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

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HEALTHCARE
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Politiques de Santé

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

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

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

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

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

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

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EDITORIAL

Engaging with Policy Makers: The Need for Accessible and Timely Health Services and Systems Research in 2020

In its conception, *Healthcare Policy* was a partnership between the Canadian Institutes of Health Research's Institute of Health Services and Policy Research (IHSPR), the Canadian Association of Health Services and Policy Research and Longwoods Publishing. With the support of IHSPR's scientific director at the time, Dr. Morris Barer, the objective of the journal was to "stimulate communication and cross-fertilization between researchers and healthcare decision makers" (Government of Canada 2006). With a strong focus on knowledge translation and interdisciplinary research, the journal links policy makers with researchers, thus carrying its founding objective forward as a guiding principle for *Healthcare Policy*.

With the COVID-19 pandemic raging across provinces and territories, Canadians are witnessing and experiencing active policy making among public health professionals whose roles have included translating basic science and public health knowledge into public and healthcare policy. Their recommendations and resultant federal, provincial and municipal regulations and policies are being felt across all aspects of our lives – including social distancing and resource allocation, affecting tens of thousands with cancelled elective surgeries.

Their successes in slowing the spread of COVID-19 highlight the role and importance of policy making. This issue of *Healthcare Policy* is focused on generating the evidence base for decisions, actions and policy making at the federal and provincial levels. The issue's articles highlight gaps in the federal and provincial governments' policies for accessing care and therapeutics, gaps in delivery networks and the impact of not addressing social determinants of health. In each article, authors write in a style to engage with policy makers and provide a range of policy options.

Two important Discussion and Debate articles are presented with rejoinders in this issue. Each is focused on temporal policy topics – two-tier medicare and rapid review of novel drugs – facing federal and provincial governments and whose ramifications have important

consequences for a province's healthcare delivery network. The issue also includes five original research articles on a range of policy-relevant topics, such as antimicrobial resistance policies and the use of real-world evidence in evaluating a new drug's market access and funding.

Two-tier healthcare is a controversial topic among many in Canada, whose perceptions are exacerbated by lengthy wait times for some surgeries or diagnostics as experienced by some. *Healthcare Policy* is contributing to the debate and knowledge base by presenting Flood and colleagues' (2020) very thorough article on the legal aspects of the constitutional challenge unfolding in British Columbia on a physician's ability for dual practice and the role of private health insurance. The authors develop the argument that, should the case succeed in challenging existing legislation, Canadians can expect the private financing of healthcare to accelerate. Moreover, the authors strike the position that the federal and provincial governments are largely ensnared in this predicament owing to their continued inaction against enforcing (federal) or delivering (provincial) on shorter wait times.

In a rejoinder, Stephen Duckett (2020) describes the policy environment that supports dual private and public healthcare delivery in Australia. Drawing on Australia's two-tier healthcare systems to possible outcomes in provinces, Duckett pulls evidence from a range of studies, showing that the impact in Australia has resulted in deleterious effects on the public hospital system leading to the ongoing public subsidies to the private insurance sector.

Nonetheless, the outcome of the case in British Columbia aside, it does portend significant changes in regulation and policy within the provinces on healthcare delivery and financing.

In a second Discussion and Debate article, Professor Joel Lexchin (2020) uses an empirical basis for arguing that Health Canada's proposed accelerated review pathway for novel drugs is bound to be ineffective on two grounds. First, while positing that accelerated reviews are necessary, he describes that programs that expedite access are insufficiently sensitive to identifying meaningful therapeutic advantages. Second, he notes that drugs that have had an expedited review are more likely to acquire a post-market safety warning. The article concludes with a number of recommendations to strengthen the process of expedited drug reviews in Canada.

Darrow and Beall (2020) provide a thorough rejoinder to the Lexchin article. Providing a counterpoint, the authors describe that Health Canada's criteria for expedited reviews may be attributable to the agency's delicate balance of attempting to exclude low-value drugs while providing speedier access to high-impact drugs. On the second point, regarding patient safety, the authors suggest that the stage of a disease or its severity may be a confounder. The rejoinder concludes by affirming Lexchin's position that expedited reviews are important, and the authors provide four additional steps to strengthen Health Canada's expedited review process.

Tadrous et al. (2020) also shine the light of policy making on Health Canada. Their article describes a process for using real-world evidence to inform market access and funding decisions for drugs. Based on integrating data across platforms and systems, real-world evidence will have a material impact on the valuation of drugs.

Van Katwyk et al. (2020) study the prevalence and intensity of policy interventions for antimicrobial resistance across Canada. With a survey-based approach, and highlighting the threat of antimicrobial resistance, they describe that current policies are inadequate and much more can be done through regulation and policy making. The authors conclude by discussing opportunities for provinces and their health professional associations to engage in policy making.

Based in Ontario, McDonald et al. (2020) study the association between community-level marginalization and emergency-room wait time, reporting that reducing residential instability is a promising vector toward reducing emergency room use. Agnolon et al. (2020) use a retrospective case-study design to evaluate Quebec's efforts to increase breastfeeding rates in the province, reporting that past efforts were contentious and future provincial efforts should fully involve mothers. Courbage and Kalouguina (2020) report on their study of health prevention activities using survey data from the Behavioral Risk Factor Surveillance System used in the US, reporting that awareness, ease of access and quality of health information are associated with health prevention activities.

True to its original mission, *Healthcare Policy* encourages submissions that engage Canadian healthcare policy makers on timely and relevant healthcare policy issues.

JASON M. SUTHERLAND, PhD
Editor-in-Chief

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ÉDITORIAL

Relations avec les responsables des politiques : importance d'un accès opportun à la recherche sur les services et les systèmes de santé en 2020

Dès ses débuts, *POLITIQUES DE SANTÉ* a été le fruit d'un partenariat entre l'Institut des politiques et des services de la santé (ISPS) des Instituts de recherche en santé du Canada, l'Association canadienne pour la recherche sur les services et les politiques de la santé (ACRSPS) et Longwoods Publishing. Fort du soutien du directeur scientifique de l'ISPS d'alors, M. Morris Barer, l'objectif de la revue était de « stimule[r] la communication et la fertilisation croisée entre les chercheurs et les décideurs dans le domaine des soins de santé » (Gouvernement du Canada 2006). Mettant l'accent sur la transposition des connaissances et la recherche interdisciplinaire, *Politiques de Santé* entend réunir les responsables de politiques et les chercheurs, menant ainsi à bien l'objectif initial de la revue.

Avec la pandémie de COVID-19 qui fait rage dans les provinces et territoires, les Canadiens et les Canadiennes sont en mesure de voir comment les professionnels de la santé travaillent activement à l'élaboration de politiques; professionnels dont le rôle inclut la transposition de connaissances scientifiques dans les politiques publiques de santé. Leurs recommandations et les réglementations fédérales, provinciales ou municipales qui en découlent ont des répercussions sur tous les aspects de notre vie, pensons notamment aux mesures de distanciation sociale ou à l'allocation des ressources, qui affectent des dizaines de milliers de personnes en raison de l'annulation de chirurgies électives.

Leurs efforts pour ralentir la propagation de la COVID-19 met en lumière le rôle et l'importance des politiques de santé. Le présent numéro de *Politiques de Santé* porte l'accent sur la production de données probantes utiles à la prise de décision, à l'action et à l'élaboration de politiques aux niveaux fédéral et provincial. Les articles de ce numéro font voir les lacunes dans les réseaux de prestation de services et l'impact associé au fait de ne pas prendre en considération les déterminants sociaux de la santé. Chacun des articles présente une série d'options politiques et est rédigé dans un style propre à interpeller les responsables de politiques.

Deux articles de la section Discussion et débat proposent d'intéressantes pistes de réponse. Tous deux présentent des sujets politiques d'actualité – les systèmes de santé à deux vitesses et l'examen accéléré des nouveaux médicaments – auxquels font face les gouvernements fédéral et provinciaux et dont les ramifications ont d'importantes répercussions sur les réseaux de santé des provinces. Le numéro comprend également cinq articles originaux faisant état de recherches sur des sujets pertinents tels que les politiques sur la résistance aux antimicrobiens ou l'utilisation des données probantes du monde réel pour évaluer l'accès au marché et le financement d'un nouveau médicament.

Le système de santé à deux vitesses est un des nombreux sujets à controverse dans le paysage canadien. Sujet que vient exacerber la longueur des temps d'attente pour certains types de chirurgies ou de diagnostics. *Politiques de Santé* contribue à ce débat et au fonds de connaissances en présentant le travail approfondi de Flood et coll. (2020) sur les aspects légaux d'une contestation constitutionnelle qui a présentement lieu en Colombie-Britannique au sujet de la double pratique des médecins et du rôle de l'assurance-maladie privée. Les auteurs allèguent que si la contestation obtenait gain de cause, on verrait une accélération du financement privé des services de santé. De plus, ils soutiennent que les gouvernements fédéral et provinciaux sont pris au piège en raison de leur inaction pour réduire les temps d'attente, que ce soit par l'application de règles (compétence fédérale) ou par les mesures de prestation (compétence provinciale).

Dans son article, Stephen Duckett (2020) décrit l'environnement politique qui soutient la double prestation de services de santé – privés et publics – en Australie. En observant ce système à deux vitesses pour en extrapoler les effets possibles pour les provinces, Duckett présente des données provenant de plusieurs études qui montrent que l'impact en Australie a eu des effets délétères sur le système hospitalier public, ce qui a mené à des subventions publiques dans le secteur de l'assurance privée.

Néanmoins, indépendamment du résultat de l'affaire en Colombie-Britannique, d'importants changements dans la réglementation et les politiques provinciales en matière de prestation et de financement des services de santé sont à prévoir.

Dans un deuxième article de la section Discussion et débat, le Dr Joel Lexchin (2020) affirme, sur une base empirique, que la proposition de Santé Canada pour accélérer les processus d'examen des nouveaux médicaments est vouée à l'inefficacité, et ce, sur deux plans. Premièrement, tout en convenant que les examens accélérés sont nécessaires, il décrit que les programmes d'accès expéditifs ne sont pas assez précis pour permettre de dégager des avantages thérapeutiques significatifs. Deuxièmement, il observe que les médicaments qui ont bénéficié d'un examen accéléré sont plus susceptibles de donner lieu à des avertissements après leur mise en marché. L'article se termine par une série de recommandations pour renforcer le processus d'examen accéléré des médicaments au Canada.

Darrow et Beall (2020) proposent une réponse approfondie à l'article de Lexchin. En contrepoint, ils expliquent que les critères de Santé Canada pour les examens expéditifs pourraient être attribuables à la recherche d'un équilibre pour tenter d'exclure les

médicaments de faible valeur tout en permettant un accès rapide aux médicaments qui ont un fort impact. Sur le second point, en ce qui concerne la sécurité des patients, les auteurs suggèrent que le stade d'une maladie ou sa sévérité peut agir comme facteur de confusion. L'article conclut en affirmant la position de Lexchin selon laquelle les examens accélérés sont importants; les auteurs proposent en outre quatre étapes supplémentaires pour renforcer les processus d'examen accéléré de Santé Canada.

Tadrous et coll. (2020) se penchent également sur l'élaboration des politiques de Santé Canada. Leur article décrit un processus d'utilisation des données probantes du monde réel pour éclairer l'accès aux marchés et les décisions de financement pour les médicaments. En étant intégrées dans les plateformes et les systèmes, les données probantes du monde réel auront un impact concret sur l'évaluation des médicaments.

Van Katwyk et coll. (2020) étudient la prévalence et l'intensité des politiques d'intervention contre la résistance aux antimicrobiens, partout au Canada. Au moyen d'une enquête, et en soulignant la menace de la résistance aux antimicrobiens, ils rapportent que les politiques actuelles sont inadéquates et qu'on pourrait faire beaucoup mieux avec les mesures de réglementation et l'élaboration de politiques. Les auteurs concluent en présentant comment les provinces et les associations professionnelles peuvent participer à l'élaboration des politiques.

Basés en Ontario, McDonald et coll. (2020) étudient le lien entre la marginalisation communautaire et les temps d'attente au service des urgences. Ils rapportent qu'une réduction de l'instabilité sociale pourrait être un vecteur de réduction de l'utilisation du service des urgences. Pour leur part, Agnolon et coll. (2020) ont recours à une étude de cas rétrospective afin d'évaluer les mesures québécoises pour accroître l'allaitement maternel dans la province. Ils observent que les mesures prises dans le passé ont donné lieu à du mécontentement et que les efforts à venir devraient compter sur l'entière participation des mères. Courbage et Kalouguina (2020) font état de leur étude sur les activités de prévention en matière de santé. Pour ce faire, ils ont consulté les données de l'enquête du Système de surveillance des facteurs de risques comportementaux réalisée aux États-Unis. Ils rapportent que la conscientisation, la facilité d'accès et la qualité des informations en matière de santé ont un lien avec les activités de prévention.

Fidèle à sa mission originale, *Politiques de Santé* encourage la soumission d'articles qui interpellent les responsables des politiques de santé au Canada sur des enjeux actuels et pertinents.

JASON M. SUTHERLAND, PhD
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The Courts and Two-Tier Medicare

Les tribunaux et le système de santé à deux vitesses

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Abstract

Canada's single-payer healthcare system is at a critical crossroads. A legal challenge underway in British Columbia alleges that legislative restrictions on privately financed care infringe the right to "life, liberty and security" guaranteed under Section 7 of the *Canadian Charter of Rights and Freedoms*. The greatest challenge for the court will be comparing healthcare systems across disparate jurisdictions, with the future of single-tier healthcare system hanging in the balance. If successful, the case may require a major overhaul of Canada's single-payer system – a perilous task politically, if history is any guide, and this may be the system's undoing.

Résumé

Le système de santé canadien à payeur unique est rendu à un carrefour critique. Une contestation judiciaire en Colombie-Britannique allègue que les restrictions législatives sur le financement privé des soins se santé enfreignent le droit « à la vie, à la liberté et à la sécurité » garanties en vertu de l'article 7 de la *Charte canadienne des droits et libertés*. Le principal défi

pour le tribunal sera de comparer les systèmes de santé entre des juridictions disparates, avec en jeu l'avenir du système de santé à payeur unique. Si la contestation obtient gain de cause, cela pourrait donner lieu à une révision radicale du système de santé canadien à payeur unique – une tâche politiquement périlleuse, si on se fie à l'histoire, et qui pourrait mettre en péril le système même.

Introduction

Internationally, Canada's healthcare system has seen a fall in its relative performance in recent years, with Canadians reporting, among other concerns, some of the longest wait times across comparator countries (Canadian Institute for Health Information 2017). However, rather than spurring significant government action to improve healthcare for *all* Canadians, wait-time concerns are sparking constitutional challenges to overturn present legal restrictions on privately financed care, so some can both enjoy the security of a single-payer system and "jump the queue" by using private monies more easily. Although framed around patient rights, the case is equally about the economic rights of physicians: a physician-owned private for-profit clinic (Cambie Surgeries) is at the helm of the most recent constitutional challenge and looks to benefit from further privatization of the Canadian system.

Challenges to laws that limit the potential for a two-tier system are primarily grounded in Section 7 of the *Canadian Charter of Rights and Freedoms* – the right to "life, liberty and security of the person." Challengers are seeking to overturn a variety of laws that exist across Canadian provinces; these laws restrict opportunities for privately financed care (it is important to note that the Canadian system, although restrictive on the possibilities for private financing, largely embraces possibilities for private delivery [Deber 2002]). Across Canada, current laws restrict (but do not completely eliminate) a two-tier system, wherein all Canadians are insured by public medicare, but the use of private funds to buy faster or better care is permitted. These laws vary in their detail across the 10 provinces but include a mix of the following:

1. restrictions that stop a doctor who bills public medicare from charging a patient an additional amount (extra-billing);
2. restrictions that prevent physicians from billing both the public and private systems simultaneously, at least for "medically necessary" care (dual practice);
3. restrictions on physicians in the private sector charging prices for medically necessary care that are higher than those permitted in the public plan; and
4. restrictions on private health insurance for services that are covered by medicare.

All Canadian provinces have a mix of some or all of these restrictions, enacted to meet the requirements of federal legislation, the *Canada Health Act* (CHA), and thereby qualify for a federal contribution to the operation of their respective healthcare plans.

The First Successful Court Challenge

The ruling of *Chaoulli v. Quebec* (2005) was the first successful court challenge in this area. In this case, the court overturned the province of Quebec's restrictions on parallel private insurance for medically necessary care on the grounds that such a restriction, given wait times in the public system, infringed an individual's rights to life and/or security, and as such people should be entitled to buy private health insurance to help navigate their way around the wait times. Building off of *Chaoulli*, interest groups wanting to benefit from the expanding role of private financing in the Canadian system, as well as patients both harmed and distressed by increasing wait times, have launched lawsuits that expand far beyond the *Chaoulli* precedent (*Allen v. Alberta* 2015; *Cambie Surgeries Corporation v. British Columbia (Attorney General)* 2018; *McCreith and Holmes v. Ontario* 2007). The most significant of these is an ongoing case that went to trial in September 2016 in British Columbia (BC) and for which we expect a decision later this year. Launched by Cambie Surgeries Corporation (a private for-profit clinic) and led by its owner, Dr. Brian Day, the challenge is to the constitutionality of BC's *Medicare Protection Act* (MPA) laws that dampen the incentives for physicians who participate in medicare ("enrolled physicians") from sidelining in private practice (Government of British Columbia n.d.). The three laws under the challenge are as follows:

1. a ban on "dual practice," which requires physicians to choose to either bill solely the public system ("enrolled") or "un-enroll" and exclusively bill private payers (that is the patient him- or herself or their private insurer; Sections 14 and 17–18 of the MPA);
2. a law that nullifies any private insurance contracts covering publicly insured care delivered by "enrolled" physicians (Section 45 of the MPA); and
3. a ban on extra-billing so that enrolled physicians cannot charge patients above and beyond what they receive from the public plan (Section 17(1) of the MPA).

Legislative Language: Confusion and Clarity

The legislative language is quite confusing. In BC, physicians who are "enrolled" in the public system have the following two options: they can "opt in" (bill the government directly) or they can "opt out"; by opting out, they may bill patients directly, but not more than the public plan permits, and then the patient him- or herself can claim this sum from the public plan. On the other hand, physicians who are "unenrolled" are free to bill patients for services at whatever rate the market will bear in private clinics, and patients cannot claim any part of this sum from the public plan.

Cambie then is a much broader challenge than *Chaoulli*, which was restricted to a challenge to a ban on private insurance alone. The goal of *Cambie* is to make it economically attractive for physicians to work in a two-tier system, and to achieve this, it seeks to overturn the law restricting not only private insurance but also dual practice. If *Cambie* is successful in challenging the ban on dual practice, they will also incidentally be able to overturn the ban on extra-billing, as these provisions are bundled together under the same law (the reader will recall that this then would allow all physicians to not only bill the public plan but also bill an extra amount from patients, raising very significant access concerns). *Cambie*, in its closing arguments, says that it accepts the constitutionality of the ban on extra-billing but nonetheless still seeks to have the entire law struck down, leaving it to the government to respond with a more tailored legislation that bans extra-billing while allowing wholly private billing by enrolled physicians. In other words, *Cambie* suggests the formation of a new law that bans extra-billing but permits physicians to bill the public plan for medically necessary services and in addition provide private services and bill these entirely to the patients and/or their private insurers.

In terms of the challenge to extra-billing, it is relevant to note that the *Cambie* challenge was launched in response to the BC government's move to investigate Cambie Surgery Centre for extra-billing of patients – it demanded patients pay up to CA$17,000 per treatment and also billed the public system at the full medicare rate (Ministry of Health, Billing Integrity Program, Audit and Investigations Branch 2012). Nonetheless, perhaps because extra-billing is so clearly in contravention of the CHA, the *Cambie* claim has become more nuanced on this point over the course of the multiyear trial, focusing on the restrictions on private insurance and dual practice. Despite muting their attack on extra-billing in their final arguments, *Cambie* still asks that the court issue a "suspended declaration of invalidity" over *all* of the relevant laws, requiring the government to enact a response within a fixed period of time – presumably legislation that liberalizes dual practice while presumably maintaining restrictions on extra-billing. However, should the BC government fail to enact response legislation during the period of suspension, the entire suite of protections – including the ban on extra-billing – would be deemed invalid. Needless to say, this is a high-stakes game, given the challenges governments face in enacting structural reforms to health systems, an issue we return to in the Conclusion.

Cambie, if successful in whole or in part, has the potential to rapidly accelerate the privatization of healthcare financing across Canada for two reasons. First, the national impact of the *Chaoulli* ruling was limited because the majority did not reach a consensus on whether Quebec's restrictions on private insurance breached the *Canadian Charter*; writing for the majority, Justice Deschamps argued that judicial restraint favoured disposing of the matter under the *Quebec Charter* alone, and thus the technical legal ambit of that judgment was limited to Quebec alone. Second, the *Cambie* ruling has broader implications because, in addition to challenging restrictions on private health insurance at issue in *Chaoulli*, the litigation also challenges restrictions on dual practice and extra-billing – measures used in

other provinces. More fundamentally, if BC laws banning dual practice or extra-billing are overturned in whole or in part, this would strike at the heart of the CHA. To forestall this, provincial governments will have to demonstrate that wait times in their provinces are "reasonable" or that there are measures in place to ensure that Charter rights (to life and security of the person) are not unduly infringed, for example, a wait times guarantee and/or a patient ombudsman that patients can appeal to if waiting too long.

Surviving the *Charter* Challenge

In determining whether existing BC laws restrictive of the two-tier healthcare system can survive a *Charter* challenge, what will be crucial is how a court treats evidence of Canada's approach to the public–private mix relative to other jurisdictions (Flood and Thomas 2020). In short, a court is more likely to be persuaded that Canada's legislative restrictions on a two-tier system are justified for the protection of medicare if there is evidence of a similar approach in other countries (Flood and Thomas 2018). In the 2005 decision of *Chaoulli*, the majority found that Quebec (and the other provinces that similarly restrict private health insurance) is alone among comparator healthcare systems in prohibiting parallel private health insurance, and this finding grounded their ultimate conclusion that the prohibition was arbitrary and infringed the *Quebec Charter of Human Rights and Freedoms*. However, the court's approach to comparative analysis was remarkably brief and superficial, failing to note that private health insurance *serves very different purposes* across jurisdictions.

For example, private health insurance in a number of countries is not primarily used for the purposes of queue-jumping, but instead provides coverage for user charges and extra-billing charges that are mandated or permitted within the public system. In France, for example, well over 90% of the population have private health insurance, and it is used mainly to cover the mandatory co-payments that all patients must pay for all healthcare, and, further, this "private" health insurance is heavily subsidized if not directly paid for by the state, the latter being for very low–income individuals (Or and Pierre 2012). Moreover, one finds a completely different flavour of "two-tier" in Germany, where self-employed individuals have the option of withdrawing *completely* and *almost irreversibly* from the country's social health insurance scheme (akin to our public medicare) and securing coverage in a regulated private health insurance market (Schmid and Doetter 2020). In other jurisdictions, such as the Netherlands, private health insurance is mandatory for all citizens, heavily regulated to ensure comprehensiveness and accessibility, and again it is not primarily used for the purposes of jumping queues in the public system; mandatory and regulated private insurance *is* the universal system in the Netherlands (Flood and Thomas 2018).

To the extent that these French, German and Dutch systems are "two-tier" models, they are not two-tier in the sense being pursued by the Cambie clinic. Indeed, Canada's champions of privately financed care are pursuing something altogether different from what we observe in many European countries: retaining medicare coverage for all, while granting those with the financial means the option to "go private" when confronted by long wait times

for specific episodes of care. In this regard, the more apt comparators are systems such as those of Ireland, New Zealand, England and Australia, the first three of which have historically struggled with long wait lists *despite* the existence of a two-tier option (Vinberg et al 2013). The Irish experience with the two-tier system has been so destabilizing that it is driving major reform to strengthen and protect the public healthcare system (Thomas et al. 2020). Despite this, advocates of privately financed care insist on the logical fallacy that because some high-performing European systems allow "two-tier care" – a concept defined so loosely as to be almost meaningless – there is no drawback in Canada's abandoning its hard-won commitment to single-tier care. This kind of magical thinking has gained increased popularity in political discourse. Thus, the fair resolution of upcoming constitutional challenges will depend on the courts carefully reviewing comprehensive evidence of comparative health policy while acknowledging the deep complexity of the health policy choices that governments face given the particular context and history of the Canadian healthcare system. The claim made by the applicants in *Cambie*, that liberalizing hard-won laws protecting public medicare will improve public medicare by transforming it into a European-style system, has the allure of an easy fix – but is a mirage.

Given the problems rife across Canadian healthcare at the moment and high public concern about wait times and a lack of determined governmental response, there will be many who are sympathetic to the *Cambie* challenge, believing that perhaps this kind of disruptive approach may kick-start real reform across the system. The applicants in the *Cambie* case are seeking to persuade the court that they need not deeply consider the policy consequences of a decision to overturn laws protecting public medicare. Their argument is that having proclaimed laws limiting two-tier care as unconstitutional, it will then fall to the government to respond with a new set of laws, and the court should not worry exactly what those laws or policies may be, provided they are constitutionally compliant, what is known in constitutional parlance as "dialogue theory" (Hogg and Bushell 1997). On its face this sounds feasible – that the courts overturn laws and that governments respond by bringing forth new laws that are constitutionally compliant to achieve their objective. But this stance assumes that provincial governments will be motivated to protect public medicare: some provinces may in fact welcome the courts forcing a two-tier model upon Canadians without having to bear adverse messy political ramifications. Some provincial governments may view two-tier care as a way to relieve the political pressure on them to improve public medicare and to further placate doctors desirous of even more autonomy and more ways of earning extra income.

Thus, the "dialogue" *Charter* theory assumes that governments are motivated to protect the laws that have been found to be unconstitutional and that new laws can be introduced with relative ease (Kent 2001). Given the fierce battles that occurred between doctors and governments surrounding the birth of public medicare (also mentioned in Marchildon 2020), it is naïve to assume that provincial governments will necessarily respond to a loss in the *Cambie* case by taking bold steps to tackle wait times or will carve out a small niche for

the two-tier system while protecting a healthy core of public medicare. Moreover, although (some) physicians, private clinics and private insurers form a natural and economically motivated alliance pushing for the expansion of privately financed care, effective coalition-building on the opposing side – demanding the protection and improvement of universal healthcare and insisting upon management of wait times – is infinitely more challenging. Indeed, the recent struggles to bring about universal pharmacare illustrates this problem with (to date) strong and intense opposition from private insurers and drug companies, drowning out the more diffused voices of the uninsured and underinsured or those who are insured but still pay some of the highest prices in the world for pharmaceuticals.

Still, there is hope that if the courts overturn laws that are vital to the CHA, the federal government will lean in to provide more meaningful reform, for example, insisting that in exchange for federal transfers, the provinces truly meet the criterion of accessibility under the CHA. Section 12(1) of the CHA requires that provinces ensure "reasonable access" and on a basis that does not "impede or preclude, either directly or indirectly whether by charges made to insured persons or otherwise" such reasonable access. Surely it is past time that this criterion was rendered meaningful by the federal government insisting upon reasonable wait times in exchange for federal investments.

Conclusion

It is long past time that the federal and provincial governments took steps to address the problem of wait times, which have severely undermined public confidence in medicare, softening them up for the false prophets claiming privatization will make things better. Moreover, we know from experience that the key to improving wait times is better management and not a huge investment of resources. Examples include Ontario's Cardiac Care Network that significantly improved access to care by centralizing the triage of cardiac patients, reducing what were perilously long wait times and improving outcomes, and Alberta's evidence-based approach to knee and hip replacements under the leadership of the late Dr. Cy Frank, creating single-purpose clinics where care is standardized according to the best available evidence, which dramatically improved wait times for orthopedic patients without requiring a significant investment of resources (McMurtry 2015; Usher and Frank 2008). The problem of wait times can be solved for all Canadians with political will, but to achieve this, Canadians must demand more of their politicians when it comes to healthcare. As Canadians we have been too content to rest upon the fact that we outperform the US healthcare system. We need to do much better than that and insist upon high-performing healthcare systems from coast-to-coast with timely access to the care we need.

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Commentary: The Consequences of Private Involvement in Healthcare – The Australian Experience

Commentaire : Conséquences du volet privé dans les services de santé – l'expérience australienne

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Abstract

The Cambie proposition is the American individualistic one: If I can afford to pay for quick access to care, then that should be my right. It denies any concept of universalism, of the common good or that your rights might adversely impact my rights and my healthcare experience. Some private care proponents offer the magical prospect that this quicker access for the wealthy few has no impact on access for the many. It is even sometimes perversely argued that if the wealthy pay for access outside the public health system, that reduces demand for public care, freeing up space for others and, hey presto, magically everyone benefits from the increase in inequality. The Australian experience is that this magic does not work.

Résumé

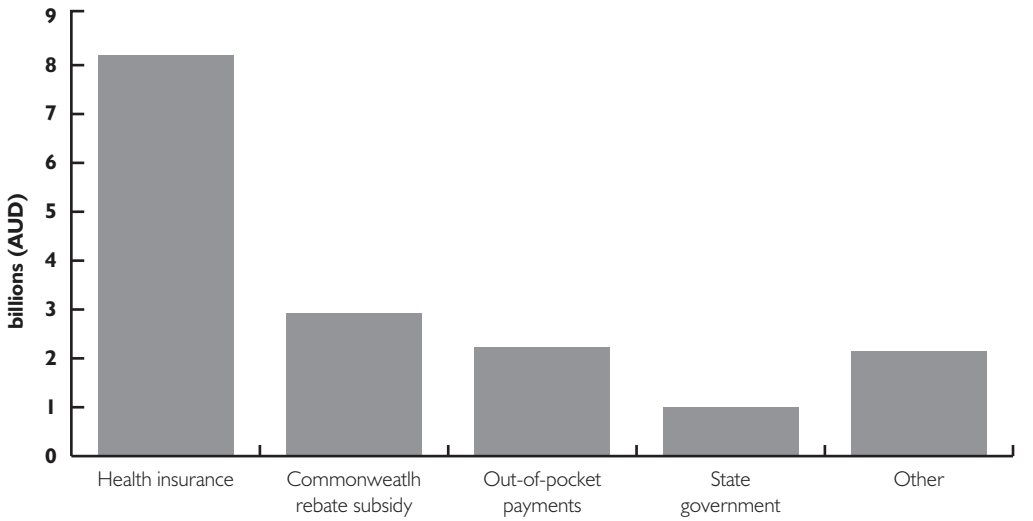
Le point de vue de Cambie correspond à l'approche individualiste des États-Unis : si j'ai les moyens de payer pour un accès plus rapide aux soins de santé, je devrais en avoir le droit. Ce point de vue fait fi de tout concept d'universalité, du bien commun et du fait que les droits de l'un peuvent affecter négativement les droits et services pour autrui. Certains défenseurs des services privés affirment magiquement que l'accès accéléré des mieux nantis n'a aucun impact pour les autres. On affirme même parfois que si les mieux nantis paient pour un accès en dehors du système public de santé, cela réduit la demande, libérant ainsi des places pour les autres et, comme par magie, tout le monde profite de cet accroissement des inégalités. L'expérience australienne montre que la magie ne fonctionne pas.

The Australian System in Brief

Hospital care in Australia involves a mix of public and private funding and public and private provision. About 45% of the population has private insurance for some level of hospital care, with private insurance subsidized by the government for people with lower to middle incomes (Duckett and Cowgill 2019). In parallel, all Australians have access to public hospital care under the public universal scheme, Medicare.

Private health insurance is a major funding source for private hospitals, accounting for about 50% of private hospital revenue. The Commonwealth government subsidies for private health insurance, paid through insurers, account for a further 18% of private hospital income (Figure 1).

FIGURE 1. Private health insurance funds about half of private hospital expenditure



Note: Data show private hospital expenditure from 2017 to 2018 (billion AUD)
Source: Australian Institute of Health and Welfare (2019)

About 40% of all hospital admissions are to private hospitals, as are about 60% of all surgical admissions (Duckett and Nemet 2019). Private hospitals mainly focus on elective procedures – less than 1% of emergency admissions are to private hospitals, and these admissions account for only around 0.5% of all admissions to private hospitals. Most elective procedures are undertaken in private hospitals.

Public hospitals are more evenly distributed across Australia. There are a few private hospitals in rural and remote areas, and private hospitals are more common in wealthier suburbs where private insurance is more prevalent. Academic medicine is mostly concentrated in public hospitals, and most complex care (such as major trauma, advanced cancer care and organ transplantation) is only undertaken in public hospitals.

The relationship between public and private funding and care is complex. Private hospitals engage in cream skimming, focusing on patients with lower complexity on average

(Cheng et al. 2015). Public hospitals may welcome this: Overburdened public hospitals willingly transfer insured patients with less complex needs or those who are in their recuperative phase to private hospitals. Public hospitals receive patient transfers from private hospitals where something has gone wrong (Brameld et al. 2006; Cheng et al. 2015), a hidden cross-subsidy from public hospitals to private hospitals.

There has been no coherence or consistency in the rhetoric about the roles of the two systems or the basis for public subsidies for private insurance (Duckett and Nemet 2019). Policy makers at various times have suggested that private care substitutes for public care, that it complements public care, that Medicare is a universal scheme or that Medicare is a residual scheme. The lack of clarity means that the policy on both public and private health insurance and private healthcare is an incoherent mess.

Creation of a large private sector weakens planning and system integration. Private hospitals operate autonomously and do not have to cooperate with the public sector.

The Australian experience is that a large private sector changes the dynamics of public policy. Rather than pursuing policies to ensure that the public system can meet demand, alternative policies to subsidize the private sector come to the fore and become entrenched and difficult to unwind. With almost half the population having private health insurance, the political dynamic is that the Labor Party, who might otherwise be more skeptical of the value of health insurance, cannot afford to alienate such a large proportion of the population. Labor knows that if it were to signal a policy of withdrawing subsidies, it would be vehemently opposed by insurers who would attempt to mobilize their contributors against such a policy.

The overwhelming academic evidence is that Australia's A$6 billion annual subsidy to private health insurance subsidies is not value for money (Cheng 2013, 2014; Colombo and Tapay 2004; Doiron and Kettlewell 2018; Frech and Hopkins 2004; Lu and Savage 2006; Vaithianathan 2002). If this annual subsidy is abolished, the cost of additional demand in the public sector would be less than the current subsidies. Despite this, no major political party will challenge the industry.

Private Care, Public Waiting

The evidence suggests that, contrary to what is often argued, relatively more private provision in Australia is associated with prolonged, not shortened, waiting (Duckett 2005, 2018). Waiting times in Australia's mixed public–private system are longer than in Canada's all-public system (McDonald and Duckett 2020).

The direction of causation could be hypothesized to go in either direction: Longer waits in the public sector create a demand for private care (the Cambie argument) or private care thrives by stifling public provision, thus creating longer waits, and this is enabled by "dual practice," surgeons working in both the public and private sectors.

The former hypothesis assumes that public and private care are substitutes – that increases in private admissions reduce demand in the public sector. This is not always the case, partly because thresholds for admission to private hospitals are lower than those for

public hospitals, and there is more low-value care in private hospitals (Badgery-Parker et al. 2019; Chalmers et al. 2019).

The latter hypothesis has two foci: The first, ascribing nefarious motives to surgeons – that they personally inflate waiting times in the public sector to encourage patients to shift to private care (Ferrinho et al. 2004).

The second, a more benign reason why undersupply of public care occurs alongside additional private care, is medical workforce limitations. Many surgeons practice in both the public and private hospitals. Surgeons generally receive high levels of remuneration in private hospitals (where they are paid on a fee-for-service basis) compared to public hospitals (where they are often paid on a salaried or a part-time salary basis). Fee-for-service remuneration yields greater payment per hour than salary payments.

Given the limitations on the supply of surgeons, expansion of demand for private care will often result in a reduction in availability of surgical time in the public sector (Cheng et al. 2013a; Cheng et al. 2013b; Cheng et al. 2015). This dynamic aspect of the public–private interface is often ignored by advocates of expanding private care, who implicitly assume that surgical time is infinitely elastic.

Conclusion

The evidence from Australia suggests that the community will not benefit from an expansion of private funding. The mixed public–private funding and provision has had a deleterious effect on the Australian hospital system.

In contrast to the claims by proponents (Flood et al. 2020), increased private provision does not lead to improved access to public care to any significant extent, nor does it reduce waiting times. It does, however, allow higher incomes for doctors and provides business opportunities for investors in private hospitals.

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Health Canada's Proposal to Accelerate New Drug Reviews

Proposition de Santé Canada pour accélérer la politique d'examen des nouveaux médicaments

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Abstract

Health Canada is proposing to update its accelerated review pathways to get important new drugs into the market more quickly. To date, the two pathways that Health Canada uses have not demonstrated that they can identify therapeutically valuable new drugs. Drugs approved under the two pathways also have a greater likelihood of acquiring a serious safety warning post-marketing compared with drugs approved through the standard review pathway. The new proposals from Health Canada will not go far in rectifying this situation, and major changes are needed. Health Canada needs to present evidence that the changes it is proposing will actually allow these pathways to fulfill the set objectives and support health benefits for Canadians.

Résumé

Santé Canada propose une mise à jour de ses processus d'examen accéléré pour mettre plus rapidement sur le marché de nouveaux médicaments importants. À ce jour, il n'est pas démontré que les deux processus employés par Santé Canada permettent d'identifier de nouveaux médicaments qui soient profitables sur le point thérapeutique. Les médicaments

approuvés en vertu de ces deux processus sont aussi plus susceptibles de donner lieu à des avertissements sérieux après leur mise en marché, comparativement aux médicaments approuvés selon les processus d'examen normaux. La proposition de Santé Canada ne permettra pas de rectifier cette situation et d'importants changements sont nécessaires. Santé Canada doit présenter des preuves que les changements proposés permettront effectivement à ces processus d'atteindre les objectifs établis et d'apporter des avantages en matière de santé pour les Canadiens.

Introduction

To obtain authorization to market a new active substance (NAS, a molecule never marketed before in Canada in any form), companies typically file a new drug submission (NDS) with Health Canada, which includes preclinical and clinical scientific information about the product's safety, efficacy and quality and information about its claimed therapeutic value, conditions for use and side effects (Health Products and Food Branch 2006). Health Canada then has a 300-day period to evaluate this information and make a decision about whether to allow the product to be sold, that is, whether to issue a notice of compliance (NOC).

In an effort to ensure that promising therapies for serious, life-threatening or debilitating illnesses reach Canadians in a timely manner, Health Canada has developed two other pathways for approving an NAS. These are described in detail elsewhere (Lexchin 2015b), but, briefly, the first of these is a priority review that involves the company submitting a complete NDS but with a review period of 180 days (Health Canada: Health Products and Food Branch 2009). The second is the NOC with conditions (NOC/c; Health Canada 2016), whereby Health Canada will give a conditional approval based on limited evidence – Phase II clinical trials or trials with only surrogate markers. In return for NOC/c status, companies commit to further studies that definitively establish efficacy and submit the results of these to Health Canada. If these studies are not completed or negative results are obtained, it could lead to the cancellation of marketing authorization. Collectively, these two review pathways are referred to, in this article, as accelerated reviews.

Health Canada began a regulatory review of drugs and devices in 2017, and as part of this process, it issued a "Draft Guidance: Accelerated Review of Human Drug Submissions" to update its accelerated review pathways (Health Canada 2019) and conducted a consultation on that document from May 7 to July 21, 2019 (Government of Canada 2019). In the document, Health Canada lays out three policy objectives:

> support earlier access by way of shortened review times, to new or promising new drugs ... better align Health Canada's prioritization of drug reviews with the needs of the Canadian health system; and ensure transparency of any conditions that may be associated with a market authorization.

I argue that a review of Health Canada's two accelerated review programs is necessary, and in this analysis article, I will present evidence that has been published in a series of research articles starting in 2012, which shows that neither of these programs is achieving their objectives. I then compare Health Canada's record in using accelerated reviews with other regulatory authorities' record of the same. Finally, I critique the proposals from Health Canada and offer suggestions for more fundamental reforms.

Much of the analysis that I will be presenting is based on evaluations of the additional therapeutic effectiveness of new drugs. Those evaluations are drawn from two sources – *Prescrire*, the English language version of the French drug bulletin *Prescrire International* and the ratings produced for the Canadian Patented Medicine Prices Review Board (PMPRB) by its Human Drug Advisory Panel (HDAP). Both organizations use rigorous methodology and produce unambiguous evaluations of therapeutic value. In deciding on the level of therapeutic innovation, HDAP considers two primary factors – increased efficacy and reduction in the incidence or the grade of important adverse reactions – and nine secondary factors – route of administration, patient convenience, compliance improvements leading to improved therapeutic efficacy, caregiver convenience, time required to achieve the optimal therapeutic effect, duration of usual treatment course, success rate, percentage of affected population treated effectively and disability avoidance/savings. The primary factors are given the greatest weight, followed by an assessment of any additional improvement as a result of the secondary factors (PMPRB 2014). *Prescrire* assesses the therapeutic value of medicines through a multistep process. First, it "examines the condition or clinical setting for which the drug is proposed; then the natural course of the disease, the efficacy and safety of existing treatments, and the most relevant outcome measures. This is followed by a systematic search for clinical data on the efficacy and adverse effects of the new drug, and an assessment of the level of evidence. Based on [its] independent analysis of clinical data, [it] form[s] a judgement as to whether or not the new drug is beneficial for patients or whether or not its harmful effects outweigh the benefit" (Prescrire Editorial Staff 2011).

Evaluation of Health Canada's Current Accelerated Review Pathways

Priority review

A total of 426 drugs were approved by Health Canada between 1997 and 2012. Of these, 345 were evaluated by the PMPRB and/or the French drug bulletin *Prescrire International* (English version) to determine if they offered a significant therapeutic improvement over the drugs already on the market. Only 52 of the 345 (15.1%) were rated as innovative, but Health Canada gave a priority review to 91 of these (26.4%).

The therapeutic value of new drugs as determined by the PMPRB and/or *Prescrire International* was compared with whether the drugs received either a priority or standard review from Health Canada using kappa values that measure interrater agreement – in this case whether Health Canada's decision to use a priority review for individual new drugs

aligned with their therapeutic value. Yearly kappa values comparing the therapeutic evaluations given by Health Canada and by the PMRPB and/or *Prescrire International* on an individual drug level ranged from a low of −0.091 in 1998 to a high of 1.000 in 2010. Kappa values were at or below 0.400 in nine of the 16 years, meaning a level of agreement of fair or less in those years. The overall kappa for the 16 years was 0.334 or fair. There is no evidence that Health Canada's ability to determine which products offer significant therapeutic gain improved over the time that Health Canada has been granting priority approvals.

Based on a drug-by-drug comparison for all drugs evaluated by the PMPRB and/or *Prescrire International*, the positive predictive value of Health Canada's ratings was 36.3%, meaning that it gave a priority review to 91 drugs, but only 33 were evaluated as innovative (Lexchin 2015a).

An analysis comparing post-market safety of drugs approved through the priority and standard review pathways found that, if the products received a standard review, there was a 19.8% chance that Health Canada would issue a serious safety warning about the drug compared with a 34.2% chance for a drug with a priority review. The possibility that these differences could be explained by either the mechanism of action of the drug in question or by the seriousness of the diseases that priority review drugs were indicated for were both investigated and rejected (Lexchin 2012).

Finally, Health Canada gives a priority review to over 40% of first-in-class drugs, but only 16% have significant therapeutic advantages over existing products (Lexchin 2016).

Notice of Compliance with conditions

From the inception of the NOC/c policy in 1998 to the end of 2017, there were 89 NOC/cs issued for 70 unique drugs – 52 for new drugs and 37 for new indications for existing drugs. New drugs approved with an NOC/c represented 9.5% of 546 new products approved by Health Canada. The PMPRB and/or *Prescrire International* evaluated the additional therapeutic value of 78 of the new drugs or new indications for existing drugs, and 54 (69.2%) offered minimal to no additional therapeutic value. As with the priority approval pathway, there is no evidence of any improvement in Health Canada's ability to determine whether products approved under this policy offer significant therapeutic gains.

A total of 50 NOC/cs (56.2%) were fulfilled and 31 (34.8%) were not fulfilled, and in eight (9.0%) cases, either the indication or the drug was withdrawn. The median time to fulfillment was 1,040 days. Twelve NOC/cs took more than five years to fulfill their conditions. The unfulfilled NOC/cs had been issued for a median of 1,161 days, and 10 had been outstanding for more than five years (Lexchin 2018b).

Comparing post-market safety of drugs approved through the NOC/c policy with that of drugs approved through a standard review shows that the former was more likely to acquire a serious safety warning than the latter (Lexchin 2015b).

Many of the confirmatory studies that Health Canada accepted as fulfilling the conditions had significant limitations. Twenty (55.6%) of the 36 studies used surrogate outcomes,

the median age of patients in all of the studies was under 60 years and except for four (14%) out of 29 studies, men outnumbered women (Lexchin 2018c).

Finally, Health Canada is lacking transparency, given that it does not provide any public information about the status of confirmatory studies that have not been completed.

Both accelerated review programs combined

From January 1, 1995, to December 31, 2016, Health Canada approved a total of 623 NASs. Out of these, 509 (81.7%) were evaluated for their therapeutic innovation either by the PMPRB and/or *Prescrire International*. Health Canada used an accelerated review pathway for 159 of the 509 drugs, whereas only 55 were judged to be therapeutically innovative by one or both of the independent reviews. Forty-two of the 55 drugs that were therapeutic innovations received an accelerated review, 13 received a standard review and 117 that were not therapeutic innovations also received an accelerated review. There was poor concordance between Health Canada's decision that a drug merited an accelerated review and assessments of the drug's therapeutic value. The kappa value comparing the therapeutic rating from PMPRB and/or *Prescrire International* to the use of Health Canada's accelerated review programs for the entire period for all 509 drugs was 0.276, a value considered as "fair agreement" (Lexchin 2018a).

Quality of Reviews: Health Canada vs. Other Regulatory Authorities

Research in other jurisdictions has also evaluated the post-market safety and degree of therapeutic innovation of drugs approved through accelerated pathways. The evidence about whether accelerated reviews lead to more post-market safety issues is mixed. One American study (Mostaghim et al. 2017) found an association between shorter review times and more safety warnings. But faster regulatory review speed by the European Medicines Agency (EMA) was not associated with a greater likelihood of post-market safety events (Zeitoun et al. 2015), and a second US study found that post-market events were statistically significantly less frequent among drugs with shorter review times (Downing et al. 2017). The evidence about how well regulatory agencies can predict which drugs approved through accelerated reviews will offer significant therapeutic advances is more uniform, at least with regard to oncology drugs. After a median follow-up of 4.4 years, only one of 15 oncology drugs approved by the Food and Drug Administration (FDA) through an accelerated pathway had a definite survival benefit, compared with six in which there was no survival benefit and eight in which the overall survival benefit was unknown (Kim and Prasad 2015). A second study of 93 oncology drugs granted an accelerated approval by the FDA between December 1992 through May 2017 found that confirmatory trials demonstrated improvements in overall patient survival for only 19 products (Gyawali et al. 2019).

Health Canada's Proposals for Accelerated Approvals

What I present here is not a comprehensive examination of the proposals in Health Canada's draft guidance document, but rather it is meant to show the weaknesses in some of the measures that Health Canada plans to introduce. To qualify for an accelerated approval, Health Canada states that

> the sponsor should be able to demonstrate that the therapy provides – or has the potential to provide – a statistically significant and clinically relevant improvement in efficacy or decrease in risk such that the overall benefit/risk profile is improved over any available therapy or drug marketed in Canada.

However, relying on the sponsor, who stands to financially benefit from getting the drug to market faster, to be objective about its product is not sufficient. Before making a decision about using an accelerated pathway, Health Canada should convene a panel of independent clinical experts to seek their advice about the likelihood that the product under consideration would be a significant therapeutic advantage and be at least as safe as existing therapies for the same condition.

The draft guidance encourages sponsors to request a pre-submission meeting with Health Canada, i.e., a meeting that would take place before filing the documentation for approval, so that the sponsor can outline the evidence of effectiveness for Health Canada. The EMA conducts similar meetings and the European Ombudsman organized public consultations on this practice. In response, the International Society of Drug Bulletins and *Prescrire* filed a presentation pointing out that by providing advice, the "EMA puts itself in a position where it assists companies…by telling them the level of clinical evaluation it is likely to consider adequate to issue a positive opinion on a marketing authorisation application," thus creating a conflict-of-interest (COI) situation (International Society of Drug Bulletins and Prescrire 2019). The presentation forcefully made the point that the EMA should have a procedure for managing these COIs that includes "measures that enable the public to freely and easily verify that nobody who provided pre-submission scientific advice on a medicine is involved in assessing any subsequent marketing authorization applications for the same medicine." The draft guidance from Health Canada neither makes any mention of having a distinction between the Health Canada officials who attend the pre-submission meeting and those who eventually will be evaluating the documentation nor does it deal with public access to information about who from Health Canada attended the meeting.

Notably absent from the draft guidance are any specific requirements for the evidence that companies will have to present to get their drugs approved through an accelerated pathway. Previous research has shown that drugs approved based on trials that used surrogate outcomes, used placebo controls and enrolled small numbers of patients and were short-term are more likely to overestimate or generate spurious treatment effects (Davis et al. 2016).

The only reference to evidentiary requirements in the draft guidance is the following statement:

> When received, it is expected that the submission will contain the information and material for the purposes of Division 8, Part C of the *Food and Drug Regulations* and be subject to the *Guidance Document: Management of Drug Submissions and Applications*.

Health Canada should be demanding higher premarket evidentiary standards when considering drugs for an accelerated review, or if the evidence is not available in the premarket period, it should make approval conditional on that evidence being generated in the post-market phase. Specifically, unless there are strong reasons for not doing so, clinical trials should have to use hard clinical outcomes instead of surrogate outcomes, comparators should be existing therapies rather than placebo controls, trial times should be long enough to detect rarer safety issues and validate ongoing treatment benefits, and except for drugs for orphan diseases, patient numbers should be large enough to look at important subgroups.

Finally, for drugs approved through the NOC/c pathway, the draft guidance goes into considerable detail about the requirements that companies have to meet in the post-market phase, including providing yearly status reports on the progress of ongoing confirmatory trials. However, there is no mention that either a full description of the trials or the status reports about them must be publicly available.

Conclusion

This review has shown that there is a lack of clear evidence of therapeutic benefits for most drugs approved through these two pathways and of a higher rate of serious post-market safety concerns for drugs that have been approved more rapidly as compared with standard review process. Specifically, the following serious deficiencies exist in the two accelerated review programs:

1. The large majority of drugs approved under both the priority review program and the NOC/c pathway do not offer any significant therapeutic improvement over drugs already on the market.
2. Drugs approved through either pathway are more likely to acquire a serious safety warning compared to drugs approved through the standard review pathway.
3. Health Canada's ability to determine which products approved under the two accelerated review pathways offer a significant therapeutic gain has not improved over the time that these pathways have been in operation.
4. The confirmatory studies that Canada accepts to remove conditions for drugs approved under the NOC/c policy have significant limitations.

5. Health Canada lacks transparency about the confirmatory studies that need to be completed for drugs approved under its NOC/c policy. Specifically, it provides no publicly available information about confirmatory studies that have not been completed and studies for some drugs have not been completed for over five years.

The rationale for using accelerated review pathways is to get important therapeutic advances to patients in a timely manner, but Health Canada's use of these pathways to date has not fulfilled this objective, and its proposals in the draft guidance will not correct this situation. Moreover, the use of these pathways comes with both health-related costs and resource costs. Before any changes are made, Health Canada needs to present evidence that the changes it is proposing will actually allow these pathways to fulfill the objectives that it has set out for them and lead to significant health benefits for Canadians.

Competing Interests

From 2016 to 2019, Joel Lexchin was a paid consultant on two projects: one looking at developing principles for conservative diagnosis (Gordon and Betty Moore Foundation) and the other deciding what drugs should be provided free of charge by general practitioners (Government of Canada, Ontario Supporting Patient Oriented Research Support Unit and the St Michael's Hospital Foundation). He also received payment for being on a panel at the American Diabetes Association, for giving a talk at the Toronto Reference Library, for writing a brief in an action for side effects of a drug for Michael F. Smith, Lawyer and, from the Canadian Institutes of Health Research, for presenting at a workshop on conflict-of-interest in clinical practice guidelines. He is currently a member of research groups that are receiving money from the Canadian Institutes of Health Research and the Australian National Health and Medical Research Council. He is a member of the Foundation Board of Health Action International and the Board of Canadian Doctors for Medicare. He receives royalties from University of Toronto Press and James Lorimer & Co. Ltd. for books he has written. There was no funding associated with this study.

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Commentary: Expedited Regulatory Review of Low-Value Drugs

Commentaire : Examens réglementaires expéditifs pour les médicaments de faible valeur

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Abstract

Lexchin has criticized Health Canada's recently published draft guidance on accelerated drug review, expressing concern over agency conflicts of interest and observing that priority review and notice of compliance with conditions correlate poorly with therapeutic benefit. Although agency operations may be imperfect, perhaps the most important finding of Lexchin's research is that only 11% of newly approved drugs provide meaningful benefit over standard treatments. To improve the expedited review process in light of these findings, we suggest eliminating user fees and fully funding the review process with public monies, reserving the use of expedited approval pathways for when preliminary measures of benefit are so large that traditional approval thresholds can be met earlier in the clinical trial process, improving labelling to quantitatively communicate drug benefits and risks, and avoiding the use of titles such as "priority" review, which could imply a magnitude of clinical superiority that has not been established.

Résumé

Lexchin a critiqué la version provisoire des lignes directrices de Santé Canada sur l'examen accéléré des médicaments, publiée récemment, en se disant préoccupé par les conflits d'intérêt de l'institution et en observant qu'il y a une faible corrélation entre, d'une part,

l'examen prioritaire et les avis de conformité avec conditions et, d'autre part, les avantages thérapeutiques. Bien que les activités de l'institution soient imparfaites, la principale découverte de Lexchin est sans doute que seuls 11 % des médicaments nouvellement approuvés apportent un avantage significatif par rapport aux traitements habituels. Pour améliorer le processus d'examen à la lumière des résultats de Lexchin, nous proposons d'éliminer les frais de service et de financer entièrement le processus d'examen avec les fonds publics, tout en réservant les voies d'approbation accélérées pour les cas où le constat préliminaire des avantages est si important que les seuils d'approbation traditionnels peuvent être atteints plus tôt au cours de la phase d'essai clinique, en améliorant l'étiquetage pour communiquer quantitativement les avantages et risques liés aux médicaments et en évitant l'utilisation d'énoncés tels qu'« examen prioritaire » lesquels portent à croire à un degré de supériorité clinique qui n'a pas été établi.

Introduction

Over the past two decades, national drug regulatory agencies around the world have introduced special approval programs to accelerate the development and review of novel therapeutics. Because these programs promote the earlier availability of medicines and allow revenue to begin accruing sooner, they have been welcomed by seriously ill patients and the pharmaceutical industry alike. However, the value of expedited programs depends on the extent to which the associated drugs provide actual patient benefits while avoiding harm.

In an insightful new analysis, Lexchin critically examined two special pathways used by Health Canada to expedite the development and review of new medicines: priority review, which provides an accelerated review target of 180 days rather than the usual 300 days, and notice of compliance with conditions (NOC/c), which provides a review target of 200 days and allows approval based on "promising evidence" such as surrogate end points or Phase II trials, on the condition that post-approval studies confirm benefit (Health Canada 2019). Based on his previously published research spanning 2012 to 2019, Lexchin argued that Canada's drug regulatory agency has been unable to reliably identify high-value drugs, that drugs approved under the two special programs have a greater likelihood of acquiring a safety warning or being withdrawn for safety reasons and that the recently proposed guidance will not address these problems.

Lessons from Lexchin's Work

Perhaps the most important lesson from Lexchin's work is that few new drugs provide substantial therapeutic benefit over what is available from existing treatments. In his most comprehensive analysis of 509 drugs approved between 1995 and 2016 for which independent therapeutic ratings were available, he found that only 55 (11%) provided meaningful therapeutic benefit (Lexchin 2018). Even among drugs receiving either type of expedited treatment, only 26% were found to have such a therapeutic benefit (Lexchin 2018) (separate analyses by Lexchin using more limited data found comparable figures of 36% for priority

alone [Lexchin 2015a] and 31% for NOC/c alone [Lexchin 2019]). Because a priority review serves to allocate limited agency resources, providing this faster review process to drugs that do not add substantial additional benefit dilutes the value of this pathway for manufacturers of drugs that do add meaningful therapeutic benefit. Advancing approval times also extends the effective patent period (Beall et al. 2019), increasing the financial reward for low-value products.

Another reason to exercise caution when contemplating the use of a new drug, especially those receiving expedited treatment, is that shorter clinical use and limited trial data mean that safety risks are less well characterized. Lexchin's work revealed that expedited drugs are more likely to receive a new safety warning or be withdrawn for safety reasons: 41% for a NOC/c (Lexchin 2015b) and 34% for priority review, versus 20% for a standard review (Lexchin 2012). Drugs receiving an NOC/c, by definition, are approved on the basis of more limited or uncertain data, with greater certainty expected to be achieved only after approval.

Although the therapeutic benefit of most new drugs, including most expedited drugs, is therefore disappointing according to independent expert reviews, it is less clear that Health Canada's record in expediting new drugs is itself problematic. Lexchin observed that regulatory grants of expedited status are frequently discordant with external appraisals of therapeutic value. He calculated kappa values, which are measures of interrater agreement with a theoretical maximum of 1, to be just 0.276 (priority and NOC/c together) and 0.334 (priority only), both in the "fair" range (Lexchin 2015a, 2018). However, when the data underlying the kappa values are presented differently, Health Canada's record appears less dismal. Of the 509 drugs approved between 1995 and 2016, 454 (89%) provided little or no additional value, of which Health Canada correctly declined to provide an expedited review to 337 (74% of 454) drugs (specificity). Of the 55 (11% of 509) drugs with additional value, Health Canada correctly identified and expedited 42 (76%) drugs (sensitivity; Lexchin 2018).

Improving both specificity and sensitivity simultaneously is desirable but challenging. Criteria for an expedited review could be tightened to reduce the number of low-value drugs given special treatment, but doing so could increase the number of higher-value drugs that are excluded, and vice versa. As Lexchin (2018) noted elsewhere, decisions to grant expedited treatment are made earlier in the development process, whereas the appraisals of therapeutic value on which he relied are made after more evidence is available, possibly explaining some of the discordance.

It is equally uncertain how Health Canada's approach to an expedited review causes more post-approval safety issues. The review programs, of course, cannot change the pharmacokinetics or pharmacodynamics of the drug substance but could affect the extent to which safety concerns are disclosed before versus after approval. Lexchin (2012) rejected the possibility that higher rates of post-market safety issues for expedited drugs could result from disease severity, but this conclusion is based on an earlier finding that rates of safety issues were similar between drugs receiving priority versus standard review within five

serious-disease categories – cancer, HIV/AIDS, inborn errors of metabolism, multiple sclerosis and the prevention of transplant rejection. These categories may be too broad to capture the types of differences likely to lead to the addition of a new safety warning. For example, drugs directed to later stages of disease or intended for use after previous lines of treatment have failed may be more likely to both receive expedited treatment and have unknown safety concerns, even within the same therapeutic category. Priority review may thus simply identify drugs that are more likely to receive safety warnings in any event, providing useful information to patients and clinicians, but little insight into whether regulators are striking the right balance.

As with drug approval itself, the decision to grant expedited treatment should be free from conflicts of interest. Lexchin observed that sponsors financially benefit when their products are expedited and argued that Health Canada should therefore convene independent panels of clinical experts to determine which experimental products are the most promising. However, agency personnel are themselves independent experts, or should be (Ferrera et al. 2014; Freedman 1976), and convening expert panels imposes costs in terms of both time and money, partially undermining the goal of an expedited review before it has begun. Concerns exist about the extent to which regulatory agencies have been captured by the industry, such as by the payment of industry user fees (Darrow et al. 2017), but members of expert panels can (and frequently do) have similar or more severe conflicts of interest (Bélisle-Pipon et al. 2018; Hayes and Prasad 2018). Regardless of the identity of the expert, the drug sponsor will be providing the data on which the expert's decision or recommendation is based. Publicly funded testing of new drugs has been proposed (Baker 2008), but it has not yet received mainstream support.

Conclusion: Conflicts of Interest

Conflicts of interest are also problematic, according to Lexchin, when the agency officials who provide guidance to companies before submission also assess the resulting marketing submissions. The growth in expedited development programs means that agency personnel have increasingly served as *de facto* consultants to the industry (Darrow et al. 2014) – a role that arguably should be fulfilled by private firms – and it is important that regulators not commit themselves to approving a drug for which benefits do not outweigh risks. At the same time, this interest must be balanced against the reasonable expectations of sponsors that requirements will not change after applications have been submitted. If those providing guidance to sponsors are different from those ultimately making the approval decision, it will increase the risk of inconsistent interpretation of regulatory requirements on which a sponsor has justifiably relied and burden the agency by requiring that additional personnel become familiar with complex applications.

Nevertheless, there are four steps that could help Health Canada and its foreign counterparts to improve the integrity of drug review programs, including expedited review

processes. First, concerns over agency capture and conflicts of interest could be mitigated by eliminating user fees, fully funding regulatory agencies with public funds and more strictly limiting conflicts of interest of those invited to serve on advisory panels.

Second, trends toward lower evidence requirements (Darrow et al. 2020) could be reversed. Because approximately 89% of newly approved drugs provide little or no therapeutic advantage over standard treatment, there is no public health reason to rush most treatments to the market. Approval based on limited evidence, such as surrogate end points, non-randomized and unblinded trials or approval following Phase I or II trials, should be limited to exceptional cases for which preliminary measures of benefit are so large and convincing that traditional approval thresholds can be met earlier in the clinical trial process. Even among the 11% of drugs offering meaningful benefits, few will meet this standard (Darrow et al. 2018).

Third, the benefits and risks known to exist should be clearly communicated to patients and physicians using quantitative measures. Existing drug labelling is lengthy, complex and poorly understood (Shrank and Avorn 2007). A drug facts box, analogous to nutrition labelling, has been demonstrated to reduce exaggerated expectations of drug benefit/risk ratios (Schwartz et al. 2009). As is done in the UK, newly approved drugs could bear an inverted triangle on their labels for some time, such as five years or until confirmatory trials are completed. Such a symbol would serve as a warning that limited evidence is available to support benefit and that unknown risks might still emerge.

Fourth, expedited programs should not be given names that imply large benefits, because, by definition, such benefits have not been established at the time unapproved drugs receive the designation. In particular, the term "Breakthrough" may imply benefits that are not justified by the evidence (Darrow et al. 2018). Health Canada's use of "NOC/c" appropriately avoids this potential pitfall. "Priority review," although an accurate description of regulatory treatment, could be replaced with a more neutral title, such as a "180-day review", to avoid implying greater benefits than are actually provided.

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RESEARCH PAPER

Developing a Canadian Real-World Evidence Action Plan across the Drug Life Cycle

Développement d'un plan d'action canadien fondé sur les données probantes du monde réel tout au long du cycle de vie des médicaments

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Abstract

Policy makers face challenges with the number of drugs for rare indications and rapidly rising costs. In facing these challenges, decision-makers see real-world evidence (RWE) as an opportunity. Health Canada and the Canadian Agency for Drugs and Technologies in Health (CADTH) recently announced their intent to co-develop an action plan to optimize the process for the systematic use and integration of RWE into both regulatory and reimbursement decision-making in Canada. When implemented, this will have a significant impact on how drugs are approved and paid for in Canada. We highlight the key opportunities, barriers and future directions related to the use of RWE throughout the life cycle of drugs in Canada.

Résumé

Les responsables des politiques sont confrontés au grand nombre de médicaments pour les indications peu fréquentes et à l'accroissement rapide des coûts. Face à ces défis, les décideurs sont conscients des possibilités que peuvent apporter les données probantes du monde réel (DPMR). Santé Canada et l'Agence canadienne des médicaments et des technologies de la santé (ACMTS) ont récemment annoncé leur intention de développer conjointement un plan d'action pour optimiser le processus d'utilisation systématique et d'intégration des DPMR dans la prise de décisions réglementaires et de décisions de remboursement au Canda. Une fois mise en œuvre, cette politique aura un impact significatif sur la façon d'approuver et de rembourser les médicaments. Nous mettons de l'avant les principales occasions, obstacles et directives à venir quant à l'utilisation des DPMR dans le cycle de vie des médicaments au Canada.

Background

Healthcare decision-makers such as drug regulators and payers face challenges in curbing rising drug costs and a rapidly growing number of rare indications (CADTH 2016). These challenges, associated with the advent of technological advances in identifying rare conditions and available treatment options, come at a time when there is a demand for quicker access to novel treatments (CADTH 2016, 2018; Krause and Saver 2018). To address these challenges, decision-makers see the use of real-world evidence (RWE) as an opportunity to make better and more informed decisions related to market access and funding (CADTH 2018). RWE is often defined as clinical evidence derived from sources other than traditional randomized controlled trials (RCTs). RWE leverages data collected in the routine care of patients through mechanisms such as electronic medical records, healthcare claims data or disease registries. Studies leveraging these data can be based on a variety of study designs, including observational studies and pragmatic clinical trials.

The use of and demand for RWE by regulatory, reimbursement and healthcare decision-makers have quickly expanded (CADTH 2018; Krause and Saver 2018). Currently, the use of RWE has largely been limited to the post-marketing safety evaluation of drugs and

supplemental evidence for submissions. In Canada, Health Canada and CADTH held a joint workshop in 2018, launching an initiative to integrate RWE throughout the life cycle of drugs (IHE 2018). At this workshop, they announced the intention to co-develop an action plan to optimize the process for the systematic use and integration of RWE into both regulatory and reimbursement decision-making in Canada. The development of this action plan will aim to outline activities that need to be taken across the drug life cycle to support the optimal use of RWE in Canada. The full integration of RWE will have a significant impact on how drugs are approved and paid for in Canada, but multiple challenges will need to be addressed for RWE's potential to be fulfilled. We aim to highlight the key opportunities, barriers and future directions related to the optimization and integration of the use of RWE throughout the life cycle of drugs in Canada.

Challenges and Opportunities

Currently, drug regulators face challenges in a dynamic ecosystem; these challenges present opportunities for the use of RWE. Specifically, in the past decade, there has been a significant rise in the cost of all new drugs and the number of drug treatments (Mullard 2020). Specific pressure has been added in the area of drugs for rare diseases, as the rise of genetic biomarkers has resulted in further subdivision of populations driving the number of orphan drug indications higher, a form of "high-tech salami slicing." Two significant challenges have accompanied these shifts in drug development: identification of rarer indications and increases in cost of treatments.

Some of the recently approved drugs are much more likely to include those that are intended for use in much smaller populations, many of which meet the definition of rare disease. The number of "orphan drugs" – a US Food and Drug Administration (FDA) designation for drugs for rare diseases – approvals have increased five-fold from an average of 15 approvals per year in the 1990s to over 80 in 2017 alone (Bagley et al. 2018; CADTH 2016). Given that these drugs target smaller populations, the efficacy and safety evidence for these drugs tends to be developed in relatively smaller studies, which can undermine their reliability. For example, recent Phase III studies studying sebelipase alfa in lysosomal acid lipase deficiency had 36 individuals in the intervention group of the study (Burton et al. 2015). In contrast, a recent Phase III trial of dapagliflozin for the treatment of type 2 diabetes had 695 subjects in the intervention arms (Frías et al. 2016). These smaller studies introduce a higher level of uncertainty related to the efficacy and safety of these products. This uncertainty due to smaller studies for drugs makes regulatory decisions related to both market entry approval and pricing negotiations challenging (Raphael et al. 2020). The integration of RWE would allow the inclusion of further evidence to support RCT evidence and strengthen the reliability of results. Similarly, often RCT evidence does not include evidence to support the use of medication in more vulnerable subpopulations, such as pediatric or older adult population. RWE can serve as a key opportunity to support the expanded use of medications in older adults not currently supported by traditional RCT evidence.

A challenge that the recent shift in the drug development landscape presents is the rising prices associated with new treatments, for both rare and common indications. Strikingly, the number of approved drugs in Canada with price tags over $10,000 annually increased from 20 drugs in 2005 to 124 in 2015 (Government of Canada 2016). The combination of limited evidence and steeper prices has created a need for more information to assess value as drug prices are negotiated. The consideration of incrementally accrued RWE into negotiated flexible pricing arrangements has the potential to reshape how much we pay for drugs in Canada. A broader strategy incorporating RWE would support the need for more progressive listing agreements, such as pay-for-performance and outcome-based reimbursement models, that have the potential to reduce drug prices (Keohane and Petrie 2017; Vlaanderen et al. 2018). These models are not new and have been touted as potential solutions for years but have had low uptake to date owing to the complexity of application for making decisions (Vlaanderen et al. 2018). Both of these highlighted challenges present a timely opportunity for the development of a more coordinated and systematic approach to the generation and the use of RWE that has the potential to reshape the drug regulatory approval and the reimbursement process. Full integration of the use of RWE into the drug-approval life cycle, from pre-market to post-market, may advance our ability to approve drugs earlier for rare diseases, more adequately monitor safety and improve our ability to assess the economic value of therapies. Furthermore, the inclusion of RWE may allow for more robust assessments and reassessments of the effectiveness and impact of drugs.

Barriers

As exciting as the potential impact of RWE implementation may be, there are important barriers to its adoption that must be considered as an action plan is developed. These barriers have been highlighted through early discussions with stakeholders, such as regulators and funders, and include the alignment of stakeholders, development of RWE standards that account for the diversity of RWE use-cases and development of standards that align with international initiatives for high-quality RWE (IHE 2018). Full implementation of RWE must overcome complex and challenging issues that have been cited by stakeholders.

First, the implementation of RWE throughout the drug-approval life cycle will have a significant impact on a large number of stakeholders, including payers, regulators, manufacturers, patients and clinicians, who all have differing interests. As frameworks are developed, it is essential to keep in mind that these various stakeholders have varied but overlapping foci and motives. A successful action plan must aim to balance many of the interests and prioritize transparency where feasible, to develop trust among stakeholders. It is important to recognize that this action plan will not always directly fulfill all interested parties' interests, as some may be opposing; however, a comprehensive action plan that is developed collaboratively will acknowledge these differences in a transparent manner while capitalizing on the benefits of mutual engagement. Developed frameworks must not lower established standards of decision-making structures but will need to define roles and expectations of all parties involved.

Second, the implementation of RWE will have a wide array of clinical areas, drugs and gaps in evidence that will require varying methods, designs and data. For example, study designs and data needed for a rare cancer treatment to gain market approval will differ from those that are developed to support an outcome-based reimbursement model for a new asthma inhaler. Importantly, recent work has highlighted the need to more greatly improve real-world data to allow the potential alignment and replication of clinical trials (Bartlett et al. 2019). Potential improvements cited include expansion to include patient-reported outcomes, clinical insights using natural language processing and linking to medical devices. No action plan can or should aim to be prescriptive or attempt to define all available permutations. Rather, a successful action plan should aim to describe and advise on potential actions to address and handle the diversity of applications, allowing flexibility in the adoption of RWE while ensuring the development of the highest quality decision-grade evidence. Importantly, ensuring evidence quality should leverage decades of methodological development in observational research and be informed by the understanding of limitations of this type of research. The action plan developed must balance risk and benefits to patients and not be seen as a means to rapidly allow access to the market and reduce the evidence threshold. RWE must and should be used as a tool to augment current evidence regulatory standards and not a process to bypass them. Important lessons can be learned from the current use of RWE in both the US and Europe (Avorn and Kesselheim 2015; Davis et al. 2016; Fralick et al. 2018). For example, recent oncology drug approvals by the US FDA have highlighted the benefit of expedited approval but increased uncertainty around clinical benefits (Raphael et al. 2020).

Finally, drug development and pharmaceutical policy is a global issue, and thus, the action plan should be developed with an eye toward the ongoing international initiatives in other major jurisdictions, such as those at the European Medicines Agency and the US FDA (Krause and Saver 2018; Plueschke et al. 2018). The Canadian action plan should consider the current and ongoing initiatives. For example, when considering the development of data collection and analysis standards, it is important to align with market standards and leverage ongoing international standards. This will also be an opportunity to learn from other jurisdictions such as those that leveraged RWE to conduct performance-based pricing (Wenzl and Chapman 2019). Not aligning with international standards will lower the potential for uptake and engagement by stakeholders that operate across jurisdictions, specifically manufacturers.

What the Future Holds

Leveraging Canada's growing national pharmaceutical enterprises, such as the pan-Canadian pharmaceutical alliance, and growing data infrastructure is a crucial opportunity for the Canadian healthcare system to be a world leader in the integration of RWE in decision-making throughout the life cycle of drugs. Canada is uniquely situated to have a robust and unified drug life-cycle process with access to rich data sources and capacity. Various

international jurisdictions have aimed toward the implementation of RWE in specific points of the drug life cycle, mainly focusing at the point of market entry. Canada aims to be one of the first jurisdictions to implement RWE throughout the life cycle of the drug. This is illustrated by the fact that the action plan is being co-developed by Health Canada, CADTH and National Institute of Excellence in Health and Social Services (IHE 2018). In addition, the current focus of health technology assessment and price negotiation at a national level allows a potential broader inclusion of RWE. To our knowledge, no other jurisdiction has developed any initiatives that leverage both health technology assessment and regulators to develop a robust set of activities that spans the entirety of the drug life cycle. This presents a key opportunity to leverage RWE to inform market entry as well as reimbursement models such as conditional and performance-based reimbursement models. This important initiative will help to reframe the way we think about how drugs exist in the healthcare ecosystem. Importantly, this signals a shift in the classic siloed approach to drug policy and a shift toward a more integrated approach that will reduce duplication and capitalize on the strengths of the stakeholders involved. Expanding our focus from market entry to ongoing monitoring of agents in the healthcare environment will allow RWE to develop ongoing evidence. This reframing will allow the integration of current evidence that will help improve how we use and pay for medications in Canada.

We aim to develop an action plan for the use of RWE that will help Canada take advantage of the opportunity to optimize our $30-billion national investment on drugs. Importantly, this initiative comes at a time of an active national discourse on the potential implementation of a national pharmacare strategy. The stakes could not be higher for us to develop a novel, Canadian-style framework that balances the needs of stakeholders, ensures quality of RWE, leverages capacity and improves access and value of medications. We are confident that the challenges decision-makers face will allow for a key opportunity for the success of RWE integration through the maturation of drugs and reshaping the life cycle of drugs in Canada.

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RESEARCH PAPER

Ten Years of Inaction on Antimicrobial Resistance: An Environmental Scan of Policies in Canada from 2008 to 2018

Dix ans d'inaction face à la résistance aux antimicrobiens : analyse du contexte des politiques canadiennes de 2008 à 2018

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Abstract

We surveyed Canadian healthcare experts to identify policies to address antimicrobial resistance (AMR) in Canada between 2008 and 2018. Respondents identified AMR policy interventions implemented in Canada during the previous 10 years. Additional policies were identified through systematic searches of seven electronic databases and a review of government documents. Fifty-two unique policies were identified, with at least one policy in most

provinces and territories. This environmental scan suggests that Canadian AMR efforts are disjointed and inadequate, given the urgency of this public health threat. Governments have mostly refrained from using more powerful policy tools, including regulation, legislation and fiscal measures.

Résumé

Nous avons mené une enquête auprès d'experts canadiens des services de santé afin d'identifier les politiques de lutte contre la résistance aux antimicrobiens (RAM) au Canada entre 2008 et 2018. Les répondants ont identifié des politiques d'intervention contre la RAM mises en place au cours des 10 années précédentes. Des politiques supplémentaires ont par ailleurs été décelées au moyen d'une recherche systématique dans sept banques de données et par un examen des documents gouvernementaux. Cinquante-deux politiques ont été dénombrées et la plupart des provinces et territoires comptaient sur au moins une d'entre elles. Cette analyse du contexte porte à croire que les efforts canadiens contre la RAM sont incohérents et inadéquats face au caractère urgent de cette menace en matière de santé publique. Les gouvernements se sont généralement abstenus d'employer des outils politiques plus puissants comme, notamment, la réglementation, la législation ou des mesures fiscales.

Introduction

Addressing rising rates of antimicrobial resistance (AMR) is a top challenge for the Canadian health system. Drug resistance is a naturally occurring phenomenon, whereby microbes evolve to become resistant to the antimicrobial drugs that we depend on to treat infections. Human actions – particularly the overuse, misuse and abuse of antimicrobials in humans, animals and agriculture – have accelerated this process (Holmes et al. 2016).

AMR will have severe health and economic consequences; rising AMR jeopardizes future health system capabilities in Canada. Effective antimicrobials are needed for a range of routine medical procedures, including surgeries and chemotherapy treatments. As resistance becomes widespread, our ability to carry out these procedures is threatened. Health system costs will also increase because patients with resistant infections are more expensive to treat. The Council of Canadian Academies (CCA 2019) estimates that AMR was responsible for 5,400 deaths and 880,000 days in hospital in 2018. Meanwhile, the Organisation for Economic Cooperation and Development (OECD 2018) estimates that the effects of AMR cost the health systems of developed countries US$3.5 billion per year, and the CCA (2019) calculated that AMR reduced Canada's GDP by CA$2 billion in 2018.

Although antimicrobials are life-saving drugs, a large proportion of global antimicrobial use is inappropriate. Antibiotics, which treat bacterial infections, are commonly used in Canada and the US to treat conditions caused by microbes for which these are totally ineffective (Chua et al. 2019). Close to half of Ontario seniors are given antibiotics for respiratory tract infections that are not caused by bacteria (Silverman et al. 2017). The leading strategy for tackling AMR is education with the goal of reducing the inappropriate use of

antimicrobials through increased provider and patient knowledge (Van Katwyk et al. 2018, 2019). However, drug resistance in Canada is part of a larger global problem, and investments, coordination and political support for policy interventions are needed to collectively address AMR at all levels of the health system.

To date, it has been difficult to take stock of organized efforts to address AMR in Canada, or to identify policies and programs perceived to be successful in the Canadian context. The first Canadian action plan on AMR was released in 1997 with the goal of reducing overall antimicrobial prescriptions by 25% within three years (Government of Canada 1997). Unfortunately, the lack of complete antimicrobial use data from 1995 to 1999 impeded efforts to estimate the full impact of this plan (Finley et al. 2013). Although early estimates suggested that the 1997 action plan was beginning to have an impact (Conly 2002), it is unclear to what extent the government's call to action was implemented or sustained. A study of national programs undertaken from 1995 to 2010 described four major AMR programs in Canada during that time (Conly 2012), and other ad hoc programs have been launched since 2010. The Canadian Committee on Antibiotic Resistance, which was established during this period to perform a collating and coordinating role for stakeholder groups across Canada, published a series of reports and action plans highlighting AMR challenges in Canada but was disbanded in 2009 following funding cuts (Conly 2002; NCCID 2014; Nicolle 2012). We now lack a current description of Canadian policy interventions addressing AMR. We undertook this environmental scan to identify and catalogue recent Canadian policy interventions on AMR, with the aim of better understanding existing AMR efforts across the country and critically evaluating whether Canada has taken sufficient action to mitigate this important threat.

Methods

Policy interventions

We defined policy intervention as any public- or community-focused intervention to reduce AMR or inappropriate antimicrobial use in humans through education, restriction, incentivization, coercion, training, persuasion, changing of the physical or social context, modelling of appropriate behaviour or reduction of barriers to action, in accordance with the Behaviour Change Wheel (Michie et al. 2011; Van Katwyk et al. 2019). National, provincial/territorial and local interventions were included; however, clinical interventions and interventions focused on individual hospitals, pharmacies and other healthcare facilities were not included.

Data collection

SURVEY

We circulated a short e-mail questionnaire to identify AMR policy interventions between

2008 and 2018. This e-mail questionnaire asked respondents (1) if they were aware of any policy interventions related to AMR or antimicrobial use in Canada during the specified period, (2) when and where these interventions were undertaken, (3) what their goals were and (4) whom we could contact to obtain more details about the policies. We used purposive sampling to ensure a range of responses from federal, provincial, territorial and municipal levels and across human health sectors; e-mails were sent to a judgment sample of 253 experts who, in our view, were likely to be aware of AMR programs operating in Canada as a result of their professional roles. We anticipated that experts would potentially identify the same policies, and given our multistream approach to data collection, our sampling strategy prioritized geographic representation and professional representation above response rate. This sample included members of Canada's AMR Steering Committee, Council of Chief Medical Officers, academic researchers and representatives from health professional associations (medical, dental, pharmacy and nursing), regulatory colleges, hospitals and federal, provincial, territorial and municipal governments. Experts were encouraged to forward our e-mail to anyone who they thought might be able to provide relevant insights. E-mails in English and French were sent in February 2018, and follow-ups were sent two weeks after the initial e-mails. Where additional information was needed, we followed up with the respondent and conducted targeted Web searches.

SYSTEMATIC LITERATURE SEARCH

We conducted a systematic search for published literature on interventions to change antimicrobial use in Canada. In consultation with three research librarians from health science, social science and the government, we developed a structured search query to capture published evaluations of interventions that aimed to reduce antimicrobial use. Seven electronic databases from medicine and the social sciences (MEDLINE, CINAHL, Embase, PAIS Index, Cochrane Central Register of Controlled Trials, Web of Science and PubMed articles not indexed in MEDLINE) were searched from inception to January 28, 2019, without language or date limits. The full search strategy has been published elsewhere (Van Katwyk et al. 2017). We limited the search strategy to records that included the term "Canada" or named a province or territory in the abstract, author affiliations or keywords, and which were published after 2008. One author (Susan Rogers Van Katwyk) reviewed the abstracts and full texts of these studies to identify the ones that described a Canadian policy intervention between 2008 and 2018.

REVIEW OF GOVERNMENT AND POLICY LITERATURE

Finally, we conducted a grey literature search for policy and government documents on AMR. We conducted targeted Web searches of the Government of Canada website and targeted Google searches for "antimicrobial resistance" combined with the names of the provinces and territories. Additional grey literature sources were identified by key informants.

We reviewed the reference lists of identified documents to identify other grey literature sources. We also requested a list of all funding announcements related to AMR between 2008 and 2018 from the Canadian Institutes of Health Research (CIHR).

Analysis

For each identified policy intervention, we attempted to identify the intervention region, setting, time frame, goals and affiliated organizations. Regions were coded by province/territory, or as a national effort if the policy had a broader reach. We coded interventions as communication, legislation, service provision, regulation, fiscal, guideline and environmental and social planning interventions in accordance with the policy categories of the Behaviour Change Wheel (Michie et al. 2011) and our recent systematic review (Van Katwyk et al. 2019). The communications category was subdivided into educational programs and campaigns, events, action plans and communication tools.

We did not collect demographic data about survey respondents, as they were not the focus of this research project. Respondents' geographic location and professional affiliation were known from the development of our judgment sample, and we report on the distribution of these characteristics. Respondents who were affiliated with multiple types of bodies (e.g., government officials who held academic appointments) were coded according to their primary affiliation. The University of Ottawa Office of Research Ethics and Integrity determined that ethics approval was not required for this project.

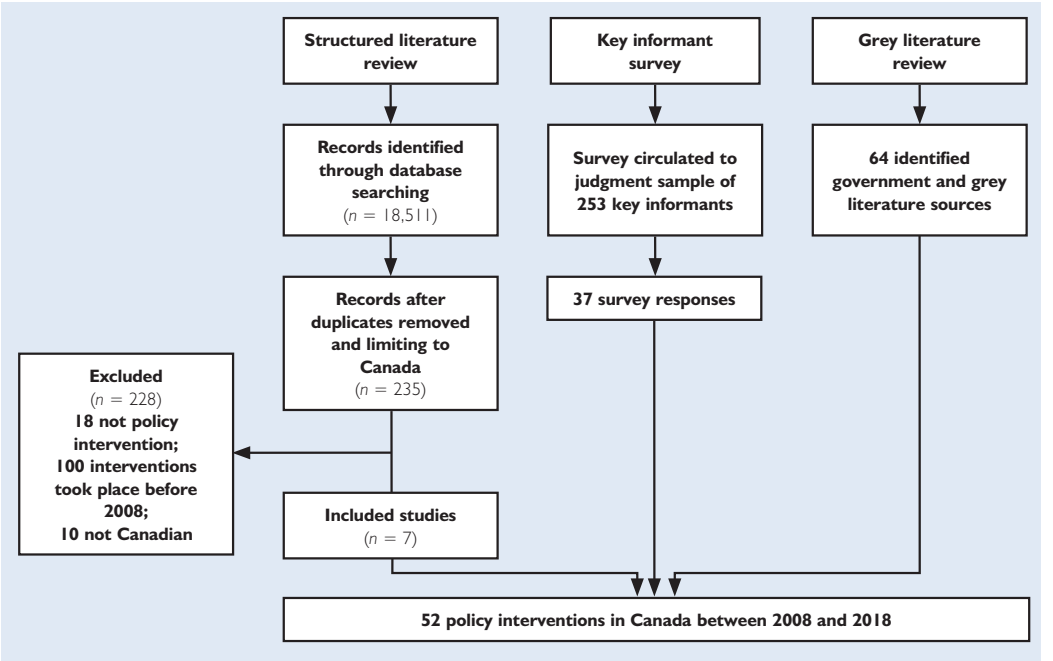
Results

Thirty-seven experts responded to the survey, including at least one respondent from every province and territory, except Newfoundland and Labrador. Experts represented federal (n = 3), provincial (n = 8) and regional (n = 4) governments, as well as academia (n = 4), medicine (n = 5), nursing (n = 4), pharmacy (n = 4), dentistry (n = 2), veterinary medicine (n = 2) and civil society (n = 3). CIHR launched 14 funding calls on AMR from 2008 to 2018. Our structured literature review identified 235 studies that included the term "Canada" or named a province or territory. Ultimately, we identified six studies that reported evaluations of Canadian policy interventions between 2008 and 2018 (Dickson et al. 2017; Fuertes et al. 2010; McKay et al. 2011; Announcement: Get Smart About Antibiotics Week 2016; Patrick et al. 2009; Zoutman and Ford 2012). Our grey literature search identified an additional 63 government and policy documents that were screened to identify policy interventions in Canada between 2008 and 2018; a full list of these sources is provided in Appendix 1 (available online at www.longwoods.com/content/26224). Figure 1 summarizes our three streams of data collection, and Box 1 shows a timeline of key actions, statements and policy papers in Canada between 2008 and 2018.

Altogether, we identified 52 programs active in Canada at some point between 2008 and 2018. The distribution of programs by region is shown in Figure 2; at least one program was identified in all provinces and territories, except Nova Scotia, New Brunswick and

Newfoundland and Labrador; however, more than half of the identified interventions were organized at the national level (n = 33). Programs varied considerably in size and reach, from a one-page leaflet, to a series of tweets, to a fully integrated regional-level stewardship program. As such, a higher number of implemented interventions does not necessarily indicate increased action or focus on AMR.

FIGURE 1. Flowchart describing our three-stream approach to identifying policy interventions in Canada between 2008 and 2018



Between 2008 and 2018, CIHR announced 14 grant calls related to AMR and awarded $32.5 million to 77 teams (Box 1). These awards were to promote research in strategic areas, ranging from clinical and biological aspects of resistance to social science and global governance efforts. Many of these funding efforts have been in partnership with foreign governments: directly with the UK in 2008–2010, and, more recently, through the Joint Programming Initiative on AMR (JPIAMR). (Box 2 is available online at www.longwoods.com/content/26224.)

The most commonly identified interventions (n = 29) were communication interventions. Other identified interventions were guidelines (n = 9), regulations (n = 7), service provision (n = 5) and fiscal measures (n = 2). We did not identify any AMR-focused legislation or environmental and social planning programs. Among the included interventions, we are aware of five that have been quantitatively evaluated (Dickson et al. 2017; Fuertes et al. 2010; McKay et al. 2011; Patrick et al. 2009; Zoutman and Ford 2012).

BOX 1. Timeline of key AMR events and reports, 2008–2018

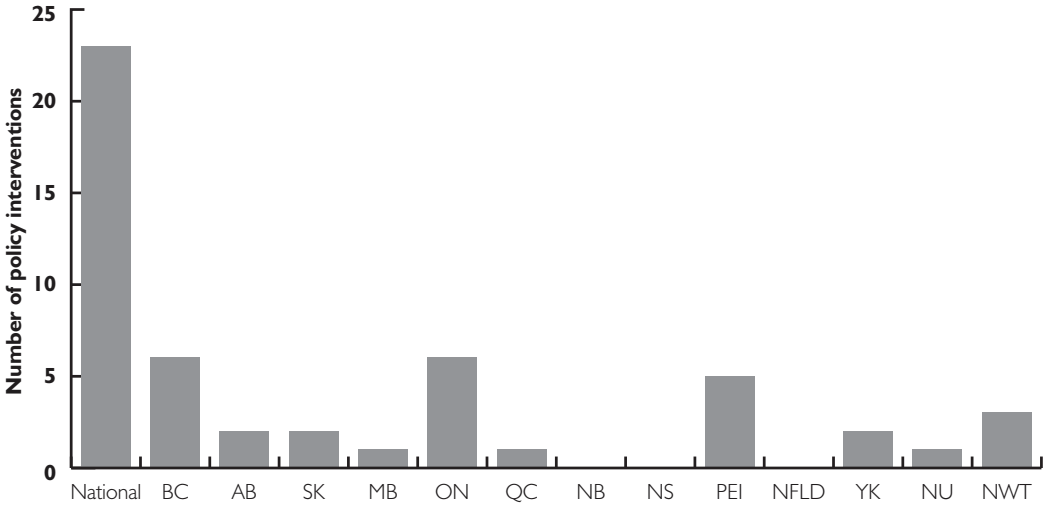
Date	Event
Jan 2011	The Public Health Agency of Canada identifies antimicrobial resistance as one of the most significant public health risks facing Canadians.
Mar 2013	Ontario Medical Association release policy paper: When Antibiotics Stop Working
May 2014	Canadian Paediatric Society release position statement: Antimicrobial Stewardship in Daily Practice
Jun 2014	Canadian Public Health Association release a Statement of Concern on Antimicrobial Resistance
Oct 2014	Antimicrobial Resistance and Use in Canada: A Federal Framework for Action released
Oct 2014	Expert Advisory Group on Antimicrobial Resistance established
Jan 2015	Global Health Security Agenda identifies AMR as a priority; Canada a leading country
Mar 2015	Federal Action Plan on Resistance and Use in Canada: Building on the Federal Framework for Action
Apr 2015	Auditor General Report on AMR – "Significant work remains to be done"
Apr 2015	Canadian Federation of Medical Students and Students for Antimicrobial Stewardship Society release policy paper
Oct 2015	Canada and G7 Health Ministers commit to strengthening antibiotic stewardship programs for professionals in medical and vet fields
Oct 2015	Canada joins Transatlantic Task Force on AMR
Jan 2016	AMR endorsed as a priority at the "Canadian Health Ministers' Meeting"
Apr 2016	HealthcareCAN report: Building Canada's Antimicrobial Stewardship Action Plan
Apr 2016	Pan-Canadian Public Health Network release report: Antimicrobial Stewardship Report
Jul 2016	COA, CDA and AMMI release consensus statement: Dental Patients with Total Joint Replacements
Nov 2016	Canada announces $9 million to WHO to support implementation of the GAP
Nov 2016	Canadian Institutes of Health Research hosts Multi-Stakeholder Antimicrobial Stewardship Expert Forum
Jan 2017	Canadian Paediatric Society re-affirm position statement: Antimicrobial Stewardship in Daily Practice
Aug 2017	Tackling Antimicrobial Resistance and Antimicrobial Use: A Pan-Canadian Framework for Action
Oct 2017	Canada becomes Chair of the Global Health Security Agenda AMR Action Package
May 2018	HESA presents: A Study on the Status of Antimicrobial Resistance in Canada and Related Recommendations to the House of Commons
Jul 2018	Government Response to HESA Study: A Study on the Status of Antimicrobial Resistance in Canada and Related Recommendations
Jul 2018	Progress Report on the 2015 Federal Action Plan on Antimicrobial Resistance and Use

Note: COA: Canadian Orthopaedic Association; CDA: Canadian Dental Association; AMMI: Association of Medical Microbiology and Infectious Disease; GAP: Global Action Plan; HESA: House of Commons Standing Committee on Health

Communication interventions

Among the communication interventions, we identified 16 educational programs, largely public awareness campaigns targeting health professionals and the public (Table 1, available online at www.longwoods.com/content/26224). Many of the identified programs were provincial or regional variations on well-known programs such as "Do Bugs Need Drugs?" "Bugs and Drugs" or the annual Antibiotic Awareness Week. The Do Bugs Need Drugs?

FIGURE 2. Distribution of identified policy interventions and programs across Canada



program has been linked to improvement in clinical knowledge of appropriate antibiotic treatment (McKay et al. 2011), and an ecological study has linked the program to declines in antimicrobial prescribing (Fuertes et al. 2010). Other smaller programs included radio broadcasts from the Northern Antibiotic Resistance Partnership, Twitter campaigns co-led by the Association of Medical Microbiology and Infectious Disease and the National Collaborating Centre for Infectious Disease and events organized by the Students for Antimicrobial Stewardship Society, a program organized by health professional students.

We identified three national frameworks and action plans released by the Public Health Agency of Canada (PHAC) in 2014, 2015 and 2017 (Government of Canada 2017). We also identified a provincial action plan that was in development in Quebec at the time of our survey, but no details were available. Three short educational events (1 to 2 days) were identified, two of which were hosted by CIHR and one by Health PEI. The remaining communication interventions included leaflets, posters and other tools to engage patients in discussions about antimicrobial use and to provide physicians with up-to-date information on antimicrobial prescribing.

Fiscal measures

We identified two fiscal policies (Table 2, available online at www.longwoods.com/content/26224), but neither provided funding for AMR action within Canada. The federal government provided $250,000 to support the World Bank in writing a report on AMR (World Bank 2017) and committed $9 million to the World Health Organization to support the development of national action plans in low- and middle-income countries.

Guidelines

We identified nine guideline interventions, seven of which were released by the federal or provincial governments, and two of which were collaborations among health professional associations (Table 3, available online at www.longwoods.com/content/26224). Guidelines were released in response to the development of resistance in particular pathogens of concern, including methicillin-resistant *Staphylococcus aureus* and extensively drug-resistant *Neisseria gonorrhoeae*. A rigorous quasi-experimental evaluation of the effectiveness of introducing these new gonorrhea guidelines in Ontario found that uptake of the revised treatment guidelines was very slow. Following the release of new guidelines, the proportion of physicians prescribing according to treatment guidelines dropped by over 60% and never returned to pre-intervention levels (Dickson et al. 2017).

Regulations

We identified seven regulation interventions from 2008 to 2018 in Canada (Table 4, available online at www.longwoods.com/content/26224). The largest among these interventions was a regulation by Accreditation Canada requiring hospitals and long-term care facilities to have an antimicrobial stewardship program to receive accreditation. Only two regulations were identified at the level of the federal government: Health Canada implemented a regulation requiring a standard statement about AMR to be included on the drug monographs of all antibiotics, and Correctional Services Canada is in the process of developing a stewardship program for implementation in all their facilities.

Service provision

We identified five service provision interventions (Table 5, available online at www.longwoods.com/content/26224), two from Ontario and three from British Columbia. All five interventions provided education and training sessions on antimicrobial stewardship within the health system, often including audit and feedback on antimicrobial use rates. Three programs were delivered by, or in partnership with, provincial governments. Two programs were delivered in partnership with regional health units.

Discussion

Principal findings

AMR is among the top global threats facing humanity. Yet, the efforts identified in this environmental scan are too few, too small and too uncoordinated to meaningfully address this global threat. Our scan suggests that 10 years of AMR efforts in Canada have mostly consisted of a disjointed series of small projects that are inadequate to meet the Government of Canada's own AMR goals. Governments at all levels have prioritized small, education-based programs, rather than making use of the more powerful regulatory, fiscal and legislative

policy levers at their disposal. Furthermore, the programs identified are not all based on scientific evidence or evaluated using rigorous scientific methods. There is only limited evidence that public awareness campaigns are effective at reducing antimicrobial use in the long term (Cross et al. 2016; Price et al. 2018), and there is no evidence that shows what program elements make an effective public awareness campaign (Van Katwyk et al. 2019). Indeed, at least one study showed that passively providing patients with information through posters and leaflets is ineffective (Hallsworth et al. 2016).

We believe Accreditation Canada's regulatory approach requiring all hospitals and long-term care facilities to implement antimicrobial stewardship programs is potentially more effective at reducing antimicrobial use. Although evidence that accreditation leads to improved care is weak (Brubakk et al. 2015), there is strong evidence that antimicrobial stewardship is effective (Davey et al. 2017). A rigorous evaluation of Accreditation Canada's program would be useful, particularly if it could identify the most effective components of a stewardship program. Other evidence-informed actions are the service provision efforts by the British Columbia Ministry of Health and Health Quality Ontario to provide audit and feedback on antimicrobial use to health professionals and long-term care facilities (Ivers et al. 2012).

We found relatively few references to clinical practice guidelines in this scan. Although we recognize that our search strategy may have missed examples of clinical practice guidelines, we note that guidelines are an important component of an AMR response. To respond to growing AMR, guidelines need to be regularly updated, widely disseminated and rapidly adopted by health professionals, although the simple production of guidelines without corresponding dissemination and implementation efforts is insufficient to address AMR (Dickson et al. 2017; Grol and Grimshaw 2003).

We identified few published or planned evaluations of policy effectiveness, and it was often unclear why an intervention was expected to work. For example, to the best of our knowledge, there is no evidence to suggest that placing warning labels about AMR on product monographs will change patient or professional behaviour. Although experimenting with new policies and strategies is essential for responding to AMR, policies planned without clear theories of change are unlikely to be effective.

Our findings suggest a surprising lack of engagement with AMR from key actors, including health professional associations and regulatory colleges. The Association of Medical Microbiology and Infectious Disease Canada is involved in many AMR efforts across Canada, and the College of Family Physicians of Canada has partnered with Choosing Wisely Canada on the Antibiotics Wisely campaign. Beyond these examples, we found only a few statements of concern released by the medical associations, and a guideline statement from the Canadian Dental Association. An effective, coordinated AMR response will require substantially more effort to integrate professional associations and bodies from medicine, dentistry, nursing and pharmacy.

The federated nature of the Canadian health system makes the provinces and territories responsible for regulating health professionals and antimicrobial use. The Office

of the Auditor General of Canada (OAG 2015) found that the PHAC had not yet succeeded in mobilizing all federal, provincial and territorial partners and stakeholders toward a Pan-Canadian Strategy on AMR. We saw limited evidence that Canadian provinces were independently pursuing regulatory approaches to addressing AMR. Provincial government responses have largely focused on educational campaigns and prescribing guidelines, and, as far as we are aware, only Quebec is developing a provincial AMR action plan. The lack of action or action plans from other provinces and territories emphasizes the need for increased commitment, coordination and collaboration among government actors. The forthcoming Pan-Canadian Action Plan on AMR should provide a platform for increasing collaboration across levels of government; however, fulfilling the obligations of this action plan will require more action from provinces and territories than has been seen to date.

Policy implications

Despite the activities catalogued in this environmental scan, the rates of community antimicrobial use in Canada have been stable since 2013 (PHAC 2018). Increasing resistance highlights the extent to which the resources committed to AMR are incommensurate with the scale of the collective action problem. AMR represents a major threat to the sustainability of the Canadian healthcare system and requires substantially more focused investment and attention. Although Canada has taken on AMR leadership roles abroad, the level of political engagement, funding and regulatory and legislative action on AMR in Canada appears to be limited. Although PHAC provides routine funding for AMR surveillance and awareness campaigns, our scan did not identify any announcements of new domestic funding beyond CIHR research grants.

Framing AMR as a problem of individual patient and prescriber behaviour has unsurprisingly led to a series of AMR responses focused on education. This strategy recognizes that providers are more likely to prescribe antibiotics when patients request them (Coenen et al. 2006, 2013; Llor et al. 2013). However, antibiotic prescribing is also shaped by a series of health systems factors and social determinants of health, such as healthcare access, clinic volume, socio-economic status and patient–provider trust (Cole 2014; Gjelstad et al. 2011; Tangcharoensathien et al. 2018).

There are many policy approaches that have not been tried in Canada (Van Katwyk et al. 2019), including several legal, regulatory and fiscal strategies. To address AMR effectively, we need to make full use of these more powerful strategies and build a coordinated, evidence-based suite of policies to address AMR at multiple levels. Recent calls from CIHR and JPIAMR to fund social science and behaviour change research on AMR may lead to useful new strategies, and all policy interventions should be paired with appropriately rigorous evaluation plans to better inform resource allocation and shared learning across provinces and territories. As a starting point, provinces and territories should focus on improving and harmonizing the collection of data on AMR and antimicrobial use across the country,

which will facilitate future evaluation efforts. The forthcoming Pan-Canadian Action Plan on AMR may provide the necessary platform for the federal and provincial governments to pursue a much ambitious AMR strategy. Future AMR action must move beyond simply integrating existing public communications campaigns and tools and toward effective, integrated, regulatory, legislative and fiscal measures.

Strengths and limitations

This report adds to the growing literature on AMR inaction in Canada. By surveying experts across Canada, we have captured data on AMR policy efforts at the national, provincial and territorial levels and those organized by academics and civil society. Although we aimed to be comprehensive through our combination of questionnaire, grey literature and published literature searching, some policies and programs may not have been captured if these were not identified by experts and if their Web resources were no longer available. We received responses from only 37 of our 235 experts and are more likely to have missed policies in regions or professions where we received fewer responses. This purposive sampling strategy focused on experts who currently hold positions where they would be aware of AMR programs in Canada; however, it is possible that we missed earlier programs because of staff turnover. We did not attempt to contact people who had moved on from their expert positions in the public health community. Similarly, online grey literature searching privileges recent sources over older documentation, particularly for defunct organizations such as the Canadian Committee on Antibiotic Resistance, whose Web resources have been removed. We have attempted to overcome these limitations by combining research strategies and, to the best of our ability, verifying our information through other sources. Finally, we chose to limit the scope of this study to policy interventions to reduce human antimicrobial use. We recognize that the Health Canada's Veterinary Drugs Directorate has made policy changes on antimicrobial use in animals that were not included in this report.

Conclusions

AMR is a major threat to public health and healthcare in Canada. Our review suggests that the AMR interventions in Canada over the past 10 years have been too few, too small and too uncoordinated to adequately address the threat posed by AMR. Increased commitment to AMR, including multisectoral inter-agency cooperation and funding, is needed to ensure that future interventions are effective, evidence-informed and sufficient for Canada to overcome this looming threat.

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Conflict of interest

Steven J. Hoffman is Scientific Director of CIHR's Institute of Population and Public Health. The views expressed in this article are those of the authors and do not necessarily reflect those of CIHR or the Government of Canada.

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RESEARCH PAPER

Examining the Association between Community-Level Marginalization and Emergency Room Wait Time in Ontario, Canada

Examen du lien entre la marginalisation communautaire et le temps d'attente au service des urgences en Ontario, Canada

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Abstract

Objective: This study examines the association between community-level marginalization and emergency room (ER) wait time in Ontario.

Methods: Data sources included ER wait time data and Ontario Marginalization Index scores. Linear regression models were used to quantify the association.

Results: A positive association between total marginalization and overall, high-acuity and low-acuity ER wait time was found. Considering specific marginalization dimensions, we found positive associations between residential instability and ER wait time and negative associations between dependency and ER wait time.

Conclusions: Reductions in community-level marginalization may impact ER wait time. Future studies using individual-level data are necessary.

Résumé

Objectif : Cette étude examine le lien entre la marginalisation communautaire et le temps d'attente au service des urgences en Ontario.
Méthode : Les sources consultées comprenaient les données sur les temps d'attente aux urgences ainsi que les données de l'indice de marginalisation ontarien. La quantification des liens s'est faite au moyen des modèles de régression linéaire.
Résultats : Nous avons constaté un lien positif entre une marginalisation totale et le temps d'attente aux urgences pour les affections générales, complexes et mineures. Quant aux aspects propres à la marginalisation, nous avons observé des liens positifs entre l'instabilité résidentielle et le temps d'attente aux urgences, et des liens négatifs entre la toxicomanie et le temps d'attente aux urgences.
Conclusion : Une réduction de la marginalisation communautaire pourrait avoir une incidence sur les temps d'attente aux urgences. Il faudrait maintenant mener des études qui se pencheraient sur les données au niveau individuel.

Introduction

The emergency room (ER) is a major point of entry for individuals requiring healthcare. Across developed countries, timely access to ER care is a priority, and high ER wait time reflects an inability of healthcare systems to adequately meet the needs of their populations (Downing et al. 2004; Watson et al. 2007). For individuals using the ER to access care, the impact of long wait times is profound; increased wait times are associated with decreased satisfaction and quality of care and increased risk of physical discomfort, medical error, morbidity and in-hospital mortality (Giuntella et al. 2018; Health Quality Ontario 2016; Mahmoud and Hou 2012; Marco et al. 2012; Vegting et al. 2015). Past studies have shown that hospital size, visit frequency and the acuity of visits explain some, but not all, of the variations in ER wait time between hospitals (Horwitz et al. 2010; Knowles et al. 2017). Typically, low-acuity (non-emergent) ER visits contribute less to ER wait time per visit and in total (Dinh et al. 2016); in contrast, high-acuity (emergent) visits preceding hospital admission have the longest ER wait time (Horwitz et al. 2010). Two studies defined ER wait time: Giuntella et al. (2018) defined it as the time from triage until discharge or hospital admission; Horwitz et al. (2010) defined it as the time from triage until first assessment by a physician.

Despite the importance of ER wait time as an indicator of healthcare access, no studies have, to the best of the authors' knowledge, considered how ER wait time may be higher or lower across communities with different levels of marginalization. Marginalization is

defined as material and social disadvantage in one social group compared to other social groups. Marginalization can be evidenced by low socio-economic status, residential instability, poverty, dependency and poor healthcare utilization (Lynam and Cowley 2007). Marginalization impacts mental and physical health across the life course (Lynam and Cowley 2007).

Past research on the links between marginalization and the healthcare system focused on the health system in the US and Europe. These investigations have primarily examined the number of ER visits, rather than ER wait time, and have shown that marginalized groups visit ERs more frequently and require greater levels of care than non-marginalized groups. For example, marginalized people who are homeless in the US are less likely to use primary and preventive care, potentially increasing the number of ER visits in areas with relatively large homeless populations (Kushel et al. 2006). Likewise, marginalized individuals with chronic conditions are more likely than their non-marginalized counterparts to delay care, possibly resulting in a greater need for intensive ER services and higher visit frequencies in European and US ERs (Begley et al. 2011; Gunnarsson et al. 2013). Notwithstanding delayed care, economically disadvantaged persons in the US are more likely to present to ERs with poorer overall health than individuals from higher socio-economic strata (Bisgaier and Rhodes 2011).

Research exploring possible associations between marginalization and ER service use is inconclusive, and no past research has, to the authors' knowledge, examined the association between marginalization and ER wait time. Some work suggests that poor access to primary care physicians, which is more common among marginalized populations, may be associated with larger numbers of ER visits (Harris et al. 2011). However, research focused on Canadian ERs highlights that factors such as low educational attainment and low income at the individual and community levels may be more important determinants of high levels of ER utilization than poor access to physicians (Mian and Pong 2012; Ohle et al. 2017). Within the UK, greater community deprivation is associated with increased numbers of low-acuity ER visits (Harris et al. 2011). These findings contrast with studies suggesting that marginalized groups in the US use ER services less frequently (Tarraf et al. 2015).

Given the paucity of research exploring ER wait time and marginalization, we searched the literature for all developed countries and could not find any published research exploring whether ER wait time varies between communities with different levels of marginalization. Additionally, we found limited Canadian research that explores how community-level marginalization impacts ER care and no information about marginalization and ER wait time. As a result, we examined the association between community-level marginalization and ER wait time in the province of Ontario, Canada. Specifically, we looked at total community-level marginalization and four specific dimensions of marginalization, namely, residential instability, material deprivation, dependency and ethnic concentration.

This study reflects a principal goal of public health, namely, to facilitate equitable access to healthcare (Taillepierre et al. 2016). One important means of fostering equity is to focus

on the social determinants of health, including marginalization (Hall et al. 2016). The results of this study will be valuable for policy makers, health system managers and politicians because the study will serve as the first step toward understanding the degree to which community-level marginalization is associated with ER care in the form of wait time.

Data and Methods

Study region and data

Ontario is Canada's most populous province, with over 14 million inhabitants and approximately 39% of the country's total population. In 2017, 166 Ontario hospitals had an ER and, as part of the Ontario Wait Time Strategy (Ontario Ministry of Health and Long-Term Care 2013), the Ontario Government provided publicly available wait time information for 119 of these ERs. We obtained the 2017 ER wait time data from the provincial government in fall 2018, before these data were removed from public access. ER wait times were measured in hours and calculated as the length of time between triage (i.e., being seen by a nurse upon arrival) and discharge from the ER, either to be sent home or admitted to the hospital.

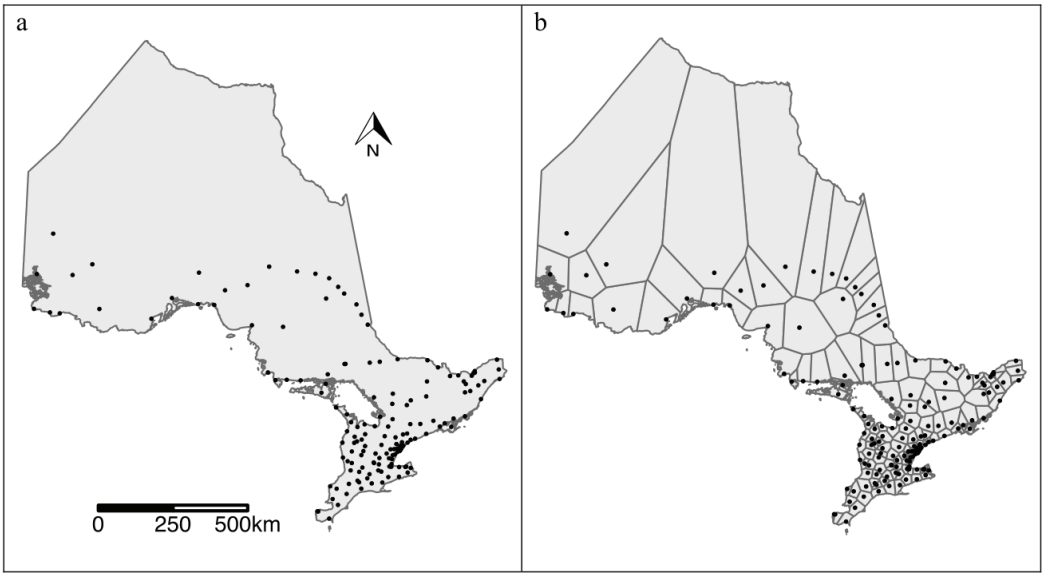
The ER wait time data included measures of the median, average and 90th percentile wait time for three types of ER visits: all ER visits, high-acuity ER visits and low-acuity ER visits. Acuity ratings were based on ER nurses' triaging of new arrivals to the ER, with triaging undertaken using the Canadian Triage and Acuity Scale (CTAS). CTAS scores ranged from 1 (most serious) to 5 (least serious); scores between 1 and 3 indicated high-acuity patients and scores between 4 and 5 indicated low-acuity patients (Health Quality Ontario 2018).

Marginalization data were obtained from the 2016 version of the Ontario Marginalization Index (ON-Marg) at the census subdivision level (CSD) (Public Health Ontario 2016a). CSDs approximate the geographical boundaries of municipalities (Statistics Canada 2018). Of the 575 CSDs in Ontario, 411 had marginalization data available through ON-Marg (Public Health Ontario 2016a). ON-Marg uses census data to measure total marginalization and four specific dimensions of marginalization: residential instability (type and density of residential accommodations and family structures), material deprivation (income, education, housing quality and family structures), dependency (number of children, seniors and those not participating in work) and ethnic concentration (visible minority status) (Public Health Ontario 2016a). These four dimensions are independent of one another and provide a more comprehensive representation of marginalization than other area-based deprivation indices that focus only on low socio-economic status (Matheson et al. 2012). The ON-Marg scores were calculated using 18 census variables and converted to standardized scores ($\mu = 0$, $\sigma = 1$). High index scores indicated higher levels of marginalization. Further details about ON-Marg are available elsewhere (Public Health Ontario 2016b).

Aligning hospital and census data

Because ER wait time data were available at the hospital level and marginalization data were available at the CSD level, our analysis had to account for the geographical misalignment of these data. To do so, we first geocoded the street addresses of the 166 Ontario ERs (Figure 1a) to the geographical coordinates (latitudes and longitudes). Second, we created a set of Thiessen polygons (Kopec 1963) to define the service area for each of the ERs (Figure 1b). Thiessen polygons take a set of input points (i.e., hospital locations) and construct one polygon around each input point such that any location within the polygon is closest to only its input point and not any other input point in the data set (Brassel and Reif 1979). Applied to define ER service areas, Thiessen polygons assume that individuals living within a given service area are more likely to visit the nearest hospital than any other hospital in the province. For reference, Thiessen polygons are often used in contexts where the "closest assignment" is considered reasonable, such as in the creation of hospital service areas, school service areas and coverage areas for police, fire and emergency services (Feng and Murray 2018; Pearce 2000; Schuurman et al. 2006).

FIGURE 1. ER service areas for the province of Ontario



(a) Locations of ERs with available wait time data in the province of Ontario (n = 166) and (b) Service area boundaries defined using Thiessen polygons

Calculating marginalization scores for ER service areas

Each CSD was assigned to one or more ER service areas based on the intersection of the CSD boundaries and the ER service area boundaries. Marginalization scores were calculated for each ER service area using three approaches: arithmetic mean, geographically weighted average and population-weighted average. The arithmetic mean approach calculates service area marginalization scores as the average of the marginalization scores of the assigned

CSDs. This assumes that each CSD that intersects with a service area has an equal weight (or contribution) to the marginalization score within a service area but does not consider differences in CSD size or population. For the geographically weighted average, service area marginalization scores were calculated based on the proportion of CSD area (km^2) that overlapped with a service area. For example, if two CSDs overlapped with one ER service area and constituted 90% and 10% of the total service area size, then the geographical weights used to calculate service area marginalization were 0.9 and 0.1, respectively. For the population-weighted average, we used population weights based on the relative population sizes of the overlapping CSDs to calculate service area marginalization scores. In this case, CSDs with large population sizes had larger contributions to the service area marginalization scores than CSDs with small population sizes. Comparing and contrasting the results of the average, geographically weighted and population-weighted marginalization scores helps to understand the degree to which these assumptions influence the association between ER wait times and community-level marginalization.

Because some CSDs had missing marginalization data, when less than 50% of the CSDs assigned to a given service area had missing data, the total marginalization scores for the ER service area were calculated as the average of the available CSD marginalization scores. When more than 50% of the CSDs assigned to a given service area had missing marginalization data, a marginalization score was not assigned to the ER service area and it was excluded from analysis. Missingness of 50% or more was used as the cut-off because any resulting average marginalization scores would not represent a majority of an ER service area's population.

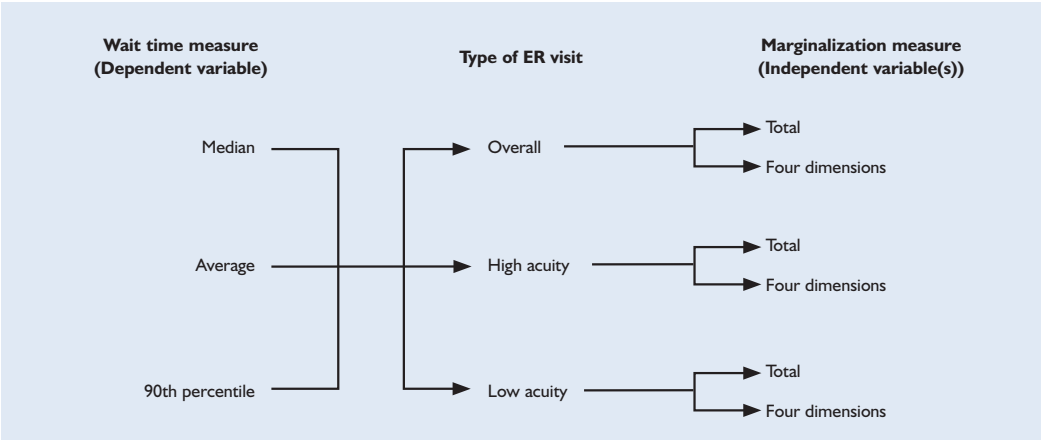
Regression analysis

The associations between marginalization and ER wait time were quantified via three sets of linear regression models. Each set of models focused on a different method of computing ER wait time: median wait time, average wait time and 90th percentile wait time. Within each set of models, we ran subsets of models based on wait times for overall, low-acuity and high-acuity ER visits. We examined different acuity levels because of reports that marginalized populations were more likely to visit ERs for low-acuity concerns (Mahmoud and Hou 2012; VanStone et al. 2013). As such, areas with high marginalization could have longer wait times for low-acuity visits than all ER visits or high-acuity visits. Each visit type was regressed on total marginalization and the four specific dimensions of marginalization in separate regression models. The modelling approach is depicted in Figure 2. We re-ran each set of models three times to account for the different weighting schemes used to compute service area marginalization scores (arithmetic mean, geographically weighted and population-weighted).

Software and ethics

We used QGIS v3.4.1 mapping software (Geographic Information System – Open Source Geospatial Foundation Project, Geneva, Switzerland) to create the ER service areas and

FIGURE 2. Data analysis approach used to quantify the association between ER wait time and marginalization



assign the CSDs to the service areas. The regression analyses were undertaken using R v3.5.1 (R Foundation for Statistical Computing, Vienna, Austria). The threshold of statistical significance was $\alpha = 0.05$.

This study did not require research ethics approval because it was conducted with publicly available data collected at the population level.

Results

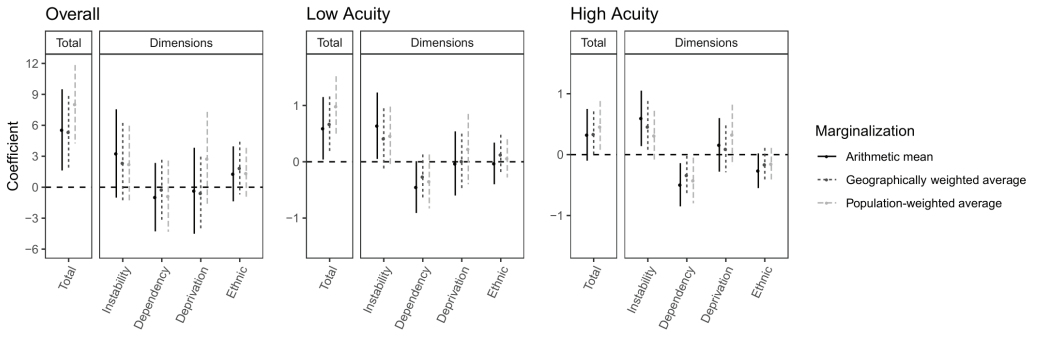
Overall, two types of data missingness were possible. The first occurred when more than 50% of CSDs had missing data, as a marginalization score was not assigned to the ER service area. The second type of missingness occurred when ER wait time data were missing. Of the 166 service areas created, 118 were included in our analyses because these had both ER wait time and marginalization data. There were 33 ER service areas that had missing marginalization data in over 50% of the CSDs assigned; these areas were not included in our analyses. In addition, there were 15 ER service areas that had marginalization scores assigned to the service area but were missing ER wait time data; these ER service areas were also not included in our analyses.

Using the Wilcoxon rank-sum test, we found some statistically significant differences in marginalization scores between the ER service areas with (n = 118) and without (n = 15) missing ER wait time data and with less than 50% of CSDs missing marginalization data, specifically among the dimensions of dependency, deprivation and ethnic concentration (Tables 1–3, available online at www.longwoods.com/content/26223). There were no statistically significant differences in marginalization scores between ER service areas with (n = 118) and without (n = 15) missing ER wait time data and with less than 50% missing marginalization data for total marginalization and residential instability.

In general, the coefficient signs, magnitudes and statistical significance levels were relatively consistent across the regression models analyzing median ER wait times and the three

different versions of marginalization (Figure 3). Focusing on total marginalization, a positive and statistically significant association with overall and low-acuity median ER wait time was observed for the arithmetic mean, geographically weighted and population-weighted versions of marginalization (Tables 4–6, available online at www.longwoods.com/content/26223). Total marginalization was also positively associated with median ER wait time for high-acuity visits; however, this coefficient was not statistically significant.

FIGURE 3. Regression coefficients and 95% confidence intervals for median ER wait time and marginalization



Considering the individual dimensions of marginalization, residential instability was positively associated with median ER wait time for overall, high-acuity and low-acuity visits across all marginalization calculations; however, this association was only statistically significant for the arithmetic mean (low and high acuity) and geographically weighted (high acuity) versions of marginalization. Furthermore, there was a negative association between dependency and overall, high-acuity and low-acuity median ER wait time that was observed consistently across the arithmetic mean, geographically weighted and population-weighted versions of marginalization. Like residential instability, however, these results had varying levels of statistical (in)significance. There was no clear relationship with median ER wait time for all types of visits when considering the deprivation and ethnic concentration dimensions of marginalization. In the multiple regression models, the variance inflation factors were less than five, which suggested that multicollinearity did not impact the model results.

Consistent with the results for median ER wait time, statistically significant positive associations were observed between total marginalization and both overall wait times and low-acuity wait times for the average and 90th percentile wait time measures (Tables 7–12, available online at www.longwoods.com/content/26223). Further, our results exploring the association with instability and ER wait time were consistent across all wait time variables and observed across all marginalization calculations (Figures 4 and 5, available online at www.longwoods.com/content/26223).

Discussion

To our knowledge, the present study is the first to consider marginalization for ER service areas in Ontario or elsewhere. Further, this is the only study to examine ER wait time, rather than Ontario ER visit frequency (VanStone et al. 2013), as the outcome in relation to community marginalization. We found population-level positive associations between total marginalization and median ER wait time in Ontario.

Interpretation

Our results suggest that communities with higher levels of total marginalization, and residential instability in particular, have longer ER wait times across all types of visits as well as both high- and low-acuity visits.

Our results complement the findings of social determinants of health research, which often report associations between high levels of marginalization and lower access to healthcare. Previous studies show positive associations between greater community deprivation and increased numbers of low-acuity ER visits (Harris et al. 2011). Other studies link minority status, material disadvantage and economic disadvantage to increased use of ER services (Haggerty et al. 2007; Kushel et al. 2006; Mian and Pong 2012). Therefore, our findings appear to be situated in a chain of events, whereby marginalization increases the frequency of ER visits, which places a heavier demand on ER services and leads to a longer ER wait time.

We found that instability as a specific dimension of marginalization was positively associated with ER wait times. This result aligns with investigations showing that residential instability is a crucial social determinant of health (Carder et al. 2018; Gadermann et al. 2019). Within a Canadian context, recent studies have linked residential instability to poor health status and increased healthcare utilization (Harris et al. 2019; Jaworsky et al. 2016). Aspects of residential instability, such as living alone or having recently moved, may result in an increased need for emergency services whereby individuals are brought to ER settings. Within the context of our research, increased healthcare utilization may place a greater demand on ER services, increasing ER wait time overall.

To date, to our knowledge, no studies have considered community levels of dependency, deprivation or ethnic concentration and their associations with ER wait time. We found levels of dependency, defined by ON-Marg as the number of children, seniors and adults who are not participating in paid work, to be inversely associated with ER wait time. These results appear to counter published studies undertaken in related research areas. For example, at the individual level, unemployment was found to be positively associated with healthcare utilization in Canada (after controlling for mental health treatment) (Kraut et al. 2000) and the US (Kuka 2000). One would thus expect to find longer wait times in areas with higher levels of dependency. Perhaps our results reflect the ecological fallacy, and further research using individual-level data is required to explain our findings.

The results for deprivation and ethnic concentration do not show any stable patterns across the different analyses. At the community level, this suggests an absence of effect for

these two dimensions of marginalization. However, individual-level relations may differ from the findings of our study.

The results from our study can inform the policy process. Sound public health initiatives should be based on evidence suggesting the potential for change (Baicker and Chandra 2017; Roberge et al. 2010). In the context of the social determinants of health, the types of initiatives that bring about positive changes to the social condition and improve population health are often resource intensive. Prior to the initiation of new policies, evidence-based assessments should be completed to assess whether the potential health benefits will eclipse the cost of resources. The reduction of community-level marginalization is a resource-intensive process; however, our study suggests that this process may reduce ER wait time, particularly if efforts are focused on reducing community residential instability. Policy makers can use this information to further evaluate the health and social benefits, and costs, of programs designed to ameliorate community-level marginalization.

Strengths and limitations

One strength of this study was the ON-Marg data set's use of large sample sizes to generate marginalization scores. In addition, ON-Marg is stable across diverse geographical areas, such as urban and rural areas (Public Health Ontario 2016b). Marginalization scores assigned to CSDs were likely to be representative of the levels and types of marginalization experienced by Ontario communities (Public Health Ontario 2016b). Of course, our study used ecological-level data, meaning that its results might not be applicable at the individual level.

Another notable strength of this work is the robust analyses completed. By using three marginalization calculations (arithmetic mean, geographically weighted and population-weighted), we complete the same analyses with different assumptions regarding the aggregation of data across spatial scales. Similarly, median average and 90th percentile wait time measures were considered. Comparing the results of these analyses shows that there is consistency in our results, providing evidence that the results of this study reflect an ecological association between community marginalization and ER wait time.

One limitation of this study is that the Thiessen polygon method for developing ER service areas assumes that individuals attend the ER closest to their place of residence. This assumption may not always be true and could have introduced non-differential misclassification into our study, thereby biasing results toward the null hypothesis.

Moreover, our analyses had to overcome missing data. Although we could not comment on the nature of the missingness, we acknowledge that marginalization was, at times, greater for service areas with missing wait time data than for those without missing wait time data. If complete marginalization data were available, the strength of the inverse associations seen for dependency would decrease, and the strength of the positive association seen for deprivation would increase. With respect to the ethnic concentration dimension, areas with missing ER wait times had lower marginalization scores than areas with complete wait time

data. Complete data for this dimension would result in the positive associations being pulled toward the null and inverse associations moving away from the null. Overall, compared to residential instability and total marginalization, less confidence can be placed in the results for the dependency, deprivation and ethnic concentration dimensions (Tables 1–12 and Figures 4 and 5, available online at www.longwoods.com/content/26223).

Finally, several potentially useful covariates were not publicly available. Hospital capacity and overcrowding may contribute to ER wait time (Horwitz et al. 2010; Knowles et al. 2017), yet the provincial government did not make these data publicly available. Data on time to first assessment by a physician were also not publicly available. Using a population-weighted approach to calculate marginalization scores allowed us to consider population as a surrogate for hospital capacity and visit frequency. Future work should incorporate measures of hospital capacity and time to first assessment by a physician in regression models.

In conclusion, this study shows that total community-level marginalization is associated with increased ER wait time in Ontario, particularly for the residential instability dimension of marginalization. Further investigation of this association at the individual level is necessary to gain a more complete understanding of the link between marginalization and ER wait time.

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RESEARCH PAPER

Triggering Institutional Change: Examining the Development of the 2001 Quebec Breastfeeding Policy

Déclencher le changement institutionnel : examen de l'élaboration de la politique de 2001 sur l'allaitement maternel au Québec

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Abstract

Background: The Quebec Government published Canada's first breastfeeding policy in 2001 with the goal to increase breastfeeding rates in the province.
Objective: To ultimately contribute to more informed policy decision-making, this investigation aimed to identify key stakeholders and understand events and processes that contributed to the establishment of this policy.
Methods: Building from the neo-institutional theory, this was a retrospective case study. Interviews with key informants were conducted, and several texts were compiled. Hybrid thematic analysis was used to analyze text transcribed verbatim from interviews. Resulting

themes, summary of archival material and temporal bracketing were adopted to elaborate a historical narrative of the development of the policy.
Results: The emergence, development and initial implementation of the Quebec breastfeeding policy phases were traced from 1977 to 2009. The policy was triggered by a grassroots health professional movement that advocated for years for a cultural change toward breastfeeding in Quebec. Once Quebec's Ministry of Health finally accepted dialogue, institutional actors cooperated to formulate the policy. However, conflicts arose because of the Ministry's increasingly centralized mechanisms of governance. By 2009, discontent was so pervasive that several health professionals and other breastfeeding actors created an independent organization to further support breastfeeding, out of the Ministry's scope of control.
Conclusion: Collaboration in this domain was possible when shared decision-making was accepted, but conflict emerged when the institutional actor with formal authority re-adopted traditional top-down modes of action.

Résumé

Contexte : Le gouvernement du Québec publiait en 2001 la première politique au Canada d'allaitement maternel dans l'optique d'accroître les taux d'allaitement naturel dans la province.
Objectif : En vue de fournir un apport à la prise de décisions politiques informées, cette enquête vise à identifier les principaux intervenants et à comprendre les événements et processus qui ont contribué à l'élaboration de cette politique.
Méthode : Il s'agit d'une étude de cas rétrospective qui s'appuie sur la théorie néo-institutionnelle. Des entrevues auprès d'intervenants clés ont été menées et plusieurs textes ont été compilés. Les transcriptions des entrevues ont été analysées au moyen d'une analyse thématique hydride. Les thèmes qui en ont découlé, un sommaire des documents d'archives et la décomposition temporelle ont servi à l'élaboration d'un discours narratif sur l'élaboration de la politique.
Résultats : L'émergence, l'élaboration et la mise en œuvre initiale des phases de la politique québécoise d'allaitement maternel ont été retracées de 1977 à 2009. La politique tire son origine d'un mouvement de professionnels de la santé qui, pendant des années, ont plaidé pour un changement de culture en faveur de l'allaitement maternel au Québec. Une fois que le ministère québécois de la Santé a accepté d'entamer le dialogue, les acteurs institutionnels ont collaboré à l'élaboration de la politique. Toutefois, des conflits ont survenu en raison des mécanismes de gouvernance de plus en plus centralisés mis en place par le Ministère. Dès 2009, le mécontentement était si répandu que plusieurs professionnels de la santé ont créé, avec d'autres intervenants en faveur de l'allaitement, un organisme indépendant pour encourager l'allaitement, organisme dont la portée restait en dehors des contrôles du Ministère.
Conclusion : La collaboration dans ce domaine a été possible quand on a accepté de partager la prise de décisions, mais les conflits ont survenus dès que l'acteur institutionnel détenant l'autorité officielle a adopté de nouveau les modes d'action hiérarchiques habituels.

Introduction

The scientific community and international health organizations alike view breastfeeding as the optimal way to feed newborns and infants (Victora et al. 2016). It has been about 30 years since the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) launched the Baby-Friendly Hospital Initiative (BFHI) to promote breastfeeding around the world (WHO and UNICEF 1989; UNICEF 1990). Most WHO members have endorsed the BFHI and progressively translated the WHO/UNICEF strategies into regional and national breastfeeding policies (Aryeetey and Dykes 2018; Dyson et al. 2010).

Within this international context, Quebec (Canada's largest province) had the lowest breastfeeding rates in the country in 1996–1997, with an initiation rate of 58% at birth and 35% at three months, compared to the Canadian national rates of 77% and 54%, respectively (Health Care Canada 2000). In response, Quebec's Ministry of Health (MoH) recognized breastfeeding as a provincial public health priority in 1997 and aimed to increase Quebec's breastfeeding rates to 80% at birth, 60% at three months and 30% at 6 months by 2002 (Department of Health and Social Services publications 1997). In 2001, Quebec became the first Canadian province to publish a breastfeeding policy entitled *L'allaitement maternel au Québec : Lignes directrices* ([LD]; Ministère de la Santé et des Services sociaux du Québec 2001). In addition, the BFHI was integrated into Quebec's 2003–2012 provincial public health program (Publications du ministère de la Santé et des Services sociaux 2003). Overall breastfeeding rates in Quebec increased significantly following the adoption of the LD: in 2005–2006, the rates reached 85% at birth and 67%, 56% and 47% at two, four and six months, respectively (Neill et al. 2006). However, exclusive breastfeeding rates were only 52% at birth and 3% at six months (Neill et al. 2006) despite global recommendations to exclusively breastfeed for the first six months of life (WHO 2003), indicating that public health efforts were still needed in the province.

This inquiry was part of a larger evaluative study conducted from 2009 to 2012, whose overarching goal was to contribute to evidence-based policies and strategic decision-making related to breastfeeding in Quebec (Semenic et al. 2012). The purpose of the present investigation was to examine in depth the processes whereby the LD policy came into existence. Three interrelated research questions guided the investigation: (1) How did the LD unfold over time? (2) Who were the key actors and critical decisions and events that influenced the elaboration and implementation of this breastfeeding policy? (3) How did the newly created provincial breastfeeding mechanisms of negotiation contribute to the LD elaboration and adoption?

Theoretical Framework

We adopted the neo-institutional theory as a theoretical perspective for this empirical investigation. Widespread in organizational studies (Greenwood et al. 2008), the neo-institutional theory (Scott 2004):

> ... attends to the deeper and more resilient aspects of social structure. It considers the processes by which structures, including schemas, rules, norms, and routines become established as authoritative guidelines for social behavior. It inquires into how these elements are created, diffused, adopted, and adapted over space and time, and how they fall into decline and disuse (p. 2).

Institutionalists were initially interested in studying the influence of environmental conditions on organizations, and how organizations should conform to institutional templates to gain *legitimacy* in the *institutional field* (i.e., the aggregate of organizations and other actors that operate in the same sphere of institutional life; DiMaggio and Powell 1983). They have more recently focused on understanding the roles played, and actions undertaken, by individuals and organizations in *institutional change* (Battilana 2006). In this context, the phenomenon labelled *institutional entrepreneurship* is defined as "the activities of actors who have an interest in particular institutional arrangements and who leverage resources to create new institutions or to transform existing ones" (Maguire et al. 2004: 657). *Institutional entrepreneurs* are therefore those social actors (individual and collective) that make institutional change possible (Hardy and Phillips 1998). More or less powerful *social positions* occupied by actors in the institutional field will facilitate or prevent their abilities to act as institutional entrepreneurs (Battilana 2006).

Institutional change is not only a *political* but also a *collective* endeavour. Institutional change is "a dialectical process in which partisan actors espousing conflicting views confront each other and engage in political behaviors to create institutions" (Hargrave and Van de Ven 2006, p. 864). Unfolding in several consecutive *phases* (Hargrave and Van de Ven 2006), the collective action characteristic of institutional change requires that actors adopt different *strategies of engagement* to support, or eventually resist, institutional change (Hardy and Phillips 1998). Actors' strategies of engagement in institutional change can be cooperative (*collaboration* and *compliance*) or conflictual (*contention* or *contestation*; Hardy and Phillips 1998; Table 1). To adopt any of these strategies, actors must mobilize the *power attributes* (i.e., formal authority, control over critical resources such as expertise and money and discursive legitimacy; Hardy and Phillips 1998; Table 2) associated with their social position in the institutional field (Battilana 2006). Figure 1 represents the adaptation of these theoretical insights into the present investigation.

Material and methods

RESEARCH DESIGN

This was an intrinsic qualitative case study (Stake 1995). As the case was related to the LD policy, the study was located at the institutional macro level of analysis. The case study was retrospective, beginning with the initial actions undertaken by the actors involved in the LD's formulation. The Research Institute of the McGill University Health Center at Montreal, Quebec, granted ethics approval for the study (# GEN-09-095).

FIGURE 1. The problem definition process – transforming political issues into policy problems

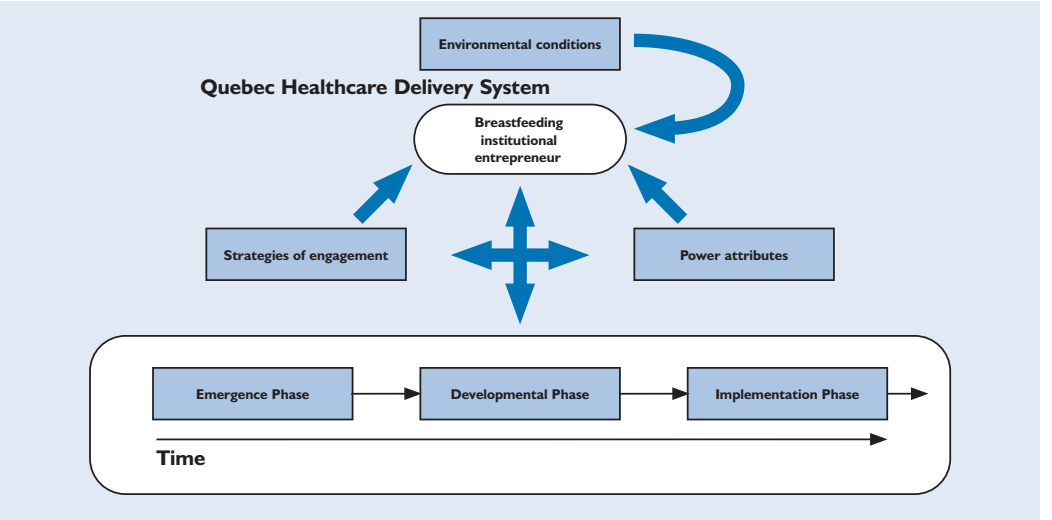

TABLE 1. Strategies of engagement in an interorganizational domain

Strategy	Modality	Definition
Cooperation	Collaboration	Interaction mutually and highly cooperative
	Compliance	Cooperative interaction but only on the surface
Conflict	Contention	Adversarial relationships
	Contestation	Challenging attitudes and behaviours vis-à-vis existing powerholders

Source: Adapted from Hardy and Phillips 1998

TABLE 2. Power in an interorganizational domain

Source of power	Definition
Formal authority	Recognized, legitimated right to make a decision
Scarce or critical resources	Control over critical resources such as expertise, money and information
Discursive legitimacy	Legitimated to speak for issues and other actors of the domain

Source: Adapted from Hardy and Phillips 1998

PARTICIPANTS AND SAMPLING STRATEGY

We adopted purposeful sampling (Patton 2002) to solicit the participation of key individuals who were knowledgeable about the historical development of the LD: (1) health professionals and managers who participated in the writing of the LD, (2) health professionals and managers who were involved in one or more mechanisms of negotiation put in place to implement the policy and (3) civil servants directly responsible for the breastfeeding policy at the Quebec MoH over time. To maximize diversity in points of view and opinions, we selected participants following a maximum variation sampling strategy (Patton 2002) using

two major criteria: position occupied in the institutional domain (i.e., local, regional or provincial) and role (e.g., health professional, manager or representative of breastfeeding community organization). Owing to the large period covered (more than three decades), we first elaborated an initial list of potential participants and progressively completed it via snowball sampling (Patton 2002), for a final sample of 25 participants.

DATA COLLECTION

The first author conducted individual face-to-face semi-structured qualitative interviews (Rubin and Rubin 2012) with 17 key players in the elaboration of the LD between October 2009 and February 2010. Seven had actively participated in the process over time, and the remaining 10 were members of one or more of the following provincial committees (Table 3, available online at www.longwoods.com/content/26221): the Baby Friendly Certification Committee (n = 5), the Quebec Breastfeeding Committee (Comité québécois en allaitement [CQA]) and the Breastfeeding Consultation Committee (Table de consultation en allaitement [TCA]; n = 5). In February 2010, with the support of three research assistants, the lead author also conducted a focus group (Krueger and Casey 2000) with eight members of the Provincial Committee of Breastfeeding Representatives (Table nationale des répondantes en allaitement maternel – see Table 3.

We also retrieved a significant amount of archival material pertinent to the LD, such as minutes of committee meetings, successive drafts of the LD and e-mails. We organized this material by event and date to facilitate data triangulation, as well as the detailed description of the case (Berg 2001; Green and Thorogood 2014). We gathered data until saturation was reached (Boutin 2000).

DATA ANALYSIS

The first and second authors established a preliminary list of initial codes from the above-mentioned theoretical framework. Then, with the support of the ATLAS.ti – a well-known software for qualitative data analysis – the lead author transcribed content verbatim from interviews and coded the material following a deductive–inductive approach (Table 4, available online at www.longwoods.com/content/26221). Both authors progressively validated codes as data were collected. Successive iterations allowed the emergence of recurrent patterns (Braun and Clarke 2006), and the three co-authors further discussed and validated the resulting themes. This thematic analysis and the careful reading and triangulation of the material allowed us to adopt a narrative strategy (Langley 1999) through which we constructed the history of the LD. The narrative was broken down into several phases through temporal bracketing (Langley 1999).

Results

We identified three important *phases* in the elaboration of the LD in Quebec. For each of those, we detailed the *context*, the most important *decisions and actions* undertaken by

breastfeeding *institutional entrepreneurs* (Table 3) and the key *events* that had an influence on how the LD unfolded over time. Respecting the confidentiality and anonymity of the participants prevents the identification of the source of the quotations selected to illustrate the study findings.

From 1977 to 1997 – emergence phase

The emergence phase in the history of the LD precedes the Quebec MoH's formalization in 1997 of a breastfeeding working group to elaborate the LD. This 20-year period witnessed the advent of different provincial initiatives to improve women's and perinatal health in Quebec, including the legalization of midwifery. Throughout these years, breastfeeding practices were primarily promoted by community organizations:

> There was a void! There were not many things that were done apart from that [self-help groups]. We must never forget … I think that breastfeeding has survived in Quebec … it was a lot thanks to self-help groups … And I think that all women who were breastfeeding and giving support to others were much more important in those years than the health care system.

Over this period, we identified two major institutional entrepreneurs: Dr. Milk (fictitious name) and the MoH. Dr. Milk was a family physician who, in her own words, "decided to play the role of human milk representative." Her professional engagement regarding breastfeeding began in 1977, when she participated in a conference about the humanization of births. She then progressively modified her clinical practice, and a few years later, opened a breastfeeding clinic: "I created the breastfeeding clinic to support the mothers who had difficulties to breastfeed, and did not find the support they needed from their families or the health professionals they had consulted."

Deeply convinced of the necessity to sensitize the MoH about the low breastfeeding rates in Quebec, Dr. Milk decided to send letters to different health policy decision-makers in 1991, an initiative that lasted for years. By that time, she also contributed to the creation of a first local breastfeeding working group, whose principal purpose was to lobby the MoH for greater breastfeeding support. Dr. Milk was the undisputable leader of this health professional movement, and her collaborative approach was undeniable: "[Dr. Milk] was the element needed to trigger all this, but she also consulted a lot of people."

The LD's emergence phase ended when the MoH Public Health Division finally responded to Dr. Milk's long pending requests: In a letter dated January 31, 1997, they informed Dr. Milk that they would like to hire her services as a medical consultant to put in place a ministerial plan to sustain, promote and protect breastfeeding.

From 1997 to 2001 – developmental phase

This phase extended from the recruitment of the members of the LD's ministerial working

group to the LD's publication in 2001. During this period, the breastfeeding landscape was fertile in activities and events related to breastfeeding. For instance, in 1999, the Brome-Missisquoi-Perkins Hospital, in Cowansville, Quebec, was the first Canadian hospital to receive the BFHI certification. The same year, several nurses and physicians working in the Quebec City region united to better advocate for breastfeeding. This group constituted the core of what would later become one of the regional breastfeeding committees. Nevertheless, at this phase, as noted by one of the study participants:

> There was not much dialogue, and when I arrived in '99, we were still in the early stages of dialogue. [...] It was a dialogue that was still fragile, where people did not trust each other ... There were not many projects started and it was the beginning, you know? The beginning of knowing ... each other, to trust each other.

Three specific actors could, however, be considered institutional entrepreneurs during this phase: (1) Dr. Milk as President of the ministerial Working Group on Breastfeeding; (2) the Working Group itself, composed of about a dozen members and operating at the Social Services Divisions of the MoH; and (3) the Breastfeeding Coalition, created in 1998, which involved a variety of breastfeeding key actors in the province, highly regarded by their peers for their expertise and discursive legitimacy regarding breastfeeding.

Dr. Milk's authority in the process was so strong that, having been co-opted by the MoH, she was given responsibility for selecting the members of the ministerial working group. As illustrated below, Dr. Milk looked for a high degree of expertise around the table to make the task as efficient as possible:

> We decided to create a working group with people who knew breastfeeding, who were interested in breastfeeding. We could have done a task force ... just get a medical representative, a nurse representative, a dietitian representative, a self-help group representative, but we thought there was so much work to be done that, if we went to include people who did not know breastfeeding, it would take longer to reach a consensus. We made the choice. I would say that really it was because we wanted to have people who knew breastfeeding to be able to get a result maybe faster.

Heterogeneity among group members was also sought to develop a policy document based on the perceived needs of different people working in the field. In the group, "all were invited to participate and bring their point of view," and each one of the members had the "feeling of being welcome, and that our opinions, our participation were important for the elaboration [of the LD]." What is more, the group established fruitful relationships with external actors such as different community groups, as well as the provincial Breastfeeding Coalition. The collaborative strategies adopted led to the development of a very inclusive policy document that centred on the implementation of four key strategies, namely, the Baby Friendly

Initiative, breastfeeding community-based support, an effective system for monitoring breastfeeding rates and the exercise of MoH's and healthcare system's influence to involve other sectors in the protection of breastfeeding. The document also carefully defined the specific responsibilities of the various stakeholders involved in breastfeeding in Quebec.

However, the developmental phase did not evolve without difficulties. Notably, the financial resources provided by the MoH to the Working Group were insufficient, resulting in a delayed timeline (4 years) for the writing of the LD. Also, owing to lack of resources for this initiative, the MoH waited another full year before finally releasing the LD. This decision upset members of the Breastfeeding Coalition, who threatened to publicize the delay. A conflictual dynamic therefore disrupted the Breastfeeding Coalition. The *tour de force* ended with the disbanding of the Breastfeeding Coalition, and the constitution of a new board under the MoH's control – the TCA – which integrated some former members of the Breastfeeding Coalition.

From 2001 to 2009 – implementation phase

This phase began when, immediately after the LD was released, the MoH appointed its first ministerial breastfeeding authority (MBA1) to ensure the policy implementation. The phase finished in 2009, when the Quebec Breastfeeding Movement (Mouvement allaitement du Québec [MAQ]; Table 3) came into existence. Four major events punctuated this eight-year period: (1) the publication of the Quebec Public Health Program in 2003; (2) within the MoH, the transfer of the breastfeeding dossier from the Social Services Division to the Public Health Division in 2006; (3) the resulting change of ministerial breastfeeding authority in 2006; and (4) the emergence of the MAQ.

Among the numerous breastfeeding actors that we could identify during this phase, four may be considered institutional entrepreneurs: MBA1, the CQA, the MoH and the MAQ. One of the study participants described MBA1 as follows:

> It is a person [...] who represented everyone. That is, a very, very human woman who was sensitive to our passions, who was as passionate as we were. So ... she was a very credible person. In addition to knowing all the policy decision-makers, we felt she was concerned about our concerns.

Moreover, MBA1 recognized the great scope of action that breastfeeding experts outside the governmental structure possessed:

> At the meetings with the Quebec Breastfeeding Committee [CQA], for example, […], she told people: "Give me a hand, send letters to the Ministry." She [MBA1] encouraged people to mobilize for the dossier to move forward, but ... She asked to exert pressure. She often used this tactic.

MBA1 also pushed enormously for the National Treasure to approve the financial resources needed to implement the LD across the province. This budget boosted the motivation of people on the ground and was perceived as the MoH's political will to enhance breastfeeding in the regions. However, several participants thought that the amount allocated (CA$900,000 per year) was not at all enough to put in place all the elements proposed in the LD:

> It is impossible to do it with this budget. That is why people had to believe that the project was interesting, motivating and mobilizing enough for people to say: "OK! Well, there is not a lot of money. We will see how we can use it at best." Every region used a lot of imagination to decide what they would do with that amount, and despite everything, we moved forward. Sure! Money was not a factor that hurt, but it was not a factor that facilitated the process either because we did not have enough money on the table. This is very, very clear! There is no other project in Quebec of this size that can be compared to breastfeeding for which there has been so little money put in by the Ministry.

Nevertheless, a great deal of enthusiasm prevailed at the earlier stages of the LD implementation, mainly thanks to the CQA. The actors involved in the process, those at the MoH level as well as those at the regional and local levels, worked in close collaboration through the different mechanisms of governance created for the LD (i.e., CQA and TCA) to be properly adopted in the province.

The breastfeeding dossier was further advanced when the Baby Friendly Initiative was included in the 2003 Quebec Public Health Program. Although this initiative was part of the LD, the LD policy was much more ambitious because it also included other interventions:

> The Baby Friendly Initiative is something extraordinary, I think, that provides quality of care to all families and young children. On the other hand, it [the BFI] is very, very focused on the healthcare network. So, we want the network to change its practices to improve the quality of services that we give to families, that's good, there, but all that it is not ... it is not enough to change a culture. And to achieve results that will be permanent, where we will really have a change in the health of the population, we must not work solely on the network, we must not work only on a strategy. And it is not for nothing that there were four strategies in the LD, it is that we really wanted to make that cultural change.

In 2006, MBA1 had to step down from her position because of personal issues, and MBA2 was appointed in her place. At the same time, the MoH decided to transfer the breastfeeding dossier to the Public Health Division, which had a much more centralized

functioning. This decision downplayed the role of the CQA and TCA, whose meetings eventually ceased. Breastfeeding provincial actors outside the MoH increasingly felt they had lost the shared decision-making power they enjoyed when the dossier was under the responsibility of the Social Services Division:

> So, there, in Public Health, we have entered in a much more rigid framework where the Ministry takes much more room in the decisions and we are executors. We can suggest, advise ... but that is all. Before, we had decision-making power.

Discontent and disappointment became increasingly prevalent among actors outside the MoH, which had progressively transformed their initial strategy of collaborative engagement into one of compliance first and then of contention. The corollary of the latest conflictual exchanges was the creation of the MAQ on April 7, 2009. The MAQ integrated health professionals and other individuals from the regional and local institutional levels deeply committed to the breastfeeding project and dissatisfied with the way the MoH was centralizing power decision-making regarding the LD:

> The people at …, other people I have spoken to, are as disappointed as I am. Then, we would like to restart again, and we will need to restart something. Because we will not let that [the LD] die at the Ministry. That is the idea right now. We say that since the Ministry has abandoned us somewhere, well, we are going to water the plant like this.

In sum, the MAQ, as a collective institutional entrepreneur in the latest stages of the LD implementation phase, held expertise in breastfeeding and strong legitimacy among people at the local and regional levels. The MoH maintained formal authority and control over the financial resources that could advance the breastfeeding dossier. Although these two actors had attributes of power that could be considered complementary, there was no discussion or formal meeting scheduled between them at the time we finished data collection for this study.

Discussion and Conclusion

This research first highlights the crucial role played by a very motivated group of health professionals who, working in an international political context favourable to breastfeeding, behaved as institutional entrepreneurs in triggering the process of formal development of the LD. Their deep shared belief that breastfeeding is the optimal way to feed infants and young children, and their perseverance over years, promoted collective engagement led by the individual who possessed the necessary power attributes (i.e., expertise and discursive legitimacy; Hardy and Phillips 1998) to pave the way for the LD. By finally accepting their request, and formally supporting this group of highly committed professionals, the MoH mobilized its

authority and the financial resources for the materialization of this policy. Consistent with prior work, which highlights perseverance and self-efficacy as personal traits of entrepreneurs (Markman et al. 2005), this finding corroborates the attributes and ways in which to behave for institutional entrepreneurs to trigger institutional change.

Second, the study highlights the capacity of different institutional actors to overcome challenges and begin working together (i.e., collaborate) in the achievement of a common goal. Once the LD was elaborated and released, the relationships between professionals at the local and regional levels and the policy makers involved in the implementation of the LD were characterized by dialogue and cooperation. Several governance structures for the implementation of the LD were set up to support this institutional enterprise, which effectively allowed negotiation and power sharing. Actors who occupied different social positions in the institutional field and possessed different power attributes, but who collectively shared the common interest of facilitating breastfeeding practices, were all engaged in a strategy of collaboration (Hardy and Phillips 1998) in the initial phases of LD implementation.

Third, whereas this investigation confirms the political nature of collective institutional action, it stresses the enduring character of different actors' institutional logics, that is, "the socially constructed, historical patterns of material practices, assumptions, values, beliefs and rules by which individuals produced and reproduce their material subsistence, organize time and space, and provide meaning to their social reality" (Thornton and Ocasio 1999: 804). In our case, the relations among breastfeeding actors, cooperative during the phases of development and early implementation, progressively shifted to conflict when the LD dossier was transferred to the Ministry's Public Health division, whose much more centralized ways of behaving appeared difficult to harmonize with those of professional actors strongly committed to foster a provincial cultural shift toward breastfeeding. The MoH thereby perpetuated a traditional top-down approach, which generated conflictual responses from local and regional professionals. It then followed that the governance structures put in place to elaborate and implement the LD became progressively obsolete. It is important to remember that, according to Hardy and Phillips (1998), conflict cannot occur without the opposite party also having power to confront the one with formal authority. Said differently, in this case, local and regional actors' discursive legitimacy and expertise were powerful attributes that allowed them to react against the top-down decision-making advanced by the actor with formal authority. This finding highlights that the "bridges" that might harmonize the respective institutional actors' logics of action may remain fragile, requiring a continuous process of reconstruction through collective action to reach common goals, which is in line with the dialectical nature of change processes described by Hargrave and Van de Ven (2006).

Fourth, the study points out the inescapable key role that the actor with authority and financial resources plays in institutional change, even if, as in our case study, this actor (i.e., the MoH) rather (re)acted to tenacious pressures from other more proactive players in the provincial breastfeeding landscape during the phase of LD emergence. Without the mobilization of the MoH's power attributes within a logic of collective action, the LD elaboration

and implementation would not have taken place. This reinforces the idea that "[t]he dominant members of a collaboration will be those with greater formal authority, resources and discursive legitimacy" (Phillips et al. 2000: 3).

The study finished at a moment of high tension among breastfeeding actors. The reported progressive deterioration of the relations between these actors responded to their difficulties, particularly those of MoH, to depart from their traditional ways of behaving and keep investing in collaborative strategies of engagement for the sake of breastfeeding in the province. As a way to move forward, we refer to Wijen and Ansari (2006) who suggest that "[i]n situations where groups of stakeholders are concerned about a common issue or problem [...], the only road to achieving change is by developing collaborative solutions [...] and a collective logic of action ..." (p. 1081). That said, the political nature of these processes is pervasive. After this study was completed, the MoH decided to not only integrate the LD in a more general provincial public health policy but also financially support the MAQ shortly after it was created, as well as promote BFHI certification and breastfeeding education programs for healthcare providers.

A final observation arising from this study is the relative absence of mothers in the Quebec's breastfeeding policy journey so far. There are several reasons sustaining mothers' decision-making about feeding their babies with breastmilk or formula (Radzyminski and Callister 2016) and, likewise, stopping breastfeeding once this practice was initiated (Brown et al. 2014; Morrison et al. 2019). In an era of person-centred care (Bhattacharyya et al. 2019; Santana et al. 2018) and partnerships with health users (Ministère de la Santé et des Services sociaux du Québec 2018), and when the most recent available rates of exclusive breastfeeding for six months or more in Quebec still remain the lowest in Canada (Statistics Canada 2013), mothers should be considered *leading* actors in the development and implementation of breastfeeding-related policies. Therefore, for collaboration around such policies to be reconstructed in this institutional field, health professionals and political actors should take a step forward and fully involve mothers in this institutional endeavour (Semenic et al. 2012). This would ensure more success for institutional work in fostering and maintaining breastfeeding practices (Lawrence and Suddaby 2006).

Despite its considerable scope and rigour, this work has some limitations. Whereas all the study participants were individual or collective key actors in the development of the LD, and given the long period considered, not *all* the study participants were involved in all phases of the history of this policy. In addition, because of its retrospective longitudinal design and the political nature of the phenomenon under scrutiny, our research was based on what participants recalled or decided to share with us. The validity of these data was, however, strengthened with the use of extensive archival material that helped us ensure the congruence of what was said.

This investigation makes two major contributions. For research, it demonstrates the usefulness of empirically applying the concept of institutional entrepreneurship to understand the extremely complex processes of public health policy development and adoption.

Institutional theories constitute a dominant approach in the macrosociological understanding of how organizations operate (Lawrence et al. 2011). However, its uptake by healthcare policy scholars has been rather limited so far. The present work contributes to fulfill this research gap. We do so by addressing one of the major streams of current institutional scholarly work, that is, institutional entrepreneurship. Moreover, this was done in a comprehensive way because the focus was on not only actors (actor-centric accounts) but also their actions (process-centric accounts) over time (Hardy and Maguire 2017). For policy decision-making, the study specifically pointed out that, to achieve their shared goal of protecting, promoting and effectively supporting a public health practice (in this case breastfeeding), all stakeholders have to recognize the need to (re)construct a logic of collective action, which requires mutual recognition and collaborative strategies of engagement in the institutional field.

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Conflict of Interest

Maria Carolina Agnolon and Charo Rodríguez report no conflict of interest. Julie Lauzière was a member of the CQA from mid-2004 to its dissolution in 2006 and has been a member of the MAQ since its inception.

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RESEARCH PAPER

On Portfolios of Preventive Decisions for Multiple Health Risks – Evidence from US-Based Data

Portefeuilles de décisions de prévention face aux risques de santé – une analyse sur données américaine

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Abstract
Individuals face multiple health risks and therefore can undertake many preventive activities simultaneously, thus creating a portfolio of preventive activities. In this article, we first investigate the determinants likely to influence the composition of portfolios of preventive activities. Second, we look at the interactions between preventive activities. We use the US Behavioral Risk Factor Surveillance System survey data set conducted in 2016, comprising 22,510 observations from 50 states and US territories. Our results show that information-related variables, in particular, being aware of illness, having access to information and having a personal doctor, increase the portfolio size of preventive activities. We also show that vaccinations tend to be performed together with screening activities and to a lower extent with exercising.

Résumé
Les personnes font face à de nombreux risques en matière de santé et, par conséquent, peuvent prendre plusieurs mesures préventives simultanément, créant ainsi un portefeuille

d'activités de prévention. Dans cet article, nous nous intéressons d'abord aux déterminants susceptibles d'influencer la composition de tels portefeuilles. Ensuite, nous étudions les interactions entre les diverses activités de prévention. Nous avons recours aux données de l'enquête du Système de surveillance des facteurs de risques comportementaux réalisée aux États-Unis en 2016, laquelle comprend 22 510 observations provenant de 50 états et territoires des États-Unis. Nos résultats montrent que les variables liées à l'information – en particulier, être au fait de la maladie, avoir accès à l'information et avoir un médecin de famille – font croître le contenu du portefeuille d'activités de prévention. Nous démontrons également que la vaccination tend à accompagner les activités de dépistage et, dans une moindre mesure, l'activité physique.

Introduction

Given that individuals face multiple risks, for example, risks of cancers, influenza and heart attacks, they are most likely to undertake different preventive activities simultaneously, for example, cancer screenings, vaccination, health checkup and regular physical activity (Spring et al. 2012). Hence, they create a portfolio of preventive activities. Understanding the drivers of such portfolios of preventive activities is crucial to design efficient health policies. Indeed, public authorities must be able to foresee the potential outcome of a policy and to predict the spillover effects of a prevention-oriented policy before implementing it, especially when another program is already targeting a different prevention type. The importance of information in driving specific preventive activities has already been highlighted in existing literature, including awareness of health issues (Slark and Sharma 2014), health literacy (DeWalt et al. 2004; Fernandez et al. 2016), health knowledge (Vanslyke et al. 2008) and the role of the general practitioner as a means and source of health information (McIlfatrick et al. 2013; Qi et al. 2006). Along with information, other determinants of specific preventive activities include socio-economic factors, such as age, marital status, the level of income and self-reported health (Dorner et al. 2013; Welch et al. 2008), as well as risk attitudes (Hoebel et al. 2014) and health insurance (Simon et al. 2017). However, most of this literature addresses the determinants of one specific preventive activity instead of a whole portfolio of individual preventive decisions. We thus aim to fill this gap in the literature by specifically considering, in this article, the drivers of the number of preventive activities, that is, of the size of portfolios of preventive activities. We especially focus on health-related information drivers, including experience with health risks as related to being a caregiver, having easy access to health information and having a general practitioner. The determinants of one preventive activity can also affect the realization of another, giving rise to the issue of complementarity between preventive activities (Beydoun and Beydoun 2007). For instance, Carlos et al. (2005) showed that prostate-specific antigen (PSA) screenings are more likely to be performed with a colorectal cancer screening. Welch et al. (2008) documented that regular physical exercise and being a nonsmoker are determinants of feminine cancer screening. However, considering

statin use and health behaviours as preventive activities, Kaestner et al. (2014) found conflicting evidence for the hypothesis that investments in disease prevention are complementary. The question of complementarity, hence, remains open. We hypothesize that the relationship between preventive activities might depend on their nature, for example, being behavioural or medicalized. In this article, using the US Behavioral Risk Factor Surveillance System (BRFSS) survey data set, which encompasses many types of preventive activities, we aim at (1) investigating the determinants likely to alter the composition of portfolios of preventive activities, with a focus on the role played by health-related information, and (2) identifying preventive activities that are complementary to each other and encourage each other's uptake.

Methodology

Data

For the purpose of our study, we used the BRFSS survey data set. BRFSS is a health-related phone survey, which is carried out yearly in all the 50 states of the US with the District of Columbia and three US territories. The BRFSS collects state data about US residents regarding their health-related risk behaviours, chronic health conditions and use of preventive services. The BRFSS data set was particularly well suited for our analysis, as it contains information on several types of preventive activities, including both medical and nonmedical preventive activities, namely mammography, Papanicolaou (Pap) test, human papilloma virus (HPV) test, blood stool test for colorectal cancer, colonoscopy, PSA test, checkup, tetanus and flu vaccinations and exercising. We used the 33rd wave conducted in 2016, which is composed of 22,510 complete observations.

Variables

DEPENDENT VARIABLES

We used two types of dependent variables for preventive activities classified by gender. We subdivided the population into two groups, individuals below and above 50 years, following the U.S. Preventive Services Task Force recommendations regarding cancer screenings (U.S. Preventive Services Task Force 2008). This allows for a better tailored portfolio, as several cancer screenings are not available or are very rarely administered below the age of 50. The first dependent variable was the sum of preventive activities per individual performed during the past 12 months. These preventive activities are presented in Table 1. The number of performed preventive activities summed up to a maximum of six for women below 50 years and up to a maximum of nine for women above 50 years. As for men, this number went up to four for men below 50 years and seven for those above 50 years.

TABLE 1. Portfolios of preventive activities

	Prevention before the age of 50			Prevention after the age of 50		
	Behavioural	**Screenings**	**Vaccination**	**Behavioural**	**Screenings**	**Vaccination**
Men	Exercise	Checkup	Flu Tetanus	Exercise	Checkup Blood stool Colonoscopy PSA test	Flu Tetanus
Women	Exercise	Checkup Pap test HPV test	Flu Tetanus	Exercise	Checkup Blood stool Colonoscopy HPV test Pap test Mammography	Flu Tetanus

The second type of dependent variable was a selection of preventive activities, which were segregated in three types according to their nature, that is, behavioural preventive activity, screenings and vaccinations, as presented in Table 1. The classification of preventive activities by types allowed us to investigate the interactions between preventive activities of different natures. The underlying hypothesis was that relationships between preventive activities may depend on the type of prevention, and the former may change depending on the individual's age.

INFORMATION-RELATED VARIABLES

We defined three variables to account for the role of health-related information on preventive activities. The first variable was a caregiver dummy variable. The underlying assumption justifying the use of this variable was that caregivers have a greater experience with health risks and their consequences, which may in turn incentivize them to pay more attention to their own health (Banford et al. 2001; Broughton et al. 2011). This variable, hence, proxied the effect of awareness about potential health issues and their consequences. The second variable was a dummy variable assessing the ease with which the respondent gets advice or information about health or medical topics if needed. This variable allowed to control for the accessibility of information to the individual, which in turn may influence preventive decisions. The third variable was a personal doctor (PD) dummy depending on whether the individual reported having one person he/she thinks of as a PD or healthcare provider or not. Having a PD is a well-recognized source of health information, and individuals reporting having a PD should be more likely to have better and more personalized information about the benefits of preventive activities (Noar et al. 2007).

OTHER VARIABLES

Following the literature, we included a set of control variables that have been shown to affect preventive decisions. We first included a series of socio-economic factors, namely, age, marital status, number of children below 18 years, education higher than high school, preferred race, employment and income. Concerning health-related control variables, we included health

coverage, which is a dummy variable assessing whether the respondent has any kind of health coverage, including health insurance, prepaid plans such as health maintenance organizations (HMOs) or government plans such as Medicare or Indian Health Service. We also included the subjective health, which was a count variable ranging from 1 (*poor*) to 5 (*excellent*). Finally, we added a health-risk tolerance variable to capture the idiosyncratic relationship of the respondent to health risks. This variable was a dummy controlling for whether the respondent smoked in his/her entire life at least 100 cigarettes, has driven drunk at least once in the past 30 days or has had a red or painful sunburn that lasted a day or more during the past 12 months.

DESCRIPTIVE STATISTICS

Table 2 (available online at www.longwoods.com/content/26222) provides a concise description of the set of variables used in the next section's econometric specifications.

Econometric methodology

Following Carlos et al. (2005) and Welch et al. (2008), who used the same BRFSS data set, our first regression was a linear model with White standard errors to correct for heteroskedasticity. The dependent variable was the number of individual preventive activities. The explanatory variables were the set of informational factors and all the individual control variables. This first model aimed at investigating the determinants of the size of preventive activities' portfolios. We also considered a submodel for which the sum of preventive activities corresponded only to either screening activities or vaccination activities to address the determinants of more specific portfolios of preventive activities, that is, a portfolio of screening activities and a portfolio of vaccination activities. The second linear regression, also corrected for heteroskedasticity with White standard errors, was run on the three groups of preventive activities described in Table 1. In addition to the information-related variables and our control variables, we included in the set of explanatory variables the other preventive activities' groups. This second model aimed at investigating the interactions between different types of preventive activities.

Results

Tables 3 through 6 are available online at www.longwoods.com/content/26222.

Information-related determinants

Starting with the caregiver variable, its effect on the size of the total portfolios of preventive activities is overall positive for individuals below the age of 50. For these individuals, having provided regular care or assistance to a person with health problems or disability during the past 30 days increases the size of the portfolio by 0.3 units for women and 0.24 for men. As for the role of ease of access to medical information, it correlates positively and significantly with the size of the overall portfolio of preventive activities indifferent of age and

gender. However, the impact of the access to health information seems to be much higher for respondents of age 50 years and above. When it comes to the portfolio of screening activities, only women of age 50 years and above seem to be affected by the ease of access to information. Regarding the variable PD, it positively and very significantly impacts the size of the overall portfolio of preventive activities disregarding age and gender. This variable is the most important driver of the size of the overall portfolio (β between 0.50 and 0.78). The presence of a PD is more valued by individuals of age 50 and above, as it represents for both men and women, one third to one half of the standard deviation of the size of the portfolio. The same results apply for portfolios of screenings and vaccinations.

Socio-economic determinants

Looking at the effect of some of our control variables, as shown in Table 4, being married has a positive impact on the overall portfolio of men above 50 years old. This is especially the case when it comes to the portfolio of screening activities. Looking at education, a level higher than a high school diploma leads to a larger overall portfolio in younger women and men of all ages. Healthcare coverage is also significant, mostly for portfolios of cancer screenings and vaccinations. It is also worth noting that an increase in subjective health is positively correlated with the number of overall preventive activities performed for both men and women above 50 years old. However, when it comes to portfolios of specific preventive behaviours, a decrease in subjective health leads to an increase in the number of vaccinations.

Interaction between preventive activities

For women, health screenings and vaccinations are complementary. A woman of age 50 years or older, who underwent at least one preventive activity in the "vaccination" portfolio during the past 12 months, has a "screenings" portfolio larger, on average, by 0.36 units than a woman who did not, *ceteris paribus*. Similarly, a woman who is exercising has a larger portfolio of screening activities. This relationship applies the other way round; for example, a woman above 50 years old who underwent a screening is more likely to undergo a vaccination or to exercise. The complementary relationship between health screenings and vaccinations holds for men as well, whereas the complementary relation between exercising and health screenings holds only for men below 50 years old. Exercising and vaccinations, however, present statistically weak results, and no pattern is decipherable.

Discussion

Our results can be related to previous studies. When it comes to the positive association between being a caregiver and the size of the portfolio of preventive activities, our results go along with those of Brown and Brown (2014), who showed that caregiving may yield beneficial health and well-being outcomes. One explanation could be that caregiving is associated with more preventive activities. Indeed, caring after dependent individuals seems to raise awareness about potential health problems and the benefit of preventive activities

for individuals below 50 years old. Interestingly, this variable stops being relevant for those older than 50. This could occur because individuals of age 50 and above may have already experienced health problems or may have relatives with health problems, hence rendering this feature meaningless. Therefore, raising awareness about health problems among young men tends to increase the number of screenings they perform. Our results also highlight the dominant role of the PD in driving the number of performed preventive activities. These results confirm earlier works on the topic, for instance, those of Qi et al. (2006) showing that, in Canada, the presence of a regular medical doctor was associated with increased rates of a specific preventive screening. When it comes to sociodemographic drivers, being married increases the portfolio size of preventive activities for men above 50 years old. These results are in line with the observation of Jaffe et al. (2007) and Manzoli et al. (2007), who found that mortality rates were lower for married men. Married women seem to have a positive influence on their spouse in terms of taking care of themselves, and hence, the married men perform more preventive activities. Our findings present a channel through which we observe more longevity for married men, as they perform a higher number of preventive activities. Health coverage increases the number of cancer screenings and vaccinations, which could be explained by the fact that these preventive activities are medicalized, and, hence can potentially be reimbursed by insurance. As for the role of subjective health, it seems that younger individuals are less driven by their health when deciding to perform preventive activities. However, subjective health is shown to be negatively associated with the number of vaccinations. This is in accordance with the study by Wu (2003), who showed that respondents with poorer health are more likely to be vaccinated. Finally, vaccination is shown to be positively associated with screening activities and to a lower extent with exercising. These results confirm that the complementary relationship between preventive activities depends on the nature of the preventive activities considered. Although we believe that our results provide the right correlations between the variables of interest, one important limitation of our study comes from the cross-sectional nature of our data. Therefore, causation has to be inferred with caution. In addition, our data are based on a survey that contains only self-reported answers, which can entail biases attributed to social desirability and could distort the results (Bauhoff 2011; van de Mortel 2008). Finally, the measurement or nonresponse biases cannot be entirely excluded from any survey (Schneider et al. 2012).

Conclusion

Our results offer some valuable insights in terms of prevention-oriented policies. In particular, they highlight the role and quality of health information in driving the overall portfolio of preventive activities. Not only does awareness of health issues play an important role in influencing the number of preventive activities, but, more importantly, the role of health professionals, and in particular the PD, is paramount in that respect. Hence, with the aim of developing preventive activities, PD and other health professionals should communicate further with their patients on the benefits of such behaviours. Furthermore, communication

should target single and young individuals on priority, as they are less likely to perform multiple preventive activities than married and older individuals, especially when it comes to screening activities. Another insight from our results is related to the complementarity between some preventive activities. This complementarity suggests that having performed one specific preventive activity is a cue to action to perform another. Hence, policies promoting vaccinations should also influence the uptake of screenings activities (and vice versa). Although our results apply to the US, a comparison between countries is necessary to understand whether our observations are related to a country's healthcare system or deeply rooted in human behaviour. In that respect, generalizing our study to Canada, for example, which has a universal single-payer healthcare system very different from the US system but a rather similar culture, would offer a relevant test of our results.

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