, Canada, and following its success, an accredited training program was developed to support the establishment of new clinics in other primary care settings (Lee et al. 2013; McLeod et al. 2016). Currently, there are over 100 PCCMCs across Ontario (Lee et al. 2017a). The establishment of new clinics has primarily been based on the desire of individual practice settings to meet the dementia care needs of their unique patient populations with limited planning for coordination and integration with other local geriatric services for older adults. In some areas, this has resulted in the clinics working in isolation, rather than in concert, with other geriatric services.

Two regions in Ontario were interested in implementing the PCCMC care model using a strategic, systematic implementation plan, thereby facilitating region-wide planning and collaboration among various existing agencies and specialized services for older adults. In Ontario, local health integration networks (LHINs) are regional health authorities responsible for healthcare service planning and funding; the two regions involved in this project were the Central East LHIN (CELHIN) and the Champlain LHIN. The purpose of this paper is to describe the strategic implementation of the PCCMC model of care within these two regions in Ontario, describing their rationale for adopting a systematic approach to establishing clinics in their region and key lessons learned in the regional implementation of the clinics.

Strategic Implementation in Two Regions

Champlain LHIN

The Champlain LHIN is located in eastern Ontario, Canada, bordering Quebec, covering five sub-regions in and surrounding the nation's capital, Ottawa. Demographic and health service information for this region is presented in Table 1. The process of developing and implementing the clinics is summarized in Table 2. Both tables are available at longwoods.com/content/25938.

In 2012, the increasing number of persons in the Champlain region living with dementia was a key issue driving the region's interest in improving dementia care in primary care. Key organizations involved in dementia care (Champlain Dementia Network, the Regional Geriatric Program of Eastern Ontario [RGPEO], Geriatric Medicine and Alzheimer Societies of Ottawa and Renfrew County and Cornwall and District) began planning a regional approach to identifying sustainable, collaborative and capacity-building dementia care models in primary care. There was an interest in moving more specialist care as provided by geriatricians into the community while recognizing the lack of community infrastructure to support specialist care. The PCCMC model was identified as potentially meeting this need.

A planning and implementation team was created to guide this initiative. The RGPEO invested in an advanced practice nurse role to facilitate this process. Planning was informed by a review of the literature, review of the primary care landscape and leveraging lessons learned from existing dementia initiatives. Strategies to inform this process included discussions with practice administrators to determine the potential fit of the PCCMC model, a site visit to observe the Centre for Family Medicine memory clinic team in practice and presentations on the PCCMC model to invested primary care practices and key regional stakeholders. A funding proposal was submitted to the Champlain LHIN outlining a number of initiatives to support dementia care across the continuum. Three complementary capacity-building models, including the PCCMC model, were selected to meet the unique needs and resources available to the different primary care delivery structures in the region.

The Champlain LHIN provided three consecutive one-time/one-year funding envelopes to support the training of 15 PCCMCs in the region as well as ongoing funding for dedicated staff from the Alzheimer Society to participate in all PCCMCs (Table 2). The RGPEO committed, in kind, the services of an advanced practice nurse to lead the planning and coordination of the clinics and support capacity-building needs across clinics. An awareness-raising campaign was launched to inform primary care settings in the region about the potential opportunity to establish a PCCMC. A formal readiness assessment process was established to ensure that the PCCMC model was a good fit for interested practices. Fifteen sites were selected across the region representing urban and rural, academic and non-academic and Francophone and Anglophone practices. Because 13 of the 15 clinic settings were in team-based primary care structures (Family Health Teams and Community Health Centres), these clinics were able to recruit their own interprofessional team of healthcare providers (HCPs) to construct their PCCMC team, including nurse practitioners, registered nurses/practical nurses, pharmacists, social workers, health promoters and dietitians. Two of the PCCMC settings were Family Health Organizations; thus, in-kind partnerships with local community, hospital services and the RGPEO provided the social work, pharmacist and additional nursing resources required to complete their team. In-kind support from local Alzheimer Society staff was provided to all 15 PCCMC teams. To support the goal of implementing 15 PCCMCs in the region over three years, a plan was put

in place to target the training of five clinic teams per year starting in February 2014, and by April 2016, all 15 clinics were established with 137 HCPs who had completed training. All of the clinics accepted referrals from within their practice settings, in total supporting 152 family physicians with a combined patient base of 167,923 (Table 2).

To provide ongoing regional support to the PCCMCs, the advanced practice nurse works with teams to identify and address concerns that arise with clinic implementation, develops processes to facilitate geriatrician support, identifies processes for integration with Specialized Geriatric Services to facilitate seamless transitions for patients and supports learning needs through coordination of continuing education events. Over time, the number of geriatricians providing support to PCCMCs in this region has increased from four to seven. Because the role of specialists within this care model represented a new way of working with family physicians, a collaborative framework was developed to highlight strategies to foster specialist integration into the clinic team and to optimize specialist collaboration and support for the memory clinic team, with the ultimate goal of optimizing the care of patients and families.

Central East LHIN

The CELHIN includes urban and rural areas in central east Ontario. Demographic and health service information for this region is presented in Table 1. The system of care for older adults living with frailty is coordinated and implemented through the Seniors Care Network, a network of health service programs and organizations that collaborate to deliver Specialized Geriatric Services in this region.

"Grass-roots level" interest was initiated by several physicians who approached the Seniors Care Network to explore opportunities for implementation of PCCMCs in this region. Leveraging existing resources and expertise in dementia care in the region, a planning group was formed consisting of representatives from the local Alzheimer Society chapter, Seniors Care Network and various Specialized Geriatric Service providers.

Funding was provided by the LHIN for the memory clinic training program, which was attended by not only the health professionals who would be working in the memory clinics, as is usually the case, but also health professionals in all of the relevant dementia care-related services in the region. The training was proposed as an educational opportunity and served to facilitate "buy-in" for the introduction of PCCMCs from all relevant community programs by fostering a common understanding of the scope and role of PCCMCs. This common understanding helped to overcome the initial resistance to the introduction of this new service, which was primarily related to lack of understanding of the capacity and complementary role of PCCMCs within the continuum of care for seniors.

As all of the PCCMCs were being established in practice settings without access to the required interprofessional HCPs, a shared interprofessional "mobile team" was created to support the PCCMCs. In-kind contributions of space and staff were made by the Alzheimer Society and PCCMC family practice settings. The mobile team consists of two

registered practical nurses, additionally trained in mental health, addictions and dementia as Behavioural Supports Ontario (BSO) program staff; two social workers; and two occupational therapists. (BSO is a province-wide program aimed at providing care for older adults exhibiting, or who are at risk of exhibiting, responsive behaviour [e.g., aggression, wandering, physical resistance, agitation] related to cognitive impairment due to mental health problems, addictions, dementia or other neurological conditions [Gutmanis et al. 2015].) Many of these HCPs were recruited from existing local community geriatric services, which helped to integrate all relevant dementia care programs into the PCCMC care model. These included the Alzheimer Society First Link program (McAiney et al. 2012), the BSO program and local Geriatric Assessment and Intervention Network teams (Seniors Care Network 2015). Integration of team members from these programs facilitated access to various community services and improved communication and coordination of care through PCCMCs. To help foster relationships between interprofessional HCPs and physicians who had not previously worked together with an interprofessional team, and to support the logistical requirements of mobile clinical work, which included home visits, the PCCMC program manager role was created. This program manager supports implementation across participating primary care practices and connects via a formalized committee structure to specialized geriatric services to collaborate in planning, coordination and regional quality improvement initiatives, aligning local and regional services.

In total, 70 individuals completed the memory clinic training program in March 2016, 33 representing primary care and 37 representing the Specialized Geriatric Service programs coordinated by the Seniors Care Network and Alzheimer Society staff. Following completion of the training program, four new PCCMCs were created. Three of the clinics are supported by the mobile team, and one clinic created its own interprofessional team supplemented with HCPs from the Seniors Care Network's local Geriatric Assessment and Intervention Network team. All four clinics have an assigned geriatrician to provide consultative support; these geriatricians attended the memory clinic training program. Two of the clinics accept referrals for patients rostered within their practice settings, whereas the other two additionally accept referrals from outside of their practice setting. In total, these clinics support a very large number of medical practices in the regions (Table 2).

Evaluation Methods

Up to 16 months following the establishment of their PCCMCs (10–12 months in the CELHIN; 12–16 months in the Champlain LHIN), all team members, initiative leads and partners were invited to participate in individual telephone interviews to gather their perceptions regarding how dementia care in the region has changed as a result of the PCCMCs (e.g., What do you think are key impacts of the memory clinics on the system of care for persons with dementia in your region? In what ways has the care for persons with dementia in the region improved with the development of the memory clinics?). A total of 32 interviews

were completed (CELHIN, *N* = 13; Champlain LHIN, *N* = 19). Across both regions, interviews were completed with physicians (*N* = 11), allied health professionals (*N* = 12) and initiative leaders/partners (*N* = 9). Interviews ranged in length from 14 to 51 minutes (average = 27 minutes).

Interviews were completed by one author (L.M.H.) to ensure consistency, digitally recorded and transcribed. Within each region, saturation was achieved (little or no new information was gathered from the latest interviews). Transcripts were analyzed using a qualitative naturalistic inquiry approach to develop an understanding of impacts at both patient and health system levels (Lincoln and Guba 1985). Transcripts were analyzed by one author (L.M.H.) and then reviewed by a research assistant to confirm reliability in the emerging themes; this process required several iterations to achieve greater clarity in the final themes generated.

Team members from each clinic tracked all referrals and assessments completed in the first nine months of clinic implementation, collecting information on number of referrals, urgency status (urgent, non-urgent), number of patients assessed, number awaiting assessment and number of assessed patients who were referred to specialists for further consultation. Wait time for assessment was calculated as the difference between the date of referral and date of assessment. A key outcome indicator for this initiative is the number of established clinics that continued to operate nine months following launch.

This study was approved by the Hamilton Integrated Research Ethics Board, McMaster University.

Results

In the Champlain LHIN, 14 of 15 clinics continue to operate in the longer term (some up to four years). One clinic chose to suspend acceptance of new referrals, though they continue to see patients already assessed for follow-up; a number of reasons influenced this decision, including the low number of referrals, a younger demographic within the practice setting and quick access to specialist consultation. In the CELHIN, all four established clinics continued to operate in the longer term (two years).

Across both regions, 925 patients were referred to PCCMCs, of which 631 (68%) were assessed and 209 (23%) were awaiting assessment (Table 3). Across both regions, the average wait time for assessment was one month (1.2 months; SD = 1.4 months); 87% (*N* = 548) of the patients were assessed within three months of referrals, whereas 38% (*N* = 242) were assessed within a month of referral. Across both regions, 12% of the patients assessed were subsequently referred for specialist consultation.

TABLE 3. Primary and secondary outcomes by referral status

Tracked data	Percentage (#)	
	Central East LHIN (*N* = 4 clinics)	Champlain LHIN (*N* = 15 clinics)
Total number of referrals	409	516
Number of urgent referrals*	11 (2.7%)	23 (4.5%)
Number of patients assessed*	273 (66.6%)	358 (69.4%)
Number of patients awaiting assessment*	111 (127.1%)	98 (19.0%)
Wait time for assessment** (months), mean, standard deviation	1.1 (1.3)	1.2 (1.4)
Referrals for specialist consultation***	30 (11.0%)	48 (13.4%)

* Percentage is based on the total number of referrals in each region.
** Calculated as the difference between the date of referral and date of assessment.
*** Percentage is based on the total number of patients assessed in each region.

Regarding impacts associated with the PCCMCs, the qualitative analysis of interview transcripts generated five major themes: (1) earlier identification and intervention; (2) increased capacity for dementia care in primary care; (3) better patient and caregiver experience with care; (4) improved continuity, integration and coordination and care; and (5) system efficiencies. These themes were common across both regions. Table 4, available at longwoods.com/content/25938, presents a description of these themes with illustrative quotes.

Discussion

The PCCMC implementation experiences in the CELHIN and the Champlain LHIN highlight the value of a strategic system-wide approach to implementation, which allowed for the integration of the model within the system of existing services for older adults across sectors, ensuring alignment with regional strategic plans and visions for seniors' healthcare. The process built on, complemented and enhanced the strengths of the region's current service offerings and contexts and expedited assessments, while also avoiding competition and duplication with existing established services. For example, in the CELHIN, the planning committee provides a practical forum for identifying the best service to be the lead, or primary, service provider for particular patients based on unique patient needs. The different services build on the work of each other so that if a patient is transferred between services, they avoid repeating assessments completed by the previous service.

Strategic implementation also allowed each region to capitalize and make efficient use of existing staff, programs and strategies for seniors and dementia care. These improved efficiencies have the potential to result in cost savings to the system. Across both regions, a number of factors supported improved integration of dementia care services. In the Champlain LHIN, assigning several geriatricians to support PCCMCs fostered a strong sense of specialist support of this initiative and positive relationships between primary care and specialist care, establishing the foundation for true collaboration. In the CELHIN, the

creation of a mobile team with team members drawn from various existing regional programs served to improve integration and coordination of care with other services. Participation of the PCCMCs in the regional operations committee has strengthened and entrenched this service within the system of Specialized Geriatric Services. In both the Champlain LHIN and the CELHIN, the role of the clinic coordinator was critical to the successful strategic implementation of PCCMCs. Integration of HCPs from the existing geriatric services in both LHINs also proved to further support and develop the clinical capacity of the PCCMC. A growing body of literature on integrated care provides evidence that collaboration between healthcare professionals can be enhanced through development of a structure for team work, sharing of team resources and organizational supports (administration, facilities) and mechanisms for communication and coordination (San Martin-Rodriguez et al. 2005). Interprofessional team-based care, with ongoing care coordination, communication and information sharing among all care providers, is the mainstay of person-centred care (American Geriatrics Society Expert Panel on Person-Centered Care 2016) and has been identified as essential for integrated care (Gonzalez-Ortiz et al. 2018). Community-based integrated systems of care for older adults have demonstrated improved quality, coordination and continuity of care and health outcomes for older adults (Bernabei et al. 1998; Johri et al. 2003; McAdam 2008). Engagement of local services in service planning and implementation is important to the success of new health innovations. In this instance, the bringing together of key players from various community programs (Alzheimer Society, BSO, Specialized Geriatric Services) supported by clinic coordinators contributed to better system navigation, integration and care coordination. Consistent with the findings of other studies (Lee et al. 2014a), collaboration and communication across multiple organizations and programs in the Champlain LHIN and the CELHIN facilitated improved access to community services and better, more seamless transitions between services for patients and caregivers. Effective implementation of new health innovations to affect system change has been demonstrated to require consideration of facilitating factors at micro (individual), meso (organizational) and macro (community and system) levels and how these levels interact and collaborate to affect change (Chaudoir et al. 2013; Durlak and DuPre 2008; Wandersman et al. 2008). The findings from this study demonstrated that both regions were able to affect change at all levels to improve dementia care. Consistent with the literature on effective practice change, the memory clinic training program has demonstrated its ability to facilitate practice improvements through multiple and best teaching practices (Lee et al. 2013, 2014c) and drawing on principles of effective program planning (Caffarella 2002; Kern et al. 2009). These training strategies have included case-based learning, feedback and practice and mentorship opportunities (Bell 2002; Bero et al. 1998); access to guideline-based interventions (Colon-Emeric et al. 2004); and access to expert resources and ongoing support (Stolee et al. 2015). Facilitating factors within practice settings that have enabled practice change and memory clinic implementation have included selection of highly motivated team members (Mazmanian and Davis 2002), access to enabling resources such as clinical support tools (Bloom 2005;

Mazmanian et al. 2009) and clinic flow templates (Berwick 2003), organization and management support (Bradley et al. 2003; Broad 2005; Stolee et al. 2005), and support and commitment from identified champions, physicians and interprofessional team members (Resnick et al. 2004). At a system level, clinic implementation in both regions was facilitated by cross-sector and service collaborative partnerships; these types of partnerships have been identified as important to the effectiveness of interventions that affect health system changes (Mitchell et al. 2015; Mitchell and Shortell 2000; Nicholson et al. 2013) and particularly important to the development of a comprehensive system of care for dementia (Hogan et al. 2008; Patterson et al. 2001).

Communities of practice (CoP), groups of individuals with shared interests, represent a significant opportunity for healthcare improvements (Endsley et al. 2005; Ranmuthugala et al. 2011; Wenger et al. 2002) and can break down silos of care. Regional implementation supported the development of CoP by having local teams train and attend "Booster Days" together, which are annual refresher days that provide an opportunity for PCCMC clinicians to network and learn from one another, further supporting cross-service and cross-sector collaboration (Lee et al. 2017b). Relationships between clinic coordinators and local teams as well as the PCCMC model being endorsed as part of a regional dementia strategy served to foster the CoP connectedness. As mentioned above, strategic regional implementation can facilitate greater opportunities for integration and alignment with existing regional programs particularly when establishing clinics on a large scale. This is important for sustainability and further development, efficient use of limited system resources and potential inclusion of PCCMCs in other health system initiatives, such as coordinated intake systems for specialized geriatric services, as was the case in at least two regions in the province.

In both regions, the majority of patients (>67%) referred to the PCCMCs were assessed during the evaluation period. Although the number of patients awaiting assessment in Champlain at the end of the evaluation period likely had wait times for assessment consistent with those who were assessed, wait times for awaiting assessment (N = 111 for assessment across four clinics) in the CELHIN were likely longer. This reflects a steady increase in referrals over time as the capacity of the memory clinics to assess and manage memory concerns became better understood and as some referrals to specialists were redirected to the memory clinic. On occasion, some of the clinics would hold an extra clinic per month to manage the increasing wait list and reduce wait time to assessment.

Across both regions, the rate of referrals to specialists (12%) is consistent with ideal models of chronic disease management where the majority of care for chronic conditions is managed within primary care (Scott 2008) and only the most complex of cases are referred for specialist management; this 12% referral rate represents a substantive reduction from the estimated rate of referral of up to 82% to geriatric specialists for memory concerns in typical family practice (Pimlott et al. 2006). Given this rate of referral to specialists, it could be estimated that the PCCMCs across both regions have the potential to avert 758 referrals (82%

of 925 referrals to PCCMC) that would otherwise have been made to specialists. Anecdotal evidence, collected in the key informant interviews (Table 4), has also suggested system efficiencies related to reduced emergency department visits due to early identification and intervention and proactive approaches to care that prevent crises that can lead to use of acute care and institutionalization. While outcomes related to improved patient care, reduced rates of referrals to specialists and potentially reduced emergency department visits are consistent with those of PCCMCs across the province (Lee et al. 2010, 2017a), the strategic implementation processes in the Champlain LHIN and the CELHIN appeared to contribute to other outcomes such as improved integration and coordination with services and sectors across the regions.

While specialists integrated into the PCCMC care model in these regions have been geriatricians, there is growing recognition that geriatric psychiatrists and cognitive neurologists have unique and important roles to play in dementia care. An initiative is currently underway to establish and evaluate a triad of specialist support for memory clinics (geriatricians, geriatric psychiatrists and cognitive neurologists); this will provide greater opportunities for integration and coordination with specialist services and for capacity building among the PCCMCs.

A number of key lessons were learned in the regional implementation of PCCMCs. Across regions, there was strong organizational buy-in for the PCCMC model and readiness for change, particularly as measured in the Champlain LHIN, both of which have been identified as key factors impacting successful implementation of new innovations (Dijkstra et al. 2006; Scott et al. 2003). Both regions also had well-established Specialized Geriatric Services for older adults, and implementation of PCCMCs provided a greater recognition among these services of the capacity that exists in primary care for quality dementia care. Designated PCCMC coordinators in each region were important to facilitating, strengthening and sustaining the PCCMC initiative. This vital role was credited with driving and overseeing all stages of planning, development and ongoing implementation; serving as the PCCMC "point person" to whom all inquiries could be directed; and reinforcing system efficiencies with continuous quality improvement efforts aimed at refining, evolving and growing the PCCMC initiative. Access to standardized training and continuing education was viewed as critical to implementing the PCCMC model, and in the CELHIN, inclusion of professionals working in other services served to increase understanding of the role of primary care in dementia care, which in turn increased buy-in for the model and supported collaborative efforts across sectors. Moreover, inclusion of specialists in the training served to solidify support for the model, as they better understood the role of the PCCMC within the system of dementia care in the region and increased their understanding of the learning needs of the PCCMC teams, further contributing to collaboration between primary care and specialists.

Implementation of the PCCMCs within both regions was not without challenges. Space needs and administrative support for the clinics were underestimated. Policies and procedures for privacy and clinical documentation needed to be developed for mobile

interprofessional teams to practice in locations where they were not employees. In both regions, team members who were not employees of the organization hosting the memory clinic were required to sign confidentiality agreements to access and document in the electronic medical record. In many instances, these team members had to learn multiple documentation systems as these were not consistent across all clinic settings. Within two practice settings
in the Champlain LHIN, a memorandum of understanding regarding the roles of non-employees working within the clinics was developed and is signed on an annual basis. In the Champlain LHIN, further development of the collaboration between the specialist and primary care will continue to evolve in supporting an upstream approach to early detection and intervention. The issue of sustainability of the clinics has been an ongoing challenge that includes not only the need for a sustainable operational funding model but also the training and recruitment of new PCCMC team members to manage clinic expansion and staff turnover.

From a funding perspective, a regional approach to implementation can assure accountability for achieving deliverables pertinent to the delivery of dementia care, support equitable access to health services, enable economies of scale when considering training costs and foster coordination among clinics and integration with existing specialist services through the allocation of dedicated clinical resource personnel. A strategic approach to implementing PCCMCs organizes services at a system level and can promote sustainability, which is particularly relevant as Ontario engages in building a cohesive dementia care strategy.

The usual system of care for dementia has been criticized for its limited integration and coordination between various medical, social and community services (Bruce and Paterson 2000; Samsi and Manthorpe 2014; Tan et al. 2014). Efforts to improve care coordination have typically been aimed at the patient level with the use of individual case management models (Bass et al. 2015; Khanassov and Vedel 2016), with less attention paid to coordination and integration across health sectors. The PCCMC care model aims to address these limitations by implementing interprofessional team-based care management that is rooted in primary care but linked to specialist care and services. The PCCMCs continue to evolve with the structured integration of geriatric medicine, geriatric psychiatry and cognitive neurology to further develop collaborative working relationships and improve care capacity and integration.

There are a number of limitations to the evaluation of memory clinic implementation. Interviews were conducted with clinic team members and leaders; the perspectives of practice setting management and health system leaders are not known. Interview questions focused on the identification of practice improvements and impacts associated with the clinics, which may have biased the findings. Measurement of outcomes and impacts were primarily based on anecdotal evidence. Further research is needed to better delineate the health system and efficiencies afforded by the PCCMCs, namely, the impact of early identification and intervention by the PCCMCs on utilization and cost of health services, specifically emergency

department visits, hospital admissions and long-term care placements, and how better integrated and coordinated care can impact health service utilization and health outcomes. More research, with rigorous methodologies, such as case-controlled, time-series methods, and multiple case-study designs, is needed to further our understanding in this area.

Conclusion

This paper offers insight into a coordinated and systematic approach to implementing the PCCMC model region-wide. Strategic, regional implementation of PCCMCs provides a significant opportunity to support better integrated and coordinated dementia care across services and sectors. In two regions in Ontario, regional implementation has fostered a higher level of collaboration between PCCMCs, Specialized Geriatric Services and community services, and thereby led to a stronger CoP than would otherwise be possible. Lessons learned from this initiative can inform the implementation of other primary-care-based initiatives for complex chronic conditions of older adults.

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RESEARCH PAPER

Orphan Drug Pricing and Costs: A Case Study of Kalydeco and Orkambi

Tarification et coûts des médicaments orphelins : étude de cas sur le Kalydeco et l'Orkambi

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Abstract

Background: A common narrative is that high prices are necessary for "orphan drugs" because of the fewer patients. In the context of state health insurance systems, the high prices create significant challenges because of limited budgets.

Results: This study carefully examines both costs and revenues of two drugs for cystic fibrosis (ivacaftor and lumacaftor), showing that, for this important example, prices are not high because of fewer patients. The study then explores the justifications usually given for high orphan drug prices, including the need to support research and development for new drugs. Each of these standard justifications is shown to be inadequate; instead, it appears that the exercise of market power in the presence of insurance is the dominant driver of high prices.

Interpretation: Insurers need to re-examine how they address high-priced drugs.

Résumé

Contexte : On entend souvent dire que les prix élevés des « médicaments orphelins » sont inévitables en raison du petit nombre de patients. Dans le contexte des systèmes publics d'assurance santé, les prix élevés pausent d'importants défis, notamment à cause des limites budgétaires.

Résultats : Cette étude a examiné attentivement les coûts et les revenus de deux médicaments pour traiter la fibrose kystique (l'ivacaftor et le lumacaftor) et démontre que, dans le cas présent, les prix ne sont pas élevés à cause du nombre de patients. L'étude explore ensuite les raisons habituellement invoquées pour le prix élevé des médicaments orphelins, notamment les besoins en recherche et développement pour les nouveaux médicaments. Il s'avère que chacune de ces raisons est discutable; il semble plutôt que les forces du marché et la présence de modes d'assurance constituent les principaux facteurs des prix élevés.
Interprétation : Les assureurs devraient réexaminer leur façon de traiter les médicaments onéreux.

Introduction

Orphan drugs are at the forefront of pricing pressure in pharmaceutical companies. Numerous new drugs for rare diseases and conditions are priced at over $200,000 per year of therapy; some generate revenues over $1 billion a year (Cohen and Felix 2014; Côté and Keating 2012). Affordability of orphan drugs is a global problem, with high prices limiting access even in the richest of countries, and creating many challenging questions for policy makers (Côté and Keating 2012). Should patient access to new products be sacrificed to create a stronger bargaining position on price? How do we determine that a price is excessive, if ever?

In England and Wales, Vertex's drugs Kalydeco (ivacaftor) and Orkambi (ivacaftor + lumacaftor) have become a *cause célèbre*, as the National Health Service offered a five-year contract of about $650 million (US$ used throughout) to gain access to Vertex's drugs. Vertex has since refused, leading to calls for government intervention to seek a compulsory license (Boseley 2019). In Canada, a class action suit has been launched against a provincial government in a bid to force it to provide insurance coverage for Orkambi (Seucharan 2018).

One of the responses to high drug prices has been the renewed interest in understanding the costs of drug development and supply. In the US, notably, as one of the responses to high prices, there have been many proposals by states that require companies to disclose costs of drug development (Sarpatwari et al. 2016). This paper uses the example of two high-priced drugs used in the treatment for cystic fibrosis (CF), chosen because a credible estimate of anticipated global revenue of the products over their lifetime is available to demonstrate the value of looking at total revenues and costs.

An Illustration: Ivacaftor and Lumacaftor

Ivacaftor (Kalydeco) is indicated for the treatment of CF in patients with certain genetic mutations. Only 2,600 patients globally had the specific genetic mutation that made them eligible for the first approved indication of ivacaftor (Vertex Pharmaceuticals Incorporated

2012). In response, Vertex, the manufacturer, priced Kalydeco in the US at about $300,000 per patient per year of treatment following its Food and Drug Administration (FDA) approval in 2012 (Silverman 2017). Starting in 2016, Vertex marketed a combination product (Orkambi) consisting of ivacaftor and lumacaftor, designed to address a more common mutation. Vertex now indicates that its addressable population globally is over 25,000 patients, which massively increases Vertex's potential revenues (Leiden 2015). Orkambi is priced in the US at $259,000 per patient per year (Weisman 2015). The pricing of these medications has been challenging for insurers (Grant 2017; O'Sullivan et al. 2013; Senior 2015).

Public agencies in various countries have examined the cost-effectiveness of Kalydeco and Orkambi, and the assessments have shown that for the purpose of improving population health, these products have proved to be expensive (Gulland 2016; Haute Autorité de Santé 2016; National Centre for Pharmacoeconomics 2016; Pharmaceutical Benefits Scheme 2013). Indeed, there have been concerns about the effectiveness of Orkambi despite the price (Therapeutics Initiative 2017, 2018). A commonly cited threshold for identifying a drug as being cost-effective is $50,000 per quality-adjusted life-year (QALY) generated (Neumann et al. 2014). The Canadian Agency for Drugs and Technologies in Health (CADTH) estimated that Kalydeco's cost per QALY was $640,000, whereas that for Orkambi was $3.6 million (CADTH 2015; Canadian Observational Cohort Collaboration [CDEC] 2016). Despite the high prices for these products, insurers have felt obliged, in many cases, to insure the products because they did not want to deny patients access to the modest health improvements they promised.

Before exploring the rationale for such high prices, this paper offers a brief analysis of the revenues and costs attributable to these drugs as an important background for understanding the pricing model.

Vertex's revenues

This section calculates the net present value of the expected revenues of Kalydeco and Orkambi. It is possible to turn to a commercial transaction that reveals anticipated revenues with a high degree of credibility. The Cystic Fibrosis Foundation Therapeutics (CFFT) paid for the initial basic research on ivacaftor and lumacaftor, as well as part of Phase 1 clinical trials, in exchange for royalty on the sales of these two products and a third investigational drug (Werth 2014). The complete terms of the royalty are not public; it is in the range of "single digits to sub-teens" (Vertex Pharmaceuticals Incorporated 2014). This means that the upper bound of the royalty is 12.9%. In addition, the royalty is 8% on the first $250 million of annual sales (Vertex Pharmaceuticals Incorporated 2006). A reasonable middle estimate is that royalty averages about 10%, with upper and lower bounds of 12% and 8%, respectively. In 2013, Royalty Pharma purchased CFFT's future royalty stream for these products for $3.3 billion cash. (At the time, Orkambi was still in Phase 3 trials; the third

drug was not approved until 2018, and so, it is reasonable to assume that its value in 2013 was minimal.) This implies that the 2013 net present value of the expected future revenues of these products was approximately $33 billion. This estimate of revenues is highly credible, as Royalty Pharma, a privately held trust with rights to 44 products, would have thoroughly evaluated the royalties for which it paid $3.3 billion. (The amount paid by Royalty Pharma is approximately in line with the following calculation: if Vertex earns $250,000 per patient per year after discounts, and it sells to 25% of the global CF population, the net present value of revenues over 12 years is approximately $37 billion. Twelve years is applied, as this is the exclusivity period assumed for Orkambi by Vertex in its submission to CADTH [CADTH Common Drug Review 2018]. I assume a 10% cost of capital and 2% annual price increase for the products.)

Thus, we can conclude that the net present value of the revenues from Kalydeco and Orkambi, adjusting for discounts granted, risks of competition from alternative therapies, changes in regulatory status, changes in insurance status and the like, was approximately $33 billion as of 2013. It is important to note that by relying on Royalty Pharma's payment, we do not have to rely on confidential prices to estimate Vertex's revenues.

Vertex's production, sales, general and administrative costs

Pharmaceutical companies, including Vertex, have considerable expenses related to production, sales and administration. It is reasonable to use Vertex's 2016 and 2017 financial reports to make an estimate (Vertex Pharmaceuticals Incorporated 2017/2018). The goal in this section is not perfect precision; instead, the desired outcome is to obtain a sense of the scale of production, sales, and general and administrative costs.

According to Vertex's 2017 10-K (a public report filed with the Securities and Exchange Commission), in 2016 and 2017, royalty expenses and production costs averaged 12.6% of revenues, which were derived almost exclusively from the sales of Kalydeco and Orkambi.

In addition, in 2016 and 2017, Vertex's sales and general and administrative (SGA) expenses averaged 24.3% of revenues. I assume all of these costs relate to Kalydeco and Orkambi. (If some related to products in development, this would, if anything, increase the calculated profitability of Kalydeco and Orkambi.) Because Kalydeco and Orkambi were growing in sales in 2016, it seems likely that the selling costs, particularly those related to promotion, will fall relative to sales over time.

The net present value of estimated revenues and costs as of 2013 are presented in Table 1, which shows upper and lower boundaries in addition to a middle estimate. The upper boundary assumes the values that will lead to the largest profits for Vertex (i.e., highest revenue, lowest cost). After deducting royalties, cost of production and SGA expenses, one can calculate "quasi-rents" – the profits of Vertex that are attributable to its investment in developing Kalydeco and Orkambi. The middle estimate is $21.1 billion.

TABLE 1. Vertex revenues and costs for Kalydeco and Orkambi (US$ billion)

	Middle	Upper	Lower
Revenues ($)	33.0	41.3	27.5
Royalties and production costs ($)	4.2	3.3	3.3
Percentage of revenues (%)	12.6	12.6	12.6
Selling, general, administrative ($)	7.7	6.4	8.6
Percentage of revenues (%)	23.3	15.6	31.1
Quasi-rents ($)	21.1	31.5	15.6
R&D cost ($)	2.5	1.3	5.0
Profits ($)	18.6	30.3	10.6

Is $21.1 billion a reasonable return on the investment Vertex made in developing these medicines? To answer this question, we must first consider Vertex's contribution to developing these products and conducting the required clinical trials both before and after regulatory approval.

Vertex's R&D costs

Estimating drug development costs is challenging. A 2011 systematic review of studies on this topic finds little agreement, with estimated average development costs ranging from $160 million to $1.8 billion per drug (Morgan et al. 2011). DiMasi et al. recently estimated that the average cost of drug development, fully accounting for the risk of failure and the cost of capital, and including post-approval requirements, is approximately $2.8 billion (DiMasi et al. 2016). This figure has attracted many criticisms, including the use of confidential data provided by the industry (Avorn 2015; Carroll 2014). If one accepts the DiMasi estimates, a reasonable rate of return on investment in developing a drug would be achieved if a firm earns quasi-rents with a net present value of $2.8 billion. (Estimates of the cost of drug development use a net present value calculation as of the date of approval, which is consistent with the treatment above of revenues, costs and quasi-rents.)

Vertex was not solely responsible for the drug development cost, as CFFT paid for most (if not all) of the pre-clinical expenses and part of the ivacaftor Stage 1 clinical trial (Werth 2014). Pre-clinical costs typically represent roughly 40% of total costs (DiMasi et al. 2010), so Vertex's share of costs is approximately 60%. Given this adjustment, for two new drugs, and using DiMasi's estimates, Vertex's share of costs for two drugs is approximately $3.4 billion.

The net expense to Vertex is, however, substantially reduced because of a US tax credit for clinical trial expenses for orphan drugs (Seoane-Vazquez et al. 2008). This tax credit was worth 50% of qualifying costs. Clinical trials are not the only cost of development; costs

related to chemicals, production process development and regulatory submissions are also included. If the tax credit amounted to 25% of Vertex's clinical expenditures, then Vertex's development costs would be approximately $2.5 billion on a risk-adjusted basis. In effect, if the quasi-rents from Kalydeco and Orkambi were $2.5 billion, Vertex would be fully compensated. Supplementary Appendix 1 provides an estimate of the R&D costs for these products specifically using Vertex's public financial records; this places Vertex's risk-adjusted R&D expenditures in the same range. The upper and lower boundaries in Table 1 assume Vertex to have spent 50% less or 50% more than the estimated middle R&D cost.

Discussion

Vertex is expected to earn substantial profits on its investment, as Table 1 shows. These large profits are only obtained thanks to the high prices charged. This makes it important to address the question of whether payers should support these substantial profits. Four justifications are commonly presented for high orphan drug prices.

Benefits to patients

First, it is asserted that these medicines provide "significant" clinical benefits to patients (Taylor-Cousar et al. 2016). For most patients, the benefits of these medicines are considerably limited, whereas many lower-priced medicines in other disease areas also provide similar or greater benefits. For example, Sovaldi, which is itself famously high-priced, provides a high cure rate of hepatitis C virus for a one-time cost of about $80,000, which compares favourably to the $250,000 annual cost of Kalydeco or Orkambi, and its cost per QALY has been estimated at being in the range of $50,000 (CADTH 2014). Given the limited budgets, spending on high-cost drugs squeezes out other treatments.

Every funding decision has an opportunity cost, and if payers are looking to maximize health benefits from their limited budgets, then they should not insure drugs with a low benefit/cost ratio. If the cost of a product per QALY exceeds that of displaced interventions, insuring that product will *decrease* population health (McCabe et al. 2008).

Support for continuing investment

The second justification is that high prices support investment in innovation. Vertex's CEO stated that "the company was relying on the income from Kalydeco to finance its goal of curing cystic fibrosis by 2020 (Werth 2013)." Indeed, Vertex recorded losses in 2015 and 2016, even though its revenues far exceeded its costs of production, royalties, SGA and interest, because of a substantial investment in R&D.

From an economic perspective, this justification is counterintuitive, and wrong. Patents create an incentive to invest in developing products valued by the market. The investment comes first, and the reward of monopoly over invention follows. Shareholders can choose to take profits as dividends or re-invest the profits. The decision to invest in new drug R&D

is driven by the hope of a high return from that investment. It seems improbable that if the products Vertex is currently developing are approved, Vertex will discount them because their costs had been covered through profits earned on Kalydeco and Orkambi.

Expected prices need to be high enough to stimulate R&D investments; similarly, current prices should fairly compensate investments made in the past. However, we should not justify high prices today by the prospect of future medicines that will also be high-priced. The society needs a sustainable system of pricing in which investments made today can be appropriately compensated when they turn into valuable products.

Fewer patients

The third rationale explaining the high prices for Kalydeco and Orkambi is fewer patients, which means high R&D costs per patient. On this basis, Vertex executives have made a case for the high price of the drugs (Nocera 2014; Verstraten 2014). The same theme is restated in general about drugs for rare diseases: "Pricing of orphan drugs is unique because R&D costs need to be recouped from a small number of patients." (Picavet et al. 2014).

The claim that prices should reflect the number of patients seems reasonable but does not justify *any* price no matter how high. If a company claims that a high price is needed because of high costs per patient, the price should be no higher than those risk-adjusted costs including the cost of capital (Berdud et al. 2018; Fellows and Hollis 2013). Although insurers may find that they cannot apply a standard cost-effectiveness threshold to orphan drugs such as Orkambi, there is a reasonable argument that prices far above this threshold should not simply be enabling excessive profits. For Vertex, the claim that prices must be high because of fewer patients is inconsistent with the enormous profits that the company is making from the sale of its drugs; a much lower price would still be enough to compensate the company.

Profits are an incentive mechanism

Another common argument is that the prospect of large profits stimulates firms to address the problems that are of greatest importance. However, in a healthcare system with a limited medicines budget, if one firm gets more, others must get less. Thus, if one company captures unexpectedly high profits, the incentives to create new drugs are not increased: revenues are simply spread among companies in a different, less predictable, way.

Controlling orphan drug prices

As the example of Kalydeco and Orkambi shows, pharmaceutical companies do not set prices based on the cost of production or development but on the price that will be profit-maximizing, given the policies in place. Patients could not normally afford extremely high prices, and it is only because of insurance that high prices can be profitable for such companies. Insurers, in this context, have a critical role in deciding what to insure. This decision

should arise from carefully considered policies. The use of a cost-effectiveness threshold may not suffice in all situations, and it will often fail to apply well to drugs for rare diseases, as they are frequently priced far above the normal threshold. In many cases, pharmaceutical companies can take advantage of poorly designed policies to raise prices indiscriminately. For example, Turing Pharmaceuticals purchased the rights to an older drug, pyrimethamine, and then attempted to raise its price in the US by 5,000% (Ghinea et al. 2016).

We should distinguish Vertex from a company like Turing. Vertex helped bring new, valuable drugs to market, as opposed to increasing generic drug prices rapaciously. But the policy framework that allowed Turing to increase prices is the same one that allows Vertex to charge a price that is far above its costs, while "justifying" its pricing based on high costs per patient. Insurers have no easy solution to high prices: Should they pay whatever the company asks, or hold the line and watch patients suffer and die? Turing's strategy, being transparently abusive, elicited outrage; Vertex's strategy has elicited concern about how patients can access needed medicines.

Vertex's financials show that high prices are not justified by costs or the need to support innovation. Instead, the prices seem more designed to reward shareholders: Vertex's previous CEO has been selling stock options in Vertex according to an approved trading plan, with a net profit of approximately $1 million per week, or approximately $50 million for 2015 (Vertex Pharmaceuticals Incorporated 2017). Without Vertex's aggressive pricing, shareholders and the executive team would have to do with less. Would the high-price strategy be acceptable to payers if they fully understood why the prices for these drugs are so high? There are approximately 180 patients in Canada who are eligible for Kalydeco under provincial insurance plans (Cystic Fibrosis Canada Kalydeco 2017). At $225,000 per patient, they will generate approximately $41 million in revenues per year, or a little less than the former CEO has been earning.

Insurers should critically analyze the prices that they pay and the claims made about costs. There may be a role for greater transparency to inform insurers about what are the true average costs of developing drugs, as has been proposed most recently by the Italian Government (Ministero della Salute of Italy 2019). Such data would help establish maximum prices when insurers feel compelled to provide access to drugs but not to provide excessive returns to shareholders.

Conclusions

This study has shown that the pricing of Kalydeco and Orkambi is far higher than is needed to recover the costs of development, even assuming that such costs are as high as the most generous estimates. That is, a large fraction of the price represents excess returns for shareholders of Vertex, rather than a reasonable payment for its investment. The situation calls for payers to explore new strategies for addressing the challenges created by high-priced drugs.

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Note

Following the acceptance of this manuscript, Vertex Pharmaceuticals contacted the author and requested to clarify several issues that were – in their opinion – inaccurate. The author had responded to the queries. For the purpose of transparency, the editors of the journal have decided to include the correspondence from Vertex Pharmaceuticals and Dr. Hollis' response as part of the manuscript as an online Appendix, available at longwoods.com/content/25937.

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RESEARCH PAPER

Decision-Making on New Non-Drug Health Technologies by Hospitals and Health Authorities in Canada

Prise de décision par les hôpitaux et les autorités de la santé au sujet des nouvelles technologies non pharmacologiques au Canada

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Abstract

Introduction: Unlike those for publicly funded drugs in Canada, coverage decision-making processes for non-drug health technologies (NDTs) are not well understood.

Objectives: This paper aims to describe existing NDT decision-making processes in different healthcare organizations across Canada.

Methods: A self-administered survey was used to determine demographic and financial characteristics of organizations, followed by in-depth interviews with senior leadership of consenting organizations to understand the processes for making funding decisions on NDTs.

Results: Seventy-three and 48 organizations completed self-administered surveys and telephone interviews, respectively (with 45 participating in both ways). Fifty-five different processes were identified, the majority of which addressed capital equipment. Most involved multidisciplinary committees (with medical and non-medical representation), but the types of information used to inform deliberations varied. Across all processes, decision-making criteria included local considerations such as alignment with organizational priorities.

Conclusions: NDT decision-making processes vary in complexity, depending on characteristics of the healthcare organization and context.

Résumé

Introduction : Contrairement aux processus de prise de décision concernant les médicaments financés par l'État, on ne connaît pas bien ceux qui concernent la couverture des technologies non pharmacologiques (TNP).

Objectifs : Cet article décrit les processus actuels de prise de décision concernant les TNP dans divers organisations de santé au Canada.

Méthodes : Un questionnaire autoadministré a été employé afin de déterminer les données démographiques et financières des organisations, suivi d'entrevues en profondeur auprès de hauts dirigeants d'organisations volontaires afin de comprendre les processus décisionnels concernant les TNP.

Résultats : Il y a eu 73 réponses au questionnaire et 48 entrevues téléphoniques (avec 45 participations aux deux activités). Cinquante-cinq processus distincts ont été répertoriés, dont la majorité concernait le matériel d'équipement. La plupart d'entre eux comportent des comités multidisciplinaires (avec représentation de médecins et de non médecins), mais il y a une variation dans le type d'information utilisée pour éclairer les délibérations. Dans tous les processus recensés, les critères décisionnels tiennent compte de considérations locales telles que l'adéquation avec les priorités de l'organisation.

Conclusions : Les processus décisionnels concernant les TNP présentent divers degrés de complexité, laquelle varie en fonction des caractéristiques de l'établissement de santé et du contexte.

Health Technology Assessment and Management in Canada

Canada has had a long tradition of health technology assessment (HTA) and was one of the first countries to institutionalize HTA processes (Battista 1992; Battista et al. 2009; Feeny and Stoddart 1994; Menon and Stafinski 2009). However, HTA processes for drugs and non-drug health technologies (NDTs) (such as medical devices, diagnostic tests and surgical procedures) have evolved along different trajectories. Thirty years ago, individual jurisdictions in Canada had separate HTA processes for making decisions on which drugs to cover through public plans. Those processes typically included an expert committee who reviewed applications from manufacturers and formulated recommendations (Menon 2014). Pan-Canadian, centralized approaches (the Common Drug Review and the pan-Canadian Oncology Drug Review) that make recommendations to provincial federal and terrirtorial public drug plans excluding Quebec now exist (Canadian Agency for Drugs and Technologies in Health [CADTH] 2019a, 2019b). However, there is no similar pan-Canadian process for non-drug technologies (NDTs). While Alberta, British Columbia, Ontario and Quebec have established formal provincial mechanisms for assessing NDTs to inform decision-making, other jurisdictions have primarily relied on rapid response services offered by CADTH.

It has been reported that between 1996 and 2008, expenditures on NDTs in Canada grew by $23 billion, compared to $5 billion for drugs (Grootendorst et al. 2011), leading to questions about the added value of these technologies. (A residual approach, which included both the cost of purchasing a health technology and the costs associated with their use, was used to generate such estimates, and therefore, $23 billion is likely an overestimate.) In response, a Federal/Provincial/Territorial Policy Forum discussed the possibility of establishing a centralized NDT review process, and more recently, the Conference of Deputy Ministers of Health identified health technology management (HTM) as a priority for Canada. Specifically, it tasked CADTH with the development of a pan-Canadian HTM strategy to "improve" how NDTs are adopted and diffused into institutions across Canada (CADTH 2016).

However, implementation of an effective HTM strategy first requires an understanding of how NDTs currently "enter" healthcare organizations in Canada. The last major study of decision-making processes for NDTs in Canadian hospitals was published 25 years ago (Deber et al. 1994). Since then, substantial changes in technology and in the organization and funding of health systems across Canada have taken place, creating a need to revisit this topic.

Objective

This project aimed to understand how decisions around the introduction of NDTs are made in different healthcare organizations across the country and what types of information are used to inform them.

Methods

The project, which included two parts, was overseen by a pan-Canadian advisory committee (PAC) comprising seven healthcare system executives, four senior-level individuals from HTA organizations and four academic researchers.

Part 1

A self-administered survey (Appendix 1, available online at longwoods.com/content/25936) was sent to the heads of healthcare organizations who were identified through the 2012 Guide to Canadian Healthcare Facilities and the PAC. It contained questions on the demographic and financial characteristics of the organization, their approaches to funding NDTs and the extent to which NDT decision-making was seen as a challenge. It also invited organizations to participate in Part 2 of the project, which involved in-depth telephone interviews. The survey was pilot-tested with PAC members prior to its administration.

To optimize response rates, the Dillman Tailored Design Survey Method (Dillman et al. 2014) was used. Questionnaires included cover letters co-signed by the lead researcher, a member of the PAC and the President and CEO of HealthCareCAN (an organization of 45 health institutions across Canada). Two rounds of reminder letters and surveys were sent (both by e-mail and regular mail) to non-responding organizations. In addition, PAC members personally contacted organization leaders by telephone and/or e-mail.

Responses were analyzed quantitatively using basic descriptive statistics.

Part 2

Telephone interviews were designed to elicit in-depth information on the scope of NDTs considered, decision-making structures (e.g., committee membership, mandate) and processes (e.g., initiators of NDT requests, information used to support/inform deliberations, factors involved in decisions/recommendations). Each interview involved a minimum of two researchers. Two were female (PhD, MPH) and three were male (MD, MHA, MA). Three were academic researchers and two were consultants. All of them had previous experience conducting interviews. None of the interviewers had a prior relationship with the participants, who were also unaware of the characteristics of the interviewers. There were no other participants in the interviews. In compliance with ethics approval for the project granted by the University of Alberta Health Research Ethics Board 2, interviews were not audiotaped, but detailed notes were taken. Also, member checking, in which interviewees receive the opportunity to review notes for accuracy, was performed.

Responses to categorical questions were analyzed quantitatively using basic descriptive statistics. Responses to open-ended questions were analyzed qualitatively using thematic analysis and constant comparative methods. Specifically, open coding was first used to analyze responses line by line in the notes and identify as many concepts (codes) as possible.

New codes were continually compared to those already assigned to chunks of text in the notes to reveal any consistencies and differences. Patterns between codes were examined to develop potential categories. Then, axial coding was used to make connections between categories and determine those which represented the central focus (axial categories). The resulting codes were subsequently converted into themes. When themes comprised a step in a decision-making process, they were organized sequentially to create a visual display of their interconnectedness. To minimize interpretation bias, all of the responses were coded independently by two researchers.

Results

Seventy-three organizations completed Survey 1 (response rate: 20%) (Figure 1). Almost half of the organizations reported that decision-making on NDTs was extremely or very challenging (83% of these were Regional Health Authorities [RHAs], Centres Intégrés de Santé et de Services Sociaux [CISSSs] or academic hospitals with budgets ranging from $35 million to $13.6 billion). Forty-three per cent found it moderately or slightly challenging (51% RHAs/CISSSs/academic centres, with budgets ranging from $42 million to $3.8 billion). The remaining 8% indicated that it was not challenging at all. These organizations provided largely non-technology-intensive services (e.g., palliative care, rehabilitation and mental health) or comprised non-university-affiliated community care centres.

Forty-seven of 75 organizations from eight jurisdictions (two procurement organizations were also invited at the suggestion of interviewees) participated in key informant interviews (Survey 2) within the available time for data collection. A comparative analysis of characteristics between participating and non-participating organizations revealed no statistically significant differences (e.g., in budget or hospital size). The 48 participating organizations consisted of 26 hospitals (11 academic hospitals), 10 health authorities, eight CISSSs/Centres Integrés Universitaire de Santé et de Services Sociaux (CIUSSs), one local health integration network (LHIN) and two procurement organizations. CISSSs/CIUSSSs combine various institutional health and social service providers (hospitals, nursing homes, Centres Locaux de Services Communautaires (CLSCs), youth detention centres, etc.) into a single organization. LHINs are responsible for planning, integrating and distributing funding from the government for all public healthcare services at a regional level. Up to three interviews were conducted with each of the participating organizations. Interviewees varied in their roles within organizations and included CEOs, other senior executives (vice-presidents, chief financial officers, chief operating officers, chief information officers), executive directors, directors, managers, department chairs, clinical program leads and administrators. On average, interviews lasted between one and two hours.

The 47 organizations yielded information on 55 separate processes. Their characteristics are summarized in Table 1.

TABLE 1. Characteristics of organizations ($N = 47$) participating in Part 2 (telephone interview)

Characteristic	Number (%) of organizations
Type of organization	
Academic centre(s) only	16 (34)
Non-academic centre(s) only	20 (43)
Both academic and non-academic centre(s)	8 (17)
Not applicable	3 (6)
Size of organization (based on number of beds)	
Small (<100 beds)	7 (15)
Medium (100–1,000 beds)	28 (60)
Large (>1,000 beds)	10 (21)
Not applicable	2 (4)
NDT funding source(s)*	
Hospital foundations	41 (87)
Specific/targeted government grant	34 (72)
Global budget government funding	32 (68)
Research funding	16 (34)
Manufacturers	11 (23)
Other	3 (6)
Not applicable	2 (4)

* more than one category may apply

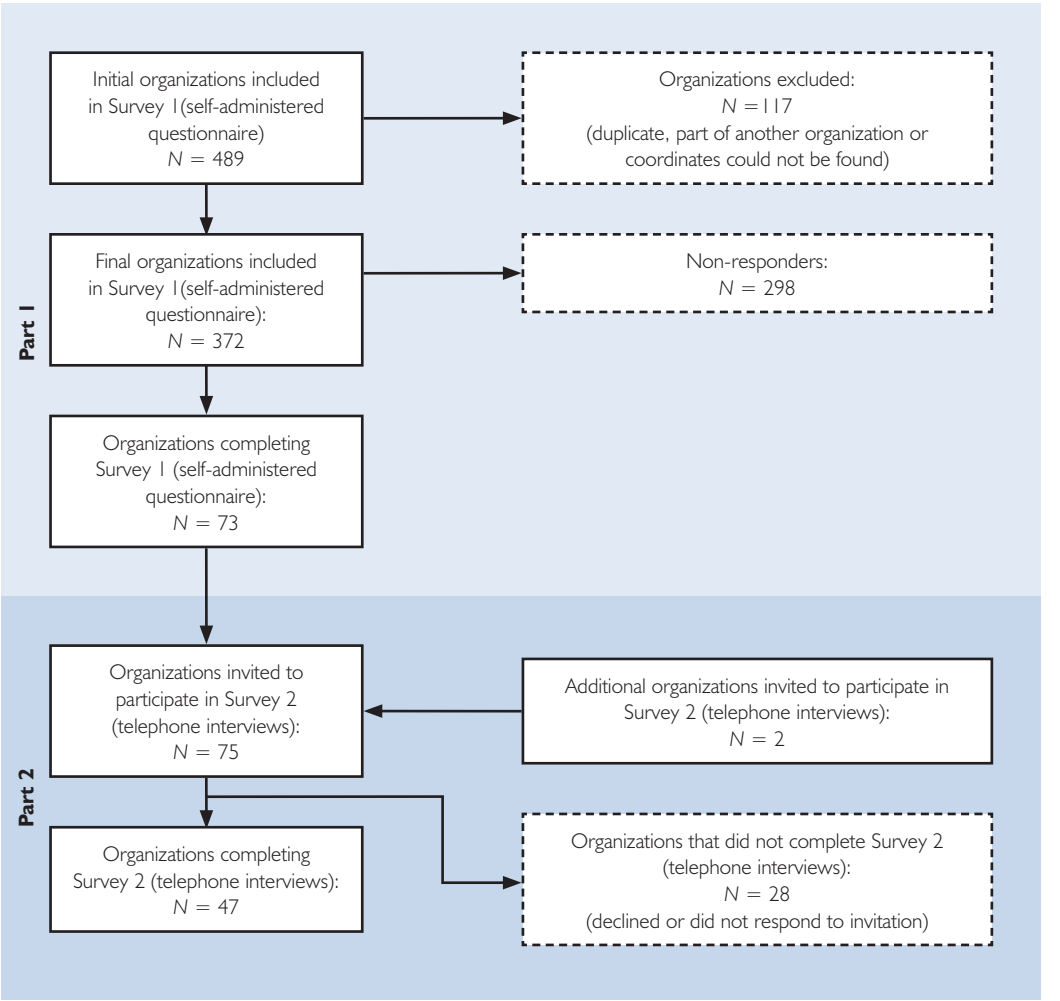
Organizational budgets

Annual operating budgets were between $1 million and $13.6 billion (mean: $879.9 million).

SCOPE OF NDTs CONSIDERED

Centralized organizational processes were identified for new capital or new non-capital technology, NDTs for off-label use or those not licensed for sale in Canada and existing NDTs. Consumables and supplies were excluded because their processes varied widely, even within a single organization, and were less complex in terms of the factors considered and implications for the organization. Technologies within a previously approved budget were also excluded, since the extent of decision-making required was largely limited to a purchasing authorization, requiring little additional review.

FIGURE 1. Number of organizations participating in each step of the project



CAPITAL/NON-CAPITAL

Fifty-five centralized decision-making processes were identified: 28 (51%) for capital equipment only, three (6%) for non-capital equipment only and 24 (43%) for both. Ten were applicable to NDTs within a specific program area only (e.g., diagnostic imaging, interventional radiology or ambulatory care technologies).

OFF-LABEL USE

Only four organizations had established processes for identifying and addressing off-label use (three academic teaching centres and one RHA that included an academic teaching centre).

UNLICENSED TECHNOLOGIES

Health Canada's Special Access Program (SAP) allows healthcare providers access to technologies that have yet to receive regulatory approval. Seventeen (36%) organizations had

used SAP to introduce new NDTs; 14 were academic centres, which viewed the SAP as an important tool to support innovation in their efforts to be recognized as "cutting-edge" institutions.

EXISTING TECHNOLOGIES

In 10 organizations (21%), decision-making processes included some mechanism for reviewing existing technologies. However, these were usually informal and applied on an ad-hoc basis. In most cases, such technologies were identified as a result of utilization monitoring. None of the organizations had implemented separate, explicit processes for managing the exit of NDTs or for making disinvestment decisions in a systematic way.

STRUCTURE

FORMAL/INFORMAL

Almost all of the processes identified by organizations were specified by the respondents as "formal," and about two-thirds were tied to annual budget planning.

TIMING OF DECISIONS

Across organizations, requests for NDTs had been made on an ad-hoc basis or at regular scheduled periods. Often, ad-hoc requests arose through donors and were for consumables or low-cost or replacement technologies. Timed acquisitions were typically for capital equipment or new initiatives (10 of 55 processes [18%]). The majority of processes (41) were used for both ad-hoc and planned decision-making and linked to the organization's annual budget planning cycle. Typically, NDTs with a larger impact (not explicitly defined) or above a certain cost were a part of the annual process.

PROCESS

NDT decision-making processes typically had four sequential components: (1) initiation of requests, (2) information requirements, (3) development of recommendations and (4) formulation of decisions.

REQUEST INITIATION

In all cases, physicians or clinical program leaders could formally propose a new NDT. In almost half of the processes, formal requests (usually requiring the completion of a standard template or preparation of a business case) from other healthcare professionals were also accepted. Requests were forwarded to a committee (42 cases), an individual (two cases) or both (13 cases), depending on whether separate processes exist for capital equipment or multiple organizational levels are involved and the potential budget impact (cost threshold). Committee included (at a minimum) physicians and clinical managers/department directors.

INFORMATION REQUIREMENTS

All processes considered information on safety and budget impact, and most relied on evidence of effectiveness and cost-effectiveness (Table 2 available at longwoods.com/content/25936). Patient preference information was considered in nearly half of the processes when available, but none routinely collected it in a systematic way. The most common sources of information were expert clinical opinion, peer-reviewed literature and regulatory documents. Whereas two-thirds of the processes used HTA reports from Canadian HTA bodies (i.e., documents containing findings from technology assessments conducted using well-established HTA methods), an almost equal proportion considered promotional material from manufacturers. Sources of information on public/patient preferences were organizational councils or groups with patient/public members. Only three processes appeared to have a minimum evidence threshold requirement, although the threshold was not specified by respondents.

RECOMMENDATIONS

Recommendations were formulated by multidisciplinary committees with representation from medical and non-medical departments/programs (Table 3 available at longwoods.com/content/25936). However, the breadth of representation from non-medical departments/programs appeared to be greater for capital planning/equipment committees. All processes required evidence of clinical benefit and alignment of the NDT with organizational priorities. The vast majority also took into account cost/affordability/sustainability, regulatory status and speed of uptake of the technology. The last, which relates to the "learning curve," is particularly relevant to NDTs, as their effectiveness relies on characteristics of the user (the healthcare provider) and the system within which the technology is used. In multi-site organizations, equity across institutions was an important consideration. Political factors (desire to satisfy stakeholders, consumer demand and prestige of requestor/technology) also played a role, and according to respondents, it could be a significant one when decisions were not "clear-cut." About half of the processes, predominantly in academic centres, considered innovativeness/economic development. Respondents expressed a desire to be at the "leading edge" of research and innovation.

DECISIONS

Final decisions were made by either individuals, such as a senior executive, or groups, such as the senior executive/management/leadership team, the board of the organization or government; this depended on whether the decision pertained to capital equipment and on the type of organization. Innovative funding arrangements for new NDTs (excluding philanthropic funding), such as risk-sharing, were not commonly reported. The exceptions were four organizations in which a manufacturer had provided the equipment and a higher price was paid for the consumables/supplies and six organizations in which lease arrangement contracts were established with the manufacturer.

EVALUATION OF DECISIONS

The implementation of specific new NDTs was reported as being evaluated (usually on an ad-hoc basis) in two-thirds of the organizations. A lack of capacity was cited by the remaining organizations as the reason for the lack of post-implementation evaluation.

OTHER INFORMATION FROM THE SURVEYS

ORGANIZATIONAL CONSIDERATIONS

Many respondents reported that their organizations were "in a state of evolution." At the time of the study, two were in the midst of major structural changes. About one-quarter indicated that they are moving toward more standardized processes for NDTs. An equal number mentioned that the study had prompted them to consider developing not only formal post-implementation evaluation processes but also the capacity needed to achieve successful change management related to NDTs.

CENTRALIZED/PROVINCIAL PROCESSES

Organizations that used HTA reports as a source of information mentioned limitations of such reports. Although they provided clear and concise evidence of clinical effectiveness, they lacked the context-specific information required for decision-making. This suggests that a single HTA capable of addressing the needs of many health organizations may not be adequate.

OTHER CHALLENGES

Regardless of policies and processes that may exist, there always appeared to be ways of getting around them, particularly in the case of smaller, less-expensive items (e.g., surgical tools). To quote, "smart advocates can get most things done through this approach." An additional concern was funding for new NDTs. Many organizations relied on philanthropic foundations for the financial resources needed to acquire one-off innovative and expensive technologies.

Limitations

The response rate was 20%, lower than recently published expected values of approximately 30% for "top management" (Anseel et al. 2010). This may be explained by the fact that the study was commissioned during a time when several healthcare systems were undergoing significant changes, particularly in Quebec and Nova Scotia. Organizational structures and roles were being modified, making it difficult to identify an individual with the appropriate level of accountability who could meaningfully participate in the survey. Also, based on the differing positions held by interview participants, senior executives (to whom the initial survey was sent) may not always have been involved enough in NDT decision-making to feel comfortable responding to questions about their processes. The low response rate may well limit the generalizability of the findings of this study.

The results of this study were based on information from members of organizations who agreed to participate. Whether other individuals within the same organization would have provided the same responses is unknown.

Discussion

This study was undertaken to address a gap in our knowledge of how individual health organizations manage decisions on new NDTs across Canada, including current "decision points" in the organization and the types of data and information required. Such information is needed to determine whether a centralized HTA process for NDTs in Canada is feasible.

The last Canadian study on technology decision-making in health institutions was published 25 years ago (Deber et al. 1994). The authors concluded that most of the decisions on new technologies were made by administrative, medical, board or mixed committees. In addition, they found that technical experts, such as biomedical engineers, played a minimal role. Our study also demonstrated that committees play a major role in NDT decision-making. Regarding the involvement of technical experts, little has changed in the past 25 years. Their involvement remains minimal. In contrast, the use of information on clinical effectiveness and cost-effectiveness appears to have increased significantly. This is likely attributable to the advent of "evidence-based medicine" in the mid-1990s, investments in the development of HTA capacity and improved access to HTA information over this period.

Studies on factors addressed in HTAs used to support NDT decision-making elsewhere in the world have produced results consistent with those of this study. In a review of official documents from member organizations of the International Network of Agencies in HTA from nine countries, seven attributes of HTA were identified for organizational decision-making: clinical (safety and efficacy), economic (comparing costs and benefits), social and ethical, organizational (such as clinical expertise, training, environment, culture), innovation and "admissibility" (defined as regulatory factors) (Usaquén-Perilla et al. 2017). In a university medical centre in the Netherlands, HTA was expected to address the consequences of adopting a new NDT on the hospital as an organization (van der Wilt et al. 2016). Therefore, questions such as "What are the implications on operating room flow?", "Is training required?", "Are there training and research opportunities?", "Is this in line with the strategic direction of the institution?" and "What might it replace locally?" needed to be addressed. Finally, a survey of more than 100 hospital managers in Europe concluded that institutional NDT decision-making requires information on the organizational, strategic and political implications of adoption, and that the focus of any economic evaluation should take the perspective of the institution, not just a societal perspective, which is typically what provincial/state HTA bodies adopt (Kidholm 2016).

Issues pertaining to the introduction and use of NDTs (e.g., prestige of a healthcare organization and ties to physician reimbursement) are, in general, more complex than those surrounding drug therapies. Organizations have created multiple levels of scrutiny for

managing NDT requests, which involve different steps and types of information. As a result, different NDT issues challenge organizations at any single time point. Whereas the findings on clinical safety and effectiveness of a new NDT may be portable across organizations, the need for local contextualization (institutional priorities, local budgetary circumstances, the role in research/innovation, etc.) would make the HTA requirements of an organization somewhat unique. Consequently, a centralized pan-Canadian review of NDTs, unless it only addresses clinical effectiveness of a technology, may offer limited value.

Conclusions

The results of this study provide important "baseline" information on the current state of NDT decision-making in healthcare organizations across Canada. Such information is critical to the development of relevant, feasible strategies for managing NDTs in Canada.

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RESEARCH PAPER

The Introduction of New Non-Drug Health Technologies into Canadian Healthcare Institutions: Opportunities and Challenges

Mise en place de nouvelles technologies non pharmacologiques dans les établissements de santé au Canada : occasions et défis

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Abstract

Introduction: A recent pan-Canadian survey of 48 health organizations concluded that structures, processes, factors and information used to support funding decisions on new non-drug health technologies (NDTs) vary within and across jurisdictions in Canada.
Objectives: The objectives of this paper were to elicit the views of key stakeholders on the following: (1) possible rationale for these findings, (2) enablers and barriers to the adoption of new NDTs, (3) approaches to optimizing the usefulness of health technology assessment (HTA) and (4) creation of a centralized pan-Canadian review process for NDTs, similar to that already in place for prescription pharmaceuticals.
Methods: A one-day facilitated roundtable involving 12 purposefully selected participants who were healthcare institutional/organizational leaders, hospital-based HTA program leaders and academic experts in HTA was conducted.
Results: Participants validated the survey findings and identified the following two enablers of technology adoption: (1) access to dedicated information resources and (2) inclusion of innovation in organizational priorities. Participants also identified four barriers, including the lack of (1) consistent decision-making processes within an organization, (2) agreement on what is affordable, (3) integration of HTA and procurement and (4) HTA literacy. Suggested approaches to optimizing the use of HTA focused on embedding the local context into assessments.
Conclusions: Given the nature of NDT decision-making and the importance of accounting for local factors in such processes, the value of a centralized HTA review mechanism similar to that in place for drugs may be limited.

Résumé

Introduction : Un récent sondage pancanadien auprès de 48 établissements de santé a permis de conclure que les structures, les procédés, les facteurs et l'information utilisés pour appuyer les décisions de financement pour les technologies non pharmacologiques (TNP) varient d'un gouvernement à l'autre.
Objectifs : Cet article vise à recueillir les points de vue des principaux intervenants sur les sujets suivants : (1) l'explication possible de ces conclusions, (2) les facteurs favorables et les obstacles à l'adoption de nouvelles TNP, (3) les façons d'optimiser l'utilité des évaluations des technologies de la santé (ETS) et (4) la création d'un processus d'examen pancanadien centralisé pour les TNP, semblable à celui actuellement en place pour les produits pharmaceutiques délivrés sur ordonnance.
Méthode : Nous avons organisé une table ronde d'une demi-journée avec animateur et douze participants délibérément choisis pour leur qualité de dirigeants d'établissements et d'organisations de santé, de directeurs de programmes d'ETS en milieu hospitalier et d'experts universitaires en matière d'ETS.
Résultats : Les participants ont entériné les conclusions du sondage et identifié deux facteurs

favorables : (1) l'accès aux informations pertinentes et (2) la présence de l'innovation parmi les priorités organisationnelles. Les participants ont aussi identifié quatre obstacles, notamment (1) le manque de processus décisionnels cohérents au sein de l'organisation, (2) l'absence de consensus sur la définition d'un prix abordable, (3) le manque d'intégration entre les activités d'ETS et celles liées aux acquisitions et (4) les lacunes dans la littératie en matière d'ETS. Les suggestions pour optimiser la démarche d'utilisation des ETS portent sur l'intégration du contexte local dans les évaluations.
Conclusions : En raison de la nature des décisions concernant les TNP et de l'importance de tenir compte des facteurs locaux dans le processus, l'utilité d'un mécanisme centralisé pour l'examen des ETS – semblable à celui actuellement en place pour les médicaments – pourrait être limitée.

Introduction

Technology has been a mainstay of healthcare, leading to improved health outcomes for many people. At the same time, it has been a major driver of growth in health expenditures. According to the Organisation for Economic Co-operation and Development (OECD), "Technology can only generate value in health systems if the health benefits of these technologies outweigh the cost they impart. This can only be achieved by promoting access to and appropriate use of technologies that are safe, performant, effective and clinically useful." (OECD 2017). The OECD made several recommendations, including "Use health technology assessment (HTA), coverage and pricing policies to encourage value-for-money." (OECD 2017, pp. 13–15).

Canada was one of the first countries to establish institutionalized HTA (Battista et al. 2009). The Canadian Agency for Drugs and Technologies in Health (CADTH), funded by the federal, provincial (excluding Quebec) and territorial governments, has been operating for three decades. In Quebec, the provincial government has established the Institut national d'excellence en santé et services sociaux (INESSS). Over the past 15 years, HTA activities have largely focussed on pharmaceuticals. Centralized assessment processes for the review of new pharmaceuticals being considered for coverage through participating federal, provincial and territorial public drug plans have been created. They generate a single coverage recommendation, thus largely replacing the need for jurisdiction-specific review processes. The exception is INESSS, which undertakes a similar review process for Quebec.

There are no parallel processes for non-drug technologies (NDTs), but individual provinces have established mechanisms for generating HTA information: INESSS in Quebec, Health Quality Ontario in Ontario, Health Evidence Reviews in Alberta and BC Health Technology Assessment in British Columbia. The provinces and territories (particularly

those without formal HTA mechanisms) also rely on CADTH for information on select technologies. Lastly, several teaching hospitals have established HTA units to support decision-making at the institutional level (Martin et al. 2016), and in Quebec, by law, all academic medical centres must have their own HTA capacity (Lepanto 2016).

Given the successful introduction of centralized HTA processes for pharmaceuticals, development of a parallel system for NDTs has been proposed more than once over the past decade. In 2012, the possibility was discussed during a federal/provincial/territorial policy forum, and in 2016, the Conference of Deputy Ministers of Health formalized health technology management (HTM) as a priority for Canada and tasked CADTH with the development of a pan-Canadian HTM strategy to "improve" how NDTs are adopted and diffused into institutions across Canada (CADTH 2016).

As a first step, Health Canada commissioned a study to understand how decisions on NDTs are currently made across the country. This study involved a survey of and interviews with senior/executive-level leaders of healthcare institutions and organizations, as well as a day-long facilitated roundtable. The survey and interviews were designed to understand existing NDT review mechanisms, including the types of information used and structures and processes for making funding decisions. The results of the first parts of the study have been reported in an earlier manuscript (Stafinski et al. 2019). In this manuscript, we report on the roundtable.

Methods

A day-long facilitated roundtable was held. Roundtables convene a small number of participants to deliberate over a clearly defined topic. Twelve individuals were invited to participate spanning the following three groups: (1) leaders of healthcare institutions who make NDT decisions, (2) leaders of hospital-based HTA programs and (3) academic researchers with expertise in HTA and HTA-informed decision-making. Individuals from the first two groups were identified through the survey and purposefully selected to represent a range of healthcare organizations (community-based hospitals, tertiary care centres, academic teaching hospitals, shared services and regional health authorities) and geographic locations. Academic researchers, from the third group, had a publication track record in HTA and served on advisory committees of HTA organizations. The number of participants was limited to 12, ensuring enough diversity within the group to capture a range of NDT decision-making contexts and providing equal opportunity for each individual to participate (Riggas et al. 2010/2011).

The day-long session followed standard roundtable processes and was facilitated by a member of the research team with experience running similar sessions (DM; Scottish Health Council 2014). After introductions and a description of the context and aims for the session, two health services researchers (DM and TS) presented findings from the survey and interviews. Participants were asked whether they were consistent/inconsistent with their expectations, and to identify reasons for the patterns/trends observed across different

institutions. The second part of the session focussed on general issues related to HTM. These issues included enablers of and barriers to NDT adoption and the potential value of a centralized, pan-Canadian HTA process for NDTs. To encourage contributions from everyone, the nominal group technique was used. Participants first self-formulated their thoughts and then shared these in a round-robin fashion (Delbecq and Van de Ven 1975).

The roundtable was recorded, and detailed notes were taken by three researchers (TS, AN and OB). Transcripts and notes were analyzed independently by two researchers using content analysis (TS and DM). Initial categories and codes were developed based on the questions asked during the roundtable (deductive coding). Open coding was then used to capture additional emergent ideas (inductive coding). Participants were de-identified and assigned a number (e.g., P1, P2, etc.) during transcript analysis. To improve the accuracy and credibility of the results, member-checking (circulating results to participants) was performed.

Results

The roundtable included seven senior executives (two from academic teaching hospitals, one from a tertiary care centre, one from a provincial shared services organization, two from regional health authorities and one from a community hospital) and two hospital-based HTA unit leads. Collectively, they spanned Nova Scotia, Quebec, Ontario, Manitoba, Alberta and British Columbia.

Feedback on presentation of survey and interview findings

None of the participants expressed surprise over the findings, reiterating that healthcare organizations are complex systems in which one process for making decisions on all NDTs would have limited application. Larger organizations typically have more than one process because the decision-making authority is often distributed among multiple individuals who have different budget thresholds based on their position. NDTs can range from relatively inexpensive single-use devices (e.g., a stent) to expensive capital equipment (e.g., MRI machine), involving ongoing maintenance and eventual replacement after several years. The seniority of individuals making decisions and scrutiny over the process tend to increase with the budgetary impact of the technology. All decision-making processes were found to require information on safety and budgetary impact. According to the participants, this can be explained by the need to meet accreditation standards that are primarily designed to enhance quality and safety, reduce risk and ensure fiscal accountability. A minority of the processes consider patient preferences. One participant indicated that a lack of resources has precluded implementation of initiatives that are aimed at eliciting patient preferences around specific technologies/services. "To do that would involve resources we just don't have right now" (Participant [P] 1). A second participant questioned whether such initiatives are necessary because the choice of outcomes measured in studies used to inform questions about the safety and clinical efficacy/effectiveness of an NDT should reflect in part what matters to

patients. It was found that of the seven criteria used by at least 75% of processes, five are context-specific. Their application requires consideration of institution-specific factors, including alignment with institutional priorities, availability of similar services elsewhere, affordability, desire to please stakeholders and speed of technology uptake. Finally, based on the results of survey, philanthropic foundations are the most common funding sources for NDTs. "It has almost become a necessity, a part of standard operating procedures." (P2). One participant argued that this "reliance stems from major cuts that were first made to healthcare budgets over three decades ago" (P4).

Enablers of and barriers to the adoption of new NDTs

Participants stressed the importance of focusing on "appropriate" adoption of new NDTs. "It's not about adoption, in generic terms, it's about appropriate adoption." (P2). "Appropriateness" was conceptualized in the following two ways: "providing the right care to the right patient at the right time" and ensuring "the benefits of a technology outweigh the harms to patients, providers and the broader health system" (P1). Two enablers of "appropriate" adoption were identified.

(1) *Access to dedicated resources for supporting decision-makers' information needs:* Participants from organizations with HTA capacity in-house described it as an "essential resource for understanding the potential impact a technology may have on our organization" (P9). In contrast, participants from organizations without such capacity viewed information availability as a challenge. "We have no dedicated HTA resources. We have to go with what is presented in the business case, which has usually been done off the side of someone's desk." (P1). Potential opportunities for sharing HTA information across organizations were discussed. All participants viewed evidence addressing safety and clinical effectiveness as portable, but they questioned the transferability of information on economic and system implications: "When I go googling on my own and find an HTA from somewhere else, I often quickly come to the conclusion that the only bit I can use is the clinical part" (P4). "We thought we could just use the [name removed] report, but found out the economic model had a different care pathway." (P4).

(2) *Inclusion of innovation in organizational priorities:* In some organizations, particularly those formally affiliated with academic institutions, innovation is a part of the mission. They have created strategies and programs designed to foster collaborative relationships among innovators, healthcare providers and administrators and to encourage the development of technologies that better align with the institution's values and needs. "We offer a 'living lab' for innovators and in return we have real world evidence that we can use when it comes time to make a purchasing decision." (P5). The role of pilot studies in efforts to enable appropriate adoption of NDTs was also discussed. Although conceptually appealing, their management has challenged healthcare organizations. Pilots have

become "a way to get the technology through the back door." (P9). Executive leaders are often unaware of pilots. A technology (e.g., medical device or piece of equipment) is lent to individual clinicians, programs or departments, and "they get to try it out for a while. The pilot lasts as long as it takes for staff to grow to like it and want to keep it. Then I find out about it because I get asked for money to pay for it" (P5). Tensions between providers and the executive leadership team surface when a disconnect arises between the technology's value proposition and the priorities of the organization. Participants discussed ways of mitigating these issues, recognizing that pilots, when managed effectively, offer a useful tool for generating evidence that directly relates to an organization. The establishment of formal processes for overall management of pilots was proposed.

Participants identified four main barriers to the appropriate adoption of new NDTs:

(1) *Lack of consistent approaches to technology decision-making within an organization:* Depending on the type of organization, the decision-making authority is delegated to leads of sites, programs or departments. Individual leads determine how decisions on new NDTs within his/her portfolio are made, resulting in multiple processes of varying complexity within the organization. In some cases, "a physician just says 'in my field, this is the new standard,' and it's in" (P2). In multi-site organizations, different processes have generated different decision outcomes on the same technology. Thus, "there is quite a disparity in what folks have for equipment" (P6). This disparity has, at times, affected equity in access to services. "We had two patients who both had the same thing but they got offered different treatment options because one lived near [name of hospital removed] and the other lived near [name of hospital removed]." (P6). Participants discussed ways to alleviate this issue, noting that "not everybody is at the minimum standard. We have two major centres and they can't agree on anything. How do you stop something to bring everyone else to a minimum level?" (P5). Development of a corporate-level strategy for NDTs was proposed, as "currently, health technology does not appear to have a corporate focus" (P3). It was agreed that such a strategy could provide the foundation for a standardized NDT decision-making process because "without a standardized process, opportunities to ensure new NDTs are introduced and used appropriately may be lost" (P3).

(2) *Lack of consensus around what is affordable:* Participants first deliberated over the meaning of "affordability" and agreed that "affordability is a function of income, costs, and value judgements, and value judgements are a reflection of values" (P1). The term "values" was then discussed. "There is no shared understanding of values" (P8). "We use the word a lot and I don't know that the values I have in my head are those everyone else in the room are thinking ..." (P3). The importance of establishing a set of values

to guide priority-setting for NDTs was stressed. It was felt that these values reflect those of society because the healthcare system is publicly funded. They also discussed the extent to which societal values may differ from those of patients, providers and payers and concluded that "we don't really know" (P4). "We have to make efforts to get at this kind of information." (P7). "And once we know them, there needs to be a higher level discussion around what we can afford." (P3). In this context, the reliance on philanthropic foundations for funding of new health technologies was raised again. Often, funding is tied to priorities established by the donor, which differ from those of the organization. "Once that funding dries up, the hospital gets saddled with the costs for a technology that it didn't need in the first place." (P2). There was consensus around the need to work more collaboratively with foundations, and several ways were proposed that (1) involve foundations in yearly priority-setting activities, (2) co-create a menu of priorities to facilitate conversations with donors and (3) engage foundations in HTA activities. This third suggestion related to the Institute for Healthcare Improvement's Quadruple Aim Framework, which had been adopted by some organizations. "Each time a new technology is brought forward, whether it be by a donor or a site chief, we have to ask ourselves what added value it brings to each of those quadrants ... and if we don't think enough for what it costs, then that means we can't afford it." (P7).

(3) *Lack of integration of technology assessment and procurement processes:* Typically, procurement becomes involved only after a technology has been assessed and approved for purchase. Therefore, it does not require HTA information. One participant explained that "procurement folks look at price, whereas the funding committee looks at value" (P6), resulting in the selection of a particular model or make of a technology based on the lowest price, rather than its value to the health system. However, "it could look like it is cheaper, but what if it causes more pain or is more difficult for staff to use?" (P7). The need to consider downstream costs was also raised. "Sometimes you spend the extra money on company X's because you'll have fewer costs downstream." (P8). Since most of the information needed to determine the value of a technology has already been generated either through an HTA or through deliberations among those involved in making the funding decision, steps toward closing the gap between the two processes might include sharing information with and involving procurement in the funding decision stage. "It only makes sense to have procurement at the HTA table," and "the earlier you can get procurement in this, the better" (P6).

(4) *Lack of understanding of HTA and its role in supporting decision-making:* Despite HTA's long history in Canada, its use in NDT decision-making across institutions remains limited (Stafinski et al. 2019). Participants argued that "there is a lack of HTA literacy in many healthcare organizations" (P9). HTA literacy was defined as "the ability to identify, understand, interpret and communicate findings from HTA" (P3). As stated by

one participant, "executives need to learn how to use HTA" (P4). This first requires an understanding of the main decision outcome HTA aims to inform (i.e., appropriateness of care). "It is time we narrow the discussion to appropriate care for appropriate patients" (P5). These questions demand consideration of the clinical, economic, social, legal, ethical and system (including workforce) implications of introducing a new technology; thus, HTA needs to be comprehensive. Since HTA resources are scarce, it was suggested that technologies assessed be limited to those for which there is an existing technology that could be replaced as a result of its adoption. "HTA resources are limited ... they need to be used in the right way ... we probably need to say to each other that we are in a zero sum game – thou shalt not do technology assessment without a comparator." (P8).

A broader discussion around ways to optimize the usefulness of HTA in healthcare organizations emerged. Participants proposed the following:

(1) *Identify the right technologies for assessment:* The "value of HTA lies in what we are assessing" (P8). Priority-setting for new NDTs and, by implication, HTA, is essential, as the number and range entering the Canadian market are significantly greater than the resources available to pay for them. In addition, new NDTs cannot continue to be introduced into the healthcare system without re-assessing existing NDTs to ensure their utilization remains relevant and appropriate. "We want an equal number of investment and disinvestment topics." (P9).
(2) *Establish a "single entry point for the review of new technologies"* (P9)*:* There was broad consensus around the need for a more systematic, streamlined approach to the review of new NDTs, beginning with the establishment of a single point of entry. That entry point (individual, unit or office) would receive all requests for new NDTs, including those for potential pilots. It was acknowledged that although they may not all require the same level of scrutiny, they should be "entered into a centralized repository of innovations" (P6) to better facilitate their management.
(3) *Ensure context is embedded into HTA:* The difference between HTAs of pharmaceuticals and of NDTs was stressed. "Usually, a new drug doesn't mean I will need to think about renovating an OR (operating room) and hiring a new surgeon." (P4). Decision-makers need to consider factors such as the availability of existing supportive services; patient care pathways; impact on workflow, beds and wait times for other services; and additional infrastructure requirements. "These are not the same for all facilities" (P2). One participant concluded, "For these technologies, when it comes right down to it, it is all about context" (P6).
(4) *Include analyses of downstream issues:* One participant reminded everyone that "We've been talking about using a lifecycle approach to evaluate technologies for a long time now. If we did that, we could better manage what happens downstream" (P10). An example of a case in which the addition of a set of screening tests had overwhelmed lab services, resulting in delays to the analyses of other tests, was provided. Participants

agreed that "economic analyses within HTAs should incorporate implementation considerations that could have downstream consequences" (P7).

(5) *Align HTA reviews with research processes:* In general, the production of HTAs to support NDT funding decisions remains separate from an organization's research programs. Participants argued that if the two were more closely linked, there may be opportunities to conduct studies that generate real-world evidence on emerging technologies for which the evidence is promising but insufficient to warrant immediate adoption. There would also be opportunities to review evidence from any pilots of new technologies and determine whether it supports adoption within the organization. According to one participant, "we should look at managed entry as a more routine mechanism for introducing innovations rather than an exception" (P8).

Usefulness and feasibility of a centralized review process

The possible value of a pan-Canadian centralized review process was discussed. It was agreed that information on the safety and effectiveness of an NDT may be useful to all institutions/organizations if it is assumed that the comparator technologies and, moreover, priorities for NDTs are the same. One participant explained, "I already get physicians coming to me with a report from somewhere else saying that we need this technology when what we have to begin with isn't even the same" (P5). Participants proposed the development of tools organizations could use to customize reports to reflect their local context. However, some raised concerns over the need for institutional resources to do that on an ongoing basis. Consequently, there was consensus among participants that given the nature of most NDTs, a centralized review comparable with that for drugs would likely be infeasible.

Participants proposed an alternative process in which assessments of technologies tied to priority areas shared by most healthcare organizations across Canada would be conducted to support decisions around their appropriate use. For example, there is "a need for good HTA being accessible and easily digestible for the funding and prioritization phase in the capital equipment replacement timeline" (P1). To this end, tools for contextualizing reviews to individual healthcare organizations should accompany them, as it was recognized that no single economic model can capture differences in the delivery of care across organizations in a meaningful way.

Limitations

The study has two main limitations. First, only one roundtable was conducted. Although efforts were made to select participants who represented a broad range of organizational perspectives, it is not possible to comment on the generalizability of the findings to all senior executives, institutional directors of HTA units and academic experts involved in NDT decision-making across Canada. Second, although two participants were from Ontario,

neither held a senior-level executive position. However, both had worked closely with senior executives in healthcare organizations for over 20 years and, therefore, had an in-depth understanding of NDT decision-making processes in Ontario.

Discussion

In this paper, we reported on the deliberations of a pan-Canadian roundtable on processes for making decisions on the adoption of new NDTs. Participants validated the findings of a survey of 48 health institutions from eight Canadian jurisdictions (Stafinski et al. 2019), identified barriers and enablers to the appropriate adoption of new NDTs and proposed a number of ways to improve the usefulness of HTA. In particular, they stressed the importance of ensuring that the local context is embedded in assessments. The need for contextualized HTA has been recognized by jurisdictions internationally, leading to the establishment of institution-based HTA units in many countries (Ehlers et al. 2006; Sampietro-Colom and Martin 2016). Participants argued that a lack of HTA literacy among health leaders has precluded its widespread incorporation into decision-making processes. This has also been identified as a limitation of HTA use in other countries (Hivon et al. 2005). Finally, participants questioned the usefulness and feasibility of creating a centralized HTA process for NDTs, which mirrors that already in place for new pharmaceuticals. Over the years, other countries have engaged in similar debates, and for largely practical reasons, responsibility for making NDT decisions remains at a local or regional level (OECD 2017).

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